1. Overview


1.2 The Research Strategy outlines research governance and structures for the Agency and identifies aims, definitions, principles and actions. A key element of the strategy's research governance is the establishment of a Research Ethics Committee for the Agency with the purpose of reviewing research proposals with regard to the extent to which they comply with recognised ethical standards.

1.3 These guidelines set out the rationale; membership; and operating principles, procedures and protocols for the Agency's Research Ethics Committee. The guidelines are based predominantly on the Economic and Social Research Council Framework for Ethics Updated January 2015 and the Department of Health (2011) Governance arrangements for research ethics committees: A harmonised version.
2. Research Governance and Research Ethics Committees

2.1 Research is essential for protecting and improving health and well-being, as well as for achieving, modern, effective services (Department of Health, UK, 2011). Research can sometimes involve an element of risk as researchers cannot predict the outcome with complete certainty. Research may also involve additional burdens that exceed those involved with standard care. Proper research governance arrangements are essential, therefore, to ensure that service users and the public can have confidence in, and benefit from, high-quality, ethical research.

2.2 Research governance aims at encouraging and sustaining a research culture that promotes excellence in research conduct and reduces unacceptable variations in practice (Department of Health, UK, 2005). These objectives are achieved through a series of principles, requirements and standards.

2.3 Ethical review of research is an essential component of research governance. Research ethics in Ireland are governed by legislation in the form of EU directives, existing policy, national and professional guidelines. One of the aims of the Health Information Bill is to provide a national approach to research ethics and it will legislate for the Health Information and Quality Authority (HIQA) to become the supervisory body for recognizing and monitoring Research Ethics Committees for research under the EU Clinical Trials Regulations and all other types of health research in Ireland. It is as yet unclear if social science research will come under the remit of HIQA. These guidelines will be reviewed in line with any relevant developments under the work of HIQA in relation to Research Ethics Committees.
3. **Research Ethics Committees**

3.1 Research Ethics Committees aim to protect people who take part in research. This helps promote public confidence about the conduct of researchers and the dignity, rights, safety and well-being of research participants. Public confidence in research will result in more people being encouraged to take part in research and this in turn will lead to more, better and speedier improvements to health and social care (Department of Health, UK, 2011, p7).

3.2 Research Ethics Committees are independent and impartial. A Research Ethics Committee’s (REC) opinion must be free, and must be seen to be free, from conflicts of interest. This includes freedom from pressures of:

- Political influence
- Institutional affiliation
- Trade union or profession-related interests
- Direct or indirect financial inducement or any impression thereof
- Coercion
- Strategic concerns
- Market forces
- Agency, discipline or topic related bias

(Department of Health, UK, 2011, p 15)

3.3 The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability of its decisions (ESRC, 2015).

3.4 A REC is a group of people appointed to review research proposals to assess formally if the research is ethical. A REC will provide independent advice to participants, researchers, funders, sponsors, employers, care organisations, and professionals on the extent to which proposals for research studies comply with recognised ethical standards (HIQA, 2012).

3.5 The primary role of a REC is to protect the dignity, rights and welfare of research participants.
4. Child and Family Agency Research Ethics Committee

4.1 Key operating principles

4.1.1 These guidelines apply and REC review is required where research relate to the following areas of the Agency’s responsibility:

- Potential research participants identified from, or because of their past or present use of services provided by the Agency (including services provided under contract with the private, voluntary or community sectors).

- Potential research participants identified because of their status as relatives or carers of past or present users of the Agency’s services.

- Potential research participants identified because of their status as providers of the Agency’s services.

4.1.2 Under the terms of these guidelines, all data collection and analysis involving human participants and/or personal data should undergo ethics review prior to the research commencing, with the exception of the following, which are not considered ‘research’:

- Routine audit
- Performance or service reviews
- Quality assurance studies or reviews
- Testing within normal educational requirements

4.1.3 The principal ethics consideration of the REC will be given to ensuring the maximum benefit of the research whilst minimizing the risk of actual or potential harm. The procedures of the REC will seek to protect, as far as possible, all groups involved in the research, including participants, researchers and research teams throughout the lifecycle of the research (ESRC, 2015).

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1 Source: Economic and Social Research Council (2015) Framework for research ethics: Updated January 2015
4.1.4 The lifecycle of research includes:

- the planning stage
- the period for which the research is active
- the knowledge exchange and impact activities
- the dissemination process
- the archiving, future use, sharing and linking of data.

(ESRC, 2015, p 20)

4.1.5 There are six key principles of ethical research that the Agency expects to be addressed:

- Research participants should take part voluntarily, free from any coercion or undue influence, and their rights, dignity and (when possible) autonomy should be respected and appropriately protected.
- Research should be worthwhile and provide value that outweighs any risk or harm. Researchers should aim to maximize the benefit of the research and minimize potential risk of harm to participants and researchers. All potential risk and harm should be mitigated by robust precautions.
- Research staff and participants should be given appropriate information about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks and benefits, if any, are involved.
- Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.
- Research should be designed, reviewed and undertaken to ensure recognized standards of integrity are met, and quality and transparency are assured.
- The independence of research should be clear, any conflicts of interest or partiality should be explicit.

(ESRC, 2015, p4)

4.1.6 The Child and Family Agency REC will review research proposals in terms of their ethical appropriateness. This entails consideration of:

- The design of the research
- The outputs of the research
- The proposed conduct of the research
4.1.7 The REC will operate according to the law in the conduct of its business by following due process and complying with its own standard operating procedures.

4.1.8 The Child and Family Agency REC review will be competent, timely and authoritative. The membership, ongoing training and performance of the REC, in addition to the operational and administrative support it receives, will be arranged to maximize the quality, rigour, and promptness of REC review and the efficiency of the decision-making processes.

4.1.9 The Child and Family Agency REC will encourage and support high impact and new forms of research.

4.2.0 The Child and Family Agency REC will be provided with the necessary resources to carry out its responsibilities efficiently, effectively and independently including administrative support of .5 W.T.E. Grade 6 Administrator.

5. Child and Family Agency Research Ethics Committee Membership

5.1 The membership of a REC should allow for a sufficiently broad range of experience and expertise to provide competent and rigorous ethics review of the submitted research proposals (ESRC, 2015). The composition and independence of the REC is important in establishing the legitimacy of the opinions expressed and the decisions made, in the eyes of the community and wider society as well as the researchers and funders of research.

5.2 The REC will have a chair and a vice-chair. Candidates for these roles are expected to have at least a year’s experience as a member of a REC. Candidates are appointed for specified periods not exceeding five years and may resign at any time.

- The Committee composition will be in line with international best practice.
- The Committee will be comprised of at least 8 members.
- The Committee will be multi-disciplinary and comprised of both men and women.
- At least one-third of the members will be lay people (at least half of the lay membership should comprise people who have never been care or educational professionals, researchers in a care or educational field, or chairs, members or directors of care service bodies, or organisations providing care).
The remainder of the committee will be expert members, who are specialists, other relevant professionals and academics.

There will be at least 3 members who are not staff of the Agency.

The Committee will be supported by an administrator who acts as Secretary to the Committee and who will be an employee of the Agency. The Secretary plays no role in the approving of research proposals.

The Committee will include the following categories of members:

- Child and Family Agency Research Lead
- Child and Family Agency Researcher
- Data Protection Specialist
- Primary Care representative
- Social Work representative
- Social Care representative
- Mental Health Service representative
- Educational Welfare Service representative
- Family Support Services representative
- Research Academic representative
- Workforce Development representative
- Domestic, Sexual and Gender based Violence Services representative
- Child advocacy representative
- Family advocacy representative
- Secretary and REC Administrator

5.3 Written terms of appointments for REC members will include the following:

- Duration of appointment
- Renewal policy
- Disqualification and resignation procedures
- Policy concerning declarations of interest
- Details of allowable expenses

5.4 In line with findings from HIQA's (2012) international review of research ethics structures, membership for the REC will be advertised publicly in the press and/or local professional and other networks. Potential candidates will be required to complete an application form and will be interviewed. The following expertise will be sought:

- Relevant methodological and ethical expertise in clinical, non-clinical qualitative and other research methodologies in health and social science fields
- Practice experience
- Statistics related to research.
5.5 All appointed REC members will have sufficient baseline knowledge of ethical issues. As condition of appointment, REC members must agree to take part in initial and continual training appropriate to their role.

5.6 Any member who has no prior experience of RECs will be required to undergo training prior to becoming a member of the Child and Family Agency REC which will help them make effective ethical judgments.

5.7 Agreed minimum standards of training and competence (which should be kept up to date with the changing ethics issues within the research lifecycle) will be developed.

5.8 Members of the Child and Family Agency REC must maintain confidentiality regarding applications, meeting deliberations, information about research participants and related matters.

6. Child and Family Agency REC Standard Operating Procedures

6.1 Standard Operating Procedures for the REC are essential to an efficient, consistent and accountable research ethics system (Department of Health, UK, 2011).

6.2 There will be a standard process for applying to the Child and Family Agency REC. Applications will be made in accordance with the process set out in the Standard Operating Procedure. This process covers the application from submission to opinion and on to subsequent notification of substantial amendments, annual progress reporting etc.

- Research which falls within the remit of the Child and Family Agency may not commence until a favourable REC opinion is given.
- The REC will publish a yearly timetable outlining the time needed to consider a proposal.
- The REC will give its opinion within a specified period of days of receipt of a valid application.
- The REC will review each research proposal submitted.
- The REC gives a favourable opinion if it is assured about the ethical issues presented by the proposed research.
- Where a proposal does not meet the expected ethical standards or changes are required, it is appropriate for the REC to give feedback on what needs to be done.
- The decisions made for each proposal, and the grounds on which it was made, will be recorded and provided to the researcher(s), and a copy kept on file with the proposal for a specified minimum period
that is consistent with policy on information retention. This period should extend beyond the lifetime of the research proposal.

- The REC will publish a summary of its opinions, whether favourable or otherwise.
- The meetings and proceedings of the REC are conducted in accordance with standard operating procedures. REC meetings are not public meetings.
- Members of the REC are expected to declare any material interests in applications to be reviewed at the commencement of each meeting.
- Where the REC needs greater understanding of the scientific or scholarly merit of a proposal in order to make a judgment about ethics issues and potentially methodologically unsound research, it will seek the advice of an independent researcher with experience and expertise in the research methods and paradigm described in the proposal.
- Where the REC needs legal advice in relation to a proposal this advice will be sought from the Agency's legal services.
- The REC will receive annual reports about the progress of the research it has reviewed. These reports will explain any developments affecting participants' dignity, rights, safety or well-being. The REC should reconsider its favourable opinion in light of relevant information that comes to its attention.
- The REC will provide supportive, reflexive governance to researchers and operate a system of ongoing monitoring and supportive reflection that promotes mutual learning for researchers and REC members.

6.3 The Child and Family Agency REC will establish and publish working procedures and systems of documentation in relation to:

1. The dates of REC meetings and the deadline for submission of applications to be considered at each meeting;
2. Preparation of agenda and distribution of papers to members in advance of meetings and distribution of minutes following meetings;
3. Sufficient time for members to review relevant documentation;
4. Minimum attendance for a quorum and procedures when meetings are not quorate;
5. The presentation of research proposals and supporting documents. Application forms and procedures will be kept as brief as possible.
6. Identifying, documenting and dealing with conflicts of interest.
7. Methods of decision making and recording decisions. The REC will record and make clear how it came to its decisions, including whether 'lead reviewers' are designated for each proposals and whether decisions can be made on the basis of the majority view.
8. Receiving and considering appeals. Grounds and mechanisms for appeal will be clearly stated and published.
9. Monitoring the conduct of research following initial review and through ongoing ethics review.

10. Receiving and considering complaints and transparency of decision making. Grounds and mechanisms for complaints will be clearly stated and published.

7. Child and Family Agency Research ethics review application forms and protocols

7.1 Research proposals, including student proposals, submitted for review to the REC will be expected to include the following information in a way that is understandable to a lay member (ESRC, 2015):

- Aims of research and the scientific background of the research
- Study design
- Participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited
- Potentially vulnerable individuals or groups (could include an identifying list)
- Methods of data collection and analysis
- Response to any conditions of use of data sets
- Applicant summary of potential ethical issues and how they will be addressed. For proposals involving collaborators this summary should be agreed by all parties.
- Benefits to research participants or third parties and how this will be maximized
- Risks to research participants or third parties and what has been done to assess, avoid or minimize risks
- Risks to researchers and in particular how researchers are protected or supported, especially in the field
- Procedures for freely given and adequately informed and valid consent – information provided and methods of documenting
- Procedures for dealing with information arising in the course of fieldwork that is a cause for concern, such as disclosures from participants, or behaviours or incidents observed that raise significant concerns about the safety or well-being of participants or other people
- How any data collected will be kept secure, and methods of transferring data within teams, in compliance with data protection legislation.
- Mechanisms for data-sharing outside the proposed research team
- Details of research activity that falls outside the jurisdiction and links to overseas institutions
- Expected outcomes, impacts and benefits of the research
• Pathways to impact and dissemination (and feedback to participants where appropriate) and possible ethics implications of these plans
• Data management and responsibility; what measures have been taken to ensure confidentiality, privacy and data protection during and beyond the end of the proposal
• Confirmation of insurance cover is a requirement for all research ethics applications.

8. Conclusion

8.1 Research is essential to the successful promotion and protection of health and well-being and to a modern effective health and social care system. Research also contributes to the efficiency and effectiveness of the content, planning, delivery and monitoring of health and social care and plays an important role in the knowledge economy (HIQA, 2012). Research governance is principally concerned with improving research, through the regulation and assurance of research quality and research ethics. The overall aim of these guidelines is to contribute to the development of a more coherent and transparent system within the Child and Family Agency that is proportionate to the governance needs and ethical risks in research with all users and providers of children’s services.
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