Review of Research Ethics Committees
&
Processes in Republic of Ireland

HSE Research Ethics Committees Review Group 2008
Addendum to the Review, September 2008

The Review of Research Ethics Committees & Processes in the Republic of Ireland was commissioned by the Medical Education, Training and Research (METR) Committee of the HSE in December 2006.

HSE-METR wishes to thank the members of the Review Group, its joint chairs, Mary Morrissey and Majella Daly and all those that contributed to the review for the considerable time and effort that went into producing the review. The review provides valuable information on research ethics committees in Ireland which will be of benefit to all those involved in health services research and research ethics processes in Ireland.

The review identified 50 research ethics committees. A further seven have been identified since the completion of the review.

Since the submission of the review, further significant progress has been made in terms of crystallising recommendations for the appropriate organisation and assignment of responsibility for research ethics on a national basis. Most notable are the recent recommendations of the Irish Clinical Research Infrastructure Network's (ICRIN) working group on “Ethics and Interaction with Ethics Committees”.

It is noted that the ICRIN Working Group make recommendations in relation to the nature of the role to be adopted by the Department of Health and Children (DoHC). It also recommends the establishment of 6-8 new ethics committees in place of the existing committees. These and other recommendations, including those contained in the HSE Review, provide the basis for the rationalisation and standardisation of the research ethics process on a national basis, in line with best practice.

HSE-METR supports the recommendations contained in the Review of Research Ethics Committees and Processes in the Republic of Ireland and agrees that there is a need to bring greater clarity, standardisation and centralisation to research ethics on a national basis. This will ensure that the rights of the patient are protected in a fair and transparent way, and that health research in Ireland continues to be promoted and facilitated.

Medical Education, Training & Research,
Health Service Executive.
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Chairperson’s Foreword

Ireland would like to continue to build its capacity as a premier place for research, development and advanced technology as the basis for social prosperity for all its citizens. This includes research in health care. Healthcare research requires participation of people and patients in the scientific evaluation of new and established treatments and practices. This requires participant knowledge, consent and an understanding of the risks involved.

It also requires effective mechanisms to ensure the safety of participants and the creation of efficient systems to promote and encourage high quality research. It is in this context that the review group examined the current landscape of Research Ethic Committees in Ireland.

The HSE Research Ethics Committees (RECs) Review Group was established in January 2007 to identify the current Research Ethic Committees in the HSE and external agencies and their processes for research ethics approval.

This review report complements the document by Irish Council for Bioethics:- ‘Operational Procedures for Research Ethics Committees: Guidance 2004’ that identifies the primary task of Research Ethics Committees as the protection of the welfare and the rights of participants in research. The Irish Council for Bioethics found that Ireland needed comprehensive guidance with respect to ethical review of research involving human participants outside the remit of clinical trials.

This HSE led review on Research Ethics Committees was commissioned by Dr. Davida de la Harpe, Assistant National Director, Health Intelligence, Population Health Directorate on behalf of the Medical, Education, Training and Research (METR) committee. I would like to acknowledge their vision and support.

This report provides the findings of a survey of the research ethics committees, consultation with stakeholders and interviews with Chairpersons of the RECs within the context which best practice models from a number of countries internationally.

As the first comprehensive multi-method study of Research Ethics Committees in Ireland, the review covers committees that approve research under the Clinical Trials on Medicinal Products for Human Use Regulations, 2004 (S.I. 190 of 2004) implementing the EU Clinical Trials Directive (2001/20/EC) and all other health service research outside the remit of clinical trials. The Research Ethics Review Group recommendations promote integrated delivery of
research ethics review in line with the objectives of the HSE Transformation Programme (2007-2010). I would like to acknowledge the excellent joint leadership of Majella Daly in the conducting of the review. The Review Group collaborated with the Office of the Minister for Children in undertaking this review, and in particular I wish to thank Dr. Heike Schmidt-Felzman who led the research on their behalf. I would like to express my appreciation for the hard work and dedication of the REC Review Group members and the wider team and experts whose consultation and range of skills were invaluable to the completion of the work. Many thanks to all of the participants in the review process.

We have identified where Research Ethics Committees are located and how they operate. We engaged and communicated with stakeholders i.e. researchers, research ethics committees members; policy makers, service user representative, services providers and experts and elicited their challenges, priorities and commitment. We also reviewed a range of REC models from other countries. All of this identified the key elements which would support an effective high quality research ethics committee framework to deliver protection for participants, advice for the researchers, education for all within a context of ensuring the scientific quality of research and atmosphere of conciliation.

The value and need for Research Ethics Committees is evident. The Department of Health and Children are the supervisory body which have the authority to implement and monitor standards and guidelines, for the thirteen REC approved for Clinical trials. For the remaining thirty seven Research Ethics Committees that were identified (and additional committees since this study was conducted) they determine their own standards based in some cases on guidelines from the Irish Council for Bioethics and other expertise and experience. The comprehensive information gathered for this report and the manner of engaging with stakeholders provides an important platform to develop consistent and effective processes for Research Ethics in Ireland. The next steps may include formulating the goals from the Review Report to become HSE policy on research ethics; define how we would know if we met these goals and identify some method to measure the progress. Ireland is generally seen as a humane and caring place and a resolution to this challenging issue of Research Ethics must be consistent with our core values.

Mary Morrissey, Chairperson.

1 Ireland here and elsewhere in the report refers to the Republic of Ireland only.
Acknowledgements

The completion of this report would not have been possible without the cooperation and assistance of many people whom we would now like to thank.

Dr. Davida de la Harpe and the Medical Education, Training and Research (METR) Committee who commissioned and supported this review.

Members of the review group were:

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The review benefited greatly from the collaboration Dr Sinéad Hanafin and Ms Anne-Marie Brooks on behalf of the Office of the Minister for Children (OMC). The research and final report were enhanced by working with the OMC commissioned research team from the National University of Ireland, Galway (NUIG) – namely Dr. Heike Schmidt-Felzman, Ms Marion Ward, Dr. Jane Sixsmith and Ms Siobhan O'Higgins.

We would like to thank all the research participants including the Research Ethics Committee (REC) chairpersons and secretaries who completed the questionnaires, and/or took part in
interviews. We would like to thank all who attended the Consultation Day on November 1st including REC members, researchers, and representatives of consumer organisations. We would like to recognise and especially thank the line managers who enabled staff to participate on the REC review group and take part in the research.

The success of the consultation day in November is strongly attributable to the excellent facilitation provide on the day by Ms. Helen Franklin, Partnership Facilitator, Health Service National Partnership Forum and other workshop facilitators. We would also like to thank the staff and management of the Education Centre at AMNCH Tallaght for providing us with their excellent facilities at such short notice. We greatly appreciate the administrative support for provided - Barbara Hennessy, Public Health; Imelda Crone, Population Health Directorate and Ros Condon, Department of Public Health, HSE South.

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Executive Summary

Research Ethics Committees (RECs) are the acknowledged international best practice structure for overseeing the conduct of ethical standards in healthcare research. They have five main functions:

- **Protection:** "contribute to safeguarding the dignity, rights, safety and well being of all actual or potential research participants." WHO 2000; to protect the rights of researchers to carry out legitimate investigation; and the Institution/Organization's reputation for research conducted and sponsored by it.
- **Advice:** can advise individual researchers on whether a project is likely to be harmful or offensive to subjects or the broader community.
- **Education:** has the task of increasing knowledge and awareness of ethical issues and regulations/directives.
- **Research Quality:** For research to be ethical, it must be scientifically sound.
- **Conciliation:** conciliation and adjudication of conflicts between investigators and participants” (O'Sullivan 2007).

However, the use of research ethics committees (RECs) in research with human subjects is a comparatively recent phenomenon. Their introduction as an obligatory part of the research process was meant to ensure those participants’ rights in research. Research Ethics in healthcare is governed by legislation in the form of EU directives, existing policy, national and professional guidelines. Historically in Ireland there has been an absence of standardisation with respect to such committees resulting in variation in practices across committees, often resulting in significant differences in the extent of delays and burdens placed on REC members, the research community and the populations. Ireland is not alone in this and internationally there have been attempts in recent years to improve the research ethics approval system.

The REC review group of internal HSE staff and external agencies was established in January 2007. The group were tasked with conducting a comprehensive review of RECs on behalf of the Medical Education, Training and Research Committee (METR) of the HSE. The overall review aimed to identify the current Research Ethics Committees (RECs) and their processes of gaining research ethics approval.

This review was conducted collaboratively with the Office of the Minister for Children who has a particular interest in the review of children’s research.

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2 Hereafter in this report this term covers all research ethics committees from the HSE, academic institutions, voluntary healthcare organisations and other organisations that review health related research.
A multi-method approach was used in the review. These were an (i) exploration of the research ethics systems used in other countries through online searches and personal communications with experts in those countries (ii) a questionnaire sent to the Secretaries of all known RECs, (iii) a Consultation Day with members of RECs, researchers, patients’ representatives, experts and policy makers and (iv) interviews with REC chairpersons and administrators. This approach allowed for a more comprehensive review and helped to ensure completeness.

The main findings were:

1. The enthusiasm of participants involved in this area and the desire to formalise a network to support the development of knowledge and expertise is clearly evident. There is a commitment to optimising the research experience to improve the health of the population while minimising the burden on RECs, researchers, and in particular, the population.

2. The need for standardisation. Participants expressed a resounding desire for standardised processes across research ethics committees. Facets of this include the development of a single application process, the agreement of standards for turnaround times of ethics applications, and guidelines for consent with vulnerable populations, composition of membership and competencies of committees and workload.

3. The need to increase the support capacity for RECs. Such support includes dedicated administrative support, access to training, and access to specialist knowledge, IT support systems, and dedicated time for participation on RECs.

4. Communication was raised as an issue at all levels of the research review process. This includes the need for improved systems at local and national levels between all stakeholders.

5. The need for high level leadership on issues such as governance, quality and accountability in a way that supports local structures.

The report makes four main recommendations to address these areas of improvement to enable RECs meet their functional responsibilities.

1. A national REC resources unit should be established which would be responsible for a number of functions such as standardisation of the REC application process and procedures.

2. A specialist panel and/or database of individual expertise should be available to steer the implementation of the recommendations of this review and as required provide expert advice on specific dilemmas for committees and the implementation of the recommendations of this review.
3. Resources should be made available to support committees locally and the national resources unit. A budget needs to be made available for this purpose.

4. Communication needs to be improved at all levels.

The review group feel the publication of this report is timely as the METR strategy 2007 has just been launched. Many of the recommendations of this review complement and support the recommendations of that strategy. The engagement of key REC stakeholders in this review opens the gate to collaborative working to implement these recommendations in line with the objectives and timelines of the Transformation Programme 2007-2010.
Introduction

Background

The use of research ethics committees (RECs) in research with human subjects is a comparatively recent phenomenon. Their introduction as an obligatory part of the research process was to ensure that participants’ rights in research as, for example, stated in the Nuremberg Code (1948) or the Declaration of Helsinki (1964) were upheld by researchers. While the first RECs were introduced in the 1960s, their development has been by no means homogenous around the world, and until today there are significant international differences with regard to most aspects of the organisation, legal status and extent of their use. While there is a tradition of highly formalised and professionalised research ethics review procedures in North America, the development of comparative structures has proceeded at a significantly slower pace in Europe and other continents. In Europe, increased attention has been paid to REC procedures after the 2001 European Clinical Trials Directive came into effect.

In Ireland in 2004 the Minister for Health and Children enacted the EU Directive 2001/20/EC on the laws, regulations and administrative provisions of Member states relating to the implementation of good clinical practice in the conduct of clinical trials and medicinal products for human use. Included in this are standards for ethical review. Regulations made by the Minister for Health and Children (Clinical Trials on Medicinal Products for Human Use, S.I. No. 190 of 2004), the report of the Irish College of General Practitioners entitled "Ethical questions to be considered by a research ethics committee when approving clinical trials which involve genetic testing" (2003) and the Health Research Board’s report "Genetic Research and Human Biological Samples: The Legal and Ethical Considerations" (2002) all offer guidance in relation to ethical review of clinical trials. Individual disciplines such as nursing, psychology and sociology through their respective associations also offer guidance on research ethics.

Overall, Ireland has been comparatively slow in adopting formalised ethics review procedures. The publication of the Operational Procedures for Research Ethics Committees: Guidance 2004 by the Irish Council for Bioethics marked the departure for more widespread attention to the implementation of structures and procedures to support good practice. The goal of the present report is to describe the current situation in Ireland and the perspectives of different stakeholders on the existing system and desirable changes.
The present review of RECs in Ireland was informed by concerns raised in the international literature on RECs. Broad agreement exists on the foundational principles and core concepts of research ethics, including:

- respect for participants’ autonomy,
- safeguarding confidentiality,
- minimising harm and maximising benefit to participants, and
- ensuring justice in recruitment for research and the application of research results.

However, a range of problematic aspects with the practical implementation of these issues in the context of RECs has been highlighted in the literature.

Common issues raised in the literature on RECs address the following areas:

I. Concerns relating to the organisation of the Research Ethics System

II. Concerns relating to comparisons of the performance of RECs

III. Concerns relating to the implementation of ineffective ethical measures

I. The Organisation of the Research Ethics System

Historically, REC systems were usually put in place or modified without these interventions being preceded by comprehensive formal assessment of the existing situation. For a long time there was a scarcity of comprehensive studies on REC systems and practices. However, in recent years, studies of RECs around the world have become increasingly common, and comprehensive reviews in the context of reforms of national systems have been conducted e.g. in the UK (COREC 2004, 2006) or New Zealand (National Advisory Committee on Health and Disability Support Services Ethics 2004). Judging from the number of published articles addressing different aspects of recent REC reforms in the UK, the research and ethics communities understand themselves as active participants in public deliberation on the REC system. Aspects that have been addressed in such reviews include surveys of REC structures (e.g. membership or the existence of standard operating procedures), remit, available resources, review parameters and processes for the review of multicentre studies, researchers’ perspectives on the review process etc.

II. Comparisons of the performance of RECs

Numerous studies on the comparison between the performance of different RECs have been conducted for many years and have generally shown that the work of various RECs can differ significantly with regard to a broad range of parameters. This applies both to international (Hearnshaw 2004, Pinkerton 2002) and national comparisons (Garfield 1995, Middle et al. 1995), and holds even in cases where a significant degree of procedural and ethical guidance has been provided (Tully 2000, Lux 2000). Consistently replicated results of such studies include the lack of uniformity in responses to identical submissions, and significant differences in the extent of delays and burdens placed on the researcher. It has been suggested that
uniform structures and procedures and improved training might increase consistency; however, as of yet, there is no conclusive evidence of this. It has been highlighted that uniform results are not achievable due to the nature of moral judgement and the specific reflective processes in the REC setting (Edwards et al. 2004).

III. The implementation of ineffective ethical measures
One of the most well researched areas of relevance to research ethics is research on different aspects of the informed consent process. A large range of literature addresses the question of the participants’ comprehension of informed consent procedures, both specifically in relation to the comprehensibility of participants’ information sheets and more generally to the effectiveness of informed consent procedures. It has been highlighted that the majority of informed consent sheets is not written in a way that is comprehensible to the average participant (Grunder 1980, Handelsman 1995). However, even if considerable efforts are made to improve participants’ comprehension of the nature of the research, participants have been shown to frequently operate under mistaken assumptions, including especially the “therapeutic misconception” (Appelbaum 1987, Snowdon 1997, Featherstone & Donovan 2002). In relation to research with vulnerable participants it has been shown that researchers are not always familiar with ethical requirements in the field; e.g. even researchers who are working with children are not always sufficiently knowledgeable about ethical and legal guidelines on the requirements of informed consent with children (Fisher-Jeffes et al. 2007).

It is against this backdrop that in January 2007 the review was commissioned. The HSE Research Ethics Committees (RECs) Review Group was commissioned by Dr Davida de la Harpe, Assistant National Director, Health Intelligence and Population Health on behalf of the Medical, Education, Training and Research (METR) committee. The Office of the Minister for Children (OMC) had at the same time commissioned NUIG to carry out research on current RECs with particular emphasis on establishing current practice in the review of research involving children. The HSE REC review group worked collaboratively with the OMC on this review and the research was managed jointly between NUIG and HSE researchers. This report outlines the findings from the review.

The overall review aimed to identify the current Research Ethics Committees and their processes of gaining research ethics approval.
Methodology

Key Points
To meet the aim and objectives of the review, four methods were used. These were an (i) exploration of the research ethics systems used in other countries through online searches and personal communications with experts in those countries (ii) a questionnaire sent to the Secretaries of all known RECs, (iii) a Consultation Day with members of RECs, researchers, patients’ representatives, experts and policy makers and (iv) interviews with REC chairpersons and administrators. This approach allowed for a more comprehensive review and helped to ensure completeness. The HSE researchers led methods (i) – (iii) and NUIG led (iv) the interviews.
Background

The HSE Research Ethics Review Group (Steering Group) formed two separate sub-groups to conduct the review. These groups were the Research Sub-group, and the Consultation Day Sub-group. Both the Steering Group and the Sub-groups met frequently to drive the project to meet its target of mid-December 2007. Shortly after commencing the review, the Steering Group became aware of a similar project commissioned by the Office of the Minister for Children (OMC) to establish current practice in the review of research involving children. The National University of Ireland, Galway (NUIG) was commissioned to undertake the research on behalf of the OMC. It was agreed that combining the projects would be of greater benefit and would maximise efficiency of resources.

The overall review aimed to identify the current Research Ethics Committees and their processes of gaining research ethics approval.

The objectives of the review were:

- To quantify the number and location of RECs in Ireland
- To identify what processes they use for granting REC approval from the application process (including any forms used), the approval process, the review process, recording processes.
- To collect any documented processes or Standard Operating Procedures (SOPs) that are available from the RECs
- To record their activity levels in 2006
- To identify the scope of research they approve e.g. hospital only, community based, clinical trials research, student research, and to identify the percentage under each category
- To identify the training needs of RECs
- To ascertain their preferred mode of training
- To ascertain REC members, researchers and participant views, attitudes and expectations for improving current RECs structures and processes.

This chapter aims to describe and explain the methods of data collection used to determine how RECs work in Ireland.
Data Collection

This review was conducted using four methods. These were an (i) exploration of the research ethics systems used in other countries through online searches and personal communications with experts in those countries (ii) a questionnaire sent to the Secretaries of all known RECs, (iii) a Consultation Day with members of RECs, researchers, patients’ representatives, experts and policy makers and (iv) interviews with REC chairpersons and administrators. This approach allowed for a more comprehensive review and helped to ensure completeness. The HSE researchers led methods (i) – (iii) and NUIG led the interviews.

RECs were identified in the first instance by using the list compiled by the Irish Council for Bioethics’ website and then by conducting an additional search on the internet for Irish RECs and by asking members of RECs if they knew of others. Contact was also made with voluntary health organisations to ascertain if they had a REC.

(i) Exploration of other countries

In the course of the review of research ethics committees in Ireland, the research ethics structures and processes of some other jurisdictions were also examined. Methods used were document review and contact with experts in other countries. The countries considered were selected on the basis of their comparability with Ireland either in terms of population size or RECs systems currently or previously in place. Countries were reviewed using the internet, face to face communications with REC experts from other jurisdictions and e-mail and telephone communications.

This is not an exhaustive or explicit literature review but is a cursory review of the systems in place in other countries. A detailed literature review will be available in the final overall OMC report of the review of RECs in Ireland, incorporating both the HSE and the academic RECs.

(ii) Questionnaire

A self-administered questionnaire was developed in conjunction with the overall project steering committee and the National University of Ireland, Galway (NUIG). It was designed for ease of use, accuracy of completion and simplicity for subsequent coding and analysis. Several drafts were produced before piloting. The questionnaire comprised six components (36 questions in total) and consisted of both open and closed questions.

The six components of the questionnaire were:
1. General Information
2. Membership of the REC
3. Training
4. Activity Levels
5. REC Remit and

The questionnaire was then piloted in one HSE institution and one academic institution. Amendments were made. (final questionnaire – Appendix 1a).

The questionnaire was distributed via post with a cover letter (Appendix 1b) to the secretaries of all Research Ethics Committees. This cover letter detailed the purpose of the study and reassured those responding that the data, although not anonymous, were confidential and that only aggregated anonymised data would be presented in the report.

An envelope was enclosed with the cover letter and questionnaire for return via FREEPOST. All RECs were given a timeframe of three weeks to respond to the postal questionnaire (distributed August 27th 2007 for return by 14th September 2007). Once the closing date for completed questionnaires had passed, follow-up calls and emails served as a reminder to those who had not responded. Most non-responders were followed up with on two occasions, after which follow-up ended.

Study Population

The questionnaire was distributed via post to

- all HSE Research Ethics Committees (as downloaded from the Council for Bioethics, Ireland website, www.bioethics.ie)- 54% of committees surveyed;
- all third level institution RECS (as downloaded from the www.bioethics.ie website and via word of mouth) - 20% of committees surveyed
- and to voluntary groups and organisations, funded by the HSE in Ireland (information made available by the NMPDU, the Federation of Voluntary bodies website, www.fedvol.ie, and known HSE linked organisations) - 26% of committees surveyed (for full list see Appendix 2).

Data Analysis

Data from the completed questionnaires were entered and analysed in SPSS Version 14.

Quality Assurance

Some of the data were double entered and assessed to ensure accuracy of data input.
(iii) Consultation Day

The Consultation Day was held in the Education Centre, AMNCH Tallaght, on the 1st November 2007. The aims were:

1. To provide feedback on the survey of Research Ethic Committees
2. To consult and hear opinions on recommendations for the future development of Research Ethics Committees and
3. To provide an opportunity for those involved in Research Ethics to meet and exchange knowledge and information. The programme for the Day is attached (Appendix 4).

Population Sample

The participants for the Consultation Day were nominated as representatives by their REC. All 50 RECs were written to asking them to nominate four members of their REC to attend the Day. They were also asked to (with their permission) forward the name and contact details of two researchers, current or recent, who could be contacted to invite them to attend the consultation seminar. All nominees were then written to asking them to participate in the Day. A total of 57 people attended the Consultation Day comprising REC experts, REC members, researchers and client advocacy groups. In addition members of the Review Group, speakers and facilitators were also in attendance.

Workshops

The participants were allocated to eight tables (approximately six at each table) according to a stratified random sample. Each table was colour coded and participants remained with the same table for both workshops. The colour coded tables facilitated ready affinity with a group and provided for easy rapport between participants. The quotations in the analysis section are recorded by table colour to ensure accuracy and transparency while maintaining anonymity. There was a facilitator from the REC review group at each table and there was an overall lead facilitator. The facilitators did not take notes or contribute views. This ensured that the opinions of participants at the table only were effectively processed and accurately represented.

There were two workshops/roundtable focussed discussions held on the day. The first asked ‘what’s currently working well and what needs improvement in RECs?’ The second workshop asked ‘how you would see things improved in the future and how could these changes be implemented?’ Each workshop was an hour long and facilitators were asked to ensure that the scribe selected by the group adequately captured the views of the group. Each table was asked to report back on three main points to the rest of the participants. All points were noted and a commitment was undertaken to forward the transcribed notes of the raw material to the participants. The three (and sometimes more) points fed back to all the
participants by the selected table rapporteur were tape-recorded (with permission) in order to ensure that the discussion and findings of the day were captured as comprehensively as possible. The co-ordinating facilitator for the day also synopsised and presented back the main points to the participants.

**Data Analysis**
All notes from the tables, tape recordings of the rapporteur and the facilitator’s synopses were transcribed. These notes were then analysed by content and emergent key themes collated.

All notes from tables and transcripts were read through in their entirety. They were subsequently read through again and initially coded. They were then read several more times to code further and the notes from the tables were cross-checked with the transcripts from the tape recordings.

**Quality Assurance**
After the first draft of the analysis was prepared two other members of the Steering Group cross checked the findings against their own coding of the transcripts to ensure reliability.

**(iv) Interview with RECs**
This research was conducted by the research team from NUIG with input in the design phase from the REC review group.

**Interview Tool**
Semi-structured qualitative interviews were conducted with REC chairpersons and REC administrators by one researcher. The aims of the interviews were:
- To identify current experiences, needs and concerns relating to the work of existing RECs
- To identify experiences, needs and concerns in relation to the review of children’s research (as part of the the terms of reference of the OMC study)
- To identify respondents’ suggestions relating to the organisation of the REC system in Ireland

The interview guidelines and prompts were developed in consultation with the Research Subgroup of the REC Review Group, to provide information that would complement information gained from the questionnaire. They were designed to capture a number of specific concerns, but also to allow for sufficient openness regarding participants’ opinions
and experiences and the specific situation of each of the participating RECs. Several drafts were produced before piloting, and relevant questions and prompts were agreed (See appendix 3).

The interviews with chairs were piloted with respondents from one academic institution and one teaching hospital and no changes were required. The interviews with administrators focused on their administrative tasks, challenges on the administrative side and their suggestions for potential supports and solutions.

Selected respondents were contacted by phone and by email initially. Contacts by email included a cover letter and further information on the research project. Phone contacts were usually followed up by an email with relevant information before participating in the interview. Attempts at contact with potential participants were usually repeated until a positive or negative response was received either by the respondent themselves or by a gatekeeper. In some cases, respondents had agreed to participate, but could not be reached within the timeframe of the research.

The main period of data collection with REC chairpersons and administrators was undertaken between early October and mid December. Most of the interviews were conducted via telephone. Most of the interviews were recorded with the agreement of participants; in a small number of interviews extensive notes were taken instead of recording.

**Study Population**

Respondents were drawn from nine academic institutions, seven HSE hospitals with Clinical Trials Committees, five HSE hospitals without Clinical Trials status, three voluntary institutions and three RECs from other organisations. Overall, 26 REC chairs and 15 administrators contributed to the interviews (seven of the administrators participated in an extensive interview; the remaining respondents reported briefly on the structure of the REC and their activities). In four academic institutions the chairpersons of several REC subcommittees were interviewed.

They were selected according to the following categories:

- HSE/Academia/Voluntary Grouping
- Geography
- Clinical trials committees
- RECs with high/low review load
- RECs with high review load of children’s research.

It was agreed that a minimum of five chairpersons from each of the following needed to be contacted - HSE clinical trials committees, HSE or voluntary non-clinical trials committees, and academic committees. Administrators with significant workload from clinical trials committees
and academic committees were contacted. During the study it was decided to increase the number of respondents from academic committees, for the following reasons.

- The identities and structures of committees in many organisations turned out to be more complex than initially assumed (in some institutions there was a large number of previously unidentified independent subcommittees).
- The requirement of including RECs with a high proportion of children's research made it necessary to include additional numbers of academic committees which reviewed high proportions of children's research.

Analysis of data

Interviews were transcribed in Word and entered into NVivo 7. A first round of coding consisted in initial free coding of issues brought up by respondents that was informed by, but not restricted to, the categories identified by the interview questions. This analysis underlies the discussion in the present report.

Further, more in-depth qualitative analysis will be conducted and presented in the upcoming report by the OMC. This will also include results from additional focus groups and interviews with other stakeholders in the area of research ethics in children's research, including REC members, children's researchers, academics and children.

Quality Assurance

The main work on the analysis was conducted by one researcher, but different members of the NUIG research team read a subset of transcripts and discussed the emerging categories. The analysis of the interviews was also discussed during meetings of the Research Sub-group of the REC Review Group.

The results of the Survey and the Consultation Day, undertaken by the HSE, are reported in detail in this report. Initial findings of the Interviews with Chairpersons of the RECs, conducted by NUIG, are also reported, but the detailed results of this component of the review will be reported in the overall Report of the Review of RECs in Ireland to be published by the OMC.

(v) Ethics

The REC review group considered the ethical issues associated with undertaking this review using the multimethod approach.

- Consideration was given to the needs of respondents and their time required for participation. The survey was made as user friendly as possible for ease and speed of completion.
- Consent was sought from participants to take part in the interviews.
• The range of stakeholders was considered and every effort was made to ensure all stakeholder groups were represented during the review.

• Benefits accrued to the stakeholders, for example, networking and development of a sustainable knowledge network, irrespective of the outcome of the review.

• The review used a multi-method approach – people could contribute in ways that suited them.

• The review built on what was already done nationally and internationally and collaborated with the research team of the OMC so there wasn't duplication of effort and stakeholders weren't overburdened with research.

• Confidentially was assured.

• In addition to circulating a copy of the overall report, a commitment was made to communicate the findings of the survey and Consultation Day to the participants of both. Quality assurance methods were incorporated at every stage of the review including the writing of the report.
Results: Section 1 - Overview of Systems in Ireland and Other Countries

**Key Points**

Of the seven jurisdictions examined outside of Ireland, six have reviewed and restructured their research ethics approvals procedures in the last few years. There are many features that are common across these jurisdictions. These include:

- developments in standardisation of the research ethics approvals systems in terms of
  - Standard Operating Procedures (SOPs) for RECs
  - Legislative framework
  - single application procedures for proposals
- simplification of the procedures
- central advisory authority with varying regional and local arrangements
- training programmes are being developed and standardised

It is worth noting however, that problems are encountered. Delays are experienced for example in areas where there are local requirements in addition to the central ethical approval and where the workload for some RECs, particularly multi-region RECs, is too much.

In summary, the experience of other jurisdictions and the recommendations of recent reports on health research in Ireland indicate that there might be significant advantages to a cohesive and integrated approach. The methods adopted may vary across jurisdictions but the common point is the need for effective delivery of the research process in a cohesive and integrated fashion. As this was not a comprehensive review of all countries, this does not necessarily reflect international practice overall.
The following countries’ systems are overviewed here: Northern Ireland, the UK, Denmark, Sweden, New Zealand, Australia and Canada. Recent reports in Ireland are also reviewed. An appended document provides an international comparative tabulation of the structures of several jurisdictions in terms of the composition of RECs, education, resources, decisions, Standard Operating Procedures. (Appendix 5)

Northern Ireland

Northern Ireland began a review of its system in 2001 at the time of the EU Directive 2001/20/EU on good clinical practice in clinical trials and before its transposition into UK law in 2004. This law brought RECs within a legislative framework, which requires a system for delivering a single ethical opinion for the whole of the UK. It established the UK Ethics Committees Authority, provided a 60 day limit on ethical opinion, as well as regulation on the composition of the committees.

The implications were that the existing RECs in Northern Ireland underwent a review and restructuring. The four existing RECs were Queen’s University Belfast (QUB), University of Ulster, Altnagelvin Hospital and Sperrin Lakeland Trust, which in total reviewed some 370 proposals per annum. Only QUB REC met frequently enough to meet the 60 day turnaround, none had the right expert/lay mix, none had publicly appointed members and there was no communication between the RECs. Since the new legislation was the responsibility of the Department of Health in England, Scotland, Wales and Northern Ireland, this meant that the university RECs could not legally be recognised for the review of Clinical Trials of Investigational Medicinal Products. This resulted in the establishment of three new Health and Personal Social Services RECs (HPSS RECs), which have now been renamed as the Health and Social Care RECs (HSC RECs).

An Office for RECs (OREC) was established in 2003 to support and manage the RECs. Research proposals go to the OREC and are assigned to the appropriate REC. Each REC has dedicated administrators and the OREC is the link from Northern Ireland to the National Research Ethics Service (NRES) formerly Central Office for RECs (COREC) in the UK.

In terms of resources and training, the OREC in Northern Ireland manages a budget to support a manager, dedicated administrative support for each REC, on-going induction and training for REC members, conferences etc. Membership is voluntary but expenses are paid. The expert/lay mix is at least one-third lay and the remainder are experts but there is no professional categorisation.

Standard processes exist; there is an on-line application form, 60 day turnaround, and a database to track projects.
Prior to application for REC approval, all Northern Ireland based researchers must have secured permission from the HSC Trust at which they plan to conduct research (as part of research governance they complete a detailed application form for that host organisation first. There is no standard turnaround time for research management approval. These forms are not the same and cannot be linked).

The REC does not perform scientific review. This is not its role; however, it does have a duty to ensure that the scientific critique is adequate, and can ask for copy of peer review reports as part of the ethical review process.

The link to the ORECNI is http://www.orecni.org.uk

Personal communication on a visit to Northern Ireland also facilitated our information.

United Kingdom
The UK NHS RECs system operates in the same way as Northern Ireland and had been administered by COREC (the Central Office for Research Ethics Committees) but COREC has since been renamed NRES (The National Research Ethics Service).

The National Research Ethics Service was launched on 1 April 2007. The NRES comprises the Head Office function (formerly COREC) and NHS RECs in England. NRES to work with colleagues in Scotland, Wales and Northern Ireland to maintain the established UK-wide framework for ethical review of research.

The National Research Ethics Service:
  o Maintains an overview of the operation of the research ethics system in England, and alerts the Department of Health and other responsible authorities if the need arises for them to review policy and operational guidance relating to Research Ethics Committees (RECs)
  o Develops and manages a national training programme for Research Ethics Committee members and administrators in England
  o Maintains close contact with officials in the Department of Health with policy responsibility for wider issues of research ethics and with colleagues from Scotland, Wales and Northern Ireland
  o With appropriate advice, develops, implements and maintains operating procedures and standards for RECs that will be consistent across the UK
NRES at the National Patient Safety Agency in England works closely with colleagues with similar responsibilities in Scotland, Wales and Northern Ireland.

NRES is also working towards developing an Integrated Research Application System for Research in the Health Service. In January 2008, a new application system will be launched. Applicants will be able to provide comment on the system and a final version incorporating this feedback will be available later in 2008. The application system will be available online.

The link to NRES is [http://www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk)

Denmark

The Danish system is interesting as the population of Denmark is very similar to Ireland. Their system is regionally based (1980). They have eight regional committees and a national committee (The Danish National Committee on Biomedical Research Ethics). Half of the members are lay, appointed by the political system and the rest are medical professionals and active researchers (1992). All research projects in Denmark involving human beings and any kind of human tissue need permission from an ethics committee. In the case of medicinal and medicinal devices trials, permission is also required from the Danish Medicines Agency. This was further amended in 2006.

The investigator, not the sponsor, must apply to the relevant regional REC and must conform to the guidelines. In the case of multi-centre trials, they need only apply to one regional committee, i.e. the Regional Committee where the Principal Investigator carries out the research. In the case of multi-national trial projects, permission from a Danish committee is always required.

Decisions can be appealed to The Danish National Committee on Biomedical Research Ethics. This committee consists of 20 members, four appointed by government (two from the Minister for internal Health and two by the Minister for Science, Technology and Innovation). The remaining 16 comprise two recommendations from each of the eight regional committees.
Sweden

Sweden, also have a regional emphasis with their REC structure, but it also appears to be more scientific and with statutory responsibility. Their structure has a statutory and legal emphasis. In 2004 a new system, based on statutory law, states that approval of a Board for Ethics Review is a mandatory legal requirement for certain types of research – “Ethics Review of Research Involving Humans”.

There are six independent regional boards based on University regions. Each Research Ethics Board (REB) is chaired by a judge. There is also a central national board for Research Ethics Review. Each board has at least two departments, one for non-medical research and one for medical research. There are a total of 16 members on each REB, the Chairperson (a judge) and 16 others, 10 of whom must have scientific competence and five representing the public interest.

The Central Board for Ethics Review can over-rule the decision of the Regional Boards for Ethics review that reject research projects. The regional boards exercise public power and consequently may be penally liable for breach of duty in cases of intention or negligence.

As with many systems the basis of the Swedish system is the Declaration of Helsinki. This means that there are qualification requirements for researchers and includes issues of informed consent. Supported by the Swedish Research Council’s Guidelines for the Ethical Evaluation of Medical Research on Humans (similar role to that of the Irish Council for Bioethics), which is the advisory board to government on ethical issues raised by scientific and technological advances in biomedicine.

Weblink:  [http://www.epn.se/start/startpage.aspx](http://www.epn.se/start/startpage.aspx)

New Zealand

New Zealand has undergone considerable restructuring in the last few years. In 2004, RECs were reduced from 15 to 7. The system is regionally based.

Seven health and disability ethics committees carry out ethical review of health and disability research in New Zealand. Six of the seven ethics committees are regional, and consider applications for research that is to be carried out entirely within just one of New Zealand's four ethics committee regions.

The Northern region is serviced by two ethics committees – the Northern X Regional Ethics Committee and the Northern Y Regional Ethics Committee. The Central Region is serviced by the Central Regional Ethics Committee. The Upper South region is serviced by two ethics
committees – the Upper South A Regional Ethics Committee and the Upper South B Regional Ethics Committee. The Lower South region is serviced by the Lower South Regional Ethics Committee. The Multi-Region Ethics Committee (MREC) considers applications for research that is to be carried out in more than one of the four ethics committee regions.

There are a total of 84 members on the 6 RECs. Each is chaired by a lay member and the deputy chair is a medic. There is a defined composition including a researcher, biostatistician, ethicist, Maori representative, lawyer and lay member. There is also a Standard Operating Procedure. There is some training but it is limited. The RECs meet monthly.

The MREC is for multi-region applications. Average turnaround is 50 days. Three additional pieces of information are also required: locality assessment; cultural and social responsibility disparity outcomes (Maori); and if using radiological equipment. There is an increasing issue however, that these are beginning to take on a life of their own. Members are nominated by the community and appointed by the Minister. There is a central application form. There is no online application procedure.

The system is currently being reviewed and may lead to a second multi-region REC.

**Australia**

Historically, Australia used an Institutional Ethics Committee (IEC) system from 1973 onwards. In 1991 the IECs assumed responsibility for evaluating study design and safety as well as ethical aspects. This led to an increase in clinical trial activity and multi-centre studies. This was a function of devolution of the Therapeutic Goods Administration’s responsibilities in the Therapeutic Goods Act.

Problems began to show. These included delays, decisions between IECs, duplication, inconsistencies, one IEC not accepting approval of another IEC. Other contributing causes included: National Statement as guidance (not regulation), variation in institutional expectations regarding the kinds of research requiring review, removal of distinction between “medical” and other research involving humans.

In the mid 1990s, there were suggestions of centralised ethics approval of multi-centre studies, but these were not recommended for several reasons: IEC had ethical obligations and legal duties to its own patients, students or staff. Important aspects of ethical review are ‘local’: best knowledge of expertise of investigators, availability of facilities etc, best knowledge of ethnic and cultural mix of local community. Other suggested solutions included
development of a standardised application form and online applications to save time and paperwork and multiple submissions.

Current status

Since 2007 there is a National Ethics Application Form (NEAF). This is being developed since 1995, it was in its final stages at the end of 2006 but is not being used by all HRECs. In 2007 there is an online application procedure but there is still a need to submit hard copies, a minimum of eight which is the minimum size of the committee. They are continuing to enhance their on-line application procedure.

The Australian Health Ethics Committee (AHEC) which is part of Australia's National Health and Medical Research Council, advises the Council on ethical issues relating to health. This includes the development of guidelines for the conduct of medical research involving humans, monitoring Human Research Ethics Committees (HREC's), and promoting public debate on health issues.

The AHEC has legal authority to develop guidelines for health research ethics and advice to National Health and Medical Research Council regarding ethical issues in health; medical research; regulation. The AHEC does not review research ethics proposals, but is the body to whom local HRECs report and provides oversight for HRECs. The National Statement is used as guidance for research ethics committees and has been revised and the new version is available online (see references below).

Canada

The Canadian Association of Research Board (CAREB) is a national membership organisation to represent Canadian Research Ethics Boards established in 2002. Health Canada is the Federal Department responsible for health. The REB was established to formalise the department’s ethics review process. They are guided by the principles of the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans which sets the standards for RE Boards in Canada. One of its major goals is to harmonise the review process by having common review procedures within a shared ethical framework.

Individual institutions are responsible for setting up their own REBs and sharing of REBs between institutions with small review loads is encouraged.

There is no streamlined process in place for multi-centre studies, leaving autonomy to the institution but encourages researchers to provide information where a proposal has been submitted, to allow for co-operation between REBs on the proposal.
In terms of training, there is a two hour tutorial for researchers. Some REBs have very elaborate support systems – administration, training and monitors - but not the majority.

There is an Interagency Advisory Panel on RE (PRE) with 12 members that continuously reviews and develops the Tri-Council policy and identifies education needs.

Other countries worth consideration are Finland, for further information use this link - http://www.etene.org/e/index.shtml. And Iceland, there is a comprehensive web site on Research Ethics Committees, this link provides user friendly documents, guidelines and other useful documents -http://www.visindasidanefnd.is/Default.aspx?id=27&cmd=submenu

Ireland

There are currently over 50 RECs in Ireland and the details of their operating procedures and processes are identified in this report. Within the past two years considerable work has been done to review and plan for developing and progressing health education, training and research in Ireland. Four reports (FORFÁS, 2006; Fottrell, 2006; Buttimer, 2006; HSE METR 2007) have been published since February 2006 all addressing the need for improved delivery of health education, training and research and the need to provide a strategic platform on which to do so. The context of these reports is briefly reviewed here. What is of greatest interest to the current report, apart from the inherent value of those reports themselves, is that they corroborate, and are corroborated by, the findings of the current review of RECs in Ireland, particularly the findings from engagement with the stakeholders. The major emphasis and focus of the four reports centre on the need for integration and streamlining of the health education, training and research processes. The current report was conducted separately but the recommendations emanating from it resoundingly echo much of the recommendations of the other reports.

In February 2006, the reports of the Working Group on Undergraduate Medical Education and Training (Fottrell Report) and the Postgraduate Medical Education and Training Group (Buttimer Report) were published. These reports made key recommendations on the structure, co-ordination, management and delivery of medical education and training at undergraduate and postgraduate levels. Both reports provided an integrated implementation strategy to enhance medical education and training.

Also in 2006, the Advisory Council for Science, Technology and Innovation published Towards Better Health: Achieving a Step Change in Health Research in Ireland. Although the focus of the FORFÁS, 2006 report is primarily on clinical research, its emphasis is also on an
integrated approach and recommends streamlining and the development of a "co-ordination mechanism" (page 4).

Section 7 of the Health Act 2004 gives statutory responsibility to the HSE in terms of research. In response to the Fottrell and Buttimer Reports the CEO of the HSE established a committee to focus on medical education, training and research (METR)

In terms of the research policy framework, the Medical Education, Training and Research - HSE Strategy report notes that

"The establishment of a unified HSE presents the opportunity to link patients’ needs with research strategy on an integrated national basis" (page 9; 2007)

Throughout that report the emphasis is on an integrated approach and its recommendations include a central advisory resource for medical education, training and research, a central support resource and the facilitation of cross directorate projects and an interdisciplinary approach. One of the key functions and roles of the 'robust central unit' is the co-ordination of research activities through the central notification of research and the maintenance of a central database, as well as the dissemination of policies and audit. One of the three senior dedicated posts of the unit will have research leadership expertise.

In terms of legislation and research in Ireland two acts of are the most significance. In Ireland in 2004 the Minister for Health and Children enacted the EU Directive 2001/20/EC on the laws, regulations and administrative provisions of Member states relating to the implementation of good clinical practice in the conduct of clinical trials and medicinal products for human use. Included in this are standards for ethical review. Regulations made by the Minister for Health and Children (Clinical Trials on Medicine Products for Human Use, S.I. No. 190 of 2004), the report of the Irish College of General Practitioners entitled "Ethical questions to be considered by a research ethics committee when approving clinical trials which involve genetic testing" (2003) and the Health Research Board’s report "Genetic Research and Human Biological Samples: The Legal and Ethical Considerations" (2002) all offer guidance in relation to ethical review of clinical trials. Individual disciplines such as nursing, psychology and sociology through their respective associations also offer guidance on research ethics. The second important act is the Data Protection Act 1997 and revised Act 2003. The Office of the Data Protection Commissioner has recently issued Data Protection Guidelines on Research in the Health Sector. "The necessity for data protection guidelines on research in the health sector arises from an acceptance that the legislative position as contained in the Data Protection Acts can be somewhat complex in terms of what is expected of a health professional, or other person owing a similar duty of confidentiality to the patient, seeking to
access patient identifiable data for research or clinical audit purposes in terms of ensuring the fundamental right and freedoms of the patient”.

Office of the Data Protection Commissioner, Data Protection Guidelines on research in the Health Sector (2007), -
Section 2 – Survey

Key Points

Structures
Research Ethics Committees have been in operation for an average of 11.6 years and have an average of 13 members, an average of five of whom are required for making decisions (quorum). A large majority of the RECs have (i) a legal person, (ii) a medical doctor, (iii) a nurse and (iv) a lay person and a minority of committees have a statistician.

All responding approved clinical trials committees (7) have (i) medical doctor (ii) a lay person and (iii) a nurse. The Clinical Trials on Medicinal Products for Human Use Regulations 2004 recommend membership of approved research ethics committees. The findings show that these seven committees are broadly in line with the regulations. Both the chairpersons’ and the members’ terms of office last on average 3.5 years.

The findings provide detailed information on the frequency of committee meetings and the activity levels of those committees. There are variations, but on average committees meet six times per year and review and approve between 11-50 research proposals. This detailed data will be useful during the implementation stage of the recommendations of this report.

Suggested areas for improvement are:
- "More formal recognition and accreditation of RECs is required.
- The freedom with which researchers have to choose which one of the 13 committees (Clinical Trials Committees) to submit has given rise to a situation of imbalance in which some committees are very busy and others are not. There is a need for a central coordinating body to manage and control the situation nationally on a daily basis and the overall process needs to be made more streamlined and efficient.
- There should be more connectivity between HSE and academic institutions
- There should be a national central resource for advice, direction, appeals, policy development etc (2)
- RECs should be professionalised”.

Resources
Although 97% of RECs have access to administrative personnel, only 13.2% have a dedicated budget. This indicates that any administrative support is voluntary or is funded through a source external to the REC. Over half of the RECs hold a database of activity. Suggestions for improvement were:
- "There should be a national minimum level of administrative or database support (factored in by HSE when assigning budgets to hospitals).
- More funding should be made available to RECS (possibly a standard application fee for all Irish committees)
- There should be dedicated administrative support(2)"

Training
A total of 43.3% of RECs provide training to REC members even though only 13.3% have a budget to put towards such training. This indicates, as for the administrative support detailed above, that funding is sourced elsewhere for training. Such training consists of (i) conferences, (ii) external training courses (these are not specified in most cases, one REC receives training from Keele University); (iii) guest speakers and (iv) introductory seminars.

A suggestion for improvement was:
- "A programme of training (free of charge and repeated regularly) should be established
- Staff and REC members should be trained”.

Processes
An average of 48.5 applications were reviewed by the responding RECs during 2006 and an average of 46.3 applications were actually approved. Forty-three percent of RECs approved all the applications they received in 2006. Sixty percent have standard operating procedures for approving applications.

Applications to the HSE RECS were largely from the medical discipline (76.5% of HSE RECs received applications from this discipline). Quite a large percentage (64%) of HSE RECs received applications from both the health sciences and nursing disciplines respectively. All academic RECs received applications from the medicine and health sciences in 2006, 62.5% from the natural sciences and engineering, 87.5% from psychology and social sciences, 7% from the education discipline and 87.5% from the social work discipline. Almost all RECs review quantitative and qualitative research with two thirds of committees also reviewing clinical audit/evaluation studies and patient satisfaction studies.

The seven responding committees approved under the Clinical Trials on Medicinal Products for Human Use Regulations 2004 reviewed an average of 14 clinical trials applications during 2006 but also reviewed a considerable number of other types of research proposals (range 31-196).

Suggestions for improvement were:
- "There should be one standard application form for all Irish committees
- There should be guidelines for student/patient research and for community healthcare centres”. 
The quantitative aspect of this survey involved the distribution of a postal questionnaire to all known RECs in Ireland to:

(i) Identify the RECs’ membership and review processes
(ii) Record the RECs’ activity levels in 2006
(iii) Identify the scope of research that the RECs’ review
(iv) Identify the resources available to the RECs’ and to
(v) Collect relevant documents relating to the work of the RECs’, including Standard Operating Procedures, application forms etc.

1. General Results

In total 50 questionnaires were distributed to research ethics committees (RECs) across the Republic of Ireland. The following diagram shows the distribution of RECs across the counties. (Please see Appendix 2 for list of these RECs).

Figure 1: Distribution of known RECs across Ireland

Of these 54% were RECs of HSE institutions; 20% were academic RECs and 26% were RECs of voluntary groups and organisations outside the HSE.

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3 These are the RECs we determined through (i) www.bioethics.ie and (ii) review of databases and (iii) contacting voluntary bodies. We now know that there are RECs in existence which we are not aware of at time of questionnaire distribution.
There was a response rate of 60% (n=30). Of these 30 respondents 56.7% (n=17) were from RECs of HSE institutions; 26.7% (n=8) were from RECs of academic institutions and 16.7% (n=5) were from RECs of voluntary groups and organisations outside the HSE.

There are 13 Clinical Trials Committees (as approved under the EU Clinical Trials Directive (2001/20/EC) S.I. 190 of 2004) in total across these 50 REC institutions. Of these committees, 12 are from HSE institutions and one is external to the HSE and has very close links. Of the 30 respondents, seven RECs were approved clinical trials committees, all from HSE institutions.

The questionnaire was posted to the secretaries of the RECs for completion, in 80% of cases the questionnaire was completed by the secretary of the REC and in 20% of cases completed by the chairperson of the committee.

Results are reported around the following four major themes, which address the Terms of Reference of the review (1) current structures (2) resources (3) training of and (4) processes of the REC.

All of the following data correspond to the 30 respondents.

Note: Total percentages may not add up to 100% due to missing values. In some cases the data may add to more than 100% due to multiple answers.

2. Structures

The REC committees have been in operation for an average of 11.6 years ranging from 9 months to 30 years (the RECs who have been longest in operation made an estimate of the number of years they have been in operation).

The number of members on the REC committees ranges from 4 to 21 members, with an average of 13 members per committee. A total of 90% (n=27) of committees have a quorum for making decisions. Of these, the number of committee members required for the quorum ranged from three to seven with an average of five committee members. Using the average figures, this indicates that potentially only 38% of the committee members are required to make a decision in most RECs.

The RECs met an average of 6.4 times in 2006, this ranged from two to 11 times (monthly basis). During 2006 these meetings lasted between 30 minutes and three hours across the RECs (average of two hours). There is no apparent link between how often the RECs meet and the length of time the meetings last. Table 1 details the numbers of committees and the
frequencies with which they meet. Also included on the table is the number of proposals reviewed by these committees.

Table 1: Number of committees, the frequencies with which they met in 2006 and number of proposals reviewed by these committees during 2006

<table>
<thead>
<tr>
<th>Number of times committees met in 2006</th>
<th>Number of Committees</th>
<th>Number of proposals reviewed by these committees in 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twice</td>
<td>5 committees</td>
<td>4-25 proposals reviewed</td>
</tr>
<tr>
<td>Three times</td>
<td>1 committee</td>
<td>6 proposals reviewed</td>
</tr>
<tr>
<td>Four times</td>
<td>4 committees</td>
<td>0-16 proposals reviewed</td>
</tr>
<tr>
<td>Five times</td>
<td>2 committees</td>
<td>0-16 proposals reviewed</td>
</tr>
<tr>
<td>Six times</td>
<td>7 committees</td>
<td>6-60 proposals reviewed</td>
</tr>
<tr>
<td>Eight times</td>
<td>1 committee</td>
<td>40 proposals reviewed</td>
</tr>
<tr>
<td>Nine times</td>
<td>2 committees</td>
<td>REC 1: 43 proposals reviewed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REC 2: 193 proposals reviewed</td>
</tr>
<tr>
<td>Ten times</td>
<td>2 committees</td>
<td>REC 1: 94 proposals reviewed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REC 2: 278 proposals reviewed</td>
</tr>
<tr>
<td>Eleven times</td>
<td>6 committees</td>
<td>6-196 proposals reviewed</td>
</tr>
</tbody>
</table>

It is evident from table 1 above that most committees met on either (i) a monthly basis (6 of the responding committees) or (ii) a bimonthly basis (7 of the responding committees) during 2006. Those RECs who meet most often seem to have a higher workload (i.e. review more proposals) than those RECs who meet on a less frequent basis.

The following table (table 2) details the approved clinical trials committees and the frequencies with which they meet. Also included on the table is the number of proposals reviewed by these committees.
Table 2: The frequencies with which the approved clinical trials committees met in 2006 and number of proposals reviewed by these committees during 2006

<table>
<thead>
<tr>
<th>Number of times committees met in 2006</th>
<th>Number of Committees</th>
<th>Number of proposals reviewed by these committees in 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Five times</td>
<td>1 committee</td>
<td>94 proposals reviewed</td>
</tr>
<tr>
<td>Six times</td>
<td>1 committee</td>
<td>31 proposals reviewed</td>
</tr>
<tr>
<td>Nine times</td>
<td>1 committee</td>
<td>196 proposals reviewed</td>
</tr>
<tr>
<td>Ten times</td>
<td>1 committee</td>
<td>94 proposals reviewed</td>
</tr>
<tr>
<td>Eleven times</td>
<td>3 committees</td>
<td>50-97 proposals reviewed</td>
</tr>
</tbody>
</table>

This table indicates that the approved clinical trials committees meet on a more regular basis than the responding RECs as a whole and review quite a large number of proposals at these meetings though many of these are not clinical trial applications. They review research proposals other than those for clinical trials research under the 2004 Directive.

The following table (table 3) details the primary function of members of the committee and the average number of such members on the committees:

Table 3: Primary function of committee members and numbers of each discipline on all responding committees

<table>
<thead>
<tr>
<th>Primary Function on Committee</th>
<th>% of committees who have these members</th>
<th>Average number of these members on the committees</th>
<th>Range of these members on the committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Doctor</td>
<td>76.7% (n=23)</td>
<td>5</td>
<td>1-14</td>
</tr>
<tr>
<td>Scientist/researcher</td>
<td>53.3% (n=16)</td>
<td>4</td>
<td>1-12</td>
</tr>
<tr>
<td>Psychologist</td>
<td>26.7% (n=8)</td>
<td>1.3</td>
<td>1-3</td>
</tr>
<tr>
<td>Ethicist</td>
<td>29.6% (n=8)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lay Person</td>
<td>70% (n=21)</td>
<td>2.7</td>
<td>1-7</td>
</tr>
<tr>
<td>Nurse</td>
<td>73.3% (n=22)</td>
<td>1.6</td>
<td>1-3</td>
</tr>
<tr>
<td>Statistician</td>
<td>13.3% (n=4)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Legal Person</td>
<td>86.7% (n=26)</td>
<td>1.1</td>
<td>1-2</td>
</tr>
<tr>
<td>Allied Health professional</td>
<td>60% (n=18)</td>
<td>1.8</td>
<td>1-7</td>
</tr>
<tr>
<td>Religious Rep.</td>
<td>36.7% (n=11)</td>
<td>1</td>
<td>1-2</td>
</tr>
</tbody>
</table>
This table indicates that the vast majority of RECs have (i) a legal person, (ii) a medical doctor, (iii) a nurse and (iv) a lay person on the committee whereas a minority of committees have a statistician or an ethicist available to them. Approximately half of all the committees have (i) a scientist/researcher and (ii) an allied health professional on the committee. The Irish Council for Bioethics in Ireland advise that REC membership should include (www.bioethics.ie):

- Member(s) with knowledge of and current experience in the areas of research which are regularly considered by the REC (e.g. scientist).
- Members with knowledge of and current experience in the professional care, counselling or treatment of people (e.g. nurse, medical practitioner, clinical psychologist, as appropriate)
- Member(s) with training in ethics (e.g. ethicist, philosopher, theologian)
- Member(s) with training in law
- Member(s) with training in statistics
- Lay member(s)

The following table (table 4) details the primary function of members on the 7 approved clinical trials committees who responded to the questionnaire and the average number of such members on these committees:

**Table 4: Primary function of committee members and numbers of each discipline on all EU approved clinical trials committees**

<table>
<thead>
<tr>
<th>Primary Function on Committee</th>
<th>Number of committees who have these members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Doctor</td>
<td>7</td>
</tr>
<tr>
<td>Scientist/ researcher</td>
<td>4</td>
</tr>
<tr>
<td>Psychologist</td>
<td>0</td>
</tr>
<tr>
<td>Ethicist</td>
<td>2</td>
</tr>
<tr>
<td>Lay Person</td>
<td>7</td>
</tr>
<tr>
<td>Nurse</td>
<td>7</td>
</tr>
<tr>
<td>Statistician</td>
<td>0</td>
</tr>
<tr>
<td>Legal Person</td>
<td>6</td>
</tr>
<tr>
<td>Allied Health Professional</td>
<td>6</td>
</tr>
</tbody>
</table>
The average number of members on these approved clinical trials committees is 17, ranging from 13 members to 21 members. As the above table indicates all of the approved clinical trials committees who responded to the survey have (i) a medical doctor, (ii) a lay person and (ii) a nurse on the committee. A high percentage of committees have a legal person and an allied health professional available to them. Only two of the committees have an ethicist on the committee. The EU Directive regulations state that research ethics committees who are approved to review clinical trials should have a membership of not more than 21 members. The survey results indicate compliance with this. At least one-third are to be lay members, the table above indicates that there are between three and seven lay persons on the seven responding approved clinical trials committees with an average of five lay persons on these committees, which accounts for approximately one third of the total as recommended.

A total of 53.3% (n=16) of RECs have one or more other members on the committee which are not included in the list above. Table 5 details these additional members.

<table>
<thead>
<tr>
<th>Table 5: Additional Committee members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dentist</td>
</tr>
<tr>
<td>Administration (Directors of Services, Hospital Administrators, Management)</td>
</tr>
<tr>
<td>Patient Representative</td>
</tr>
<tr>
<td>Philosopher</td>
</tr>
<tr>
<td>Humanities</td>
</tr>
<tr>
<td>Dentist</td>
</tr>
<tr>
<td>School Principal</td>
</tr>
<tr>
<td>Sociologist</td>
</tr>
<tr>
<td>Vet</td>
</tr>
<tr>
<td>Data Protection Representative</td>
</tr>
<tr>
<td>PCCC Representative</td>
</tr>
<tr>
<td>Clinical Risk Managers</td>
</tr>
<tr>
<td>Public Health Specialists</td>
</tr>
<tr>
<td>College Graduate</td>
</tr>
</tbody>
</table>
For all RECs the chairperson’s term of office ranged between one and six years, with an average of 3.5 years. For 73.3% (n=22) of the committees this term of office was for a set time but the chair could be elected for successive terms. In 13.3% (n=4) of committees the chairperson’s term of office was either (i) voluntary, (ii) there was no limit or fixed timeframe on the term of office.

The member’s term of office ranged from two to six years across the RECs with an average of 3.7 years. For 76.6% (n=23) of the committees the members term of office was for a set time. In 10% (n=3) of committees the member’s term of office was either (i) voluntary or (ii) had no limit.

In response to the open question at the end of the questionnaire five RECs offered additional comments in relation to structures.

- “More formal recognition and accreditation of RECs is required.
- The freedom with which researchers have to choose which one of the 13 committees (Clinical Trials Committees) to submit has given rise to a situation of imbalance in which some committees are very busy and others are not. There is a need for a central coordinating body to manage and control the situation nationally on a daily basis and the overall process needs to be made more streamlined and efficient.
- There should be more connectivity between HSE and academic institutions
- There should be a national central resource for advice, direction, appeals, policy development etc (2)
- RECs should be professionalised”.

3. Resources

Ninety-seven percent (n= 29) of RECs have access to administrative personnel. For those who do have administrative support, there is a median of two hours per week dedicated to the RECs, ranging from 30 minutes per week to 60 hours per week. However, 86.7% (n= 26) of RECs do not have a dedicated budget and so the administrative support is entirely voluntary or a budget is sourced elsewhere. For the 10% (n=3) of RECs who do have a dedicated budget, this budget is used for administrative support (part-time salaries) but it should be noted that those RECs (n=2) whose administrative support amounts to 60 hours per week are not those RECs who have a dedicated budget. Both committees are approved clinical trial committees and both have high workloads (94 and 196 applications reviewed in 2006).

Fifty-three percent (n=16) of RECs have a database of their activity and so, due to the absence of a dedicated budget, this is established without resources.
Seven percent (n=2) of RECs have other resources available to them, this includes a members extranet.

Four RECs offered additional comments in relation to resources at the end of the questionnaire:

- “There should be a national minimum level of database support
- More funding should be made available to RECS (possibly a standard application fee for all Irish committees)
- There should be dedicated administrative support(3) (factored in by HSE when assigning budgets to hospitals)(1)”

4. Training

Training is available to committee members in 43.3% (n=13) of committees. However, only 13.3% (n=4) of committees have a budget for training. Therefore in the case of nine committees training is provided without a budget. In some cases this training is provided as the need arises. Training consists of (i) conferences, (ii) external training courses (these are not specified in most cases, one REC receives training from Keele University); (iii) guest speakers and (iv) introductory seminars. Table 6 below indicates the types of training available to committees who have access to training.

Table 6: Types of training available

<table>
<thead>
<tr>
<th>Type of Training</th>
<th>% of committees who do have training (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conferences</td>
<td>15.3% (n=2)</td>
</tr>
<tr>
<td>External Training Courses</td>
<td>23% (n=3)</td>
</tr>
<tr>
<td>Guest Speakers</td>
<td>7.7% (n=1)</td>
</tr>
<tr>
<td>Introductory seminars</td>
<td>7.7% (n=1)</td>
</tr>
</tbody>
</table>

Two offered additional comments in relation to training at the end of the questionnaire:

- “A programme of training (free of charge and repeated regularly) should be established
- Staff and REC members should be trained”.
5. Processes

The number of applications reviewed by the RECs in 2006 ranged from 0-278 with a median of 36.5 applications reviewed by the RECs. The average time between the submission of the application and the first feedback to the applicant was 21.7 days, ranging from immediately to 45 days. The average time between the submission of the application and final decision ranges from immediately to three months with an average reply time of one month. When comparing the time between submission of applications, first REC feedback and final REC feedback, the time available for the process of revision and resubmission was in many cases stated as either the exact same or unrealistically short. The majority of REC proposals receives provisional approval and requires some modifications to be made before resubmitting and receiving final approval, a process that can be fasttracked, but will not be completed within just a few days. We cannot therefore accurately rely on this result and suggest that the data might indicate misunderstanding on the side of some participants. It might also be concluded that those committees that stated improbable data most likely did not have database facilities that would have allowed them to correctly calculate the exact turnaround times.

Only 60% (n=18) of RECs have standard operating procedures for approving applications.

A total of 50% (n=15) of committees have no limit on the number of times they can ask the applicant for further information.

Alternative or expedited review procedures are in place in 70% (n=21) of RECs. The alternative procedures that were documented in the survey are summarised in the following table.

<table>
<thead>
<tr>
<th>Table 7: Summary of alternative or expedited review procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Chairperson’s approval in cases where there is:</td>
</tr>
<tr>
<td>(i) no patient involvement</td>
</tr>
<tr>
<td>(ii) no direct patient contact</td>
</tr>
<tr>
<td>(iii) staff surveys</td>
</tr>
<tr>
<td>(iv) straightforward applications, subject to consultation</td>
</tr>
<tr>
<td>(v) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>(vi) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>(vii) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>(viii) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>(ix) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>(x) On discussion with one or more committee members who</td>
</tr>
<tr>
<td>2. Research which is mainly quantitative or involves non-vulnerable groups may be dealt with at department level</td>
</tr>
</tbody>
</table>

If refused, 63% (n=17) of RECs provide an opportunity for the researcher to appeal.
The following tables, 8 and 9, detail the activity levels of committees overall and specifically clinical trials committees. Clinical trials committees review non-clinical trials research as well.

**Table 8: The range of applications reviewed during 2006 against the number of responding committees and number of responding EU approved clinical trials committees**

<table>
<thead>
<tr>
<th>Number of applications reviewed</th>
<th>Number of committees</th>
<th>Number of clinical trials committees</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>11-50</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>51-100</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>101-150</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>151-200</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>200+</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 9: The range of applications approved during 2006 against the number of responding committees and number of responding EU approved clinical trials committees.**

<table>
<thead>
<tr>
<th>Number of applications approved</th>
<th>Number of committees</th>
<th>Number of clinical trials committees</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>11-50</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>51-100</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>101-150</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>151-200</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>200+</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Most RECs reviewed and approved between 11 and 50 applications during 2006. Only two committees reviewed over 151 applications during 2006 and these applications were all approved. One of these committees is an approved clinical trials committee.

An average of 14 clinical trials applications (ranging from 1-40 applications) were reviewed by the seven responding approved clinical trials committees in 2006.

Between 33% and 100% of applications reviewed by the RECs are approved (average of 61% are approved). Forty-three percent of RECs approved all the applications they received in 2006.

The HSE RECs were asked which disciplines submitted proposals in 2006. The 17 HSE RECs who responded to the questionnaire indicated that the following disciplines submitted proposals in 2006:

**Table 10: Percentage of HSE RECs receiving applications from different disciplines**

<table>
<thead>
<tr>
<th>Discipline⁴</th>
<th>% of responding HSE RECs receiving applications from this discipline</th>
</tr>
</thead>
</table>

⁴ Discipline in relation to HSE was grouped according to profession
The RECs of the academic institutions were asked which areas of research were covered by the submissions they receive.

**Table 11: Percentage of academic RECs receiving applications from certain areas of research**

<table>
<thead>
<tr>
<th>Discipline</th>
<th>% of responding academic RECs receiving applications from this area of research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine &amp; Health Sciences</td>
<td>100% (n=8)</td>
</tr>
<tr>
<td>Natural Sciences &amp; engineering</td>
<td>62.5% (n=5)</td>
</tr>
<tr>
<td>Psychology &amp; Social Sciences</td>
<td>87.5% (n=7)</td>
</tr>
<tr>
<td>Education</td>
<td>75% (n=6)</td>
</tr>
<tr>
<td>Social work</td>
<td>87.5% (n=7)</td>
</tr>
</tbody>
</table>

The following table details what types of research are reviewed by the RECs.

**Table 12: Types of research reviewed by the REC**

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>% of all RECs reviewing this type of research (n=29, missing data=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative</td>
<td>96.6% (n=28)</td>
</tr>
<tr>
<td>Qualitative</td>
<td>100% (n=29)</td>
</tr>
<tr>
<td>Clinical Audit/ Evaluation Studies</td>
<td>65.5% (n=19)</td>
</tr>
<tr>
<td>Patient Satisfaction Surveys</td>
<td>65.5% (n=19)</td>
</tr>
</tbody>
</table>

The large majority of RECs review quantitative and qualitative research (this is the case in relation to (i) HSE, (ii) academia and (iii) other areas). Over 60% of RECs review clinical audit/evaluation studies and patient satisfaction surveys. This is apparent in both the HSE and in academia.

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5 Discipline in relation to academia was grouped according to area of work
Of the research applications submitted to the RECs in 2006 the percentage involving children as research participants ranged from 0 to 80%. An average of 11% of all research applications received by the 30 RECs involved children as research participants.

The following table indicates the percentage of research applications in 2006 which involved children as research participants per REC group.

**Table 13: Percentage of research applications in 2006 which involved children as research participants**

<table>
<thead>
<tr>
<th>REC Group</th>
<th>Average % of research applications in 2006 which involved children as research participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSE</td>
<td>9% (n= 16)</td>
</tr>
<tr>
<td>Academia</td>
<td>12.25% (n=8)</td>
</tr>
<tr>
<td>Other</td>
<td>16% (n=8)</td>
</tr>
</tbody>
</table>

An average of 40% (ranging from 0% to 90%) of applications received by the RECs were from applicants completing a MSc/PhD or other qualification. The following table (table 14) details the percentage of applications received for MSc/PhD qualification by (i) all the responding RECs; (ii) the responding HSE RECs and (iii) the responding academic RECs.

**Table 14: Percentage of applications received for MSc/PhD applications**

<table>
<thead>
<tr>
<th>% of applications for MSc/PhD qualifications</th>
<th>% of all responding RECs</th>
<th>% of responding HSE RECs (n=17)</th>
<th>% of responding academic RECs (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>26.7% (n=8)</td>
<td>23.5% (n=4)</td>
<td>12.5% (n=1)</td>
</tr>
<tr>
<td>21-40%</td>
<td>16.7% (n=5)</td>
<td>17.6% (n=3)</td>
<td>25% (n=2)</td>
</tr>
<tr>
<td>41-60%</td>
<td>30% (n=9)</td>
<td>35.3% (n=6)</td>
<td>25% (n=2)</td>
</tr>
<tr>
<td>61-80%</td>
<td>10% (n=3)</td>
<td>11.7% (n=2)</td>
<td>0%</td>
</tr>
<tr>
<td>81% +</td>
<td>6.7% (n=2)</td>
<td>0%</td>
<td>25% (n=2)</td>
</tr>
</tbody>
</table>

**Geographical Remit**

A total of 70% (n=21) of RECs review applications for research to be conducted outside the location of the REC. In addition, 83.3% (n=25) of RECs review applications for research to be conducted outside the organisation where the REC is based or covers. A total of 83.3% (n=25) of RECs state that the researchers submitting their proposal to them also submit their proposal to other RECs.
Over 90% (n=27) of RECs have a standard application form upon which they accept research applications for review. The following table details the means by which these standard application forms can be submitted.

**Table 15: Means by which application can be submitted**

<table>
<thead>
<tr>
<th>Means by which application can be submitted</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Researchers submit online</td>
<td>6.7% (n=2)</td>
</tr>
<tr>
<td>Researchers submit via email</td>
<td>66.7% (n=20)</td>
</tr>
<tr>
<td>Researchers submit via hard copy</td>
<td>100% (n=29, missing data=1)</td>
</tr>
</tbody>
</table>

This table indicates that all RECs accept applications in hard copy and 66.7% accept applications via email. However, very few committees provide the facility for the applicant to submit the application online.

RECs were asked how they make information on their review procedures (such as standard application forms, and details about how to apply) available to researchers. The following graph describes how they make the information available:

**Figure 2: Modes by which information on REC review procedures are made available to researchers**

The “other” ways in which the REC review procedures are made available are as follows: (i) letters sent to heads of departments; (ii) via email; (iii) via the research committee and (iv) via research ethics advisors.
Sixty percent (n=18) of RECs monitor the research they have approved. Fifty five percent (10/18) of those who do monitor approved research, do so through requesting annual reports or annual study updates from the researcher. Other modes of monitoring research included:

- Request for interim report after six months
- Final presentation to REC at the end of research
- Request for notification of adverse events (known as SAEs - Serious Adverse Events)
- Request for notification of SUSARs (Suspected Unexpected Serious Adverse Reactions) in the case of clinical trials
- Request for notification for termination of research project.

Annual Reports of the work of the RECs are produced by 44.8% (n=13, missing data=1) of RECs.

Three RECs offered additional comments in relation to processes at the end of the questionnaire:

- “There should be one standard application form for all Irish committees”
- “There should be guidelines for student/patient research and also for community health centre”. 
Section 3 – Consultation

Key Points

- There is great commitment to and participation in RECs
- What was found to work well, where they existed, were standardised application forms, SOPs, available expertise, feedback and adequate resources
- Those areas that need improvement centre on standardised national application forms and SOPs
- There is a need for a resource of expert opinion for some RECs that they can access when the need arises
- Training and administrative resources are inadequate
- Communication needs improvement on several levels
- There is a need for the development of a knowledge network for research ethics
- Participants strongly suggested the need for a central national resource to coordinate and support some of the suggested improvements. This comment captures the essence of what was said on the day:

  "... having these frameworks in place - the central national resource, standard application form, SOPs – would help streamline the ethics approval process by limiting the number of RECs that a researcher would have to submit to and would "enable cross-recognition of approval from other RECs" (speaker light green table6)."

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6 Quotations are those from the transcripts of the recorded feedback given by a representative of each table summarising the main points of that table’s discussion after each workshop session.
Background

A Consultation Day was held in order to engage with all involved in Research Ethics Committees. One of the aims was to seek their opinion on the development of RECs in the future. Two questions were asked, namely 'What’s currently working well and what needs improvement in RECs?' and secondly ‘How would you see things improved in the future and how could these changes be implemented?’ The results of the round table discussions – table notes, recorded table summations and comments on evaluation forms - were analysed by content and emergent themes generated. These are reported here under two key headings of Structures and Processes.

Structures

Central National Resource

The participants of the Consultation Day want a standardised process for research ethics committees’ approval. The majority of the groups proposed a central national resource.

"the infrastructure at the top level is actually lacking at the moment, and we need some kind of supervisory office. So it’s already been mentioned by a number of other people where do we go for help, which ethics committee do we apply to? How do I find out how to submit my procedure and so on?" (speaker yellow table)

This would essentially be a ‘national resource’ that would help organise and channel the issues identified. This national resource would have several supporting functions. It was also felt that such a body would have an advisory function.

"an advice service to researchers and at that stage they would also be advising researchers as to other things they needed to do before they sent in their proposals for ethical approval” (speaker dark green table)

The advisory function could extend to issues of informed consent particularly for research concerning vulnerable groups such as children or people with disabilities. It is also a role that could be addressed by a Specialist Panel/database of experts (below).

"... how ethics committees approve or disapprove and application on those [informed consent] bases. Particularly for issues like children and research relating to children, or people who are cognitively impaired on a temporary basis or a progressive basis” (speaker lilac table)
Specialist Panel/ database of experts
Participants also suggested that a specialist panel/database of experts might be beneficial. RECs are sometimes asked to approve a research project but feel that to do so they need specialist input in the field being reviewed. The participants feel that access to a panel of experts that could be asked to input on particular projects would be very beneficial. This panel could simply be a database on individual experts that could be co-opted into the process when the need arises. This would avoid duplication and maximise resources.

"we were suggesting that a panel of experts would be available to the research ethics committees as well and they would be managed from here. And this panel of experts ... to do with particular areas for instance paediatrics or disability or whatever. But it also could, cover you know, be it other expertise you needed like if you had experts that you needed for the different types of research such as statistical input, qualitative input whatever you could have, they wouldn't all necessarily need to be in one place or anything, they'd just need to be managed by this national resource”
(speaker dark green table)

Participants also commented that making expertise available helps ensure that patients benefit and that the research ethics process offers protection to patients, researchers and the institution.

Current Structure
There was quite a lot of discussion around the current structure and number of RECs – 50 were identified for this review. It was suggested that the number of RECs could be reduced. One group suggested these could correspond to the HSE areas. The feasibility of a regional structure would depend on current workloads of committees within that region. This framework could help streamline the ethics approval process. Two groups questioned if it is necessary to reduce the number of RECs, expressing concern that this would result in a deskilling of ethics expertise as well as potential difficulties for local units in handing over research in relation to their areas.

"do you want to sort of suppress a whole lot of ethical committees?, They're all doing good work. ... we want a central resource, we want central support, there's no doubt about that concept”
(speaker blue table)

Suggestions were also made as to how the number of regional RECs required could be determined
“you'd look at the hours that are spent at committees and how many studies they cover... you’d work out how many committees you needed based on that, basically the number of proposals that are going through them already” (speaker dark green table)

It was suggested however, that there was a need for local management input regarding resource management of such a proposal

“the actual management of the proposal ... that side really should be dealt with at a local management level, and that should be separated from the whole ethical procedure” (speaker yellow table)

The group participants felt that there should be agreed competencies and an agreed composition for RECs to be reflective of the community the REC represents and the research.

"we suggested that there should be agreed competencies for people that go on the committee, and that the committee should be representative of the community it represents. So in other words if it’s a University or if it’s a hospital then based on what kind of research it would come through that committee, that the committee itself should be reflective of that” (speaker turquoise table)

"what are the competencies of the members of the ethics committees, what kind of training have they had and generally its somebody who knows somebody, or who, lecturers in ethics or somebody who has done a lot of research so therefore they can look at it from that perspective. So we would be saying from our group well lets look at who needs to be on an ethics committee and what’s the competencies required for that and then well lets develop standardised training programmes” (speaker lilac group)

Other comments pertaining to the existing structures and processes included that there is a lack of inclusiveness for patients. It was also commented that lay participation in RECs works well where it has been established but lay representation needs to be increased. It was also suggested that the researcher should be invited to the REC review.

“the national resource would also look after ... management and administration, the recruitment for the regional ethics” (speaker dark green table)
Multi-disciplinary committees with exposure to diverse issues and range of expertise work well, particularly specialised expertise (clinical, disability, population/public health) appropriate to the research. This should be a consideration in the composition of the RECs.

Training
All the groups reported that training needs improvement in all aspects. It was felt that training is needed for REC members, researchers, lay members, and the entire research community. Training topics included the role of RECs, types of research needing ethical approval, the application procedure, where to apply for ethical approval, and ethical issues.

"we put people into ethics committees without any training what so ever, so yeah, certainly we are heavy on the idea that there is a singular lack of training to be found there” (speaker dark green table)

"so that the membership of the ethics committee needs some sort of training to understand what their role and function is" (speaker turquoise table)

It was felt that there should be a national standard for training and perhaps that's a function of the central national resource.

"the national resource would also look after the training, the design and development of training and the delivery of it” (speaker dark green table)

It could be developed in conjunction with the Irish Council for Bioethics. It should increase public awareness through an information campaign, school resources, 'road shows' and IT and should train researchers, students and be both generic and discipline specific. It was also proposed that RECs membership should be promoted and that through educating people on the role of RECs they might be more willing to get involved which might facilitate improved lay member recruitment. Training could be provided on-line, should be up to date, ongoing and should be regular. One proposal is to review case histories from RECs for discussion and learning.

It was also felt that training in different aspects of research, such as the difference between audit and research, would be useful

"Training and understanding – membership of ethical committee, research methodology, voluntary training, awareness of difference audit vs research” (notes turquoise table)
Resources
A common thread emerging from the participants was that there is great commitment to and participation in RECs, and that there is good will and team working.

"And there is a lot of good will, I suppose that has been tested by the attendance here today so we think there is enthusiasm that can be built on”(speaker orange/red table)

Two groups also stated that there should be dedicated time for participation on RECs.

Administrative support is strongly felt to be a major benefit, where it is available and properly resourced.

"Where you have administrative support it tends to work well, where you don't, doesn’t. I think that’s self evident that we all could get more administrative support” (speaker light green table)

Administrative and secretarial support is not widely available and is badly resourced. One table summed it for all by saying that they couldn't function without these resources.

The central national resource could help facilitate management and administration as well as recruitment.

Legislative Framework
Respondents feel that value is added by going through an REC. Participants observed "a key function of the REC would always be to promote and support research”(speaker dark green table). The REC process works well where there is adequate volume of research, a focus on patients’ needs, expedited review and adequate feedback.

Participants noted that there is a legislative vacuum and there is no clarity on procedures for non-clinical trials research. Some RECs operate to their own SOPs and some follow the guidelines available from the Irish Council for Bioethics but there is no defined standard to work to.

"the clinical trials act was brought in for a specific purpose but what it has done, or what it appears to have done is has forced people into a way of thinking, that maybe, could be replicated with research that’s not of a clinical trials nature, and, what the legislative vacuum means is that there’s sort of a structures and support vacuum as well”(speaker orange/red table)
All of the proposals outlined above need to be based in a legislative or statutory framework. Four of the seven groups expressly identified the need for a legislative basis. One of the groups expanded on this to suggest that it should be along the lines of the framework in place for Clinical Trials Committees. Two of the groups specifically proposed a ‘stick and carrot’ approach in order to implement the suggestions above. There should be a government driver or legal requirement coupled with incentives such as resources to facilitate a streamlined ethics approval process. A legislative framework very much lends itself to needing a central national resource.

Multi-centre Research
Participants reported, “doing work at a multi centre level, that is problematic” (speaker orange/red table). Participants elaborated further that clarity around processes for multi-centre work would be very useful and that there isn’t somewhere currently that RECs can turn to in order to draw expert opinion.

Processes

Standard Operating Procedures
In terms of existing structures, the current format for Clinical Trials7 and the Guidelines by the Irish Council for Bioethics, are existing benchmarks that could be "a template or framework to work from"(speaker orange/red table). Another table commented that "where there were standardised forms and standardised protocols that it worked very well” (speaker yellow table).

Several of the points made relating to SOPs effectively relate to the issues raised in relation to need for a central national resource i.e., dedicated structures and processes, clear governance structures, and clear definitions between fields such as audit, research and clinical trials; would be developed through such a resource. A majority of the groups expressed a need for SOPs to include a standard checklist for approval, a ‘road map’ for researchers, timeframe for the approval process, how to give feedback both to the researcher and from the researcher to the committee, direction for research that does not fit the traditional ‘scientific’ model and students’ research, national standards for training, REC composition.

Standard Application Form

7 The EU Clinical Trials Directive (2001/20/EC) S.I. 190 of 2004
Most of the table groups reported a need for improvement in the application process to include standardised application forms, procedures and scheduling (timelines, turnaround times, and meeting schedules). The number of meetings, frequency of meetings and times for approval all vary. Participants noted that for RECs

"where there wasn't standardised protocols, things were, the whole procedure was much slower and more difficult ... we find is that if you are a researcher submitting a research proposal you may have to go into a number of different ethics committees. Each ethics committee may well have a very well designed standardised form for their own ethics committee. They tend to vary amongst different ethics committees”

(speaker yellow group)

Six of the seven groups (two groups merged for the afternoon session) identified the need for a common application process or standard application form. This form could be operated online as appropriate and could incorporate different ‘filters’ for different types of research proposal - such as research or audit, and research that doesn’t require ethics approval. They also felt that a standard application form would help facilitate issues around patient consent.

"clearly the standardised forms ... a couple of the others already mentioned it. It should be a wide based, a filter based thing because research varies hugely ... but people could be lead down certain pathways“

(speaker blue table)

Communication
Participants reported that there is a lack of communication among RECs. There is a lack of professional support for RECs and participants also felt that the relationship between the HSE nationally and all RECs needs to be improved. There are several aspects to communication around the research ethics approval process.

Feedback – to researcher
Some groups use information technology (IT) to facilitate their information dissemination about the requirements of the REC, interim results and feedback. The feedback process is also facilitated where the principal investigator or researcher has to attend an ethics committee interview. Such a feedback mechanism would facilitate expedited review and would also enable learning for the researcher and a better understanding of the research ethics approval process.

Feedback – research follow-up (Governance)
The whole issue of feedback both by the REC to the researcher submitting applications and more particularly the researcher back to RECs consistently arose.
“most ethics committees have no means of actually following this up and applying sanctions if people are not carrying out good quality research … there’s a necessity … to submit the results of their research back to the ethical committee. … so if you want to do similar kinds of research to what you have done before … you already had ethical approval to do it before we should be able to expedite the procedure so it would streamline the thing enormously” (speaker yellow table)

In general, follow-up on research is poor. A feedback system would also ensure greater transparency and learning and would help ensure quality assurance to the central national resource, the stakeholders and the community.

“how do you feed this back … around the place … suppose there was a requirement to give a sort of annual report each year in which it gave its lesson and obviously you’d have to work out what the annual report in a standardised way would be, but the key thing would be what issues did we cover, how many pieces of research did we cover, what were the learning points that we discovered during the year” (speaker blue table)

“another important issue for our group was the issue relating to the follow up, the closing of the loop really of the research activity, and that really its an ethical issue and it really should be a concern to the committees themselves as to, has the research actually been completed in the way you said it should be in your original application form” (speaker lilac table)

Participants felt that communication must be enhanced between all parties in the ethics review process and that a central national resource would be facilitative in this

“communication is a big thing and we thought communication between the committees, communication from the committees to the researchers back from the researchers to the committees we need to set up a whole system around all of that … the most crucial thing in terms of making all this happen, is that the committee, committees and think along your national resource and the whole drivers behind it” (speaker dark green table)

This point was reiterated by the blue table who felt that what work was done by the REC, how much and what was learned should be communicated to a central resource.

Communication – to researchers & the community
Participants felt that the responsibility for raising the profile and awareness of the REC should lie with the REC but also with the National Resource.

"the committee itself should be responsible for awareness raising among its own community about what it does, either through an internet site or leaflets or seminar awareness or whatever but that they should take on that responsibility” (speaker turquoise table)

It was also noted that having a contact person for the REC works well.

Other topics raised at the consultation though not in detail include: research governance, informed consent issues, over-researching of particular populations, licensing of researchers [training and sufficient standards for REC members] and accreditation issues could similarly be addressed.
Section 4 - Preliminary findings from REC Interviews

Key Points
It is important to be aware that the preliminary analysis cannot at this point provide a more in-depth understanding of the data, in particular with regard to differences between various categories of committees (Clinical trials committees, small hospital and voluntary committees, academic committees), and with regard to understanding of connections between different concerns and positions taken. However, on a very general level, certain trends from the interviews can be stated:

- The good will and enthusiasm of those participating in REC work who take an active and constructive interest in optimising the existing system
- The importance of resourcing RECs adequately in terms of administrative support and administrative infrastructure
- The perceived need for discussion, networking and sharing of good practice between different RECs
- The need for fostering research ethics awareness and competence among different stakeholders, including not just the REC community, but also e.g. researchers and organisations.
- The perceived need for some changes to be made regarding streamlining the review of applications currently reviewed by several committees
- The perceived need for a central contact point with responsibility for Research Ethics in Ireland that could fulfil a range of functions, including e.g.
  - the dissemination of relevant information
  - the development of ethical guidelines
  - the development of central databases (e.g. regarding experts or potential REC volunteers),
  - the provision of training
  - the facilitation of networking
  - the development of standards of good practice and administrative tools
  - the facilitation of a reform process regarding current inefficiencies in the system

As apparent from the above, the qualitative interviews highlighted areas that were broadly in accordance with the data gained from the consultation day, albeit with slightly different emphases in places, e.g. regarding

- the importance of networking (highlighted even more strongly in the interviews than during the consultation day),
- the roles of a potential central contact point (somewhat less enthusiasm for national standardisation of forms and procedures in the interviews than during the consultation day),
- the role of institutional committees (significantly more emphasis on preserving the role and autonomy of individual committees in the interviews).
This is a preliminary analysis of the qualitative data from the interviews with REC chairpersons, REC administrators, REC members and researchers. It was deemed important by the REC review group to include the emerging results, to highlight both where these further reinforce the results from the questionnaire and consultation day and where new aspects or different emphases were brought up by participants. A complete analysis of the interviews will be presented in the forthcoming report by the Office of the Minister for Children to be completed in Spring 2008. In the following, we will focus on preliminary results from the interviews with chairpersons and administrators, and discuss especially their answers to the first and third area of interest.

Areas of interest addressed in the interviews

Interview participants were asked questions relating to the following three areas:

1. Experience of review work in their own REC
2. Experience with the review of children’s research (to meet the TOR of the OMC review)
3. Suggestions for change to the existing REC system in Ireland

Depending on the type of REC and the range of its review experiences, the interview questions were adapted to the situation of the respondents. Results from the second part of the interviews, regarding children’s research, are included insofar as they add relevant information to results from parts 1 and 3. (See appendix 3 for full interview schedule)

Preliminary results from the interviews

Chairpersons’ interviews

In the chairpersons’ interviews, their views on what were essential requirements for the functioning of an REC were guided significantly by their own REC experience, especially by challenges that they had encountered, but also by those aspects of committee work that they had personally experienced as successful. Aspects that were highlighted frequently included:

A. REC membership
   - availability of motivated and committed members
   - availability of membership from a broad range of specialties and backgrounds
   - respectful interactions and communications between members
   - willingness to spend substantial amounts of time for REC work

B. Administrative support
   - availability of appropriate administrative support for a significant number of hours, preferably a fulltime position
   - good and timely flow of communication and necessary paperwork between different stakeholders in the review process
C. Functioning processes

- clarity of REC role and procedures
- availability of clear application form that is tailored to the requirements of the research that is reviewed by committee

D. Adaptability and competence building

- willingness to learn from previous experience and revise and evolve REC processes based on such experience
- competence building as a group through REC work and open discussions

One issue that was mentioned comparatively rarely at this stage, but gained prominence in the third part of the interviews on suggestions for change was the perceived need to be informed, updated and trained on current good practice and relevant developments in research ethics and to have the opportunity to be in ongoing communication with members of other RECs in Ireland (see below).

With regard to the question of what was working well in their own committee, the most frequently mentioned aspect was the enthusiasm, commitment and mutual respect of the membership. Success in the recruitment of an adequate membership was also mentioned. Administrative support was also regularly highlighted, most frequently in those committees where substantial administrative support had been made available by the institution, but sometimes also in other committees where the functioning of the committee depended to a large extent on the engagement and good will of secretaries assigned to the task. Members’ efficiency in realising review processes was also emphasised.

The large majority of chairpersons reported several challenges without specific prompting. Interestingly, only some of the least resourced and experienced committees reported no significant challenges, which seemed to be mostly related to a lesser degree of awareness of potential pitfalls and potential areas of improvements. Among the challenges mentioned (prompted and unprompted), the following appeared to be most frequently mentioned:

A. Workload

- strongly increasing demands on the committee
- no acknowledgement by institution in terms of setting time apart for REC work or provide other incentives
- extent of paperwork
- sometimes unclarity regarding remit and potential for duplication of review (hospital vs. academic committees, hospital vs. community care, institution vs. region, ill defined overlap with other committees)

B. Administrative support
• lack of adequate support and other substantial constraints on use of administrative staff
• lack of awareness or acknowledgment of this need by the institution

C. Uncertainty regarding standards of good practice and current legislation
• Unclarity or lack of confidence regarding legal and ethical standards of good practice in some areas of concerns
  o E.g. informed consent with children and other vulnerable populations, participant recruitment, use of tissue and tissue banking (see below)
• Concern that REC might not be up to date with relevant developments in Irish and international legislation and general research ethics

D. Competence building and training in ethics
• Limited access to training opportunities
• Induction to REC work mostly “on the job”

E. Recruitment
• Recruitment of some groups is challenging in many RECs:
  o Lay members (usually through word of mouth)
  o Medical staff (highlighted only in some contexts, especially in RECs in clinical settings that are not teaching hospitals or academic RECs with attachment to a medical school)
  o Lawyers (usually deemed essential, but some committees had problems with access to lawyers; sometimes there were special arrangements for payment of legal members)
• Ethicists were not present in a majority of RECs, but their absence was not usually mentioned as a significant challenge

With regard to the role of the committee vis-à-vis different stakeholders, chairpersons discussed the following aspects:
A. Participants:
• unanimous understanding that primary role of REC was protection of research participants
• protection of vulnerable participants highlighted particularly strongly
• however, many hospital committees without patient representative

B. Researchers:
• nearly unanimous understanding that REC’s role for researchers should be one of support, not of hindrance
• acknowledgement that the perception of RECs by researchers is often one of hindrance
• goal of facilitating researchers in conducting research based on good ethical practice
• perception that there is a substantial, but not necessarily recognised, need for ethical awareness and competence building in the research community which RECs might be best placed to address (suggestions about broadening ethics function of REC to ethics competence building, dependent on staffing and resources)

• main problems of researchers from REC perspective are
  o development of adequate informed consent procedures and information sheets
  o inaccurate or incomplete filling in of application forms
  o misunderstanding of level of detail required in application

• perception that communication between researchers and RECs need to be improved in both directions
  o communicate REC requirements to researchers to enable a smooth review process
  o researchers to be willing to communicate research updates and final reports to REC, for monitoring purposes

C. Organisation:
• nearly unanimous view that the RECs role for the organisation was vital
• however, mixed views on whether the organisation was acknowledging importance of role

Regarding other ethical needs in the organisation, chairpersons in some health care institutions highlighted clinical ethics needs in relation to case review and the development of ethics guidelines. However, there were diverging views on whether it would be desirable to keep the REC function and clinical ethics functions separate with the majority in favour of a clear separation of roles, including membership. Another area of ethics needs mentioned in a minority of especially academic committees were professional ethics and conduct concerns.

In relation to potential desirable changes to the REC system in Ireland, the following aspects were highlighted by participating chairpersons:
A. Networking and communication on good practice (probably the most frequently mentioned aspect in the interviews):
• improve discussion and communication between Irish RECs in order to allow for broader reflection on and dissemination of good practice standards
• concern about “not reinventing the wheel” and learning from the experience in other committees
• repeated suggestion of organising meetings 1-2 times per year with REC chairpersons, REC members and administrators, and perhaps also researchers, with both a training element on a topical issue and networking opportunities
• repeated reference to self-organised initiative by administrators of Clinical Trials Committees as potential model for networking

B. Need for official contact point in relation to good practice for research ethics in Ireland
• many respondents mentioned the need for some central contact point that could provide services for RECs in respect to the following areas:
  o training for REC members (induction and ongoing)
  o the dissemination of relevant information
  o the development of ethical guidelines
  o the development of central databases (e.g. regarding experts or potential REC volunteers),
  o the facilitation of networking
  o the development of standards of good practice and administrative tools
  o the facilitation of a reform process regarding current inefficiencies in the system

C. Ethical guidelines
• Development of more extensive guidelines on specific issues or areas:
  o Informed consent, especially for persons with limited competence
  o Indemnity
  o Defining which proposals require ethical review
  o Use of tissue and tissue banking
  o Concerns in research with specific groups of vulnerable participants, e.g. children, persons with intellectual disability, patients with rare disorders, school-based research
  o General introductory document to principles and concerns in research ethics and relevant Irish legislation
• Concern that guidelines remain sufficiently general to allow for adaptation to variety of contexts and are not too specific and prescriptive to become stifling

D. Concerns relating to role of RECs
• Importance of functioning REC for individual institutions for following reasons:
  o Ownership of review process
  o Appropriateness to specific local needs and ethos
  o Dissemination of ethical awareness and competence building within institution through REC
  o Increased awareness of research conducted within institution
• Importance of autonomy of REC within institution

E. Duplication or multiplication of ethical review:
• Many emphasised that duplication or multiplication of REC review in different committees was a problematic issue for research conducted in Ireland
• Many acknowledged that some form of streamlining ethics review for proposals that go through multiple committees was desirable
• However, only some committees actually accepted approval from other RECs, most required either complete review (in most cases) or modified review (in some cases) of the proposals in their own REC
• Reasons given for continued practice of conducting review in multiple committees were:
  o REC represents the autonomy of the institution, its authority to make decisions on what should be allowed to happen on its premises
  o Need to keep control over research conducted in own institution, not just from a management point of view, but from an ethical point of view
  o Lack of trust in the ability of other RECs to address particular concerns of institution to the satisfaction of the institutional REC
  o Particular concern of significant unevenness in review processes, lack of review experience or rigour in some RECs and lack of experience with certain types of research in some RECs
• Some suggested that the goal of achieving mutual acceptance of review decisions might be facilitated if common standardised training and common standards regarding SOPs and application forms were available

F. Reduction of number of RECs in Ireland:
• A majority of those who addressed the issue highlighted strongly the potential dangers of reducing the numbers of RECs in Ireland. In addition to the concerns mentioned above regarding the role of RECs for the institution, the following concerns were voiced:
  o Unmanageable workload for a reduced number of committees
  o Worries about creating an unflexible bureaucracy to the detriment of the needs of researchers
  o Loss of relationship with researchers who conduct research in institution and lack of incentive for researchers to feedback findings to institution
  o Ethical deskillling in individual institutions
• Respondents emphasised the importance of liaising carefully and extensively with individual RECs should any such reduction be proposed

G. Clinical Trials Committees
• The existing system of Clinical Trials Committees was perceived as viable, but far from ideal
• Concerns mentioned that were relating to the current system included:
  o Lack of proper procedures of assignment of applications to different committees, allowing applicants to “cherry-pick” the committee that they perceived as most advantageous
o Strongly uneven distribution of review load between committees (partly as consequence of above), leading to different levels of review experience and expertise
o No central office or resource to advise Clinical Trials Committees; insufficient resourcing regarding a variety of aspects of review requirements, e.g. access to training, expertise, relevant information and support
o No requirement for common application forms and SOPs
o Some of the current practices and requirements were perceived by individual respondents as unnecessarily burdensome, e.g. physical amount of paperwork for individual sites vs. possibility of unified electronic data submission and storage; quorum requirements

• The potential reduction of Clinical Trials Committees to a lower number was mentioned by some respondents as likely; views on its desirability were mixed
• Concerns related to such reduction included:
  o Which criteria should be applied to decide on selection of committees (regional vs. other criteria)
  o Loss of resources for REC that lose Clinical Trials status, especially regarding administrative support that is needed for other aspects of the functioning of REC

G. Access to experts:

• Respondents from large teaching hospitals and academic institutions tended to be satisfied with their existing level of access to expertise
• Respondents from committees in other institutions felt it would be helpful if access to experts could be facilitated, especially for advice on individual applications
• It was suggested that a database of experts willing to provide advice to RECs could be created
• Some respondents envisaged a broader use of such database facility, e.g. to include volunteers especially for legal and lay membership
• Some respondents discussed the issue of giving an adjudicating role to experts in cases of difficult decisions, but most of these were very critical towards this idea, mainly due to concerns relating to the preservation of REC autonomy and the creation of an additional layer of bureaucracy.

Administrators’ interviews:

Many of the above concerns were brought up in the interviews with administrators and matched closely what was contributed from the chairpersons’ perspectives. Due to space constraints, only those issues that were specific to the administrative perspective will be mentioned here.

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A. Extent of administrative duties

- In many RECs, administrators fulfil other duties in addition to REC work; outside of the Clinical Trials Committees REC work is often not even part of their official job description and administrators are frequently under pressure to coordinate REC work with other roles.

- Many administrators (especially those that work for the REC more than 8 weekly hours) describe a broad range of duties extending far beyond the management of the paperwork, including substantial ethical advice to researchers:
  - frequent and often repeated phone contacts and meetings with researchers
  - giving advice on applications
  - proof-reading of draft applications and supporting documents like information sheets

B. Training and competence building for REC administration

- The majority of administrators describe their role as initially ill defined and would welcome more guidelines and support in relation to their role.

- Competence building for their role frequently depends to a large extent on personal initiative and the willingness of the institution to fund relevant training; several administrators described attending ethics conferences and workshops in Ireland and abroad as essential for building necessary competence for their role

- Some administrators referred to other countries where more clarity exists on required training

C. Networking and national standards

- There is a perceived need for improved communication between administrators of different committees nationally
  - Administrators of the Clinical Trials committees have begun to organise regular meetings to share experiences and address issues arising in their practice; some administrators from other committees mentioned they would also be interested in attending such meetings or would welcome if similar meetings and networking facilities were facilitated

- At least among administrators in the Clinical Trials committees there is a perceived need for streamlining the management of paperwork and monitoring activities and a wish that guidelines and infrastructure should be agreed on

- In particular, there seems to be a need for the provision of a database programme that captures relevant parameters for REC records
Conclusions and Recommendations

This review of Research Ethics Committees in Ireland provides a comprehensive and up to date picture of how RECs currently operate. The multiple approaches used in the review enabled corroboration of the findings from a number of sources. A key strength of the approaches used is that staff have now been engaged during the review process and are therefore more likely to engage in assisting and supporting the implementation of any resulting recommendations. Equally a number of experts from within and outside the HSE have engaged with the review and are available to support future developments in this area.

The key points to emerge from the review are:

1. The need for increased support capacity for RECs. Such support includes a national resource unit nationally. At REC level there is a need for dedicated administrative support, access to training, and access to specialist knowledge, IT support systems, dedicated time for participation on RECs and dedicated budgets for RECs to support their training, administrative support and IT requirements.

2. Participants expressed a resounding desire for standardised processes across research ethics committees. Standardisation was requested in relation to having standard operating procedures for application to RECs, turnaround times, and guidelines on a range of topics such as for consent with vulnerable populations, membership and competencies of committees.

3. Communication was raised as an issue of concern at all levels of the research review process. This includes the need for improved systems at local and national levels between all stakeholders.

4. The openness and enthusiasm of all stakeholders to be involved in this area and the desire to formalise a network to support the development of knowledge and expertise.

5. There is a need for high level leadership on issues such as governance, quality and accountability in a way that support local REC structures and processes.
6. There is a commitment to optimising the research experience to improve the health of the population while minimising the burden on RECs, researchers, and the in particular, the population.

The REC Review Group proposes that to promote best practice in research in the HSE and to ensure quality and safety for the public, these issues are progressed through the following recommendations:

1. Responsibility for HSE RECs

That the unified Education, Training and Research structure in the HSE take the lead in relation to Research Ethics Committees. This could be done in one of two ways:

a) Establish a national resource unit with responsibility for supporting Research Ethics Committees

or

b) Contract out the task of supporting Research Ethics Committees to an experienced organisation.

There is a need for the development of an operational plan outlining the need for appropriate resources.

The key functions and roles that need to be attended to by HSE centrally are:

- The establishment of a governance structure and a quality improvement process for REC's
- The development of guidelines and SOPs that would cover issues such as consent, relevant legislation, standard competencies required by committee members, membership of committees, turn around times for research, continuous quality assurance and the types of research the committees should approve
- The development of a communication plan
- The development of a standardised operating procedures and application forms for use by all RECs
- The development of national guidelines on feedback, review and annual reports
- The identification of training needs for REC members and the research community, and the development and co-ordination of training
- The provision of a standard database to REC activity
- The provision of a system of arbitration
- The establishment of a thoroughly integrated strategy between academic and all other RECs
- To establish a national website
• The setting up of a Specialist Panel/database of experts for REC’s, the functions of which are outlined in Recommendation 2 below.

2. Specialist Panel/database of experts for RECs

Building on the expertise of stakeholders who have contributed to the Review, it is proposed that a specialist panel/database of experts be established. Their role would include:

• Advise on the implementation of this review
• Be available to existing RECs for expert advice
• Review existing RECs structures and advise on issues of number of committees, location, membership, workload etc.
• Advise on the best way to manage ethical approval for multi-centre research
• Advise on the balance between central and local management of REC applications so that the overall process is more streamlined and efficient.

3. Resources

To ensure quality and safety in relation to research ethics:

• RECs need to be adequately resourced to perform their function in particular to ensure dedicated administrative support and a database to record activity
• Resources also need to be made available for training and competence building for REC members
• Resources are needed to implement the recommendations of this report.

4. Communication Systems for REC’s

A Communication Plan needs to be developed to ensure necessary communications systems are in place to enable:

• Communication to and from the HSE centrally
• Ease of access to REC’s for researchers
• Communication between local RECs and researchers including information on what requires REC review, how to access RECs and their procedures, and feedback mechanisms on their research proposals
• Communication between researchers and committees to include update reports and progress reports on completion of the research to the REC and to participants
• Networking and communication on good practice
• Improved discussion and communication between Irish RECs in order to allow for broader reflection on and dissemination of good practice standards and shared learning.
References


Buttimer, Dr. Jane Preparing Ireland’s Doctors to meet the Health Needs of the 21st Century


Denmark: The link to the site is http://www.cvk.im.dk/cvk/site.aspx?p=119 and a review of the Danish system is available on http://www.onlineethics.org/cms/8082.aspx


New Zealand: There is a designated New Zealand Health and Disability Ethics Committees website http://www.newhealth.govt.nz/ethicscommittees/

Northern Ireland: The link to the ORECNI is http://www.orecni.org.uk


Sweden: Further details on the Swedish system can be found on http://www.vr.se/mainmenu/researchethics.4.69f66a93108e85f68d48000116.html

The home page to Australian Research Ethics is available on http://www.nhmrc.gov.au/ethics/index.htm and the online central application form can be viewed on https://www.neaf.gov.au/

These websites were all accessed as late as December 2007.


UK: The link to NRES is http://www.nres.npsa.nhs.uk
Appendices

Appendix 1. Survey Questionnaire and Cover Letter

Research Ethics Committees Questionnaire
Review of REC Structures and Processes

General Information

1. What is the official name and address of the Research Ethics Committee?

2. Contact details for secretary completing the questionnaire:

   Name ................................................................................................................
   Address ............................................................................................................
   Phone Number ...................................................................................................
   Fax Number ........................................................................................................

3. Do you have a website? ☐ Yes ☐ No

   If yes, please state website address

   ............................................................................................................................

4. How long has this Research Ethics Committee been in operation?

   Years ...................................................... Months .................................
5. What resources are available to the REC? Please tick all that apply
   a. Administrative personnel Yes ☐ No ☐
      If yes, on average, how many hours per week are dedicated to REC work by the administrative personnel? ☐
   b. A dedicated budget Yes ☐ No ☐
      If yes, please specify the amount ☐
   c. Database of REC activity Yes ☐
   d. Other (please specify) ☐

   Membership of REC

6. How many members are on your committee? ☐

7. Do you have a quorum to make decisions? Yes ☐ No ☐

8. If yes what number is your quorum? ☐

9. How many times a year does the REC meet in 2006? ☐
   How long did the average meeting last ☐

10. Please state the number of each of the following members, on the committee whose primary function is:

    Medical Doctor ☐
    Scientist/Researcher ☐
    Psychologist ☐
    Ethicist ☐
    Lay person ☐
    Nurse ☐
    Statistician ☐
    Legal Professional ☐
    Allied Health Professional ☐
    Religious Representative ☐

    Please state the role of any other members not included above ☐
11. How long is the chair’s term of office?  
12. How long is the members’ term of office?  

### Training

13. Is training made available for REC members?  
   - Yes □  No □  
   
   If yes, please give outline of specific training

14. Is there a budget for training?  
   - Yes □  No □  

### Activity Levels

15. How many applications did the REC review in 2006?  
   If exact numbers are not available, please attempt an estimate (indicate estimate by *):

16. How many applications has the REC reviewed since its inception?  
   If exact numbers are not available, please attempt an estimate (indicate estimate by *):

17. How many applications did the REC **approve** in 2006?  

18a. If you are part of the HSE which disciplines/professions submitted proposals during 2006?

   - Medicine and Health Sciences  
   - Natural Sciences and Engineering  
   - Psychology and Social Sciences  
   - Education  
   - Social Work  

18b. If you are from an academic institution, please indicate what were the areas of research covered by these submissions?

   Tick all that are appropriate
19. Approximately what percentage of **submitted** applications during 2006 involved children as research participants? ..............................

**REC Remit**

20. Please specify the types of research reviewed by the REC (please tick all that apply):
  - Quantitative Research
  - Qualitative Research
  - Clinical Audit/Evaluation Studies
  - Patient satisfaction Surveys

21. Does your REC review clinical trials applications  Yes □ No □

   If yes, how many clinical trials did the REC review in 2006?  .............
   .............

22. What percentage of the applications are for research being conducted to complete an MSc./PhD or other qualification?  .........................
   .........................

23. Does your REC review applications for research that will be **conducted** on sites outside the location of the REC?  Yes □ No □ Unknown □

24. Does the REC review applications from **researchers** outside of the organisation?  Yes □ No □ Unknown □

25. To your knowledge, do some researchers submit proposals to more than one REC? Yes □ No □ Unknown □

**Application process and review procedures**

26. Does your REC have a standard application form?  Yes □ No □

   *(If yes can you attach a copy or include a web link?)*

   Can the application be submitted:
   - Online (through a website)?  Yes □ No □
   - Via email?  Yes □ No □
   - Hard Copy?  Yes □ No □

27. Does your REC have Standard Operating Procedures for approving applications? Yes □ No □
28. How is information on the REC review procedures made available to researchers? Please tick all that apply:

- Website □
- Intranet □
- Distribution of leaflets or brochures within the institution □
- Upon request by the researcher □
- Other (please specify) .................................................................

Please attach any leaflets/documentation relating to REC information or relevant web links)

29. Please indicate the average time in days between the submission of a proposal and the first feedback to the applicant? (If exact numbers are not available, please attempt an estimate (indicate estimate by *))

........................................... Days

30. Please indicate the average time in days between the submission of a proposal and a final decision? (If exact numbers are not available, please attempt an estimate (indicate estimate by *).)

........................................... Days

31. How many times can the REC ask the applicant for supplemental information?

...........................................

32. Are there alternative or expedited review procedures in place within your REC other than review by the full research ethics committee (e.g. chairperson’s approval, screening of applications, subcommittees)?

Yes □ No □ Unknown □

If yes please give details .................................................................
33. If an application is refused, does the REC provide an opportunity to appeal?  
   Yes ☐  No ☐

34. Does the REC monitor the research it has approved?  
   Yes ☐  No ☐  Unknown ☐
   Please Specify …………………………………………………………………………………………………………………………………………………

35. Does the ethics committee produce an annual reports?  
   Yes ☐  No ☐
   If yes can you attach a copy or provide a weblink?

36. Do you, as secretary to the committee, have any further comments?  
   ……………………………………………………………………………………………………………………………………………………………
   ……………………………………………………………………………………………………………………………………………………………
   ……………………………………………………………………………………………………………………………………………………………

Thank you for taking the time to complete this questionnaire

Dear Research Ethics Committee secretary,

The Health Intelligence function, Health Service Executive and The National University of Ireland, Galway (NUIG) (who were commissioned by the Office of the Minister for Children), are jointly undertaking a review of the structures and processes of all Research Ethics Committees’ (RECs) in Ireland. One part of the review is a survey of all RECs. The objectives of the survey are as follows:

**Objectives**

1. To identify the RECs’ membership and review processes
2. To record the RECs’ activity levels in 2006
3. To identify the scope of research that the RECs review
4. To identify the resources available to the RECs
5. To collect relevant documents relating to the work of the RECs, including Standard Operating Procedures, application forms etc.

It is extremely important for the purposes of the study that we receive accurate information from as many RECs as possible in order to be able to develop a balanced and representative view of the situation of RECs in Ireland today.

Enclosed is a questionnaire for you to complete so we can ascertain the above information. Based on the information gained from this questionnaire, the research team may also contact your REC chairperson in the coming weeks. A consultation day is also scheduled for the autumn with REC members. Using these results and evidence from other countries, recommendations for best practice for RECs in Ireland will be made.

Although the completed questionnaires are not anonymous (for contact and mapping purposes) they will be confidential. Only aggregated anonymised data will be presented in the report.

We would appreciate if you would complete the questionnaire and return it in the enclosed envelope provided by **Friday September 14th**.

If you have any questions regarding the research or if you need assistance with completing the questionnaire, please do not hesitate to contact Ms. Ruth Corcoran (contact details below).

Your co-operation and assistance are very much appreciated.

Yours sincerely,

Ruth Corcoran, Heike Schmidt-Felzmann
Department of Public Health, Centre for Bioethical Research and Analysis
HSE Population Health Directorate, National University of Ireland, Galway,
Merlin Park, Distillery Road,
Galway. Galway.
Email: ruth.corcoran@mailn.hse.ie; Email: Heike Felzmann@nuigalway.ie
Phone: 091 775723 Phone: 091 495043

**Appendix 2.** List of REC’s surveyed. * indicates the RECs that have been recognised under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulation 2004.

1. Beaumont Hospital Ethics (Medical Research) Committee*
2. Bon Secours Research Ethics Sub-Committee
3. Cappagh National Orthopaedic Hospital Research Ethics Committee
4. Clinical Research Ethics Committee of the Cork Teaching Hospitals*
5. Galway University Hospital Research Ethics Committee*
6. HSE Midland Area Research Ethics Committee
7. Ethics Research Committee HSE Mid-Western Area*
8. HSE North Eastern Area Research Ethics Committee*
9. HSE South-Eastern Area Research Ethics Committee*
10. James Connolly Memorial Hospital Research Ethics Committee
11. Letterkenny General Hospital Research Ethics Committee
12. Mater Misericordiae University Hospital and Mater Private Hospital Research Ethics*
13. Mayo General Hospital Research Ethics Committee
14. Naas General Hospital Research Ethics Committee
15. National Maternity Hospital Research Ethics Committee*
16. National Rehabilitation Hospital
17. Our Lady's Children's Hospital, Crumlin, Research Ethics Committee*
18. The Rotunda Hospital Research Ethics Committee
19. Royal Victoria Eye & Ear Hospital Research Ethics Committee
20. SJH/AMNCH Research Ethics Committee*
21. St. Patrick's Hospital Research Ethics Committee
22. St. Vincent's Healthcare Group Ethics and Medical Research Committee*
23. St. Vincent's Hospital, Fairview Research Ethics Committee
24. Sligo General Hospital Research Ethics Committee*
25. Stewarts Hospital Research Ethics Committee
26. Royal College of Physicians Ireland Research Ethics Committee
27. University College Dublin Research Ethics Committee
28. Trinity College Research Ethics Committee
29. Royal College of Surgeons Ireland Research Ethics Committee
30. Dublin Institute of Technology Research Ethics Committee
31. Dublin City University Research Ethics Committee
32. NUI Maynooth Research Ethics Committee
33. NUI Galway Research Ethics Committee
34. Waterford Institute of Technology Research Ethics Committee
35. University of Limerick Research Ethics Committee
36. Health Research Board Research Ethics Committee
37. Irish College of General Practitioners Research Ethics Committee*
38. Irish Prison Service Research Ethics Committee
39. St Francis Hospice Research Ethics Committee
40. KARE Research Ethics Committee
41. Travellers Research and Ethics Working Group
42. Daughters of Charity Research Ethics Committee
43. St Michaels House Research Ethics Committee
44. Childrens Sunshine Home Research Ethics Committee
45. St John of Gods Services Research Ethics committee
46. Sisters of Charity Research Ethics Committee
47. Cheeverstown Research Ethics Committee
48. Department of Child and Adolescent Psychiatry Research Ethics Committee
49. St Lukes Hospital Research Ethics Committee
50. Coombe Womens Hospital Research Ethics Committee
Appendix 3. Interview Schedule

Chairpersons’ interviews
In relation to the first section on their experience with research ethics review work in their own REC, the participating chairpersons were asked about the following issues:
- their views on essential requirements for successful work of an REC,
- their views on what was working well in their own REC
- their views on what challenges their REC encountered in its work, including prompts (depending on previous comments) on
  - workload
  - recruitment
  - training
  - difficult ethical issues
- the role of the REC in relation to different stakeholders, including participants, researchers, and host organisation
- their views on general ethics needs in their organisation

In relation to the second section, the participating chairpersons were asked about the following issues:
- the significance of children’s research in their review work
- common issues arising in the review of children’s research
- suggestions for potential support of RECs in the review of children’s research

In relation to the third section, the chairpersons were encouraged to make suggestions on potential changes to the REC review system in Ireland, including the following aspects:
- general suggestions for change and for what should be kept
- views regarding the review of multicentre studies
- views regarding potential reduction of committee numbers in Ireland
- views regarding the usefulness of ethical guidelines
- views regarding access to experts

Administrators’ interviews:
In relation to the first section, the participating administrators were asked about the following issues:
- description of their duties for the committee
- their view on what worked well in their own position
- their view on what challenges they encountered in their own position
- their perception of general challenges of committee work

In relation to the second section on children’s research, administrators from committees with a high review load of children’s research were asked about the following issues:
- their perception of researchers’ needs in children’s research with regard to the REC process

In relation to the third section on the committee system in Ireland, participating administrators were asked their opinion on the following issues:
- their suggestions on what might make their own work for the REC easier
- their suggestions on what might further facilitate the work of the REC
- their suggestions on what might support researchers in the REC review process
Appendix 4. Programme for Consultation Day

Research Ethic Committees - Consultation Day
Thursday 1st November 2007 - 9:00am - 4:30pm
Education Centre,
Adelaide & Meath Hospital Dublin
Incorporating the National Children’s Hospital, Tallaght.

AGENDA

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<thead>
<tr>
<th>Time</th>
<th>Speaker</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-9.30</td>
<td>Barbara Hennessy &amp; Imelda Crone</td>
<td>Registration. Assignment of delegates to groups</td>
</tr>
<tr>
<td>9.30-9.35</td>
<td>Majella Daly</td>
<td>Welcome, introduction and outline of the day. Purpose of the day.</td>
</tr>
<tr>
<td>9.35-9.45</td>
<td>Dr. Davida De La Harpe</td>
<td>Sponsor / Member of METR</td>
</tr>
<tr>
<td></td>
<td>Asst. National Director of Pop. Health</td>
<td>• Context for the Review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Purpose of the review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• What happens with the review and recommendations</td>
</tr>
<tr>
<td>9.45-10.05</td>
<td>Dr Siobhan O’Sullivan - Irish Council for Bioethics.</td>
<td>The Role of Research Ethics Committees</td>
</tr>
<tr>
<td></td>
<td>( Provisional, awaiting confirmation)</td>
<td>• Protecting the rights, safety, dignity and well being of potential participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Facilitating research for the public good</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Research requiring ethical review</td>
</tr>
<tr>
<td>10.05-10.25</td>
<td>Mary Morrissey</td>
<td>Presentation of key findings of the REC survey</td>
</tr>
<tr>
<td></td>
<td>Director of Psychology, Health Intelligence, Population Health.</td>
<td></td>
</tr>
<tr>
<td>10.25-10.45</td>
<td>Chair</td>
<td>Questions and Answers</td>
</tr>
<tr>
<td>10.45-11.05</td>
<td>Tea/ Coffee</td>
<td></td>
</tr>
<tr>
<td>11.05-12.05</td>
<td>Group Work</td>
<td>Roundtable focussed discussion – Q1a. What’s currently working well?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q1b. What needs improvement in REC’s?</td>
</tr>
<tr>
<td>12.05-12.30</td>
<td>Group Work</td>
<td>Feedback from the groups</td>
</tr>
<tr>
<td>12.30-1.45</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>1.45-2.05</td>
<td>Facilitator – Helen Franklin</td>
<td>Summation of key points from morning session</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>2.05-2.25</td>
<td><strong>Heather Hegarty</strong></td>
<td>Synopsis of what’s happening in other countries.</td>
</tr>
<tr>
<td></td>
<td>Senior Public Health Researcher, HSE South</td>
<td></td>
</tr>
<tr>
<td>2.25-3.30</td>
<td>Group Work</td>
<td>Roundtable focussed discussion</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Q2a. How would you see things improved in the future?</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Q2b. How could these changes be implemented?</em></td>
</tr>
<tr>
<td>3.30-4.00</td>
<td>Group Work</td>
<td>Feedback from the groups</td>
</tr>
<tr>
<td>4.00-4.20</td>
<td>Facilitator</td>
<td>Summation and conclusions of the day</td>
</tr>
<tr>
<td>4.20 -</td>
<td><strong>Mary Morrissey</strong></td>
<td>Next steps</td>
</tr>
<tr>
<td>4.30</td>
<td>Close</td>
<td>Evaluation sheets</td>
</tr>
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<td></td>
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<td>Thank-you</td>
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Appendix 5. International Comparison Tabulated Data

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<td>Clinical Center</td>
</tr>
<tr>
<td>CIHR</td>
<td>Canadian Institutes of Health Research</td>
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<tr>
<td>CTIMP</td>
<td>Clinical Trial of an Investigational Medicinal Product</td>
</tr>
<tr>
<td>DDER</td>
<td>Deputy Director for Extramural Research (US)</td>
</tr>
<tr>
<td>DDIR</td>
<td>Deputy Director for Intramural Research (US)</td>
</tr>
<tr>
<td>DHHS</td>
<td>Department of Human and Health Services (US)</td>
</tr>
<tr>
<td>EC</td>
<td>Ethics Committee</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (US)</td>
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<tr>
<td>GAfREC</td>
<td>Governance Arrangements for National Health Service Research Ethics Committees (UK)</td>
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<tr>
<td>GTAC</td>
<td>Gene Technology Advisory Committee (UK and NZ)</td>
</tr>
<tr>
<td>HDEC</td>
<td>Health and Disability Ethics Committee (NZ)</td>
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<tr>
<td>HRC</td>
<td>Health Research Council of New Zealand</td>
</tr>
<tr>
<td>HRCEC</td>
<td>Health Research Council of New Zealand Ethics Committee</td>
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<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<tr>
<td>IC</td>
<td>The appropriate Institute or Center</td>
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<tr>
<td>IEC</td>
<td>Institutional Ethics Committee (NZ)</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board (US)</td>
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<tr>
<td>LREC</td>
<td>Local Research Ethics Committee (UK)</td>
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<tr>
<td>MPA</td>
<td>Assurance of Compliance With DHHS Regulations for the Protection of Human Subjects (45 CFR 46) (US)</td>
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<tr>
<td>MREC</td>
<td>Multi-centre Research Ethics Committee (UK)</td>
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<tr>
<td>NEAC</td>
<td>National Ethics Advisory Committee (NZ)</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council (Aust)</td>
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<td>National Health Service (UK)</td>
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<td>National Institutes of Health (US)</td>
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<td>OHSR</td>
<td>Office of Human Subject Research (US)</td>
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<td>OPRR</td>
<td>Office for Protection from Research Risks (US)</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<td>REB</td>
<td>Research Ethics Board</td>
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<td>REC</td>
<td>Research Ethics Committee</td>
</tr>
<tr>
<td>UKXIRA</td>
<td>United Kingdom Xenotransplantation Interim Regulatory Authority</td>
</tr>
</tbody>
</table>
LIST OF DOCUMENTS CONSULTED

World Health Organisation:
Operational Guidelines for Ethics Committees that Review Biomedical Research - 2000

Council for International Organisations of Medical Sciences:
International Ethical Guidelines for Biomedical Research Involving Human Subjects 2002

Australia:
National Health and Medical Research Council – National Statement on Ethical Conduct in Research Involving Humans - 1999
National Health and Medical Research Council – National Statement on Ethical Conduct in Human Research - Second consultation draft - 2006
Joint National Health and Medical Research Council / Australian Vice-Chancellor’s Committee Statement and Guidelines on Research Practice - 1997
Australian Code for the Responsible Conduct of Research - Second consultation draft - 2006

Canada:

New Zealand:
Health Research Council - Guidelines for Ethics Committee Accreditation – 1996
National Ethics Advisory Committee – Ethical Guidelines for Observational Studies Observational Research, Audits and Related Activities – 2006
Terms of Reference for Health and Disability Ethics Committees

United Kingdom:
Governance Arrangements for National Health Service Research Ethics Committees – July 2001
Standard Operating Procedures for Research Ethics Committees – October 2006

United States of America:
Assurance of Compliance with Department of Health and Human Services Regulations for the Protection of Human Subjects (45 CFR 46)
Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects
Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health
PRINCIPLES

REQUIREMENT FOR REVIEW

All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees.

A network of ethical review should be established at the regional, national, and local levels that ensures the highest competence in review while guaranteeing input from all levels of the community.

Level of review proportional to any risks of the kind of research.

COMPETENCE

The rules of composition of the Ethics Committee must be formulated to ensure competent review of the ethics of proposed research. The rules should ensure the Ethics Committee contains the necessary expertise across a range of disciplines.

INDEPENDENCE

Ethics Committees should be constituted to ensure that their tasks can be executed free from bias and influence that could affect their independence. The Ethics Committee should be free from political, institutional, professional and market influences, including independence from the research team and sponsors of the research.

Any direct financial or material benefit that is derived from the research should not be contingent on the outcome of their review.

SUPPORT SYSTEMS

Ethics Committees or their appointing authorities must have systems to appoint members and convene them, to seek recognition if the law requires it and to support them and monitor their performance.

TIMELINESS/EFFICIENCY

Ethics Review Committees should show efficiency in their work to avoid hindering the undertaking of acceptable research. All proposed research should be ethically reviewed in a timely manner so that the turnaround time for the consideration of proposals should be as short as possible and should avoid unnecessary delays in decision-making.

REVIEW PRIOR TO START AND ONGOING MONITORING

The investigator must obtain the approval or clearance of the ethics review committee before undertaking the research. The ethical review committee should have in place mechanisms or processes that enable it to conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

NATURAL JUSTICE

All processes of the Ethics Committee should be open, transparent and fair. The Ethics Review Committee should be objective when considering proposals for ethical approval. Investigators/sponsors should be advised of the process for consideration of proposals, given the opportunity to comment on issues that arise (with reasonable time to respond), kept informed of the progress and advised of the outcome.

There should be no actual or perceived conflict of interest.

The investigators/sponsors should be informed if a decision or recommendation is made not to grant approval for a proposal, approval is withdrawn due to deviation from the protocol or...
the approval is suspended as the result of complaint. The investigators/sponsors should be given the chance to comment on the issues arising.

NOTES ON THE TABLES

- If there is no entry in the table for a given jurisdiction it indicates that a documented policy that dealt with that standard or process was not found for that jurisdiction. However, this does not mean that one does not exist.
- The NHMRC is due to very shortly release a revised and updated National Standard. For Australia the entries in italics are those taken from the second consultation draft and therefore may not represent the final form of the National Standard.
- The New Zealand system has two separate kinds of ethics committees, Institutional Ethics Committees (IEC) that are attached to an institution, usually a university, that review a broad range of research and Health and Disability Ethics Committees (HDEC) that are set up by statute that only review health and disability research. Both IECs and HDECs must conform to the Operational Standard, but for matters outside the operational standard the HDECs have a common documented approach and each IEC has its own approved policies. The standards compiled for New Zealand that are outside the operational standard are those that apply to the HDECs unless otherwise stated.
### TERMS OF REFERENCE

**Australia**
An institution, when establishing an HREC, should set out its terms of reference including:
- (a) the scope of its responsibilities for ethical review;
- (b) its relationship to other processes of research review;
- (c) its relationship to non-affiliated researchers and external organisations;
- (d) its institutional accountability;
- (e) its mechanisms of reporting; and
- (f) remuneration, if any, for members.

**Canada**

**NZ**
HDEC Terms of reference include:
- a) authority under which the EC is established;
- b) the scope of its responsibility for ethical review;
- c) relationship between terms of reference and Operational Standard;
- d) relationships to other public sector organisations;
- e) role of the EC;
- f) composition and membership;
- g) terms and conditions of appointment;
- h) roles of chair and deputy chair;
- i) duties and responsibilities of a member, including conflicts of interest and obligations of confidentiality;
- j) meetings – schedule, decision making process and observer/applicant attendance;
- k) EC actions;
- l) expert advice and consultation;
- m) second opinions and appeals;
- n) training for members;
- o) reporting requirements;
- p) fees and allowances;
- q) resourcing.

**UK**

**US**

### ACCOUNTABILITY

**Australia**
In this Statement, accountability means the measures by which any of those involved can demonstrate that their responsibilities have been, or are being, fulfilled. Typical accountability measures involve reporting from one level of the hierarchy to another higher (or more general) level.

**Guidelines for accountability**
5.7.1 Researchers have responsibilities for the ethical design and conduct of research.

The measures of accountability by which researchers demonstrate, to institutions and to ethical review bodies, fulfilment of those responsibilities appear in Chapter 5.1 Institutional responsibilities and Chapter 5.5 Monitoring approved research.

5.7.2 HRECs have responsibilities for the ethical review of research. The measures of accountability by which HRECs demonstrate, to institutions, fulfilment of those responsibilities appear in Chapter 5.2 Responsibilities of Human Research Ethics Committees.

5.7.3 Institutions have responsibilities for the conduct of research and to ensure that ethical review of research occurs. The former responsibilities, that include ensuring that research is both sound and lawful, and is conducted by educated and experienced researchers, are set out in the
Australian code for the responsible conduct of research. The latter responsibilities are set out in Chapter 5.1 Institutional responsibilities.

5.7.4 In addition to providing information annually, institutions shall provide other information about their ethical review processes to the NHMRC on reasonable request.

5.7.5 Institutions in which health and medical human research is undertaken, and which are in receipt of NHMRC research funding or intend to remain eligible for it, must be registered with the NHMRC. Registration will include information about any HREC(s) or other review bodies which the institution has decided to use, or has established, to provide ethical review of human research.

5.7.6 As provided for in the deed of agreement attached to any NHMRC funding, it will be a requirement that institutions attest annually to the NHMRC in writing that the research governance and ethical oversight processes in place remain compliant with this Statement and with the Australian code for the responsible conduct of research.

Canada
Delegated authority from the institution in which they are formed.
Institution to make clear the jurisdiction and relationship with other bodies

NZ
UK

US
Responsibilities of the Deputy Director for Intramural Research (DDIR)
The DDIR, on behalf of the Director, NIH, assumes overall responsibility for implementation of this Assurance.
All NIH IRB employees conducting or supporting research involving human subjects are responsible for ensuring that the rights and welfare of human subjects are protected. The DDIR will ensure that NIH intramural staff receive appropriate education and training regarding the requirements of the NIH MPA.
Research approved by an NIH IRB is subject to further review and institutional approval by the DDIR. In determining if the NIH shall sponsor or support such research, the DDIR will take into account program relevance and public responsibility. The DDIR may delegate this review and approval authority to other appropriate NIH officials (IC Directors, Scientific Directors, or Clinical Directors).

Responsibilities of the Deputy Director for Extramural Research (DDER)
The DDER will facilitate compliance with the NIH MPA for all human subject research conducted by NIH extramural program staff.
The DDER will ensure that NIH extramural staff receive appropriate education and training regarding the requirements of the NIH MPA.
The DDER will coordinate extramural human subject policy and education efforts with those of the OHSR, where necessary, to ensure consistent protection for human subjects through the NIH.

Responsibilities of Research Investigators, Laboratory/Branch Chiefs, Clinical Directors and Scientific Directors
Determination of human subjects involvement
Research investigators are responsible for determining whether their research activities will involve human subjects as defined in 45 CFR 46.102 (see II. A.).
When it is not clear whether their research activities will involve human subjects, investigators shall seek assistance from the OHSR or the Chair
of the appropriate IRB in making this determination. If research activities that were originally determined not to involve human subjects change such that human subjects become involved, research investigators are responsible for obtaining the required official approvals (see III. C. 2. and 3., below).

NUMBER OF MEMBERS OF EC

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirements</th>
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</thead>
<tbody>
<tr>
<td>Australia</td>
<td>A minimum of 7 members minimum 8 members</td>
</tr>
<tr>
<td>Canada</td>
<td>A minimum of 5 members</td>
</tr>
<tr>
<td>NZ</td>
<td>IEC – minimum of 10 members HDEC – 12 members</td>
</tr>
<tr>
<td>UK</td>
<td>Maximum - 18 members, minimum – 7 members Sufficient members to guarantee the presence of a quorum at each meeting.</td>
</tr>
<tr>
<td>US</td>
<td>A minimum of 5 members</td>
</tr>
</tbody>
</table>

EXPERTISE - GENERAL

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Description</th>
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</table>
| World Health Organisation | Ethics Committees should be established in accordance with the values and principles of the communities they serve. 

Ethics Committees should be constituted to ensure the competent review and evaluation of all ethical aspects of the research proposals they receive, and

Ethics Committees should be multi-disciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution and laypersons representing the interests and the concerns of the community. |
| CIOMS | A national or local ethical review committee responsible for reviewing and approving proposals for externally sponsored research should have among its members or consultants persons who are thoroughly familiar with the customs and traditions of the population or community concerned and sensitive to issues of human dignity.

National or local ethical review committees should be so composed as to be able to provide complete and adequate review of the research proposals submitted to them. It is generally presumed that their membership should include physicians, scientists and other professionals such as nurses, lawyers, ethicists and clergy, as well as lay persons qualified to represent |
the cultural and moral values of the community and to ensure that the
dights of the research subjects will be respected. They should include both
men and women. When uneducated or illiterate persons form the focus of a
study they should also be considered for membership or invited to be
represented and have their views expressed.

| Australia | Must ensure membership includes relevant expertise. *And/or experience*
| Canada | Equal numbers of men and women and 1/3 outside institution.
| NZ | Members appointed for their expertise not in a representative capacity
| UK | The basic membership requirements are designed to ensure the expertise,
multidisciplinary and independence essential to competent research ethics
review by REBs. The institution may need to exceed these minimum
requirements in order to ensure an adequate and thorough review. The
Agencies consider it essential that effective community representation be
maintained. Thus, as the size of an REB increases beyond the minimum of
five members, the number of community representatives should also
increase.

| NZ | The primary guiding principle for appointing members to the EC is to ensure
that the EC has the appropriate expertise, skills, knowledge and
perspectives to conduct ethical review of the best quality.

Members should possess an attitude that is accepting of the values of other
professions and community perspectives, and it is important for committees
to be comprised of people from a range of backgrounds and ethnicities.

Despite being drawn from groups identified with particular interests or
responsibilities in connection with health and community issues, EC
members are not in any way the representatives of those groups. They are
appointed in their own right, to participate in the work of the EC as equal
individuals of sound judgement, relevant experience and adequate training
in ethical review.

| UK | This should allow for a sufficiently broad range of experience and expertise,
so that the scientific, clinical and methodological aspects of a research
proposal can be reconciled with the welfare of research participants, and
with broader ethical implications ECs should be constituted to ensure the
competent review and evaluation of all ethical aspects of the research
projects they receive. Overall the EC should have a balanced age and
gender distribution. Members should be drawn from both sexes and from a
wide range of age groups. Every effort should also be made to recruit
members from black and ethnic minority backgrounds, as well as people
with disabilities. This should apply to both expert and lay members. Despite
being drawn from groups identified with particular interests or
responsibilities in connection with health and social care issues, EC
members are not in any way the representatives of those groups. They are
appointed in their own right, to participate in the work of the EC as equal
individuals of sound judgement, relevant experience and adequate training
in ethical review.
US
An IRB should consist of persons with varying backgrounds to promote complete review and approval of such IC research activities. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to foster respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review and approve specific research activities, the IRB shall include persons knowledgeable in the Belmont Report, relevant Federal Regulations and local and state law and professional standards of conduct.

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

No IRB shall consist entirely of men, entirely of women or entirely of members of one profession

<table>
<thead>
<tr>
<th>EXPERTISE SPECIFIC</th>
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<tbody>
<tr>
<td>Australia</td>
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<tr>
<td>≥ 1/2 member with knowledge of and experience of research areas reviewed by the EC</td>
</tr>
<tr>
<td>≥ 1 member with knowledge and experience in professional care, counselling or treatment of people</td>
</tr>
<tr>
<td>≥ 1 member who is a Minister of Religion or holds similar community role e.g. Aboriginal elder</td>
</tr>
<tr>
<td>≥ 1 member who is a lawyer, <em>not providing legal advice to the institution</em></td>
</tr>
<tr>
<td>Canada</td>
</tr>
<tr>
<td>≥ 2 members with knowledge of and experience of research areas reviewed by the REB</td>
</tr>
<tr>
<td>≥ 1 member who is knowledgeable in ethics</td>
</tr>
<tr>
<td>Biomedical research must have ≥ 1 member who is knowledgeable in the relevant law, recommended but not mandatory for all other research.</td>
</tr>
<tr>
<td>NZ</td>
</tr>
<tr>
<td>IEC –</td>
</tr>
<tr>
<td>≥ 1 member with knowledge of Tikanga Maori</td>
</tr>
<tr>
<td>≥ 1 member for each research area regularly reviewed, including qualitative and quantitative expertise</td>
</tr>
<tr>
<td>≥ 1 member with formal training in ethics</td>
</tr>
<tr>
<td>≥ 1 lawyer (preferable but not essential)</td>
</tr>
<tr>
<td>≥ 2 members from the wider community (no affiliation with the institution)</td>
</tr>
<tr>
<td>≥ 2 members from the Maori community</td>
</tr>
<tr>
<td>≥ 1 member from the student community</td>
</tr>
<tr>
<td>HDEC –</td>
</tr>
<tr>
<td>Lay membership shall include:</td>
</tr>
<tr>
<td>• an ethicist</td>
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<tr>
<td>• a lawyer</td>
</tr>
<tr>
<td>• consumer perspectives</td>
</tr>
<tr>
<td>• community perspectives</td>
</tr>
<tr>
<td>Non-lay members shall include:</td>
</tr>
<tr>
<td>• two health researchers</td>
</tr>
<tr>
<td>• a pharmacist or pharmacologist</td>
</tr>
<tr>
<td>• a biostatistician</td>
</tr>
<tr>
<td>• two health practitioners</td>
</tr>
<tr>
<td>At least two Māori members. Māori members should have a recognised awareness of te reo Māori, and an understanding of tikanga Māori. All</td>
</tr>
</tbody>
</table>
members of the HDEC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

UK
The “expert” members of the committee shall be chosen to ensure that the REC has the following expertise:

relevant methodological and ethical expertise in:
- clinical research
- non-clinical research
- qualitative or other research methods applicable to health services, social science and social care research.

clinical practice including:
- hospital and community staff (medical, nursing and other)
- general practice
- statistics relevant to research
- pharmacy

US
Each IRB shall include at least one member whose primary concerns are in scientific areas.

<table>
<thead>
<tr>
<th>LAY MEMBERS</th>
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<tbody>
<tr>
<td><strong>Australia</strong></td>
</tr>
<tr>
<td>≥ 2 lay members</td>
</tr>
<tr>
<td>• ≥1 male, ≥1 female</td>
</tr>
<tr>
<td>• No affiliation with institution or organisation</td>
</tr>
<tr>
<td>• Not involved in medical, scientific or legal work</td>
</tr>
<tr>
<td>• Preferably from the community in which the institution is located</td>
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<tbody>
<tr>
<td><strong>Canada</strong></td>
</tr>
<tr>
<td>≥ 1 member who has no affiliation with the institution and has been recruited from the community served by the institution.</td>
</tr>
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</table>

If the number of members is more than five then community representation should increase.

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<tbody>
<tr>
<td><strong>NZ</strong></td>
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<tr>
<td>One half of the total membership shall be lay members, including a lay Chairperson and a non-lay Deputy Chairperson. A lay person is a person who is not:</td>
</tr>
<tr>
<td>• currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist)</td>
</tr>
<tr>
<td>• involved in conducting health or disability research or who is employed by a health agency and who is in a sector of that agency which undertakes health research</td>
</tr>
<tr>
<td>• construed by virtue of employment, profession or relationship to have a potential</td>
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</tbody>
</table>
conflict or professional bias in a majority of protocols reviewed

<table>
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<tr>
<th>Country</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>UK</td>
<td>At least three members must be independent of any organisation where research under ethical review is likely to take place. At least one third of the membership shall be “lay” members who are independent of the NHS, either as employees or in a non-executive role, and whose primary personal or professional interest is not in a research area. The “lay” membership can include non-medical clinical staff who have not practised their profession for a period of at least five years. At least half of the “lay” members must be persons who are not, and never have been, either health or social care professionals, and who have never been involved in carrying out research involving human participants, their tissue or data.</td>
</tr>
<tr>
<td>US</td>
<td>Each IRB shall include at least one member (e.g., lawyer, ethicist, cleric) whose primary concerns are in non-scientific areas and at least one member who is not otherwise affiliated with the Public Health Service or the institution, and who is not part of the immediate family of an affiliated person</td>
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### NEW MEMBERS

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>CIOMS</td>
<td>A number of members should be replaced periodically with the aim of blending the advantages of experience with those of fresh perspectives.</td>
</tr>
<tr>
<td>Australia</td>
<td>Must ensure that diversity and expertise balance maintained.</td>
</tr>
<tr>
<td>Canada</td>
<td>The terms of REB appointments should be arranged to balance the need to maintain continuity with the need to ensure diversity of opinion and opportunity to spread knowledge and experience gained from REB membership throughout the institution and community.</td>
</tr>
<tr>
<td>NZ</td>
<td>The primary guiding principle for appointing members to HDECs is to ensure that the HDEC has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality</td>
</tr>
<tr>
<td>UK</td>
<td>The appointing Authority shall ensure that a rotation system for membership is in place that allows for continuity, the development and maintenance of expertise within the REC, and the regular input of fresh ideas.</td>
</tr>
<tr>
<td>US</td>
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### SUBSTITUTES

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>WHO</td>
<td>A rotation system for membership should be considered that allows for continuity, the development and maintenance of expertise within the EC, and the regular input of fresh ideas and approaches</td>
</tr>
<tr>
<td>CIOMS</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>No member may belong to more than one category but in each category alternating members may be appointed.</td>
</tr>
<tr>
<td>Canada</td>
<td>Institutions should consider the nomination of substitute REB members so that Boards are not paralysed by illness or other unforeseen eventualities. The use of substitute members should not however, alter the membership structure.</td>
</tr>
<tr>
<td>NZ</td>
<td></td>
</tr>
</tbody>
</table>
UK  Can have deputy members and able to co-opt members up to two additional members at any meeting. A co-opted member must be or have been a member of a REC. Deputy members may not be co-opted to their own REC but can be co-opted by another REC.

Where a member provides unique expertise to the REC (e.g. pharmacy or statistical advice) the REC may, if necessary, make arrangements to appoint deputies for individual members of the committee. These deputies must have undergone the same recruitment, selection and appointment procedure as the named members, and must also have been trained in ethical review. When deputising, these members are considered full members of the committee. The names of deputies should be recorded in the Annual Report.

However, attendance of the member at the scheduled meetings must be of sufficient frequency to ensure their effective contribution to the work of the committee.

US

OFFICERS ON THE EC

WHO  ECs should establish clearly defined offices for the good functioning of ethical review. A statement is required of the officers within the EC (e.g. Chairperson Secretary), the requirements for holding each office and the duties and responsibilities of each office. Clear procedure for selecting or appointing officers should be established

CIOMS

Australia  

Canada  

NZ  HDEC - Role of Chair and Deputy Chair defined in Term of Reference  

UK  To facilitate communication, the REC may wish to designate a suitably qualified individual as Scientific Officer, who will be the principal point of liaison with applicants for more detailed discussion of issues related to the content of applications, and who can if necessary represent the committee at scientific management discussions. Depending on their background and personal expertise, this could be the Chair, Vice-Chair or Administrator, but need not necessarily be so. This work may be shared by other REC members.

US

RESOURCING

WHO  In addition to the EC officers, an EC should have adequate support staff for carrying out its responsibilities.

CIOMS  Sponsors of research and institutions in which the investigators are employed should allocate sufficient resources to the review process.

Australia  Institutions and organisations in which research involving humans is undertaken must individually or jointly establish, adequately resource, and maintain an HREC composed and functioning in accordance with the National Statement. Resources should be sufficient to make it possible for HRECs to satisfy the requirements for good ethical review, and for communicating well with researchers

Canada  REB to have appropriate financial and administrative independence.

NZ  The Ministry of Health shall employ staff and provide resources to service, advise, and administer the HDEC out of the allocated budget for ethics committees

UK  It is the responsibility of the appointing Authority to set an annual budget for the adequate support of the REC(s) for which it is accountable, irrespective of any income received from charges made for review in cases where this is appropriate

US  Each IC will provide appropriate resources to its IRB to assure proper functioning and record-keeping in conformance with the NIH MPA and 45 CFR 46
### QUORUM

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO</td>
<td>ECs should establish specific quorum requirements for reviewing and deciding on an application. These should include: Minimum number of members required to compose a quorum. The professional qualifications requirements and the distribution of those requirements over the quorum, no quorum should consist entirely of members of one profession or gender, a quorum should include at least one member whose primary area of expertise is in a non-scientific area and at least one member who is independent of the institution. Decisions should only be made at meetings where a quorum is present.</td>
</tr>
<tr>
<td>CIOMS</td>
<td>Australia Must establish a quorum and if quorum not reached must ensure that composition requirements reached.</td>
</tr>
<tr>
<td></td>
<td>Canada At any meeting, a quorum shall consist of at least seven members or the minimum number constituting a majority. The quorum must include a reasonable representation of members with health practitioner, research, ethical and community/consumer expertise, knowledge and perspectives.</td>
</tr>
<tr>
<td>NZ</td>
<td>UK Decisions should only be made at meetings where a quorum is present, Chair must attend. For meetings at which research ethical review is undertaken, a quorum shall consist of seven members. It shall include the Chair and/or Vice-Chair, at least one “expert” member with the relevant clinical and/or methodological expertise, one “lay” member, and at least one other member who is independent of the institution or specific location where the research is to take place.</td>
</tr>
<tr>
<td></td>
<td>NZ At any meeting, a quorum shall consist of at least seven members or the minimum number constituting a majority. The quorum must include a reasonable representation of members with health practitioner, research, ethical and community/consumer expertise, knowledge and perspectives.</td>
</tr>
<tr>
<td></td>
<td>US A quorum shall be defined as a majority of the voting members (fifty percent plus one) including at least one member whose primary concerns are in non-scientific areas.</td>
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</table>

### EXTERNAL EXPERTISE

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>WHO</td>
<td>CIOMS Committees that often review research proposals directed at specific diseases or impairments, such as HIV/AIDS or paraplegia, should invite or hear the views of individuals or bodies representing patients with such diseases or impairments. Similarly, for research involving such subjects as children, students, elderly persons or employees, committees should invite or hear the views of their representatives or advocates.</td>
</tr>
<tr>
<td></td>
<td>Australia EC must/should consider if advocate should be invited to meeting. The institution should establish procedures to ensure that the HREC has access to the expertise necessary to enable it to address the ethical considerations arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.</td>
</tr>
<tr>
<td></td>
<td>Canada Canada In the event that the REB is reviewing a project that requires particular community or research subject representation or a project that requires specific expertise not available from its regular members, the REB Chair should nominate appropriate ad hoc members for the duration of the review. Should this occur regularly, the membership of the REB should be modified.</td>
</tr>
<tr>
<td></td>
<td>NZ NZ Members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapū, and this should be supported and encouraged. However, the confidentiality of the proposal and details of the issue under review may also need to be protected. Members should obtain consent from the committee or chairperson before any such consultation takes place. Where a chairperson or quorum of committee members believes there is insufficient expertise on the committee to assess an application or an issue, the committee should seek additional expert advice.</td>
</tr>
</tbody>
</table>
UK | A REC may seek the advice of a referee on any aspects of an application that are relevant to the formation of an ethical opinion, and which lie beyond the expertise of the members or on which the REC is unable to agree.

Referees are not voting members of the REC.

Procedure defined for seeking advice from referees.

US | An IRB Chair may appoint ad hoc members with competence in special areas to assist in the review of complex issues that require expertise beyond that available on the IRB. These individuals may not vote with the IRB

### OBSERVERS

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<thead>
<tr>
<th>WHO</th>
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<tr>
<td>CIOMS</td>
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<tr>
<td>Australia</td>
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<tr>
<td>Canada</td>
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NZ | HDEC

As part of the accountability to the public they protect, it is desirable for the meetings of the HDEC to be open to the public. Meetings of the HDEC should therefore be:

i. open meetings for the discussion of broad issues, particularly if the HDEC is reviewing health research

ii. closed meetings when necessary to ensure the privacy and confidentiality of participants

iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.

Information about the dates and times of committee meetings should be made available to the public.

UK | Observers allowed to attend provided they have written invitation, sign confidentiality agreement and REC agree.

Observers, who shall play no part in the committee’s deliberations, may be invited subject to the minuted agreement of the REC, and subject to written invitation giving the terms under which observer status is permitted.

If an Investigator is at the meeting then they should be able to object to the presence of the observer.

Such observers should have no vested interest in, or scientific or management responsibility for, any applications being considered. Observers should be allowed only if they accept in writing the same duty of confidentiality as REC members.

US | The meetings shall be open to the public except for those discussions which deal with private or confidential information

### EDUCATION

| WHO | EC members have a need for initial and continued education regarding ethics and science of biomedical research. The conditions of appointment should state the provisions available for EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of EC members. This education may be linked to co-operative arrangements with other ECs in the area, the country, and the region, as well as other opportunities for the initial and continued training of EC members.

| CIOMS |  |
| Australia | members undertake appropriate induction, including mentoring by a current HREC member, and ongoing training; |
| Canada | REBs should also hold general meetings, retreats and educational workshops in which members can take advantage of educational opportunities that may benefit the overall operation of the REB. |
| NZ | Training should be provided for new members and chairpersons within six months of appointment to the HDEC. |
| UK | REC members have a need for initial and continuing education and training regarding research ethics, research methodology and research governance. |
| US | The NIH ensures that all researchers newly employed in its Intramural Research Program (IRP), and extramural staff involved in the planning, conduct and program oversight of research involving human subjects, complete the computer-based training program entitled "The Protection of Human Research Subjects at the NIH" |

**APPOINTMENT**

| WHO | Clear procedures for identifying or recruiting potential EC members should be established. A statement should be drawn up of the requirements for candidacy that includes an outline of the duties and responsibilities of EC members. |
| Membership requirements should include: |
| • Name or description of the party responsible for making appointments |
| • The procedure for selecting members, including method (e.g. by consensus, majority vote, appointment) |
| • Conflicts of interest should be avoided when making appointments, where unavoidable, there should be transparency. |
| CIOMS | A number of members should be replaced periodically with the aim of blending the advantages of experience with those of fresh perspectives. |
| Australia | In such manner, and for such period and on such terms EC determines. |

*The chair should be a person with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under this Statement.*

5.1.25 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.

5.1.26 Members are to be appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, community or opinion.

5.1.27 An institution that establishes an HREC should provide each member with a formal notice of appointment and an assurance of legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as HREC members.
<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
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<tbody>
<tr>
<td>NZ</td>
<td>Members of the HDEC are appointed by the Minister of Health, for a term of office of up to three years. The terms of office of members of the HDEC shall be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years. After serving the maximum six-year term, members shall not be considered for reappointment until at least three years after their retirement from the HDEC. Persons who have served six consecutive years on any HRC approved ethics committee shall not be immediately eligible for appointment to the HDEC. Those persons shall not be eligible for appointment to the HDEC until at least three years after their retirement from any HRC-approved ethics committee. Persons who have served less than six years on any HRC-approved committee will be eligible to be appointed to the HDEC for a term that is equal to the difference of six years and the term already served by that person on any HRC-approved ethics committee, or a shorter period. The Minister shall appoint a member of the HDEC to be its Chairperson. The terms and conditions of appointment for member of the HDEC also apply to the person appointed as Chair. The Chairperson shall preside at every meeting of the HDEC at which they are present. The HDEC shall appoint a non-lay member as Deputy Chairperson.</td>
</tr>
<tr>
<td>UK</td>
<td>The Health Authority is responsible for appointment of LREC members. The Department of Health or its appointed agent is responsible for the appointment of members of MRECs, GTAC and UKXIRA. The process for appointment of all officers shall be laid down in the standard operating procedures. Appointment of members shall be by an open process, compatible with the Nolan standards. Vacancies should be filled following public advertisement in the press, and/or by advertisement via local professional and other networks as most appropriate to the vacancy to be filled. Potential candidates shall be required to complete an application form. The process for selection of members shall be laid down in Standard Operating Procedures. The Chair and Vice-Chair shall be appointed as such by the appointing Authority after consultation with the REC Administrator and committee members. The appointees should have had at least one year’s experience of the work of RECs. Those appointed should have received personal training in research ethics reviewing, and possess the relevant chairing skills. Potential candidates should be offered any necessary supplementary training prior to appointment. An appointed member must be prepared to have published his/her full name, profession and affiliation.</td>
</tr>
<tr>
<td>US</td>
<td>IRB members shall be recommended by the IC Clinical Director, in consultation with the IC Scientific Director, and appointed by the DDIR for one- to three-year renewable terms. The Chair of the IRB shall be recommended by the IC Clinical Director, in consultation with the IC Scientific Director, and appointed by the DDIR. IC, Scientific and Clinical Directors may not serve as IRB Chairs. Ordinarily, the IRB Chair shall serve for two years, but the appointment may be renewed.</td>
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</table>

1 The “Nolan Standards” define seven principles of public life - selflessness, integrity, objectivity, accountability, openness, honesty and leadership.
## APPOINTMENT FORMALITIES

### WHO
Terms of appointment should be established that include the following:
- Duration
- Policy for renewal
- Disqualification procedure
- Resignation procedure
- Replacement procedure

A statement of the conditions of appointment should be drawn up that includes the following:
- A member should be willing to publicise her/his full name, profession, and affiliation
- All reimbursement for work and expenses (if any) within or related to an EC should be recorded and made available to the public on request
- A member should sign a confidentiality agreement regarding meeting deliberations, applications, information in research participants, and related matters, in addition, all EC administrative staff should sign a similar confidentiality agreement.

A statement of the provisions available for EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review and the requirements or expectations regarding the initial and continuing education of EC members.

### CIOMS

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<td>Australia</td>
<td>Formal notice of appointment and assurance of legal protection by organisation for bona fides duties.</td>
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<td>NZ</td>
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### UK
The appointed member shall be informed in writing of the terms of the appointment, including its duration, the policy for renewal, the disqualification procedure and the resignation procedure, the policy concerning declaration of interests, confidentiality requirements and details of allowable expenses.

The appointing Authority shall provide each appointed member with a personal statement regarding the indemnity provided, and its conditions.

Members should be appointed for fixed terms, normally five years. Terms of appointment may be renewed, but not normally more than two consecutive terms should be served on the same REC. A member may however subsequently serve on another REC. Simultaneous service on both an MREC and LREC is permitted.

### CONFIDENTIALITY

### WHO
A member should sign a confidentiality agreement regarding meeting deliberations, applications, information in research participants, and related matters, in addition, all EC administrative staff should sign a similar confidentiality agreement.

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### NZ

**HDEC**

Agendas and minutes of all HDEC meetings should be available to the public. Copies of proposals should be available to individuals outside the HDEC, subject to deletions in accordance with the Official Information Act 1982, and any deletions necessary to protect the privacy of individual persons. If an applicant would like their proposal to remain confidential, they must give reasons, consistent with the Official Information Act, to satisfy the HDEC that the proposal should remain confidential. The reasons for keeping a proposal confidential are subject to review by the Ombudsmen.

It is desirable for the members of the HDEC to have an opportunity to discuss issues arising from applications with key contacts and support people prior to the consideration of proposals. This process should be encouraged. However, due to the need to protect any personal information, names or identifying details should not be circulated or made known outside the HDEC. The HDEC will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

### UK

An appointed member shall be expected to maintain confidentiality regarding meeting deliberations, applications, information on research participants, and related matters.

### US

### OPERATING PROCEDURES

**WHO**

ECs should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the EC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures and the quorum requirements.

ECs should act in accordance with their written operating procedures.

ECs are responsible for establishing well-defined requirements for submitting an application for review of a biomedical research project. These requirements should be readily available to prospective applicants.

**CIOMS**

Australia

Required to have policy on:

- Frequency of meetings
- Preparation of agendas and minutes
- Distribution of papers prior to meetings
- Presentation of research protocols
- Timely consideration and review of research protocols
- Methods of decision making
- Prompt notification of decisions
- Reporting of adverse occurrences
- Appropriate monitoring
- Receiving complaints
- Advising institutions to discontinue a research project
- Fee
- Confidentiality of content of protocols and committee proceedings

(b) attendance at meetings;
(c) conduct and structure of meetings and deliberations;
(h) managing conflicts of interest;
(i) communicating with researchers, including face to face, by telephone and in writing
(j) reporting on its activities to the institution;
(m) record keeping;
(n) monitoring of approved research;
(o) handling adverse occurrences;
(p) handling of complaints
(r) accommodating observers at meetings;
(s) fees, if any, to be charged;

Canada
NZ Must comply with the Operational Standard.

UK Good standard operating procedures and accurate record keeping are important. Standard operating procedures shall be drawn up in line with national guidance, and approved by the appointing Authority. These standard operating procedures should be publicly available.

RECs shall have standard operating procedures that state:
· the Authority under which the REC is established
· the functions and duties of the REC
· membership requirements
· the terms and conditions of appointment
· the officers and the structure of the secretariat
· internal procedures
· quorum requirements
· procedures for considering applications

Standard operating procedures shall be compatible with European and UK law, and, where appropriate, to the relevant provisions in Good Clinical Practice.

RECs shall act in accordance with their written standard operating procedures. The appointing Authority is responsible for the governance of the REC in this respect, and should ensure that account is taken of all guidance issued by the Department of Health.

US

MEETINGS - SCHEDULE

WHO ECs should meet regularly on scheduled dates that are announced in advance. The meeting should be planned in accordance with the needs of the workload EC members should be given enough time in advance of the meeting to review the relevant documents

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| **Australia** | Meetings to be arranged to facilitate full attendance and fully informed discussions.  
If not full attendance responsibility of Chair to make sure skills and diversity still met.  

*As far as possible each meeting of an HREC should be arranged to allow relevant members of each category the opportunity to attend and to be fully informed by prior receipt of papers.*  

5.2.3 *Where there is less than full attendance at a meeting, the Chairperson should be satisfied, before a decision is reached, that the minimum membership listed in paragraph 5.1.21 have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.*  

5.2.4 *An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.* |

| **Canada** | Schedule of meetings to be made available to researchers.  
REBs to hold general meetings, retreats and workshops to deal with education, operational issues and policy.  
Regular attendance by REB members is important, frequent unexplained absences should be construed as resignation. |

| **NZ** | All applications received before the close off date should be considered at the next EC meeting if possible.  
If it is obvious further information is required, then it should be requested prior to the meeting at Chair’s discretion  
Each EC should have cut-off date, that doesn’t change.  
Cut-off dates and meeting dates to be advertised and administrator of ECs contact details to be included.  
Meetings of the HDEC shall be held monthly or less frequently, as determined by the workload.  
As part of the accountability to the public they protect, it is desirable for the meetings of the HDEC to be open to the public. Meetings of the HDEC should therefore be:  

i. open meetings for the discussion of broad issues, particularly if the HDEC is reviewing health research  
ii. closed meetings when necessary to ensure the privacy and confidentiality of participants  
iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.  

Information about the dates and times of committee meetings should be made available to the public. |
UK

REC should hold at least 10 scheduled meetings a year, with additional meetings when necessary. Usually a month apart but no longer than 2 months apart.
- The schedule should set out the dates, times and venues of meetings and the closing date for applications to each meeting. All members and deputy members of the REC should be issued with details of the schedule.
- Closing dates to be no earlier than 21 days and no later than 14 days before the meeting.

Schedules to be widely publicised, including any changes

It follows that there should be a sufficient frequency of REC meetings within a Health Authority “site” to complete the business in a timely manner. It is recommended that individual RECs meet monthly, but that the timing of meeting of the individual RECs within one Health Authority “site” should be staggered. REC members do not sit on the committee in any representative capacity and need to be able to discuss freely the proposals that come before them. For these reasons REC meetings will normally be held in private.

RECs shall meet regularly on scheduled dates that are announced in advance. Meetings should be planned in accordance with the needs of the workload, but RECs must meet the time standards for review. REC members should be given enough time in advance of the meeting to review the relevant documents.

Normally an appointed member shall be required to attend in full at least two thirds of all scheduled REC meetings in each year, barring exceptional circumstances.

An REC should not be expected to accept a workload that compromises the quality of ethical review. When this is likely, the Authority should establish additional RECs, or make formal arrangements for other RECs (e.g. from neighbouring Health Authorities) to provide an opinion.

US

Meetings shall be called by the Chair as often as required to accomplish the business of the IRB. The meetings shall be open to the public except for those discussions which deal with private or confidential information. Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

APPLICATION PROCESS

WHO

An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research.

The requirements for the submission of a research project for ethical review should be clearly described in an application procedure.

These should include:
- The name(s) and address(es) of the EC secretariat or members to whom the application material is to be submitted.
- The application form(s)
- Format for submission
- Documentation (see Documentation below)
- Language in which core docs to be submitted
- Number of copies to be submitted
- Deadlines for submission of the application in relation to review dates
- The means by which applications will be acknowledge, including the communication of the incompleteness of an application
- The expected time for notification of the decision following review
- The time frame to be followed in cases where the EC requests

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supplementary information or changes to documents from the applicant
  • The fee structure, if any, for reviewing an application
  • The application procedure for amendments to the protocol, the
    recruitment material, the potential research participant information or the
    informed consent form.

All properly submitted applications should be reviewed in a timely fashion and
according to an established review procedure.
UK

RECs should consider valid applications in a timely manner. A decision should be reached and communicated to the applicant within 60 calendar days of the submission of a valid application.

Only one application for ethical review should be submitted in relation to any research protocol to be conducted within the UK.

In the case of research projects with separate protocols governing one or more sub-studies in addition to the main study, a full application should be submitted for each protocol.

All new applications for ethical review to a Research Ethics Committee (REC) in the UK should be submitted on the electronic standard NHS REC application form, as published on the website of the Central Office for Research Ethics Committees.

After an initial review, any further written information or clarification may be requested from the applicant on one occasion only. During this period, the timeframe is suspended and does not recommence until a response satisfactory to the REC is received. A final decision should then be made and communicated to the applicant within the total of 60 days. For multi-centre research, this timeframe includes consideration of the locality issues.

The ethical review by the REC should occur in parallel with the consideration of the proposed research by NHS host organisations (usually by its R&D Directorate) and any relevant regulatory authorities, e.g. the Medicines Control Agency.

All properly submitted and valid applications shall be reviewed in a timely fashion and according to an established review procedure described in the REC's standard operating procedures. A valid application is one which has been submitted by an appropriate investigator, is complete, with all the necessary documents attached, and is signed and dated.

The application shall be submitted by the “principal investigator” who is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. It follows that the applicant should be of adequate qualification and expertise to fulfil this important role.

Where a potential applicant is inexperienced, there should be an identified supervisor of adequate quality and experience who will counter-sign the application form, and then share the responsibility for the ethical and scientific conduct of the research. A current signed CV of the supervisor should be submitted with the application.

RECs should ensure that their requirements for submitting an application for review are described in an application procedure that is readily available to prospective applicants. These shall be published by the REC and shall include the following:

a. the name(s) and address(es) of the REC secretariat to which the application is to be submitted
b. the application form
c. the format for submission
d. any additional documentation
e. the language(s) in which core document(s) are to be submitted
f. the number of copies to be submitted
g. the deadlines for submission of the application in relation to the review dates
h. the means by which the application will be acknowledged, including the communication of the incompleteness of the application
i. the expected time for notification of the decision following review
j. the time frame to be followed in cases where the REC requests supplementary information or changes to the documents from the applicant
k. the fee structure, if any, for reviewing an application
l. the application procedure for amendments to the protocol, the recruitment material, the potential research participant information, and the information or methods used to obtain consent
m. the process for addressing any disputed decisions
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<td>US</td>
<td>It is the policy of the NIH that its IRBs will review only research which has been reviewed by the appropriate Institute or Center (IC) and found to be scientifically meritorious, well-designed, and in keeping with ethical guidelines, program relevance and public responsibility.</td>
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### AMENDMENTS TO RESEARCH PROPOSALS

| WHO | Any protocol amendment likely to affect the rights, safety and or wellbeing of the participants or the conduct of the study requires follow-up. Any event or new information that may affect the benefit/risk ratio of the study. |

| CIOMS | The granting and continuation of ethical approval of clinical research must be on the condition that the researcher … informs the HREC, and seeks its approval, of amendments to the protocol including any: |
|       | (i) proposed or undertaken in order to eliminate immediate hazards to participants; |
|       | (ii) that may increase the risks to participants; or |
|       | (iii) that significantly affect the conduct of the trial. |

| Australia | Prior to making any study amendments or modifications application must be made to the REB Secretariat for approval for the amendment. Revised consent forms, as appropriate, should also be enclosed. A recommendation of approval of the |
amendments or study modifications is at the discretion of the REB Chair. The Chair may require a full Board review.

| NZ | Any significant alterations to a previously approved proposal must receive prior approval of EC.  

Significant changes include changes to:  
- Personnel  
- Method/procedures  
- Design  
- Duration  
- Characteristics of proposed participants  
- Method of recruitment  
- Information sheets  
- Informed consent procedures  

Additional Locality Organisations  
If locality organisation in same EC region, approval should be sought from locality organisation and sent to EC that approved original application.  
If one or more other EC regions, locality approval sought from each and sent to EC that approved original application. Locality assessments and EC proposal to MREC. MREC then responsible for oversight.  
Withdrawal of site.  
If site in same EC region, notify EC that approved original proposal.  
If result is that no longer multi-centre, must notify MREC. MREC then has discretion to send it to the relevant REC.  

| UK | Amendments submitted once the research has started shall be considered at its next meeting by the REC that approved the original protocol, and an answer given to the applicant within a total of 35 days. However, where the amendment is substantial (for example, requiring additional interventions to research participants), it may need to be treated by the REC as a new application requiring full ethical review within the standard 60-day timeframe.  

Once the REC has given a favourable opinion, the researcher is required to notify the committee, in advance, of any proposed deviation from the original protocol. The committee may then wish to review its decision.  
No deviation from, or changes to, the protocol shall be initiated by the researcher without the prior written approval of the REC, save where this is necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research. In these cases, the changes may be implemented immediately, but the REC must be informed within seven days. The REC may then reconsider its opinion.  

| US | Changes in research activities during the period for which IRB approval has already been given shall not be initiated by research investigators without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.  

Research investigators are responsible for reporting proposed changes in previously approved research activities through the Laboratory/Branch Chief, Clinical Director and/or Scientific Director to the appropriate IRB.  

STUDENTS
WHO
CIOMS
Australia
Canada
NZ
UK Research to be undertaken by students primarily for educational purposes (e.g. as a requirement for a University degree course) shall be considered according to the same ethical and operational standards as are applied to other research. In such cases the supervisor takes on the role and responsibilities of the sponsor. In reaching its decision, the REC will wish to consider the broader overall benefits gained by such research.

US

DECESSIONS

WHO The primary task of an EC lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. ECs need to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations.

When making decisions an EC should take the following into considerations:

• a decision should only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of EC staff.
• Decisions should only be made at meetings where a quorum is present
• The document required for a full review of the application should be complete and the relevant elements should be considered before a decision is made.
• Only members who participate in the review should participate in the decision
• There should be a predefined method for arriving at a decision (e.g. by consensus, by vote) it is recommended that decisions be arrived at through consensus, where possible; when consensus appears unlikely, it is recommended that the EC vote.
  • Advice that is non-binding may be appended to the decision.
  • In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
  • A negative decision on an application should be supported by clearly stated reasons.

CIOMS

Australia May approve, require amendments or reject proposal.
Decisions must be recorded in writing and reasons given for rejection.
Unanimity not required but extensions to consideration time to be considered when any member not satisfied that welfare and rights of participants protected. Transparent and consistent, if approval consistent with Statement, if rejected – refer to Statement
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| Canada | The institution may authorise the REB to accept the review of another REB.  
The level of review is to be proportionate, the higher the level of risk to participants the greater the degree of care taken to assess the application.  
REBs shall meet face-to-face to review proposals excluding expedited review.  
REB shall provide an impartial and fair hearing and provide reasoned and appropriately documented opinions and decisions.  
When the REB is making a negative decision it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision. |
| NZ | Must use defined terminology for approved, approved subject to conditions, deferred or declined.  
Decisions must be recorded in writing and given to the principal investigator  
Reasoning must be stated:  
If deferred or rejected, grounds given.  
If approved with conditions, specify the conditions, the grounds, the assessment process for compliance.  
For all cases, differentiate between grounds for the decision and comments, information or advice to applicant.  
An EC may consult and receive advice from other ECs and should carefully consider the advice. The final decision however rests with the EC and the EC should be able to justify any decision that it makes. If advice received from another EC, should be included in the annual report.  
Wherever possible, the HDEC should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions, and the Chairperson having a casting vote.  
On occasion, individual members may wish to abstain from some or all of the decision making process because of strong personal moral or religious reasons. Such abstentions shall not affect the approval process. |
| UK | An REC shall make its decisions at scheduled meetings at which a quorum is present.  
A summary of details of the application shall be made publicly available once the final decision on the application is ratified by the REC. These shall include:  
- the names of the researcher and sponsor;  
- and of the research site;  
- a simple summary of the research proposal comprehensible to a lay person;  
- the issues discussed by the committee and the committee's conclusions; and  
- its overall opinion.  
There should be a pre-determined method for arriving at a decision; it is recommended that decisions be arrived at through consensus where possible. Where a consensus is not achievable, the REC should vote.  
If a dissenting member so wishes their dissent should be recorded in the minutes Advice that is not binding may be appended to the decision  
In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified. |
An unfavourable opinion on an application should be supported by clearly stated reasons. Written submissions from absent members shall be accepted and allowed to inform the discussion, minutes should record submission of written comments, only those members who actually participate in the review by the committee at its meeting shall participate in the decision.

| US | In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The Chair shall vote only to break a tie. Research investigators are responsible for complying with all IRB decisions and stipulations and for responding in writing to IRB stipulations and recommendations within 30 days. |
|    | Possible IRB Actions |
|    | Protocol approval |
|    | Protocol approval requires the approval of a majority of the IRB's quorum. If the vote of the IRB is not unanimous, the minority opinion must be recorded in or attached to the minutes and accompany the majority decision when forwarded for final institutional review and approval. A copy of each approved protocol together with all the correspondence and approval cover sheet will be forwarded for institutional approval and signature to the DDIR or his/her IC designee (see III. A. 3.). Protocols conducted in the CC are then forwarded to the Director, CC for review and approval as per III. D. 2. Copies of protocols not conducted in the CC shall be forwarded to OHSR for entry into its database (III. I. 7.b(2)). |
|    | Protocol approval with recommendations |
|    | The IRB may approve a protocol with non-binding recommendations. PIs must respond in writing to IRB recommendations. |
|    | Protocol approval with stipulations |
|    | An IRB may approve a protocol with stipulations which must be met in writing by a PI before initiation of the research. The IRB may (i) authorize the IRB Chair to approve the response to the stipulations and forward the protocol as described in d. (1) above; (ii) authorize an IRB subcommittee to review the response to the stipulations, or (iii) request that the response be reviewed at a convened meeting of the IRB. |
|    | Tabling of protocol |
|    | Approval cannot be granted until further information is provided or specific changes are made. When the new information is submitted the protocol is reviewed by the full IRB again. |
|    | Disapproval |
|    | Notice of the disapproval is sent to the PI and includes the reasons for the disapproval and information about reconsideration. |
## Communicating the Decision

### WHO

A decision should be communicated in writing to the applicant according to EC procedures, preferably within two weeks' time of the meeting at which the decision was made. The communication of the decision should include, but is not limited to the following:

- The exact title of the research proposal reviewed.
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based.
- The names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participants information sheet material and informed consent form.
  - Name and title of applicant.
  - Name of the site(s).
  - Date and place of the decision.
  - Name of EC taking decision.
  - A clear statement of the decision reached.
  - Any advice by the EC.
  - If conditional decision, any requirements by EC, including suggestions for revision and the procedure for having the application re-reviewed.
  - If a positive decision, a statement of the responsibilities of the applicant, for example, confirmation of the acceptance of any requirements imposed by the EC, submission of progress reports, the need to notify the EC in the case of amendments etc.
  - The schedule/plan of ongoing review by the EC.
  - In the case of a negative decision, clearly stated reason(s) for the negative decision.
  - Signature (dated) of the Chair (or other authorised person) of the EC.

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### NZ

For each application it reviews, the HDEC must state to its applicant whether its action is to Approve, Approve subject to conditions, Defer, or Decline that application. It must state its grounds for any action to Defer or Decline. For any action to Approve subject to conditions, it must specify the conditions, the grounds for these, and its process for assessing whether these conditions are subsequently met. In all cases, it must state which matters its action is based upon, and which are instead matters of comment, information, or advice to its applicant.

### UK

The REC should always be able to demonstrate that it has acted reasonably in reaching a particular decision. When research proposals are rejected by the REC, the reasons for that decision should be made available to the applicant.

### US

The IRB shall notify research investigators in writing of its decisions.

## Reviewing Decisions
Researchers have a right to request, and REBs have an obligation to provide reconsideration of decisions affecting a research proposal.

REB must follow natural and procedural justice

EC must review any new information. Applicants should be informed that their any decision can be reviewed on the basis of new information.

The EC may request to review a decision wrt to new information. A request for a review should be in writing and enclose the relevant new information.

EC should review the information and decide if there are sufficient grounds for changing the decision.

Review should be open and transparent, all parties should know about it. All parties should then be informed of the decisions.

If the parties are not satisfied with the review, can ask for a second opinion from HRCEC.

Second Opinions
HRCEC responsible for these.

Sought by EC when considering a proposal or by applicant who disagrees with ECs decision.

All parties to be advised that the process is being undertaken, given a chance to comment and kept informed.

Not an appeal, review by independent EC.

Final decision rests with original EC, which must take into consideration second opinion.

Any proposal for which a second opinion was sought should be noted in the annual report.

Exceptionally, a further review of the protocol may be undertaken by a second REC.

The conclusions of ethical review bodies as to whether applications meet the requirements of this Statement involve substantive ethical judgments on which there can be justifiable differences of opinion. For this reason, this chapter does not provide for appeals to other bodies or authorities by researchers against a final decision to reject a proposal, but deals only with complaints about other decisions or requirements made during the review process.

REBs should permit review of an REB decision by an appeal board, if agreement can not be reached by discussion between the REB and the Researcher.

No ad hoc appeal boards are permitted.
The decisions of the HDEC may be appealed to the Standing Committee on Appeals convened by the National Ethics Advisory Committee, in accordance with the Terms of Reference of the National Ethics Advisory Committee and any guidance promulgated by the Standing Committee on the appeals process.

Exceptionally, a further review of the protocol may be undertaken by a second REC.

### COMPLAINTS

**WHO**

**CIOMS**

**Australia**

EC will have mechanisms for receiving and promptly handling complaints. Have a nominated person to received and respond to complaints. If complaint can not be resolved between the EC and complainant then must have a person nominated to refer it to. Nominated person details must be included in initial information to participants. EC must have mechanism for receiving complaints from researchers about consideration of their proposal.

*Institutions may expect to receive complaints relating to research from:*

(a) participants or others about researchers or the conduct of research; and

(b) participants, researchers or others about the conduct of the Human Research Ethics Committee (HREC) or other review body.

*Processes of ethical review of research should be transparent and accountable to the research participants they are intended to protect, and to the researchers whose applications are reviewed. Accessible, prompt and effective handling of complaints demonstrates this transparency and accountability. The conclusions of ethical review bodies as to whether applications meet the requirements of this Statement involve substantive ethical judgments on which there can be justifiable differences of opinion. For this reason, this chapter does not provide for appeals to other bodies or authorities by researchers against a final decision to reject a proposal, but deals only with complaints about other decisions or requirements made during the review process.*

*Guidelines for handling complaints*  
5.6.1 Where complaints raise the possibility of serious research misconduct the matter should be handled in accordance with other institutional processes established to deal with these issues (see the Australian code for the responsible conduct of research).

5.6.2 Procedures referred to in paragraph 5.2.1(p) should include written procedures for receiving and promptly handling complaints or concerns about the conduct of an approved research project and about the review of research proposals.

5.6.3 Complaints handling procedures should provide two paths, corresponding to the two categories of complaints described in the Introduction to this chapter.

5.6.4 Institutions should:

(a) establish procedures for receiving, handling and resolving complaints from research participants and others about researchers or the conduct of research; and

(b) identify a person to receive these complaints.

5.6.5 Institutions should also:

(a) establish procedures for receiving, handling and resolving complaints from researchers about the conduct of ethical review bodies in reviewing research proposals, and

(ii) participants or others about the conduct of ethical review bodies in handling complaints; and

(b) appoint a person or persons independent of all ethical review bodies to
receive, handle and resolve these complaints.

5.6.6 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the institution.

5.6.7 Institutions should publicise their complaints handling procedures.

Canada

NZ

Every EC should have a written document that describes its procedure with respect to complaints, with copies available on request.

Complaints about the performance or conduct of EC members or admin procedures (e.g. a participant’s procedure) should be made in writing to the EC or the National Coordinator.

All members to be informed of the complaint and the EC is to try to resolve it. Chair must notify National Coordinator of complaint and resolution.

All complaints should be recorded and included in the annual report.

Complaints can seek redress through judicial review or other appropriate authority,

If an admin complaint can not be resolved it should be directed to the National Coordinator for an independent review and decision. Complaints should be in writing, if not received in writing should be put in writing. Can go to EC, NEAC, HRCEC and National Coordinator should be advised.

UK

US

**DELEGATION**

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<td>Australia</td>
<td>Must have policy on delegation to a sub-committee.</td>
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Canada

NZ  If conditional approval given by full committee to meet specific requirements, full meeting may assign one or more members with appropriate expertise to assess compliance and grant final approval.

If conditions can not be met, then must be referred back to full committee.

Chair may have delegated authority to approve the following:
- Protocols that are non-contentious
- Requests for use of tissue/body parts that would normally be discarded and consumer consent given
- Student projects where time is at a premium
- Minor amendments or extensions
- Full approvals, where previous approval in principle has been given and researcher has complied with requests.

Any action under delegated authority by Chair or other persons must be reported back to the committee at the next committee meeting.

UK

US

### APPLICANT ATTENDANCE

<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
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<tbody>
<tr>
<td>WHO</td>
<td>The applicant, sponsor and/or investigator may be invited to present the proposal or elaborate on specific issues.</td>
</tr>
<tr>
<td>CIOMS</td>
<td>EC can invite applicant to be present for discussion.</td>
</tr>
<tr>
<td>Australia</td>
<td>The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers may not be present when the REB makes its decision.</td>
</tr>
<tr>
<td>Canada</td>
<td>Applicants may attend meetings, in person or by teleconference, to talk to their proposal and answer any questions the HDEC may have. Attendance is not mandatory. The HDEC should advise applicants that they may be asked to leave the meeting while the HDEC considers the proposal.</td>
</tr>
<tr>
<td>NZ</td>
<td>The applicant (and if appropriate, the sponsor and/or other investigators) shall be invited to be available to elaborate on or clarify specific issues as required by the REC at its meeting. An REC should not cause unnecessary delay by deferring consideration of an application when the necessary further information it requires could have been obtained from the applicant at the first review meeting. The Chief Investigator should be invited to attend the meeting at which her/his application is to be reviewed. In the case of applications from students the REC should consider inviting the educational supervisor. It is not the purpose of the Chief Investigator’s attendance to make a formal presentation of the study, and this should not be permitted.</td>
</tr>
<tr>
<td>UK</td>
<td>When invited by the IRB Chair, investigators are encouraged to attend IRB meetings in order to facilitate the review of their protocols.</td>
</tr>
<tr>
<td>US</td>
<td>ECs may call upon, or establish a standing list of, independent consultants who may provide special expertise to the EC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, of they may be representatives of communities, patients, or special interest groups. Terms of reference for independent consultants should be established.</td>
</tr>
<tr>
<td>Country</td>
<td>Text</td>
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<tr>
<td>Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.</td>
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</tr>
<tr>
<td><strong>CIOMS</strong></td>
<td></td>
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</tbody>
</table>
| **Australia** | EC may seek advice and assistance from experts.  
Must be satisfied no conflict of interest of expert – conflict of interest identified and managed appropriately, and confidentiality requirements apply |
| **Canada** | Members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapū, and this should be encouraged and supported. Consultation should be carried out in a timely manner.  
Where the Chairperson or quorum of HDEC members believes there is insufficient expertise on the HDEC to assess an application or an issue, the committee should seek additional expert advice.  
Advice may be sought from recognised experts with:  
i. specialist knowledge in particular fields of science and medicine;  
ii. knowledge of the experiences and perspectives of people with disabilities;  
iii. awareness of gender health perspectives;  
iv. consumer and/or research participant perspectives;  
v. an understanding of community health issues;  
vi. an understanding of relevant cultural perspectives;  
vii. an understanding of developing Māori research methodologies;  
viii. expertise in te reo Māori; and  
ix. expertise in ethical theory.  
It should be noted that the above list gives examples, without restricting the range, of external expertise that may be sought.  
Where external consultation has taken place or advice has been sought, this should be documented, and recorded where appropriate in the HDEC’s decision on a proposal. |
| **UK** | The Chair and Administrator may seek the advice of specialist referees on any relevant aspects of a specific research proposal that lie beyond the expertise of the members. These referees may be specialists in ethical aspects, specific diseases or methodologies, or they may be representatives of communities, patients, or special interest groups. Such referees are not voting members of the committee, and should not be involved in the business of the committee other than that related to the specific research proposal in question. Terms of reference for independent referees should be established. Their advice should be recorded in the minutes.  
Independent expert referees may be invited by the Chairman to attend the meeting or to provide written comments, subject to applicable confidentiality agreements.  
By invitation of the Chair, independent experts or others may take part in the discussion of the proposal at the REC meeting; however, a final decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members |
(e.g. the investigator, representatives of the sponsor, independent experts) from
the meeting, with the exception of REC administrative staff and approved
observers

US
An IRB may, in its discretion, invite individuals with competence in special areas to
assist in the review of issues which require expertise beyond or in addition to that
available on the IRB. These individuals may not vote with the IRB

PARTICIPANT INTERESTS

WHO

CIOMS

Australia
EC must consider if advocate should be invited to meeting
If research involves participants unfamiliar with English language the EC must
ensure:
Participant’s info sheet in participant’s language
Interpreter present during discussion with participants

An HREC should consider whether to consult an advocate for any participant or
group of participants to inform the HREC about how best to enable informed
decision making and understanding by these participants.

5.2.8 Where a significant proportion of potential participants in research are
unfamiliar with the language in which the research is to be conducted, an HREC
should be satisfied that all information relevant to participation has been reliably
translated into the participants’ language. This applies whether or not the
information is provided in writing.

5.2.9 An HREC should be satisfied that someone able to interpret for participants
unfamiliar with the language in which the research is to be conducted, is present
during discussions with them about the project.

5.2.10 HRECs should be satisfied that information relevant to participants with a
vision or hearing impairment is made available to them in a way that takes their
impairment in to account.

Canada

NZ

UK

US

CONFLICTS OF INTEREST

WHO

ECs should be constituted to ensure the competent review and evaluation of all
ethical aspects of the research project they receive and to ensure that their tasks
can be executed free from bias and influence that could affect their independence.

A member should withdraw from the meeting for the decision procedure
concerning an application where there arises a conflict of interest; the conflict of
interest should be indicated to the Chair prior to the review of the application and
recorded in the minutes.
CIOMS
To maintain the review committee’s independence from the investigators and sponsors and to avoid conflict of interest, any member with a special or particular, direct or indirect, interest in a proposal should not take part in its assessment if that interest could subvert the member’s objective judgment. Members of ethical review committees should be held to the same standard of disclosure as scientific and medical research staff with regard to financial or other interests that could be construed as conflicts of interest. A practical way of avoiding such conflict of interest is for the committee to insist on a declaration of possible conflict of interest by any of its members. A member who makes such a declaration should then withdraw, if to do so is clearly the appropriate action to take, either at the member’s own discretion or at the request of the other members. Before withdrawing, the member should be permitted to offer comments on the protocol or to respond to questions of other members.

Australia
Ensure no member has a Conflict of interest.
Actual and potential conflicts of interest that may affect research are identified and managed

A conflict of interest exists where a divergence between a person’s individual interests and institutional role or professional obligation raises the question whether those individual interests influence the person’s carrying out of that role or obligation.

Similar conflicts can arise where there is a divergence between the interests of an institution and the commitment it has, for example, to doing good research. A conflict of interest can compromise the validity of the research process by leading to judgements being made on the basis of factors external to the requirements of the research, or can compromise the institutional processes governing research. While financial conflicts of interest are foremost in the public mind, other conflicting interests can include private benefits significantly dependent on research outcomes or significant personal or professional advantage. A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about the integrity of individuals or the management practices of an institution.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for identifying and managing conflicts of interest
5.4.1 Institutions should establish processes to identify and manage actual or potential conflicts of interest. Where a potential conflict of interest involves an institution, the institution should inform the body reviewing the research to which the conflict relates, of the sources and nature of the conflict.

5.4.2 A researcher should disclose to the review body any actual or potential sources of conflict of interest and, when proposing and reporting the research, any affiliation or financial or other interest in the research and/or its outcomes.

5.4.3 When information provided by a researcher to a review body indicates that there is likely to be a conflict of interest that may affect the ethical conduct of the research, the review body should adopt measures to manage that conflict. These measures may include requiring that the information be disclosed to research participants, that a person other than the researcher negotiate consent with participants or that the information be disclosed in any report of the research.

5.4.4 Where information provided by a researcher indicates to a review body that there may be a conflict of interest involving the institution, the review body should notify the institution.
5.4.5 A review body should require its members to disclose any actual or potential conflict of interest in any research to be reviewed, including any personal involvement or participation in the research, any financial interest in the outcome, or any involvement in competing research. The review body should adopt measures to manage such conflicts of interest. Measures may include either exclusion or absence from some or all of the committee’s discussion and/or decision.

5.4.6 A review body may seek advice from experts to assist with consideration of a research proposal. A review body should require those experts to disclose any actual or potential conflicts of interest arising from any personal involvement or participation in the research, and any financial interest in the outcome or any involvement in competing research. The review body should adopt measures to manage such conflicts of interest. Measures may include requiring that expert to provide only written advice, as well as either exclusion or absence from some or all of the committee’s discussion and/or decision.

Canada

Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest.

If REB reviewing research in which a member of the REB has a personal interest in the research under review, that member may not be present when the REB is discussing or making its decision. REB may disclose and explain the conflict of interest.

NZ

HDEC members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the HDEC and its members and will ensure it retains public confidence.

Members should declare, and the committee regularly review their actual and potential conflicts of interest.

When HDEC members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or from undertaking an activity consistent with the HDEC’s functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the HDEC who has a proposal before the HDEC or who has an involvement in the proposal such as a supervisory role shall not take part in the HDEC’s assessment of that proposal. The member may be present to answer
questions about a proposal but should take no part in the discussion surrounding the consideration of the proposal or any decision relating to the proposal. This will allow proposals to be considered in a free and frank manner. The HDEC must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

A person may not be a member of the HDEC and National Ethics Advisory Committee or the Health Research Council Ethics Committee simultaneously

<table>
<thead>
<tr>
<th>UK</th>
<th>When making appointments, conflicts of interest should be avoided if at all possible. Where unavoidable there should be transparency with regard to such interests, and they should be recorded and published with the above personal details.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Members and deputy members should declare to the REC any interests that they may have in relation to an application of any other matter for consideration at that meeting. Declaration can be made orally at meeting or in writing or the chair.</td>
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<td></td>
<td>REC to then decide on further action of member in relation to matter, leave room, stay but don’t vote, stay and vote.</td>
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<td></td>
<td>Minutes should record conflict of interest and decision of REC on which procedure followed. Any doubt – exclusion from the meetings recommended.</td>
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<tr>
<td></td>
<td>A member should withdraw from the meeting for the discussion and decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the Chair prior to the review of the application, and recorded in the minutes</td>
</tr>
<tr>
<td></td>
<td>An REC should not review an application in which one of its own members is a named researcher; such applications should be submitted to another REC</td>
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</table>

| US | No IRB member shall participate in an IRB’s initial or continuing review of any protocol in which the member has a real or an apparent conflict of interest, except to provide information requested by an IRB |

### APPLICANT’S CONFLICT OF INTEREST

<table>
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<tr>
<th>WHO</th>
<th>CIOMS</th>
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Biomedical studies receive funding from commercial firms. Such sponsors have good reasons to support research methods that are ethically and scientifically acceptable, but cases have arisen in which the conditions of funding could have introduced bias. It may happen that investigators have little or no input into trial design, limited access to the raw data, or limited participation in data interpretation, or that the results of a clinical trial may not be published if they are unfavourable to the sponsor’s product. This risk of bias may also be associated with other sources of support, such as government or foundations. As the persons directly responsible for their work, investigators should not enter into agreements that interfere unduly with their access to the data or their ability to analyse the data independently, to prepare manuscripts, or to publish them. Investigators must also disclose potential or apparent conflicts of interest on their part to the ethical review committee or to other institutional committees designed to evaluate and manage such conflicts. Ethical review committees should therefore ensure that these conditions are met.
<table>
<thead>
<tr>
<th>Country</th>
<th>Policy</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Applicant must disclose funding sources and declare any affiliation or financial interest. EC to consider extent of the disclosure of this information. An HREC should consider how much of the information provided by the researcher about amounts and sources of funding, financial interests or affiliations, should be disclosed to research participants.</td>
</tr>
<tr>
<td>Canada</td>
<td>REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected</td>
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<tr>
<td>NZ</td>
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<tr>
<td>UK</td>
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<td>US</td>
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### EXPEDITED REVIEW

<table>
<thead>
<tr>
<th>Organization</th>
<th>Policy</th>
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</table>
| WHO | ECs should establish procedures for the expedited review of research proposals. These procedures should specify the following;  
- Nature of the applications, amendments, and other considerations that will be eligible for expedited review.  
- Quorum requirements for expedited review  
- Status of decision (e.g. subject to confirmation by full EC or not) |
| CIOMS | |
Australia

EC allowed to have process for expedited review of minimum risk to participants, but must have policy on the following:
- Class of research to which it applies;
- Scope of Chair’s authority;
- Delegation to sub-committees;
- Relationship b/w Chair of full EC and sub-committee; and
- Method of reporting and ratification of decision by full committee.

Only low risk, not if risk of physical or psychological harm or invasive procedures.
If Chair considers departure from ethical principles – send to full EC.

Institutions may establish processes for review of research involving no more than low risk to participants in ways that meet institutional responsibilities described in this section. These processes must:

(a) have due regard to Section 1, and to Sections 3 and 4 which relate to different kinds of research and different categories of research participants;
(b) involve peer review;
(c) adequately address the research methodology and the relevant expertise of researcher or supervisor;
(d) allow for interdisciplinary or multi-disciplinary research and make provision for the different scholarly standards of different disciplines;
(e) consider whether the research provides sufficient protection of participants; and
(f) ensure that scholarly standards are not confused with ethical considerations arising from this Statement or other sources (see Introduction, Ethical conduct and review of human research).

5.1.8 The processes referred to in paragraph 5.1.7 may include, but need not be limited to:

(a) review or assessment at the departmental level by the head of department;
(b) review or assessment by a departmental committee of peers (with or without external or independent members);
(d) delegated review with reporting to an HREC; or
(e) ethical review by a subcommittee of an HREC.

Research that can be exempted from review

5.1.9 Research in which the only involvement of subjects is in any of the following categories may be exempted by institutions from ethical review because it involves such low levels of risk:

(a) the collection or study of existing data, documents or records, that are all publicly available;
(b) the use of existing collections of data or records that contain only non-identifiable data about human beings;
(c) the observation of public behaviour that involves no interaction with those observed, provided the information obtained is recorded in such a manner that those observed cannot be identified in any way; or
(d) research making use of standard educational practices and conducted in established educational settings, provided there is no interaction with those participating in these activities other than giving and receiving test materials.

Institutions must recognise that in allowing exempt research they are thereby determining that the research meets the requirements of this Statement and is
<table>
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<tr>
<th>Country</th>
<th>Details</th>
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<tbody>
<tr>
<td>Canada</td>
<td>Based on the criteria below, decisions to conduct expedited review are at the discretion of the REB Chair. Urgency alone is not a sufficient criterion for expedited review. Expedited Review Criteria: The research is non-invasive. Harms cannot include: breaking of skin, noxious procedures, invasive questionnaires in vulnerable circumstances/context, or significant nuisance/inconvenience. The research involves taking additional blood samples at the time of clinically-indicated blood drawing. The allowable amount will be based on the age, weight, and health of the subjects. The research consists of a comparison of standard therapies, confirmed by peer review, and does not involve invasive outcome assessment. The research involves no direct subject contact, may involve waste or leftover tissue, blood, urine, excreta etc. and only aggregate data is being reported. Exceptions: studies involving fetal waste tissue or genetic material must be submitted for full Board review. The study involves non-invasive product testing, or quality assurance activities and publication is planned. Expedited Review Process:</td>
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</table>

ethically acceptable. If they are not prepared to recognise this, they must subject the research to ethical review
Most expedited reviews, with the exception of database or health record research, require prior REB-delegated scientific review. As part of this process, the reviewers will be asked whether there are any special or ethical issues that the Board should know about.

The REB review process will include two reviewers, Chair plus 1 other REB member, who may be selected for specific expertise. After expedited approval is granted, summary information, title of the research, names of researchers, and any other information deemed to be pertinent, on the proposal will be submitted to the REB for ratification. REB members may request a copy of the full protocol, and may request delayed ratification until the next REB meeting. In the event that the full Board does not confirm approval, the study will be halted until all issues are resolved and approval is granted by the full REB.

<table>
<thead>
<tr>
<th>NZ</th>
<th>Expedited ethics committee review differs from full ethics committee review in two ways.</th>
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<tbody>
<tr>
<td></td>
<td>a) A shortened form of application is used.</td>
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<td></td>
<td>b) The review is not conducted by the full ethics committee, but instead by one or more of its members under delegation from it; and hence it may be conducted independently of the usual meeting schedule.</td>
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</table>

11.13 Expedited review is appropriate for minimal-risk observational research: case reports or case series; descriptive studies; and questionnaires or surveys for research purposes that do not involve the collection of sensitive personal information.

11.14 Expedited review is appropriate for an audit or related activity that requires ethics committee review.

11.15 Expedited review may be appropriate for an observational study that is undertaken as part of an educational qualification, and that requires timely ethics committee review.

In this case, the ethics committee, or one or more members under delegation from it, should judge whether it is appropriate for the study to undergo expedited review. (Investigators should note that organisations that confer qualifications set their own requirements regarding ethics committee review of studies to be submitted for those qualifications.)

11.16 The reasons for allowing expedited review of observational research include that:

a) it may use data already being collected or monitored;

b) it may be undertaken by investigators who have access in the normal provision of care to all identified study data, and have supervisory responsibility for staff who have access to any other study data;

c) subsequent publication of the research may pose a minimal risk of harm to any participants; and

d) the collection and subsequent use of information for the study may pose minimal risk of harm to participants.
Note that publication is “minimal risk” if no study participant is potentially identifiable from it, and no group faces more-than-minimal harm (for example, stigmatisation) from it.

11.17 The reason for allowing expedited review of an audit and related activity is that these are typically minimal-risk activities, which, compared with research, have more predictable benefits and reduced risks.

| UK | Any local procedures for expedited review (where appropriate) outside the normal committee cycle shall be described in the standard operating procedures. REC shall establish any procedures necessary for the expedited review of research proposals. *(See Section B)*. These procedures, which should be described in full in the Standard Operating Procedures, should specify the following:
  a. the nature of the applications, amendments, and other considerations that will be eligible for expedited review
  b. the quorum requirements for expedited review
  c. the status of decisions (e.g. whether requiring confirmation by the full REC or not) |

| US | The IRB Chair refers all research protocols to either full committee review or expedited review

The IRB Chair may use the expedited review procedure:
- to review minor changes in previously approved research during the period for which approval is authorized, or to review research which involves no more than minimal risk to subjects and in which the only involvement of human subjects will be in one or more of the categories listed in Appendix J.
- Expedited review may be conducted by the IRB Chair or by one or more of the experienced IRB members designated by the Chair.

The IRB Chair or member(s) conducting the expedited review may:
- exercise all the authorities of an IRB except that the reviewer(s) may not disapprove the research. Any research that would have been disapproved shall be referred to the full committee; or
- refer research protocols to the full committee whenever the reviewer(s) judges that full committee review is warranted.

Protocols reviewed and approved by the expedited review procedure:
- require subsequent approval by the appropriate IC official;
- must be entered into the appropriate IRP NIH database(s); and
- are subject to continuing review by the IRB.
When the expedited review procedure is used, the IRB Chair, or member(s) conducting the review, shall, at the next convened meeting, inform the IRB members of, and document in the IRB minutes, research protocols which have been approved by the expedited review procedure.

Documentation of research activities that do qualify for exemption will be kept on file in the OHSR. Documentation of research activities that are determined not to be exempt will be returned to the investigator for incorporation into a protocol and submission to the appropriate IRB for review.

<table>
<thead>
<tr>
<th>RECORDS</th>
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<tr>
<td><strong>WHO</strong> Meetings should be minuted, there should be an approval for the minutes.</td>
</tr>
</tbody>
</table>

All documentation and communication of an EC should be dated, filed and archived according to written procedures. A statement is required defining the access and retrieval procedure (including authorised persons) for the various documents, files, and archives.

It is recommended that documents be archived for a minimum period of 3 years following the completion of a study.

Documents that should be filed and archived include, but are not limited to:
- Constitution, written standard operating procedures of the EC, and regular (annual) reports
- Curriculum Vitae of all EC members
- Record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members
- The published guidelines for submission established by the EC
- Agenda of the EC meetings
- Minutes of the EC meetings
- One copy of all material submitted by the applicant
- Correspondence by EC members with applicants or concerned parties regarding application, decision, and follow-up
- A copy of the decision and any advice or requirements sent to an applicant
- All written documentation received during the follow-up
- The notification of the completion, premature suspension, or premature termination of a study
- The final summary or final report of the study

<p>| CIOMS |</p>
<table>
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<tr>
<th>Country</th>
<th>Requirement Details</th>
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</table>
| Australia | EC to retain copy of protocol and application. Shall have record of the following:  
- Name of responsible institution.  
- Project ID No.  
- Principal researcher.  
- Title of project.  
- Ethical approval or non-approval date, *formal advice of*.  
- Approval or non-approval of changes to protocol.  
- Terms and conditions, if any, of approval.  
- Whether approval was expedited review.  
- Whether the opinion of another EC was considered, *name of*.  
- Action taken by EC to monitor conduct of research.  
- Relevance of privacy guidelines.  

*Correspondence between EC and HREC relating to review*  
*Proposed date of completion*  
*Duration of approval*  
*Mechanism to be used to monitor the conduct of the research*  
*Decisions and reasons for decisions*  

A file copy of each application including information sheets, consent forms or relevant correspondence, in the approved form.  

**MULTI-CENTRE**  
Also:  
Details of other centres involved  
Approval status of the study at each centre  
Details of any amendments required at other centres  

| Canada | Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB’s decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorised representatives of the institution, researchers and funding agencies.  

| NZ | EC should maintain an effective record of all proposals received. As well as the facts of each proposal:  
- Whether or not it was approved and date of approval  
- Reasons for decision  
- Approval of non-approval of any changes  
- Any terms and conditions, including monitoring  

Agendas and minutes of all EC meetings should be available to the public.
**UK**
The appointing Authority is responsible for providing suitable and discrete facilities in which the work of the REC officers and administrators can be undertaken in a confidential manner. These facilities should include adequate provision for handling and storing confidential documents.

All reimbursement for work or expenses, if any, within or related to an REC should be recorded and made available, by the Authority, to the public on request.

The REC should keep a register of all the proposals that come before it. This register will be available for public consultation. Appropriate sections shall be shared with the relevant NHS bodies hosting the research, for the purposes of governance and management. The register should form the basis of the REC's Annual Report to its appointing Authority.

Meetings shall be minuted. There should be an approval procedure for the minutes.

REC to keep a record of attendance of members at meetings, indicating whether members or deputy members were present.

An REC should retain all relevant records for a period of at least three years after completion of a research project, and should make them available upon request to any regulatory authorities.

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**US**
IRB Records
Each IRB shall maintain copies of protocols and samples of consent documents that it has reviewed; scientific evaluations, if any, that accompany protocols, including, when appropriate, a copy of the relevant clinical investigator's brochure; minutes of its meetings in accord with 45 CFR 46.115(a)(2); a current approved membership list; progress reports submitted by investigators; reports of injuries to subjects; copies of all correspondence between the IRB and investigators, statements of significant new findings provided to subjects; and documentation of collaborative and cooperative research activities occurring at other institutions with MPAs, SPAs, or other OPRR-approved assurances.

These records and documents shall be retained for at least three years after completion of the research. The records shall be accessible for inspection and copying by OHSR and authorized representatives of DHHS at reasonable times and in a reasonable manner.

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**ANNUAL REPORT**

<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
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<tbody>
<tr>
<td>WHO</td>
<td>It may be helpful to summarise the activities of the EC in a regular (annual) report.</td>
</tr>
<tr>
<td>CIOMS</td>
<td>EC to supply information or records on request.</td>
</tr>
<tr>
<td>Australia</td>
<td>EC shall report annually, including:</td>
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<td></td>
<td>• Membership, membership changes</td>
</tr>
<tr>
<td></td>
<td>• Number of meetings</td>
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<tr>
<td></td>
<td>• Confirmation of participation by required categories of members</td>
</tr>
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<td></td>
<td>• Number of protocol presented, number approved or rejected</td>
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<tr>
<td></td>
<td>• Monitoring procedures in place, and any problems</td>
</tr>
<tr>
<td></td>
<td>• Complaint procedures, no of complaints handled</td>
</tr>
</tbody>
</table>

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Canada
| NZ | The following provides a checklist of requirements for annual reporting. Annual reports should be submitted to the Minister of Health and will be tabled by the Minister of Health in the House of Representatives.

The annual report shall include information on the membership of the HDEC, including any change in the HDEC's membership or other substantive changes the HDEC or its chairperson feels should be noted.

The annual report shall also include a list of the national and multi-region research and innovative treatment protocols reviewed in the preceding year outlining the following details:

i. the research title  
ii. principal investigator  
iii. institutions where the research is to be/has been undertaken  
iv. date of first review  
v. date of final outcome  
vi. outcome (which will be one of: Approved, Approved subject to conditions, Deferred, Declined)  
vii. for each protocol deferred or declined, the reason(s) for the decision

The annual report shall also include:

i. A list of training undertaken by HDEC members, and a statement on processes for orientation and training of new HDEC members should be included.  
ii. A list of complaints received by the HDEC (if any), the actions taken to resolve the complaint and a comment on the outcome of the complaint(s).  
iii. Any areas of review that caused difficulty for the HDEC in making a decision on any particular protocol(s), and any questions on policy or other matters the HDEC referred to the National Ethics Advisory Committee or the Health Research Council Ethics Committee for comment or guidance.  
iv. a list of any advice received from other ECs

In compiling annual reports, the HDEC should take care not to provide information that would involve a breach of the Privacy Act 1993 and/or the Health Information Privacy Code 1994. |

| UK | Within six months of the end of each financial year, an LREC should submit its Annual Report to the appointing Authority, which shall consider it at a scheduled open meeting of the Authority to which the REC members are invited. In the case of LRECs, copies should be sent to all the NHS bodies within the Authority’s boundaries.

The report, which should be available for public inspection, should include:
- the names, affiliations and occupations of committee members and of deputies (if used)  
- number and dates of meetings held  
- attendance of members  
- a list of proposals considered, and the decisions reached on each  
- the time taken from acceptance of application to final decision on each proposal  
- a list of projects completed or terminated during the year  
- the training undertaken by the committee and by its members.

Similarly, each MREC shall produce its Annual Report (to include the same category items) for presentation to the Department of Health, and for publication. |
### WHO

ECs should establish follow-up procedure for following the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The ongoing lines of communication between the EC and the applicant should be clearly specified. The follow-up procedure should take the following into consideration:

- The quorum requirements, the review procedure, and the communication procedure for follow-up reviews, which may vary from the requirements and procedures for the initial decision on an application
- The follow-up review intervals should be determined by the nature and the events of the research projects, though each protocol should undergo a follow-up review at least once a year.
- A decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the ECs original decision or confirmation that the decision is still valid.

### CIOMS

The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

They should be required to monitor the implementation of an approved protocol and its progression, and to report to institutional or governmental authorities any serious or continuing non-compliance with ethical standards as they are reflected in protocols that they have approved or in the conduct of the studies. Failure to submit a protocol to the committee should be considered a clear and serious violation of ethical standards.

Ethical review committees generally have no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving humans. They may, however, withdraw ethical approval of a research project if judged necessary.
Institution and EC responsible for monitoring research, must have procedures in place
Must require at least annually reports from researchers, including:
- Progress or outcome of research
- Maintenance and security of records
- Compliance with approved protocol
- Compliance with any conditions of approval

EC can use any appropriate mechanism to monitor the research and the level of monitoring will be determined by risk to participants.

Continuing oversight of review procedures
5.1.10 Where human research is ethically reviewed and approved by a process other than HREC review, institutions must ensure, as an element of good research governance, that adequate records of the decisions made using any such processes are maintained.

5.1.11 Whatever review processes are established for different kinds of human research, institutions have a responsibility to remain alert to ethical issues in any area of human research which may warrant referral to a different level of review, including referral from exemption to low level review.

5.2.12 The ethical values and principles in this Statement should be the basis on which institutions establish review processes, allocate kinds of research to them and review those allocations.

5.1.13 Institutions must monitor the processes of ethical review of research involving low risk to ensure that they continue to provide sufficient protection for participants.

Monitoring approved research is the responsibility of the institution in which the research is conducted. Monitoring includes any process or mechanism put in place to check that the conduct of the research conforms to the approved proposal. It contributes to the safety of research participants and the maintenance of community confidence in human research.

Mechanisms of monitoring can include:
(a) reports from researchers;
(b) reports from independent agencies (such as a data and safety monitoring board);
(c) review of adverse event reports;
(d) random inspections of research sites, data or consent documentation;
and
(e) interviews with research participants or other forms of feedback from them.

Guidelines for monitoring approved research
5.5.1 Institutions have the ultimate responsibility for ensuring via their research governance arrangements that the conduct of all approved research is monitored.

5.5.2 The frequency and type of monitoring should reflect the degree of risk to participants in that research.

5.5.3 Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes and to take prompt steps to deal with any unexpected risks.
5.5.4 Researcher integrity, as demonstrated by the capacity to self-monitor research in progress, should be emphasised in educating researchers in research ethics.

5.5.5 Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.

5.5.6 At regular periods, at least annually and at the completion of the project, researchers should provide reports to institutions, which include information on at least the following matters:
  (a) progress to date, or outcome in the case of completed research;
  (b) maintenance and security of records;
  (c) compliance with the approved proposal; and
  (d) compliance with any conditions of approval.

5.5.7 Researchers should report to the review body events that might affect continued ethical acceptability of the project, including:
  (a) serious or unexpected adverse effects on participants; and
  (b) proposed significant changes in the conduct, the participant profile or the risks of the proposed research.

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Canada  
Ongoing research shall be subject to continuing ethics review.  
As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate.  
Continuing review should consist of at least an annual report to the REB.  
For some protocols, the REB may require that a monitoring committee be established
<table>
<thead>
<tr>
<th>Country</th>
<th>Requirements</th>
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<tr>
<td>NZ</td>
<td>EC should require progress reports as condition of approval, yearly, or more frequently if required. EC can require independent review or audit at any time.</td>
</tr>
<tr>
<td>UK</td>
<td>The REC should indicate at the time of approval any progress reports it requires from time to time from the applicant. It shall request a final report to be delivered within three months of completion. The REC shall require, as a minimum, an annual report from the researcher, and shall reconsider its opinion at that stage. Where the REC considers the degree of risk demands it, more frequent reports and subsequent interim review shall be required. RECs may also ask to receive reports of inspections by other authorities. Reports on success (or difficulties) in recruiting participants provide the REC with useful feedback on perceptions of the acceptability of the project among potential research participants. RECs may wish to request such reports where they anticipate potential difficulties. On the basis of any such reports, the REC may wish to review its decision. Failure to produce such required reports without a reason acceptable to the REC may result in suspension of the REC’s favourable opinion, in which case the research must cease. Other than by means of these required progress reports, the REC has no responsibility for pro-active monitoring of research, the accountability for which lies with the host NHS institution, but the REC may wish to be reassured of the process for such monitoring in certain specific cases.</td>
</tr>
<tr>
<td>US</td>
<td>Each IRB shall conduct continuing review of approved research activities at least once per year or at shorter intervals appropriate to the degree of risk. To facilitate continuing review, the PI is responsible for timely submission of requested forms/reports to the Chair of the IRB that previously reviewed the protocol. Each PI shall submit (i) the necessary forms, including the current consent document, (ii) a brief narrative to the IRB indicating the experience with the research, including subject demographics, and (iii) the reason(s) for continuing the study. On the due date, if IRB approval of continuing review has not been completed, subject accrual into the protocol is suspended. If the PI fails to submit the continuing review materials to the IRB within one month after the due date, the protocol may be terminated. Reactivation of the protocol requires submission of a new protocol to the IRB. Research investigators, Laboratory/Branch Chiefs, Clinical Directors and/or Scientific Directors are responsible for reporting promptly to the OHSR and the appropriate IRB any serious or continuing non-compliance with the requirements of 45 CFR 46, the Assurance or the determinations of an IRB. Such reports shall also be made to the Director, CC if the research activity is conducted in or by an employee of the CC. Each PI will submit (i) the necessary forms, including the current consent document, (ii) a brief narrative to the IRB indicating the experience with the research, including subject demographics, and (iii) the reason(s) for continuing the study. In addition, each IRB may require that a protocol be rewritten to consolidate amendments. The frequency of this consolidation will be mandated by the IRB. Research protocols that required full IRB review initially shall require full IRB review for continuation.</td>
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</table>
The PI has 30 days to respond to the IRB's recommendations and/or stipulations. Whenever an IRB suspends or terminates approval of research, the IRB Chair shall report the decision in writing to:
the PI,
the IC Clinical Director, or Scientific Director, as appropriate,
the OHSR, and,
the Director, CC, if the research is conducted in or by an employee of the CC.

ADVERSE EVENT REPORTING

<table>
<thead>
<tr>
<th>WHO</th>
<th>Any serious and unexpected adverse events related to the conduct of the study or study product and the response taken by investigators sponsors and regulatory agencies require the follow-up review of a study.</th>
</tr>
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<tbody>
<tr>
<td>CIOMS</td>
<td></td>
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</table>
| Australia | As a condition of approval, researchers required to report anything which might warrant review, including:  
• Serious or unexpected adverse outcomes  
• Proposed changes in the protocol  
• Unforeseen events which may affect continued ethical acceptability of the project |
| Canada | Adverse effects or unexpected events resulting from the research must be reported to the REB Secretariat immediately. |
| NZ | In general, researchers are required to immediately report all serious or unanticipated events to EC.  
Exact reporting requirements to be determined on a case-by-case basis.  

Researchers should be required to advise participants if new information relating to safety of the study becomes available.  
Timeframe required to be set by EC for reporting adverse events. |
| UK | Reports to the committee should also be required if there are any other unusual or unexpected results which raise questions about the safety of the research.  
A member of an REC who becomes aware of a possible breach of good practice in research should report this initially to the Chair and Administrator of the REC, who shall inform the appointing Authority. The Authority’s officers shall be accountable for taking appropriate action. |
**US**
The PI is responsible for reporting promptly (1) any unanticipated problems involving risks to subjects or others, or (2) unexpected serious harm to subjects and others. Written reports shall be submitted for evaluation to:

- a. The appropriate IRB;
- b. the IC Clinical Director,
- c. the Director, CC, if the protocol is conducted in the CC, and
- d. the FDA and/or non-NIH sponsor, as necessary.
- e. OHSR

### COMPLETION/ DISCONTINUATION

**WHO**
In the case of the premature suspension/termination of a study, the applicant should notify the EC of the reasons for suspension/termination, a summary of results obtained in a study prematurely suspended/terminated should be communicated to the EC.

ECs should receive notification from the applicant at the time of completion of a study.

ECs should receive a copy of a final summary or final report of a study.

**CIOMS**

**Australia**
As a condition of approval, researcher required to inform EC if project discontinued before expected completion.

EC can withdraw approval and recommend discontinuation or suspension of research, if research can not proceed within approved protocol and participants welfare at risk.

Researcher must not continue if ethical approval has been withdrawn and must comply with special conditions.

*Researchers should inform the institution, the review body that approved the research and wherever possible research participants, if the research project is to be discontinued before the expected date of completion, and why. In the case of research at more than one site, or research where there has been multiple ethical review, it must be clearly established, before the research begins, how this information will be communicated.*

*5.5.9 Where an institution or a review body is satisfied that a research project cannot continue to be conducted in accordance with the approved proposal, and that as a result the welfare of participants will not be protected, ethical approval for the research should be withdrawn. The researcher, the institution and where possible the participants should be informed of this withdrawal. The researcher should promptly suspend the research and make arrangements to meet the needs of participants. The research may not be resumed unless it is modified to provide sufficient protection for participants, and the modification is ethically reviewed and the research again approved.*

*5.5.10 In the light of reports received under paragraph 5.5.7, review bodies may require researchers to amend research procedures to protect participants. Where they are satisfied that such amendments will not achieve that end, review bodies should notify the institution of the report.*

**Canada**
The REB should be promptly notified when a project concludes.
**NZ**  On completion or discontinuation, researchers should be required to report findings or outcomes. If discontinued, reasons stated.

EC can make it a condition of approval that researchers provide summary of research or outcomes to participants, (including any adverse events).

EC can withdraw approval. Circumstances where ethical approval may be withdrawn:
- Complaints that appear to have substance.
- Proposal deviated from approved protocols
- New information suggest participants safety compromised
- Failure to report and adverse outcome
- Failure to met conditions
- Locality approval has been withdrawn and that effect viability

Registered Health Professional or researcher should be given a chance to comment on complaint.

If ethical approval is withdrawn then the applicant should be notified in writing and requested to cease all activities and advise participants of the withdrawal of ethical approval. The EC may also notify:
- Organisation employing/funding the applicant.
- Locality organisation
- Health and Disability Commissioner
- NEAC
- Other HDECs
- HRCEC
- Appropriate professional body
- Ministry of Health

**UK**  Where the research is terminated prematurely, a report shall be required within 15 days, indicating the reasons for early termination

**US**  When a PI terminates a protocol, the appropriate forms (NIH-1195-1) should be submitted to the IRB accompanied by a short narrative explanation of the reasons for termination, the research results of the protocol, and the demographics of the enrolled subjects

Each IRB shall have the authority to modify, suspend or terminate approval of research that:
- has been associated with unexpected serious harm to subjects, or
- is not being conducted in accordance with 45 CFR 46 or the IRB’s decisions, conditions and requirements

### MULTI-CENTRE RESEARCH

**WHO**  Procedures need to be established for relating various levels of review in order to ensure consistency and facilitate cooperation. Mechanisms for cooperation and communication need to be developed between national committees and institutional and local committees. These mechanisms should ensure clear and efficient communication. They should also promote the development of ethical review within a country as well as the ongoing education of members of ethics committees.

Procedures need to be established for the review of biomedical research protocols carried out at more than one site in a country.
Some research projects are designed to be conducted in a number of centres in different communities or countries. Generally, to ensure that the results will be valid, the study must be conducted in an identical way at each centre. Such studies include clinical trials, research designed for the evaluation of health service programmes, and various kinds of epidemiological research. For such studies, local ethical or scientific review committees are not normally authorized to change doses of drugs, to change inclusion or exclusion criteria, or to make other similar modifications. They should be fully empowered to prevent a study that they believe to be unethical. Moreover, changes that local review committees believe are necessary to protect the research subjects should be documented and reported to the research institution or sponsor responsible for the whole research programme for consideration and due action, to ensure that all other subjects can be protected and that the research will be valid across sites.

To ensure the validity of multi-centre research, any change in the protocol should be made at every collaborating centre or institution, or, failing this, explicit inter-centre comparability procedures must be introduced; changes made at some but not all will defeat the purpose of multi-centre research. For some multi-centre studies, scientific and ethical review may be facilitated by agreement among centres to accept the conclusions of a single review committee; its members could include a representative of the ethical review committee at each of the centres at which the research is to be conducted, as well as individuals competent to conduct scientific review. In other circumstances, a centralized review may be complemented by local review relating to the local participating investigators and institutions. The central committee could review the study from a scientific and ethical standpoint, and the local committees could verify the practicability of the study in their communities, including the infrastructures, the state of training, and ethical considerations of local significance.

In a large multi-centre trial, individual investigators will not have authority to act independently, with regard to data analysis or to preparation and publication of manuscripts, for instance. Such a trial usually has a set of committees which operate under the direction of a steering committee and are responsible for such functions and decisions. The function of the ethical review committee in such cases is to review the relevant plans with the aim of avoiding abuses.
Australia

Multi-centre research is defined as research:
At more than one institution
Jointly by researchers at different institutions
Researcher who changes affiliation to another institution

EC must ascertain if protocol already reviewed by an EC, including overseas ECs.

EC can:
• Contact or advise other ECs.
• Accept scientific/technical advice of another organisation
• Review and adopt the reasons of another EC in making its decision.
• Adopt any administrative procedures required to accelerate timely consideration and avoid unnecessary duplication.

ECs can agree that one EC will review the protocol, with the other ECs accepting the ruling and rationale.

EC may still give consideration to ethical or administrative aspects which are specific to its institution.

Researcher must:
• Inform EC of all Australian sites
• Disclose any previous decisions made by another EC
• Inform each EC if the protocol is before another EC

ECs must come to an agreement as to how the research will be monitored and fulfil its obligations to monitor

Research projects which may require multiple ethical review in Australia include:
(a) a research project conducted at more than one institution either by the same or different researchers;
(b) a research project conducted jointly by researchers affiliated with different institutions;
(c) a research project conducted at one institution by a researcher affiliated with another institution, for example, a university-based researcher conducting research at a hospital; and
(d) any other research for which more than one institution has responsibility for ethical review and approval.

Guidelines for minimising duplication of ethical review

5.3.1 Wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review and approval, whether by an HREC or other review body, they have the further responsibility to reduce or eliminate any duplication of ethical review.

5.3.2 Institutions with responsibilities for the conduct of human research must establish and publish policies for deciding when to accept the outcome of ethical review by other review bodies established at State, regional or institutional level and functioning in compliance with this Statement.

5.3.3 Those institutional policies must:
(a) identify any circumstances local to the institution that are relevant to the ethical review of human research conducted at the institution, and provide both for their disclosure to the review body reviewing that research and for their management;
(b) require communication, and the exchange of information or advice, with any other review body;
(c) permit acceptance of a scientific/technical/methodological assessment of the research by another institution or suitably qualified body, person or persons;
(d) authorise acceptance of a review body’s ethical review and approval or disapproval as meeting the institution’s responsibility for ethical review of that
human research;
    (e) specify exceptional circumstances in which the institution may request a review body that it has established to conduct further ethical review, for example, where an institution adopts research begun and ethically approved at another institution;
    (f) identify the ways the conduct of the research may be monitored and what roles the institution and the review body will have in the monitoring;
    (g) identify mechanisms for informing participants of an early discontinuance of research; and
    (h) adopt any other administrative procedures to avoid unnecessary duplication and promote timely ethical review and approval of human research.

5.3.4 A researcher developing or designing a research proposal involving two or more institutions should inform them at an early stage in this process. Those institutions should agree as early as possible about which review body will accept the role of reviewing the proposal.

5.3.5 Where a human research project is to be conducted by different researchers at more than one institution, those researchers should jointly determine, in the light of institutional policies, which institution(s) or suitably qualified other body or bodies should be asked to conduct the ethical and scientific/technical/methodological review of the project.

5.3.6 Researchers involved in human research to which paragraphs 5.3.1 to 5.3.5 apply, should make arrangements to ensure that:
    (a) each institution with responsibility for the research is informed of all other Australian sites at which the research is being proposed or conducted, and of the name and location of the body that will conduct the ethical review of the research; and
    (b) the review body is informed of any previous decisions made about the research by review bodies in overseas countries.

| Canada | Each REB is responsible for what happens in its institution. |
|        | REBs may wish to coordinate review of multicentred proposals. |
All multi-regional research is reviewed by the Multi-Region Ethics Committee. Multi-region or national research is defined as research conducted by the investigator(s) in more than one Regional Ethics Committee region or nationally, with identical methods and following the same protocol.

| NZ | For the present, multi-centre research will continue to be defined as research carried out within five or more “sites”, i.e. the area covered by five or more Health Authority boundaries, irrespective of the number of LRECs within each Authority.

For research taking place in from two to four sites, application should be made to one LREC within each of the Health Authority boundaries. However, when a favourable opinion has been obtained from the first Health Authority’s LREC, the second, third and fourth Health Authorities may, on the advice of their own LRECs, accept that opinion with further review by their own LREC only of the “locality issues”.

If recruitment is planned in five (or more) sites, irrespective of whether existing LREC approval in up to four sites has been already given, application is then required to a Multi-centre Research Ethics Committee (MREC). A favourable opinion of an MREC then covers the whole of the United Kingdom.

If the MREC declines to give a favourable opinion on the application, any existing approval by LRECs still stands, but those LRECs shall be informed of the MREC’s decision (and its reasons).

Once an MREC has declined approval, no further application using the same proposal may be made to any LREC.

The MREC (or “lead” LREC) undertakes the review of the ethics of the research protocol, including the content of the patient information sheet and consent form. No further ethical review of these items shall be undertaken by other RECs (except in the process of a “second review”).

The “locality issues” are limited to:
- the suitability of the local researcher
- the appropriateness of the local research environment and facilities
- specific issues relating to the local community, including the need for provision of information in languages other than English

The LREC should satisfy itself that the “locality issues” have been adequately considered, and that it can approve them. In undertaking consideration of the “locality issues” the REC should work closely with the NHS host organisation, which also has a responsibility for research conduct and safety.

LRECs and local NHS trusts should set up administrative mechanisms to facilitate such joint working. The detailed assessment of the “locality issues” may be undertaken on behalf of the NHS either directly by an LREC itself (or its officers), or by the NHS host (if it is a Trust) with the prior agreement of the LREC. In the latter case the Trust shall inform the LREC of the outcome of the process. The LREC shall consider the advice of the Trust and, if accepted, shall record its approval in LREC minutes. For multi-centre research, the research may not proceed until the LREC has informed the approving MREC of its lack of objection with respect to the “locality issues”.

The consideration of “locality issues” should occur in parallel with the consideration of ethical review of the research protocol by the MREC or “lead” LREC.

The decision on the “locality issues” should be made and communicated within 60
days of receipt of a valid application for this purpose.

For multi-centre research where there is no “local” researcher, and where this is confirmed by the MREC (or “lead” LREC) during its review of the research protocol, no specific consideration of “locality” issues by an LREC may be needed and the overall process of review may thus be expedited. Approval by the host NHS organisation is still required before the research may proceed.

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<tr>
<th>AREA</th>
<th>OVERSEAS RESEARCH</th>
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<tbody>
<tr>
<td>WHO</td>
<td>Procedures need to be established for the review of biomedical research protocols carried out at more than one country.</td>
</tr>
<tr>
<td>CIOMS</td>
<td>An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.</td>
</tr>
<tr>
<td>Australia</td>
<td>If research to be performed outside the jurisdiction or country of the institution, proposal to be reviewed by local REB and REB in other jurisdiction/country.</td>
</tr>
<tr>
<td>Canada</td>
<td>In the case of international studies, an application must be made to an ethics committee in the UK, whether or not the study has a favourable ethical opinion from a committee outside the UK and whether or not it has started outside the UK.</td>
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### LEGAL LIABILITY - EC

<table>
<thead>
<tr>
<th>Country</th>
<th>Text</th>
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<tbody>
<tr>
<td>WHO</td>
<td>An institution is legally responsible for HREC decisions and approvals in relation to research and should indemnify its HREC members.</td>
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<tr>
<td>CIOMS</td>
<td></td>
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<tr>
<td>Australia</td>
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<tr>
<td>Canada</td>
<td>The appointing Authority will take full responsibility for all the actions of a member in the course of their performance of his or her duties as a member of the REC other than those involving bad faith, wilful default or gross negligence. A member should, however, notify the appointing Authority if any action or claim is threatened or made, and in such an event be ready to assist the Authority as required.</td>
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<tr>
<td>NZ</td>
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<tr>
<td>UK</td>
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<tr>
<td>US</td>
<td>When research is conducted in the CC, or other NIH clinical research sites, short term medical care will be provided for injury resulting from participation in research</td>
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### LEGAL LIABILITY - RESEARCH AND PARTICIPANT INJURIES

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<th>Country</th>
<th>Text</th>
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<td>WHO</td>
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| CIOMS   | GAFREC requires NHS RECs, in the case of any research study they review, to be reassured about the insurance and indemnity arrangements and to consider provision in proportion to the risk for compensation or treatment in the event of injury, disability or death attributable to participation in the research. Before confirming a favourable opinion on any research (including both CTIMPs and non-CTIMPs), the main REC should ensure that it has received documentation from the sponsor confirming that it assure itself that the sponsor and investigators will have has appropriate insurance or indemnity cover for the potential legal liability arising from the research. The documentation should make clear the extent of the cover and the source of the funds. Applicants must provide information to the main REC to show that there are adequate insurance or indemnity arrangements to cover potential legal liability arising from the management, design and conduct of the research. In particular, applicants must show that:  
  - the financial arrangements, including insurance or indemnity, cover the research study concerned  
  - the sponsor, protocol authors, investigators/collaborators and, where applicable, Site Management Organisations will all be protected by insurance or indemnity arrangements  
  - the arrangements will provide adequate cover to meet the potential liability assessed by the sponsor. |
| Australia | |
| Canada | |
| NZ | |
| UK | |
| US | When research is conducted in the CC, or other NIH clinical research sites, short term medical care will be provided for injury resulting from participation in research |

### GUIDELINES FOR WORKING WITH ABORIGINAL POPULATIONS

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<th>Country</th>
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<td>WHO</td>
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<td>CIOMS</td>
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<table>
<thead>
<tr>
<th>Country</th>
<th>Guidelines/Policy</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Section 9 – NHMRC National Statement Guidelines for Ethical Research in Indigenous Studies – May 2000</td>
</tr>
<tr>
<td>NZ</td>
<td>Specific requirement for Maori membership on the Ethic Committee. Guidelines for Researchers on Health Research Involving Maori 1998</td>
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<td>UK</td>
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(Health Research Council of New Zealand, 2007)