

Information for Research Applicants on Research Governance Standards and Ethical Approval

May 2010

What is this information sheet for?

This paper provides basic information for applicants to CARDI on how to comply with research governance standards and especially ethical approval. Older people are an especially vulnerable group and it is important that research sponsored by CARDI is conducted to the highest scientific and ethical standards. Happily the research community in Ireland has traditionally conducted high quality, impartial and ethical research but part of our role is to champion standards and strengthen the role of older people as participants, users and beneficiaries of the research we sponsor.

This paper is intended to help applicants to think about the governance implications of their research and especially the procedures for securing ethical approval. Our approach draws on best practice in Northern Ireland and the Republic of Ireland and applies and adapts codes of practice and guidelines especially where they relate to the needs of older people.

We have developed resources and supporting materials that may help strengthen the quality of your research and ensure that we all work to achieve fair, inclusive and ethical research with and for the older community. These resources can be viewed at: <http://www.cardi.ie/researcherstoolkit>.

CARDI's Principles of Research Governance

The CARDI Research Governance Framework has three objectives:

1. To ensure that age research is carried out to the highest scientific and ethical standards;
2. To ensure that our work and supported projects and activities comply with relevant, research based legal requirements, policies and procedures in the Republic of Ireland and in Northern Ireland; and
3. To ensure that research and researchers avoid harm, minimise risk, promote user engagement and pursue progressive ethical practice.

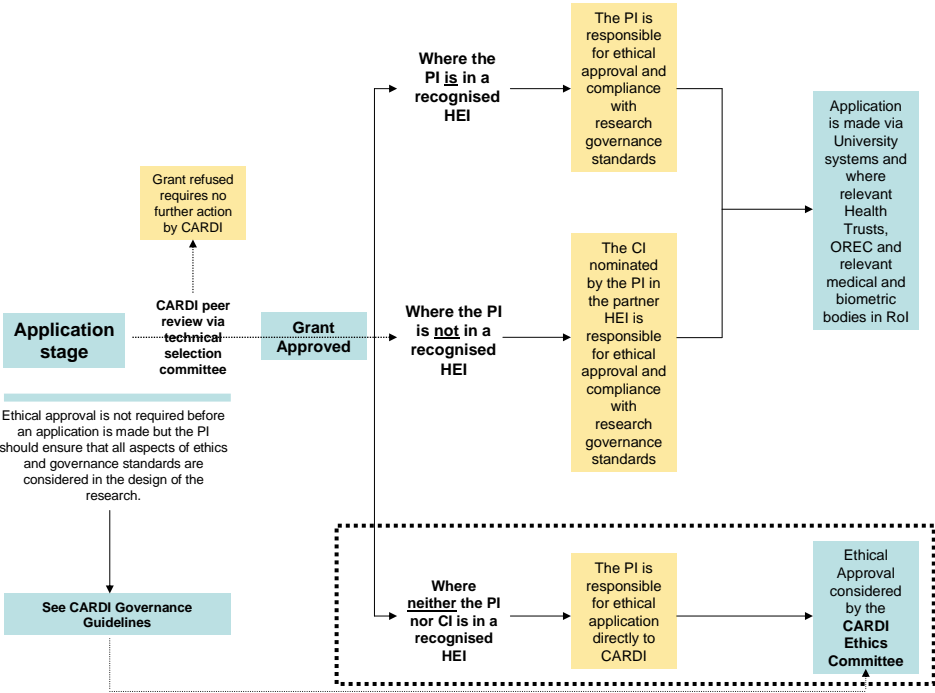
Responsibilities of the applicant researchers and their institutions

For research supported by CARDI and which involves older people and other human participants, the PI and the lead institution is responsible for ensuring that before the research commences: all staff are aware of their responsibilities and of the need for appropriate training; that the necessary regulatory and ethical approvals are in place in both jurisdictions; that appropriate indemnity arrangements are made; and that systems for reporting are in place.

In making an application to CARDI you should consider user engagement, ethics and risk and summarise how you have taken these on board in your application. The guidelines below and the resources on the toolkit page will help you to do this. Your application is considered by the

selection committee which assesses the scientific quality of the proposed project via expert peer review and looks at your consideration of user engagement, ethics and risk.

The diagram below shows that ethical approval is the responsibility of the Primary Investigator (PI) via his or her higher Education Institution (HEI). If the PI is not in a recognised HEI in the Republic of Ireland or Northern Ireland then he or she may nominate a Co-Investigator (CI) in a HEI who will be responsible for ethical approval for the whole project. This person and his/her HEI should be identified in the application. In exceptional cases where the team contains no one from a HEI then an application for ethical approval will be made directly to CARDI, via the Strategic Research Officer. For those projects the PI should contact info@cardi.ie and here, the application will be considered by the CARDI Ethics Committee, against the criteria set out in the text box below.



Cross-compliance and approvals

In Northern Ireland where the research involves NHS patients or staff, research governance approval must be obtained from the relevant Trust or Trusts (or other care organisation) and a favourable ethical opinion obtained through the Central Office for Research Ethics Committees (COREC) system. In Northern Ireland this is usually the Office of Research Ethics Committees Northern Ireland (ORECNI) [<http://www.orecni.org.uk>].

All clinical trials of medicinal products and devices are also governed by the requirements of the Medicines for Human Use (Clinical Trials) Regulation 2004, and must be approved by the Medicines and Healthcare products Regulatory Agency (MHRA) [<http://www.mhra.gov.uk>]. It is anticipated that legislation will emerge in the future regarding the administration of radioactive materials to persons; such procedures currently require approval from Administration of Radioactive Substances Advisory Committee (ARSAC).

In the Republic of Ireland it is the responsibility of the PI to obtain University ethics approval and where necessary approval by Research Ethics Committees recognised by the Department of Health and Children [http://www.dohc.ie/other_health_issues/clinical_trials/ethics_committees.html] and where

appropriate, by the Irish Medicines Board [<http://www.imb.ie>]. The Health Information Bill is scheduled to be sent to the Oireactas for approval in September 2010 and enacted by year end.

This will provide for a national process for ethics approval in health research and will be managed by Health Information and Quality Authority [HIQA] (<http://www.hiqa.ie/>). This will rationalise the organisation of ethical committees and systems including a move to a single ethics form applicable across health and social services research in the state. Applicants should familiarise themselves with legislation and compliance procedures as a result of the new Bill via the HQIA website.

Research governance standards

Researchers (and their respective institutions) should comply with a simple set of standards and ensure that the design, implementation and dissemination of their work always maintain the highest scientific and ethical qualities.

1. Researchers should be committed to the unbiased and objective pursuit of valid and reliable knowledge.
2. There is sound ethical rationale for the research methodology and appropriate dissemination and utilisation of the findings in the interests of the older community.
3. The participation of older people (and others) is based on valid informed consent. Consent should only be accepted from a gatekeeper or proxy after a reasonable attempt has been made to explain to the intended participant the purposes and implications of the research and to secure his/her consent directly.
4. Research collection, storage and use must comply with current data protection, subject access and freedom of information legislation enacted in both jurisdictions.
5. The research should be designed to reduce the barriers and strengthen the opportunity for older people to participate in the conduct, dissemination and use of the research.
6. The research must protect the physical, social and psychological well-being of older people and in cases where there is high risk of distress consideration should be given to provision of post-interview support for respondents and interviewers.
7. All researchers and interviewers must be properly trained and appropriate criminal checks must be undertaken where and when appropriate.
8. The identity of, and data belonging to, participants and potential participants should be protected throughout the research process including respondent recruitment, data collection, data storage, analysis and reporting.
9. Researchers should undertake a risk assessment especially to ensure the safety of research staff, data collectors and participants and to avoid conflicts of interests that may result in research funding or use of data.
10. Researchers must comply with human tissue, medicine for human use, clinical trials, human experimentation and animal experimentation legislation in both jurisdictions.

Contacts for further information

If you have any further queries about research governance and ethics approval please contact CARDI at info@cardi.ie or by post to:

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