Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Tús Áite do Shábháilteacht Othar
Patient Safety First

Terms of Reference

National Consent Advisory Group

Document reference number	QPSD-D-019-5	**Document developed by**	Quality and Patient Safety Directorate
Version number	V5.0	**Document approved by**	National Director of Quality and Patient Safety
Approval date	October 2011	**Revision date**	October 2012

Contents

1. Background

The issue of consent to examination and treatment in health and social care is highly complex. Under Irish law, every adult person with capacity has the right to decide what happens to their own body. This legal right is mirrored in ethical guidance for healthcare professionals who therefore have a corresponding obligation to offer sufficient information to patients to enable them to make their own voluntary and informed decisions. Other than in exceptional circumstances, it is important to note that treating patients without their consent is a violation of their legal and constitutional rights and may result in civil or criminal proceedings being taken by the patient. Such exceptional circumstances relate primarily to emergency situations where it is necessary to intervene in the absence of consent in order to preserve the patient's life or health, or where the patient lacks capacity to give personal consent and a decision is made in his/her best interests.

Furthermore, it is widely recognised that people who participate in research are entitled to a full and frank disclosure of all the facts relating to the research prior to giving consent. However, the nature of the information to be given, the way in which it is presented, and the inherent difficulty of informing participants about the uncertainties involved in research require careful consideration in order to ensure meaningful participation. Research with vulnerable groups, genetic research and research in emergency care settings raise additional challenges in the context of the requirement for informed consent.

In general terms, the constituent elements of a valid consent are:

- Decision-making capacity.
- Disclosure of information.
- Comprehension.
- Voluntariness.
- Agreement.

In everyday health and social care, circumstances arise which may challenge frontline staff in seeking informed consent from patients. These may relate to, for example, carrying out an assessment of the capacity of the patient to give consent, uncertainty regarding the age at which consent may be given, what legal issues arise regarding children of unmarried or divorced parents, children of minor parents, wards of court, and so on. Currently there are a number of local and regional policies and guidelines in place pertaining to seeking consent for medical treatment. However, there is no single national HSE consent policy and supporting documentation on this issue.

2. Role of the National Consent Advisory Group

The role of the advisory group is to propose a national consent policy and supporting documentation.

The responsibilities of the advisory group are as follows:

- Review and agree membership of group.
- Review existing policies, guidelines, national and international evidence of best practice, relevant bioethical and legal opinion pertaining to the issues of consent.
- Draft national consent policy and supporting documentation.
- Consult with relevant interested parties and the public.
- Review and incorporate feedback from consultation process as appropriate.
- Finalise and approve national consent policy and supporting documentation.
- Submit to the National Director of the Quality and Patient Safety Directorate for approval and onward submission to the HSE Management Team for ratification.
- Meet on a two-monthly basis during the development stage or more often as required.
- Convene on a quarterly basis to review implementation and revision as required.
- Provide advice and guidance on issues facing the programme.
- Maintain focus on the programme in the light of emerging issues.
- Make recommendations regarding the programme work plan and any deviation from it.
- Any concerns or issues identified through the course of the National Consent Advisory Group work which are outside the scope will be communicated to the most senior manager in the relevant directorate for attention and action.

3. Responsibilities of the Advisory Group Chair

The advisory group chair is Dr Deirdre Madden. Should the chair be unable to attend a meeting the deputy chair, will act as chair. The responsibilities of the advisory group chair are as follows:

- Set the agenda for each meeting.
- Circulate the agenda of each meeting to members and explain the agenda at the beginning of each meeting.
- Encourage broad participation from members in discussion.
- End each meeting with a summary of decision and actions.
- Working with the Quality & Patient Safety Directorate programme lead between meetings.
- Identify and oversee the progress of specific subgroups.

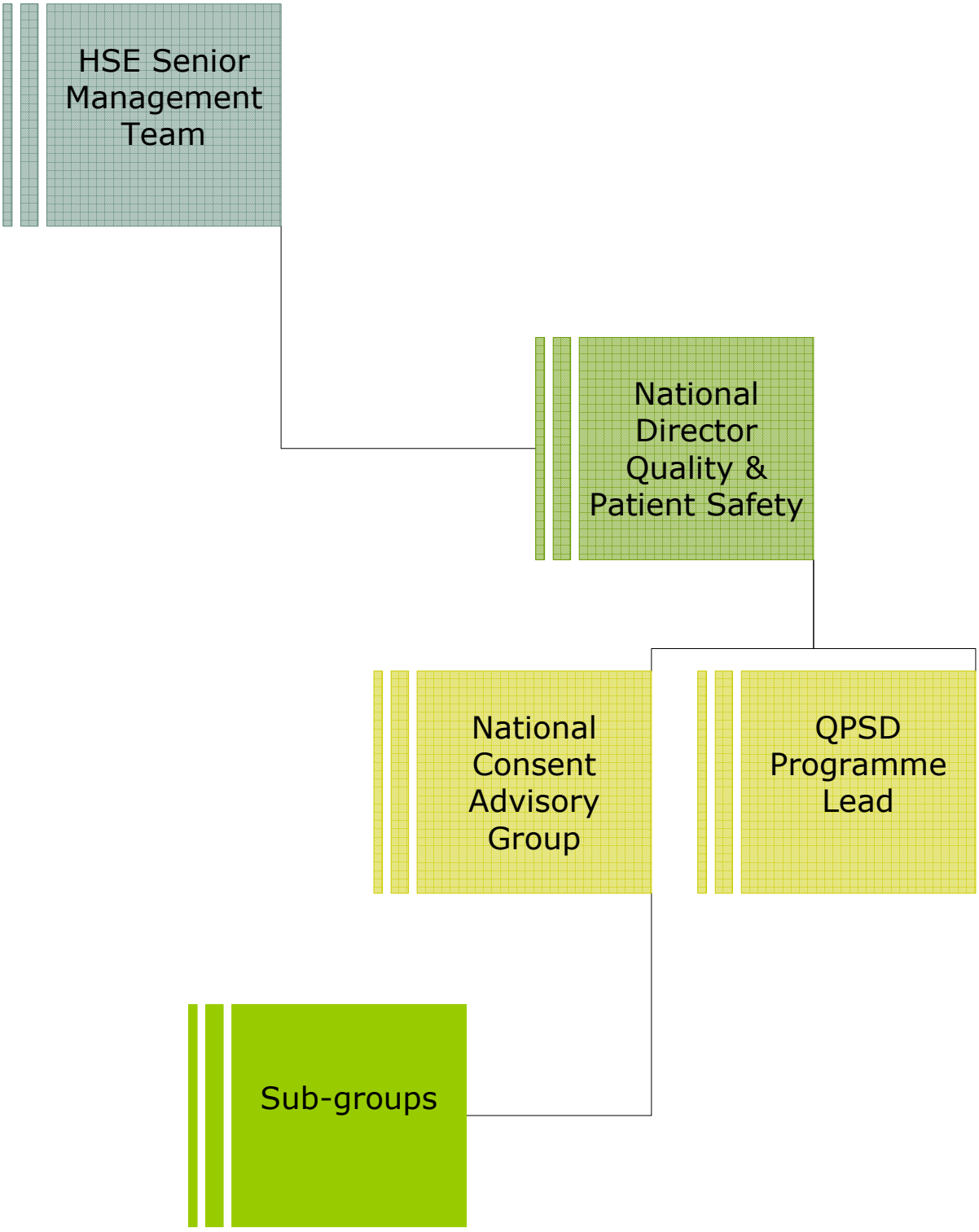
4. Responsibilities of the Advisory Group Members

- Understand the goals, objectives and desired outcomes of the programme of work.
- Attend and actively participate in advisory group meetings and subgroups meetings as required through discussion and review.
- Support open discussion and debate and encourage fellow advisory group members to express their opinions.

5. Responsibilities of Sub-group Members

- Develop documents as requested by the national advisory group.
- Attend advisory group meetings as required to present updates etc.
- Sub-group members who are not members of the national advisory group will not participate in decision making process around final document sign-off.

6. Reporting relationships



7. Membership

Name	Title	Organisation	Role
Deirdre Madden	Senior Lecturer, Faculty of Law	University College Cork	Chair
Angela Hughes	National Quality Lead	HSE, Quality & Patient Safety Directorate	Programme Lead
Ann Duffy	Clinical Risk Advisor Clinical Indemnity Scheme	State Claims Agency	Member
Anne Marie Loftus	Director of Nursing and Midwifery, Sligo General Hospital	Irish Association of Directors of Nursing and Midwifery	Member
Austin Warters	Manager of Older Persons Services	HSE	Member
Bill Ebbitt	General Manager National Disability Unit	HSE, Integrated Services Directorate	Member
Caoimhe Gleeson	National Specialist in Accessibility & Equality Officer	HSE, Advocacy Unit, Quality & Patient Safety	Member
Catherine Whelan	Director Independent Hospitals Association Ireland	Independent Hospitals Association Ireland	Member
Donal Devery	National Lead, FOI, Data Protection and Records Management	FOI, Data Protection and Records Management	Member
Gary Davis	Deputy Data Protection Officer	Office of the Data Protection Commissioner	Member
Joe Clarke	Primary Care Clinical Lead	HSE	Member
Kevin Kelleher	Assistant National Director Population Health - Health Protection	HSE	Member
Mary Donnelly	Faculty of Law	University College Cork	Member
Mary Dowling	Clinical Risk Manager	HSE, St. Lukes General Hospital, Kilkenny	Member
Mary O'Meara	Senior Medical Officer	National Immunisation Office	Member
Mary Vasseghi	Service User		Member
Phil Garland	Assistant National Director Children & Families Services	HSE	Member
Shane Brennan	Quality & Clinical Programmes Communications	HSE	Member
Shaun O'Keeffe	Consultant Geriatrician	HSE, Galway University Hospitals	Member

Name	Title	Organisation	Role
Samantha Hughes	Team Lead, Clinical Audit & Research Team	HSE, Dublin Mid Leinster	Member
Siobhan O'Sullivan	Chief Bioethics Officer	Department of Health	Member

8. Working arrangements

8.1 Working arrangements of the National Advisory Group

A minimum of 10 national advisory group members are required for decision-making purposes. The quorum must include the chair (or deputy chair) and the national quality and patient safety directorate (QPSD) lead.

- A course of action requires support from more than 50% of national advisory group members who attend the meeting if there is a quorum.
- Decisions will be made by panel consensus using, e.g. majority vote, consensus meeting/survey, Delphi process, etc.

8.2 Working arrangements of the Sub-groups

- The sub-groups will produce the documents to support the work of the national advisory group.
- The advisory group shall request the development of documents by the sub-groups through the chair of the advisory group.
- The sub-groups shall submit all documentation through the chair to the advisory group for discussion and approval.
- The sub-group chairs shall attend the advisory group meetings (as requested) to present documentation developed by the sub-groups and approved by the chair of the advisory group. The sub-groups will present a progress report against their work plan at each national advisory group meeting.
- The sub-groups shall meet as often as required but not less than once a month.
- The sub-groups do not require a quorum.
- The sub-groups may invite subject matter experts to assist with particular pieces of work; these members shall be subject to the same responsibilities as the sub-groups for the duration of their involvement.

9. Frequency of meetings

A minimum of six meetings will be held per year, with the possibility of more meetings contingent on the workload of the advisory group. Advisory group members will be expected to attend at least four meetings in the year; defaulting on this requirement may allow the chair to seek an alternate member.

10. Performance

A package will be prepared and sent to members by the advisory group secretary at least four business days in advance of an advisory group meeting. This package will include the following:

- Agenda for upcoming meeting.
- Minutes of previous meeting.
- Any other documents/information to be considered at the meeting.

11. Outputs

The National Consent Advisory Group is required to propose a national consent policy, supporting documentation and to provide expert advice on the implementation and monitoring of the policy, initially for a two-year period. The national consent policy will be completed by September 2012. The advisory group will review its purpose, aims, objectives and achievements to date at its meeting in September 2012 and report to the National Director of Quality and Patient Safety.

12. Administrative support

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