ROYAL COLLEGE OF PHYSICIANS OF IRELAND

RCPI Policy on Good Research Practice

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Version 2

Table of Contents

Introduction

The RCPI's Research Department was established in 2012 with the objective of providing a central point of focus for all of the college's research activities and to provide evidence to support the achievement of RCPI's goals.

These goals are:

1. High medical training standards
2. Optimum patient care
3. Effective health promotion

Research carried out in RCPI covers three broad areas:

1. **Effective training –** Process and outcomes of training
2. **Physician's work environment –** Impact of clinical environment on clinician wellbeing and retention
3. **Quality healthcare –** Quality, efficiency, safety and effectiveness of healthcare

RCPI research activities are overseen by the Director of Research. The guidelines laid down in this policy apply to all Trainees, Members, Fellows and all Staff in The Research Department as well as all persons conducting research in affiliation with the RCPI or undertaken on RCPI Trainees, Members, Fellows or Staff. This policy also covers individuals performing research in collaboration with, or made possible by interaction with RCPI. Collaborative research may also require additional compliance with the policies of the relevant body of the organisation with which RCPI collaborates. This policy has been adapted and developed from others in common use internationally. We undertake to inform all concerned about their rights and duties as laid out in this document.

Ethics

The following guidelines apply to all research conducted in or under the auspices of RCPI with particular emphasis on research involving health service improvement, research of a national focus and medical education research.

RCPI will take all reasonable measures to respect the autonomy of all human participants involved in our research as outlined in the relevant legislation. We will do this by ensuring all research undergoes an independent research ethics review carried out by the RCPI Research Ethics Committee.
In all cases where research is carried out under the auspices of RCPI, the college expects compliance with RCPI policies as set out in this document and additional compliance with the policies of the relevant body of the organisation with which RCPI collaborates.

Ethics Structures

The RPCI Research Ethics Committee (REC) was set up to ensure that all research carried out throughout RCPI is conducted according to best ethical practice. The committee operates in accordance with standard operating procedures developed in line with the Irish Council for Bioethics 2004 guidance document: Operational Procedures for Research Ethics Committees. The committee meets four times per year to ethically review proposals. It does not review clinical trial research proposals. Please consult the REC's operating procedures for more detail.

RCPI position on reciprocity of ethical approvals from third party collaborating institutions

RCPI recognises that our collaborating institutions conduct research under established ethical procedures and policies. The RCPI Research Department require that collaborating partners provide details on the ethical approval granted.

Integrity

All individuals carrying out research in collaboration with RCPI are expected to observe high standards of professional behaviour and integrity. Research integrity covers many issues including research misconduct, conflict of interest and policies for inquiring into allegations of research misconduct. Please refer to the National Forum on Research Integrity Position Paper Research Integrity & Research Ethics for further details https://www.iua.ie/for-researchers/research-integrity/

Research misconduct

Research misconduct is defined as but is not limited to fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It concerns any conduct which seriously deviates from accepted ethical standards in research.

Fabrication concerns the making up of data or results and recording or reporting them.

Falsification involves manipulating research materials, equipment, processes, or changing, distorting, dishonestly misinterpreting or omitting data or results such that the research is not adequately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, or dishonest use of unacknowledged sources.

Research misconduct includes misquotation or misinterpretation of other authors or inappropriate attribution of authorship. It does not include honest error or honest differences of opinion in interpretations or judgements of data. Similarly, the analysis of either old or new material and subsequent drawing of new conclusions about the data is not considered misconduct.

Research misconduct includes failure to obtain appropriate permission where required to conduct research. It also includes collaborating with others involved in research misconduct or encouraging others to be involved or concealing research misconduct by others when

there is evidence to that effect.

RCPI will take seriously any allegation of research misconduct and will respond to such allegation by a process of investigation with a view to resolution.

Deception in relation to research proposals

The RCPI Director of Research, RCPI Research Department Manager and all Principal Investigators working on behalf of RCPI will take all reasonable measures to ensure that accuracy and completeness of information is contained in applications for research funding. All information regarding the qualifications of involved research staff will be truthful.

Integrity in managing research projects

The RCPI Director of Research, RCPI Research Department Manager and any Principal Investigators working on behalf of RCPI or in collaboration with RCPI will take all reasonable measures to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects.

Sound research design

RCPI will employ sound research design and methodology in all research undertaken to ensure the reliability of data collected and the validity of research findings. Where appropriate, RCPI will seek the assistance and guidance of one or more experts in the relevant field at any stage of the research project.

Behaviour in the conduct of research

RCPI acknowledges that it must play a proactive role in helping research staff achieve Good Practice in Research. The RCPI Director of Research and RCPI Research Department Manager are responsible for taking action to make available appropriate training to research staff to ensure their knowledge and understanding of good research practice and current ethical guidelines.

In particular, research staff will ensure that their actions will not result in any unreasonable risk or harm to participants and they will only initiate or engage in research that they are competent to conduct. Where necessary, RCPI will seek the advice of an external expert, so as to enable RCPI to execute their research competently. RCPI research staff will refrain from any conduct in their role as researcher that would unfairly detract from the good name of RCPI.

Disclosure of conflict of interest

A conflict of interest can be defined as a situation where-in a person's judgement concerning a primary interest has the potential to be unduly influenced by a secondary interest. Such a conflict of interest may be financial in nature (including benefits in kind), or may be personal, academic or political. A conflict of interest can occur at any stage of the research project.

Disclosure of any potential or actual conflict of interest is essential for the responsible conduct of research, and is the responsibility of all research staff, Principal Investigators and heads of department involved in a given project. Disclosure of such interests, where they exist, must be made to the RCPI Research Ethics Committee, RCPI Director of Research, RCPI Research Department Manager, relevant collaborative institutions and Principal Investigators, as well as to journal editors and funding bodies.

The absence of conflict of interest, or an official declaration of conflict of interest for all participants of RCPI research will be disclosed at the point of contract acceptance or whenever is required by the research funding body.

Declaration of Interest documents will be kept in RCPI's Research Department for a minimum of 5 years.

Good Publication Practice

RCPI recognises the fundamental right to publish and disseminate findings of research and will respect this right in their contractual agreements with funding bodies and research partners.

RCPI aims to publish research findings in peer-reviewed journals and similarly reputable publications such as journals, books, software, policy statements, specialist conferences and expert reports. RCPI acknowledge the importance of publishing in good time, and will not withhold data that may be of interest to the public or to the advancement of knowledge. RCPI will make every endeavour not to engage in biased reporting and results will be presented for publication even if results differ from previous expectations.

RCPI research staff will ensure the absence of plagiarism in their publications through various methods. These will include the provision of a complete reference list of all sources of information used in the preparation of their article or presentation, the complete citing of sources used for tables, diagrams, quotations, paraphrases etc. included in the article, and the attainment of permission from holders of copyright where necessary.

Related material regarding research programmes on the RCPI website will be supervised and edited by the manager of the RCPI Research Department or a research staff member appointed with this duty.

Authorship rights and responsibilities in group research

In relation to authorship, RCPI follows the International Committee of Medical Journal Editors (ICMJE) criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data

All personal data collected and processed in the course of a research project is subject to the terms of the Data Protection Acts 1998 and 2003, the General Data Protection Regulation (GDPR) and the Health Research Regulations 2019 which safeguard the privacy of individuals regarding their personal data. All RCPI research staff must ensure that they are familiar with this legislation as well as RCPI internal policy.

All RCPI research staff collecting or accessing personal health data must be aware of the additional requirements covering sensitive personal data and all health research must conform to the guidelines covering research in the health sector published by the Office of the Data Protection Commissioner (*Data Protection Guidelines on Research in the Health Sector*, available on the Commissioner's website at www.dataprotection.ie).

Any RCPI research staff who become aware that they are in breach of the legislation through having been granted access to personal data, will cease the research immediately and notify the relevant Research Ethics Committee, Principal Investigator and RCPI Data Protection Officer.

In research programmes where RCPI undertake to conduct research for external organisations ,either using their data, or gathering and analysing data on their behalf, the Data Protection legislation requires that the commissioning organisation (referred to as the *Data Controller*) enter into a formal written agreement with RCPI (the *Data Processor*) to ensure the secure processing of data. If this agreement provides for RCPI to collect data of a personal nature, it is the responsibility of the Data Controller to clearly identify RCPI as the Data Processor to participants and to inform participants that this personal information will be collected by RCPI. RCPI researchers are bound by all aspects of the legislation in carrying out the contracted research work.

RCPI research staff will be required to keep clear and accurate records of the research procedures followed and of the results obtained, including interim results. Data will be retained securely in paper, electronic or other form, as appropriate to the task and type of research undertaken. This is intended to protect participant confidentiality and to facilitate the undertaking of a retrospective audit when necessary.

Data records will be monitored regularly by the RCPI research team to ensure their completeness and accuracy.

As a rule, all data will be stored for a minimum of 7 years in RCPI in accordance with data and privacy policies of RCPI. Research records relating to clinical or public health studies will be retained for a sufficiently extended period to provide scope for longer follow-up if necessary. Data is retained for as long as is required and is indicated to all parties before the data is collected. Only ethically approved data analysis may be done. Electronic data will be collected on encrypted laptops and transferred to a secure password-protected server within RCPI or in the institution of the Principal Investigator of the study in question, depending on what is most appropriate. Electronically generated data will be backed up regularly and duplicate copies will be held electronically in a secure archive. Where possible, a hard copy will be made of very important data. If it is necessary to take data off-site, the data will be taken off-site in a password-protected file on an encrypted electronic format and stored on a secure server, either in RCPI or in the institution of the Principal Investigator. If the transfer of data off-site is required, participants will be informed of this in the research consent form and will be informed of the strict security measures described above which RCPI researchers and collaborating researchers will implement in the transfer.

Data security will be the responsibility of the Principal Investigator.

Data analysis will be carried out on an encrypted laptop belonging to RCPI or to the collaborating institution and all analysis will be stored in a password-protected folder on a secure server in RCPI or in the collaborating institution.

Following data analysis, data will be stored electronically for 7 years after the submission of the final report or publication (whichever occurs last), and then destroyed. This will take the form of permanent deletion from the subfolder on the server.

The individual researchers listed in the relevant research proposal will be responsible for maintaining the confidentiality of the data collected, and when managing the dataset the research staff will ensure non-disclosure of information. Any breach of this confidentiality will be punishable by RCPI internal contractual policy.

Privacy considerations other than that of data protection

Data Protection legislation only applies in the context of living data subjects.

However, the handling of other forms of relevant personal data may require the considerations as to confidentiality or ethical codes of practice, which the RCPI's Research Department and Research Ethics Committee will give due attention to when these circumstances arise.