# Ethic reviews

## Background

These review topics and prompts draw on the seven requirements for determining whether a research trial is ethical from "*What makes clinical research ethical?*", elements of the lead reviewer form from the Health Research Authority (NHS) and checklist for ethics reviewers from the University of Sheffield.

Each application received by our RREC is considered, in detail, under the requirements below. Prompts included are not intended to be an exhaustive list.

## 1. Social or scientific value

Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge.

**Prompts**

- What is the rationale for this study?
- Is it a good idea – important and necessary?
- Does it add scientific value that will impact on people's health and wellbeing?
- Does it contribute intermediate new knowledge that is a step towards improving people's health and wellbeing?

## 2. Scientific validity

Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data.

**Prompts**

- Is there a clear aim?
- Does the study do what it says it's going to do?
- Will executing the study as described, have the potential to find what it sets out to find / show?
- Is the study design / methodology appropriate to successfully address the aims and objectives of the study?
- Is there involvement of patients, service users and the public in the design of the study?
- Have bias, confounding and chance been eliminated or reduced, as much as possible?
- Is there a valid sample size calculation?

## 3. Fair subject selection

Selection of subjects so that stigmatised and vulnerable individuals are not targeted for risky research and the rich and socially powerful are not favoured for potentially beneficial research.

The benefits and risks of research should be distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture. Involvement of patients, service users and the public in the design may provide assurances that recruitment is likely to be equitable.

**Prompts**

Description and justification of the sample population; the sampling procedure and sample selection with inclusion and exclusion criteria of research participants:

- Are those who will benefit from the study results (new knowledge) included as study participants?
- Will those who share the risk and burden of the research, benefit from the research?
- Will those who participate in the study (as a described cohort and not the specific individuals), benefit from the findings of the study?
- Is everybody, to whom the researcher wishes to generalise their research, included?
- Are exclusions scientifically justified?
- Consider the population which is likely to be included in the research and what the needs of this group might be.
- Will it be feasible for provisions to be made available for potential participants who might have difficulty understanding English?
- How are research participants recruited?
- How are the potential participants initially approached?
- How does participation impact on their clinical care?
- Are the gatekeepers involved identified and on board?

## 4. Favourable risk-benefit ratio

Minimisation of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and to society. Involvement of patients, service users and the public in the design may provide assurances that the risk-benefit ratio is likely to be favourable.

**Prompts**

- Are the potential benefits to individuals and society well described?
- Are those who are at higher risk of harm excluded from the study, presuming that those studied generate generalisable knowledge?
- Are all risks identified?
- Are identified risks minimised – steps that have been taken to minimise or eliminate the risk, hazards, discomfort, and distress and enhancement of potential benefits
- Do the benefits outweigh the risks for this study?

## 5. Independent review

Review of the design of the research trial, its proposed population, and risk-benefit ratio by individuals unaffiliated with the research.

**Prompts**

- Have you any interest to declare in the application being reviewed?

## 6. Informed consent and the quality of research participant information

Provision of information to subjects about purpose of research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate. Involvement of patients, service users and the public in the design may provide assurances that the consent process is robust, taking the needs of participants into account.

**Prompts**

- How will informed consent be obtained? Is the method appropriate? Is the wording clear?
- Who obtains the consent?
- As part of the consent process, do research participants have adequate time to consider the information, and the opportunity to ask questions?
- Is there any inducement?
- Is consent obtained to allow GPs to be informed?
- Can the researcher be sure that participants can give informed consent that is free from coercion?

- Will participants understand what is being asked of them and what they are contributing to?
- Are all of the relevant supporting documents included? (e.g. information sheets, consent forms, GP letter, interview schedules, questionnaires)
- Are materials for participants clear and free from technical terms, jargon and abbreviations as far as possible?
- Are the materials appropriate for the intended audience (e.g. children)?
- Where consent requires additional facilitating resources, such as may be required in disability research, has attention been given to varied and appropriate methods of communication, employment of advocates and interpreters and continued consent negotiation throughout the research process?
- Has language and culture been acknowledged?
- Have translation issues been considered?

## 7. Respect for potential and enrolled participants

Respect for subjects by permitting withdrawal from the research; protecting privacy through confidentiality; informing participants of newly discovered risks or benefits; informing participants of results of research; maintaining welfare of participants. Involvement of patients, service users and the public in the design may provide assurances that that respect for participants is present. Consideration will be given to the following

**Prompts**

- Impact and relevance of the research on the local community
- Description of community consultation
- The extent to which the research contributes to the enhancement of local healthcare
- Description of the availability and affordability of any successful study product to the relevant communities following the research
- The manner in which the results of the research will be made available to participants and the study communities
- Do the researchers demonstrate an awareness of research transparency? (For example, study registration, sharing of results, plans for publication)
- Is it clear to the participants who is leading the research and how to contact them?
- Safeguarding:
    - Is there an appropriate Designated Safeguarding Contact(s) named?
    - Is it clear to the participant how they can report any safeguarding concerns or incidents and how these will be dealt with (taking account local context)?
    - Is there an appropriate process for the handling and escalation of safeguarding concerns and incidents?

- If the research is collaborative, is there an agreement between parties regarding how this will be managed?

- Withdrawal:
  - Can participants change their mind/withdraw from the research?
  - Is the withdrawal process clearly explained?
  - At what stage would it be no longer possible for participants to withdraw?
- Is participant's privacy respected?
- Are the dignity, rights, safety and wellbeing of the participants considered?
- Are participants informed of newly discovered risks or benefits? How is this done?
- Are participants informed of results of research? How is this done
- How is the welfare of participants maintained?
- Arrangements and feedback at the end of the study?
- Has the researcher provided evidence of appropriate indemnity and insurance?

## 8. Confidentiality and privacy

It is important that adequate measures have been taken to ensure anonymity, confidentiality and security of personal information concerning research participants. These must be appropriate to the research project and they must be realistic.

**Prompts**

- Is it clear to the participants how the data will be managed and which organisation will be the Data Controller, including a description of provisions to ensure the confidentiality and security of personal information concerning participants?
- Is it clear to participants what the data will be used for, and the legal basis that is being relied upon for this (under GDPR)?
- Are data or samples being sent outside of Ireland? How are they protected? Are participants made aware?
- Is it clear to the participants who will have access to their data and in what form for example, aggregated, anonymised or pseudonymised (note that pseudonymised data can be restored to its original state with the addition of information which then allows individuals to be re-identified). This also includes biological samples and medical records.
- Does this take account of any intended future use?
- Are research participants, informed that access to their medical notes may be required?
- How are biological samples obtained (if applicable), what is the purpose for which they will be used and for how long with they be stored?
- Is it clear to participants how long the data (written, recorded, video, etc) or samples will be held?
- Will personal data be permanently deleted / destroyed when they are no longer required?

- Are arrangements made to deal with incidental disclosure?
- Is it clear to participants how to complain about how their personal data is being handled, should they wish to do so?

## 9. Suitability of the researcher, investigator & supporting staff

Medical research must be conducted only by people with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

**Prompts**

- Is the researcher suitable for this project?
- Do they have the necessary qualifications and skills?
- Are there are conflicts of interest?
- If they have supporting staff, do they have the skills necessary to support the research?

## 10. Other questions for consideration

**Prompts**

- Is there enough detail in the application?
- Are there any obvious gaps, ambiguities or uncertainties in how the research will be carried out?
- Are facilities being used suitable?
- Has the safety of the research team been considered?
- Is there a process in place to manage risks to the researcher/team?
- Does the research have any implications for the reputation of the HSE?
- Are there missing information, typographical errors, or application errors?