



CODE OF RESEARCH CONDUCT

Royal College of Surgeons in Ireland

Approved by SMT

CODE OF RESEARCH CONDUCT

Royal College of Surgeons in Ireland ["RCSI"]

1. INTRODUCTION

- 1.1 A central mission of RCSI is to promote excellence in research and the College strongly encourages all academic staff to be research active and to contribute to knowledge in their field.
- 1.2 RCSI embraces the traditional principles of academic freedom and recognises that members of the academic and research staff of RCSI, whether working collaboratively or individually, shall have, within the law, the freedom to question and test received wisdom, to put forward new ideas and to state controversial or unpopular opinions.
- 1.3 RCSI has a responsibility to ensure that all research carried out under its auspices meets the highest quality and ethical standards while taking account of the law and the public interest.
- 1.4 This Code addresses the issues involved in the proper conduct of research, and provides guidance on the standards expected.
- 1.5 RCSI is committed to ensuring the highest standards of integrity in all aspects of our research, founded on basic principles of good research practice to be observed by all researchers and research organisations.

The *European Code of Conduct for Research Integrity* specifies four fundamental principles that underpin all research integrity and good practice in carrying out research, which we endorse here. These principles guide researchers in their work as well as their engagement with the practical, ethical and intellectual challenges inherent in research. These principles are:

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
 - **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
 - **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
 - **Accountability** for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts.
- 1.6 All research conducted in RCSI must be consistent with the forgoing principles and with Irish law and policy, including licensing requirements, and with policies of RCSI.
 - 1.7 Researchers have a responsibility to make themselves aware of and ensure that all relevant requirements of Irish law and RCSI Policy are met.
 - 1.8 This Code incorporates the *National Policy Statement on Ensuring Research*

Integrity in Ireland which has been adopted by the Irish Universities Association including RCSI, and RCSI affirms the commitments contained therein.

- 1.9 This Code adopts the definitions contained in the National Policy Statement. If any conflict arises between the National Policy Statement and this Code, this Code shall prevail.
- 1.10 The Code applies to:
- Researchers (including academic staff, research assistants, postdoctoral researchers, research fellows, senior research fellows, research professors, academic-related staff) and other staff involved in the research process (including technical, clerical, clinical and administrative staff) employed by RCSI, whether in RCSI, or while at another institution;
 - Supervisors of postgraduate and undergraduate research;
 - Postgraduate and undergraduate students;
 - Any persons with honorary or adjunct positions involved in research within, or on behalf of, RCSI;
 - Collaborators and sub-contractors from other institutions, government bodies and industry, whether working within RCSI or not;
 - All individuals engaged in the setting of research priorities and in the assessment of research.
- 1.11 The term “researcher” is used throughout the Code to refer to any or all of the above categories, as appropriate.
- 1.12 Events may occur where there is possible infringement of this Code by a person who is not an employee of RCSI, such cases should be addressed by the respective employer, as appropriate.
- 1.13 RCSI expects all researchers to work within this Code. The Code sets out general guidance, but it is recognised that principles of good research practice will apply differently in different disciplines.
- 1.14 If researchers have any doubt concerning the applicability of a particular clause of the Code they should consult with the Research Integrity Officer.
- 1.15 In addition to the Code, researchers should make themselves familiar with any additional guidelines that are relevant to their own discipline; including for example, but not limited to, Policies relating to Intellectual Property, Conflict of Interest, Data Protection and Research Ethics. Many of these are available in the RCSI Researcher Handbook.
- 1.16 The *Research Integrity Officer* (Appendix A) is appointed by the Director of Research & Innovation who in turn reports to the Chief Executive Officer/Registrar, and has the functions conferred on him or her under this Code. If a conflict of interest arises such that the Research Integrity Officer cannot act in respect of a particular matter under this Code, or if for any other reason the Research Integrity Officer cannot act in respect of any particular issue under this Code, the Director of Research and Innovation may appoint an appropriate alternative to deal with the specific matter under this Code.

1.17 Research misconduct includes but is not limited to:

- **Fabrication** of data i.e. making up results and recording them as if they were real.
- **Falsification** of data i.e. manipulating research materials, equipment or processes, or changing, omitting or suppressing data or results without justification.
- **Plagiarism** i.e. using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs

Each of these comprises an attack on the integrity of the research record and, as such, must be vigorously defended against. Fabrication and falsification are the most serious offences that can be committed, as the development of knowledge itself is undermined.

Plagiarism may be seen as marginally less egregious than the other offences, since the knowledge core is not, in itself, damaged. However, the corrupting effect on the principle of open communication and sharing of knowledge for wider benefit, means that repeated or significant plagiarism must be regarded as extremely serious.

While Fabrication, Falsification, and Plagiarism ["FPP"] represent the most serious examples of misconduct, there are other unacceptable practices that include, but are not confined to:

- Delaying or inappropriately hampering the work of other researchers
- Misusing research funds
- Exaggerating the importance and practical applicability of findings
- Accusing a researcher of misconduct or other violations in a malicious way
- Re-publishing substantive parts of one's own earlier publications without duly acknowledging or citing the original ('self-plagiarism')
- Withholding research results
- Misrepresenting research achievements
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions
- Manipulating authorship or denigrating the role of other researchers in publications
- Citing selectively to enhance own findings or to please editors, reviewers or colleagues.
- Misusing seniority to encourage violations of research integrity
- Expanding unnecessarily the bibliography of a study
- Establishing or supporting journals that undermine the quality control of research ('predatory journals')
- Allowing funders/sponsors to jeopardise independence in the research process or reporting of results so as to introduce or promulgate bias

2. PRINCIPLES OF GOOD RESEARCH PRACTICE

2.1 RCSI cannot be prescriptive about approaches to solving particular research

problems. However, all researchers, whatever their discipline, are required to understand, and observe where appropriate, the general principles presented in Para. 2.2.

- 2.2 Good research practice includes the following, which form major headings in the remainder of this document:

Competence (Para. 4: participation only in work which the researcher is competent to perform);

Responsibility (Para. 5: creation of a positive research climate);

Compliance with standards and procedures (Para. 5);

Managing research projects (Para. 5);

Supervision and mentoring (Para. 5);

Integrity (Para. 6: honesty; openness; proactive problem solving; accuracy; objectivity; acknowledgement of contribution; declaring conflicts of interest; whistle-blowing);

Respect for the Rights and Dignity of Research Participants (Para. 7: general respect; privacy and confidentiality/anonymity; informed consent; avoidance of harm);

Data Management (Para. 8: applies particularly to research which generates outcomes which can be described as "data". Ownership of data; record keeping; data storage);

Dissemination (Para. 9: academic freedom and protection of intellectual property; publication practice).

- 2.3 Clinical research involving the participation of human subjects is also subject to this code. In line with the World Health Organisation's general definition in their *Handbook for Good Clinical Research Practice*, human research includes, but is not limited to, any research relating to human subjects including healthy volunteers that cannot be considered as an element of accepted clinical management or public health practice and that involves either (i) physical or psychological intervention or observation including clinical trials, or (ii) collection storage and dissemination of information relating to individuals involving direct contact with or use of tissues, organ or fluid samples or personal clinical data.
- 2.4 Clinical research carried out by medical practitioners should adhere to all the general principles of medical professionalism recommended by the Medical Council in the *Guide to Professional Conduct and Ethics 8th Edition 2016*.
- 2.5 Clinical trials are scientifically controlled studies undertaken in humans to establish or confirm the safety and effectiveness of investigational medicinal products. The conduct of clinical trials within RCSI will continue to be governed by the *EU Clinical Trials Directive* until such time as the *EU Clinical Trials Regulation* comes into application during 2019. However, the *EU Clinical Trials Directive* will still apply for three years from that date for (i) clinical trials applications submitted before implementation of the *EU Clinical Trials Regulation* and (ii) for applications submitted within one year after the implementation of the *EU Clinical Trials Regulation*, if the sponsor opted for the old system.
- 2.6 All clinical trials conducted in RCSI must comply with EU regulations (para 2.5) and be performed in line with EU Commission's *Good Clinical Practice Directive*. Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the

participation of human subjects. Compliance with GCP provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible.

- 2.7 The EU Commission's *Regulation 2017/556* provides detailed arrangements for GCP inspection procedures that apply to inspections by the Health Products Regulatory Authority (HPRA) of clinical trials conducted under the *EU Clinical Trials Regulation* as well as the *EU Clinical Trials Directive*. Clinical trials conducted by those to whom this Code applies (para 1.10) must adhere to these requirements and be prepared for clinical audit inspection by the HPRA. These inspections determine whether clinical trials are compliant with the clinical trial permission, the trial protocol and the applicable legislation and guidance. Information on *HPRA GCP inspections* is available at their webpage.
- 2.8 This Code should be regarded as setting minimum standards. The lack of mention in it of particular acts or omissions should not be taken as conclusive in any adjudication on professional conduct.

3. ETHICAL APPROVAL

- 3.1 Research in the medical and biological sciences, and any other disciplines involving human participants, raises particular ethical concerns. A system of ethical governance has been developed for research in these areas. Where prior ethical approval is required detailed information on institutional ethical approval processes is available from the RCSI Research Ethics website.
- 3.2 Approval from other regulatory bodies may also be required.
- 3.3 Research involving animals must have ethical approval. Researchers must ensure that they hold an appropriate license, and that their research is in conformity with current statutory regulations.
- 3.4 At an early stage in the design of any research involving animals, researchers must consider options for reduction, replacement and refinement of animal involvement.
- 3.5 Research which requires ethical approval must not commence before approval has been granted.
- 3.6 If a researcher proposes to extend a research project or deviate from approved procedure, a fresh application for approval or an amendment to the original ethics application must be made and approved by the ethics committee.

4. COMPETENCE

- 4.1 Competence is defined as the ability to apply **knowledge** and **skills** to achieve intended results.
- 4.2 Researchers are responsible for actively maintaining professional competence and knowledge within their areas of expertise.

- 4.3 Researchers must always be mindful of the limits of their own training and expertise.
- 4.4 Peer review (evaluation of scientific, academic or professional work by others working in the same field) requires that the reviewer/referee be expert in the subject under review, and if researchers consider themselves to be insufficiently expert in an area on which they have been asked to comment, they must make this clear, and are normally expected to return the material unread.

5. RESPONSIBILITY

Research Climate

- 5.1 It is the responsibility of the CEO/Registrar, Director of Research and Innovation, Dean of the Faculty of Medicine and Health Sciences, Heads of Department, Directors of Institutes and Centres, Principal Investigators and other relevant managers and supervisors, both academic and support, to ensure that an environment is created which allows research to be conducted in accordance with good research practice. This responsibility includes the possibility of intervention to uphold this code of conduct.
- 5.2 The individuals identified in Para 5.1 are responsible for establishing a research climate of mutual cooperation, in which researchers at all levels are encouraged to develop their skills and in which the open exchange of ideas is fostered.
- 5.3 All researchers must ensure that the laws prohibiting discrimination are complied with.
- 5.4 Where appropriate, reasonable accommodation should be afforded to staff or students who object on grounds of conscience to participation in particular lines of research.

Compliance with Standards and Procedures

- 5.5 Research misconduct is least likely to arise in an environment where good research practice (e.g. documentation of results, peer review of research, regular discussion and seminars) prevails and where there is adequate supervision at all levels. It is a responsibility of the CEO, Director of Research and Innovation, Dean, Heads of Department, Directors of Institutes and Centres, and Principal Investigators to implement and promote principles of good research practice (Para. 1.5 and 2.2), and to ensure adherence to appropriate standards.
- 5.6 Researchers are required to be aware of and to observe the principles of good research practice as outlined in Para. 1.5 and 2.2.
- 5.7 Researchers should also observe, where relevant, standards published by learned societies and other professional bodies.
- 5.8 Researchers are expected to be aware of and stay informed of governmental, institutional and any other regulations, standards or policies,

including national, trans- national (EU) and international legislation, in proposing, conducting and reporting research.

- 5.9 Researchers are required to comply with any relevant audit or monitoring procedures, whether internal or external. Examples of such procedures include examination of the management of specific research projects, and compliance with the requirements of external sponsors, of this Code of Research Conduct or the National Policy Statement.
- 5.10 Researchers must draft where necessary and/or follow existing Standard Operating Procedures for key pieces of equipment in the laboratory.

Managing Research Projects

- 5.11 Researchers must take all reasonable actions to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects.
- 5.12 Researchers are expected to familiarise themselves with the terms and conditions of any research contract or agreement entered into by RCSI on their behalf.
- 5.13 Researchers must follow established RCSI financial procedures, including procurement, and must practice economy in the use of resources.
- 5.14 Principal Investigators must ensure that projects operate within their allocated budget, and that no penalties are incurred by failure to meet sponsors' requirements (for example, through late submission of reports).
- 5.15 Principal investigators must ensure, in liaison with HR, that the stipends and salaries of their research staff are aligned with the relevant pay scales and that all staff positions are filled in accordance with approved recruitment procedures.

Supervision and Mentoring

- 5.16 Established researchers have an extended responsibility to nurture the appropriate intellectual, technical, ethical and career development of staff, undergraduate students, postgraduate students and other supervisees.
- 5.17 Responsibility for ensuring that students and other new researchers understand good research practice lies with all members of the research community including research support services, but particularly with Institute and Centre Directors, Heads of Departments, Principal Investigators, team leaders, grant holders and supervisors. Good practice includes mentoring early career researchers in their new environment.
- 5.18 Supervisors are responsible for supporting the overall progress of their students and research staff. They must follow good supervisory practice and any RCSI specific guidelines.
- 5.19 All new researchers and postgraduate research students must receive appropriate training and mentoring, including the recommendation of appropriate postgraduate training modules in the case of research students.

Training on research integrity must be provided for, and attended by, all researchers with appropriate attendance records maintained. Training may also involve relevant principles of research design, and the principles set out in this Code.

- 5.20 Researchers must ensure that all persons who are involved in the conduct of research under their supervision are adequately trained and perform their responsibilities competently.

6. INTEGRITY

Honesty

- 6.1 Researchers must not claim any level of competence that they do not possess, and must take all reasonable steps to ensure that their qualifications, capabilities and views are not misrepresented by others. If such misrepresentation takes place, the individual(s) affected must take necessary steps to correct it.
- 6.2 Researchers must be honest about their own actions in research and in their responses to the actions of other researchers. This requirement applies to the whole range of research work, including planning and design, applying for funding, generating and analysing data, writing, publishing results, grant and paper reviewing, and acknowledging the direct and indirect contribution of colleagues, collaborators and others.
- 6.3 Under no circumstances may researchers engage in fabrication or falsification of results or plagiarism.
- 6.4 When publishing, researchers must not misrepresent, exaggerate or distort their findings.
- 6.5 The results of clinical research and clinical trials should not withhold information relevant to full evaluation of the safety, efficacy or utility of clinical interventions, agents or devices under investigation for the benefit of medicine, patients, science and society regardless of research outcome.

Openness

- 6.6 While recognising the need for researchers to protect their own research interests and any relevant intellectual property and confidential information belonging to industry collaborators or sponsors in the process of planning their research and obtaining their results, RCSI encourages researchers to be as open as possible in discussing their work with other researchers and with the public.
- 6.7 Once results have been published, RCSI encourages researchers to make relevant data and materials available to others on request, provided that such provision is consistent with any ethical approval/consent and intellectual property rights applicable to data or materials. This should be carried out in consultation with and approval by the Head of Innovation.

Proactive Problem Solving

- 6.8 In the case of any discrepancies arising where policies, regulations or contractual terms and conditions are unclear or appear to contradict one another, researchers must take active steps to resolve the discrepancies.
- 6.9 It is a researcher's duty to ensure existing copyrights are not infringed.

Accuracy

- 6.10 Researchers must ensure that all publication and presentation of material arising from research is correct and accurate. If it subsequently becomes clear that these conditions are not met, the researcher must take appropriate steps to correct or retract the information in all outlets where it has appeared. Where appropriate, external/funding agencies must also be informed.

Objectivity

- 6.11 Researchers must always be prepared to question the outcome/s of their research. While acknowledging the time commitment involved, RCSI expects research results to be checked before being made public. It is important that ideas can be challenged and tested. Equally, it is important that researchers or research groups must not become subject to such commercial pressures (e.g. constraints imposed by a funding agency) that the normal processes of academic inquiry cannot take place.

Acknowledgement of Contribution to the Research

- 6.12 Appropriate assignment of authorship is an important facet of good research practice. Although definitive rules for authorship are difficult to formulate, RCSI requires that all those listed as authors should have made a significant contribution to the work, are familiar with its content, and can identify their contribution to it. The practice of honorary authorship is unacceptable.
- 6.13 It is good practice to discuss authorship at the start of collaborative projects, rather than when submitting for publication/presentation. All those who have made a significant contribution to the work should be included as authors, and the ordering of names should reflect the weight of individual contributions. However, it is recognised that there is no uniform convention across disciplines for doing so.
- 6.14 In all aspects of research, the contributions of formal collaborators and all others who supported the research, directly or indirectly, must be properly acknowledged, including the supplier of funding where appropriate. This provision applies to any circumstances in which statements about the research are made, including supplying information about the nature and process of the research, and publishing the outcome.

Conflict of Interest

- 6.15 Researchers must comply with RCSI's *Conflict of Interest Policy* which includes declaration of conflicts of interest.

- 6.16 A researcher asked to serve as a reviewer/referee must declare any possible conflict of interest, whether real or perceived, such as competitive, collaborative or other close relationship with one or more of the authors under review, or a close professional or commercial interest in the work. If there is any real or perceived conflict of interest, the researcher must not participate further in the review process, and must return the material unread. The researcher may consult with the Research Integrity Officer if any such circumstances arise.
- 6.17 All information made available to reviewers/referees must be treated in the strictest confidence, and they must not take advantage of any information obtained as a result of their role, e.g. either using ideas or material contained therein or presenting the information as their own. In particular they must not pirate unfunded grant applications, or make use of unpublished work without the author's permission.
- 6.18 In no case should reviewers/referees accept any bribe or inducement.
- 6.19 Researchers should take particular care with sponsored research to avoid any bias in the interpretation of results, or any explicit or implied pressure or inducement which would compromise the integrity of the research or the results.

Whistle-Blowing/Disputes

- 6.20 RCSI takes seriously any allegation of research misconduct. Any member of RCSI who believes that an act of research misconduct has occurred or is occurring should bring it to the notice of the Research Integrity Officer (rio@rcsi.ie).
- 6.21 All allegations of research misconduct or infringements of this Code will be dealt with by the Research Integrity Officer.
- 6.22 If a research integrity-related dispute arises between persons to whom this Code applies, the dispute may be referred to the Research Integrity Officer under paragraph 10.

7. RESPECT FOR THE RIGHTS AND DIGNITY OF RESEARCH PARTICIPANTS

General Respect

- 7.1 Researchers who work with human participants must have appropriate regard for the participants' moral and cultural values, and avoid or refuse to participate in research which is disrespectful of participants' legal, civil or moral rights.
- 7.2 Researchers must give particular attention to safeguarding the rights and dignity of vulnerable individuals and groups who participate in their research.

Privacy and Confidentiality/Anonymity

- 7.3 Intrusion into the privacy of participants must be kept to the minimum necessary to fulfil the purposes of the research.

- 7.4 Researchers must ensure that they fulfil all legal requirements under General Data Protection Regulations as per *RCSI's Data Protection Policies*.
- 7.5 Confidentiality and anonymity are important principles in dealing with data from participants. The term "confidential" usually refers inter alia, to the identity of participants, which should normally be kept private. It is inappropriate to use this term to refer to information which will be published: the appropriate term in this case is "anonymous".
- 7.6 Confidentiality/anonymity (as appropriate) of personal data relating to participants (including data associated with tissue and biological samples) must be protected through implementation of appropriate safeguards. Where participants' identity needs to be retained for matching of data, it must be encoded and the cipher held separately and securely. Where relevant, researchers must seek appropriate data security/management advice in relation to encryption/anonymisation.

Informed Consent

- 7.7 Researchers must obtain prior consent from participants, except where the absence of consent is permitted by law or governmental/institutional regulation, or is explicitly approved by the appropriate ethics committee. Consent, if withdrawn, is prospective. Research conducted heretofore on foot of the consent will remain but no further research will be conducted from the point at which the consent was withdrawn. The form of consent may vary according to the circumstances. However, for it to be valid, the researcher must [usually] ensure that participants:
- Have the capacity to consent;
 - Are provided in language that they can understand, with all information regarding the research that may affect their willingness to participate;
 - Have been given sufficient time and opportunity to discuss and comprehend the risks and benefits of their participation;
 - Are aware that participation is voluntary and that they may withdraw at any time;
 - Have been assured that not participating or withdrawing will have no effect on their subsequent treatment;
 - Are not under inappropriate pressure to participate; understand that they may ask questions and will be given answers regarding their participation;
 - Are advised on what form their data will be stored in and for how long;
 - Have an opportunity to withdraw data relating to themselves;
 - Understand that the intention is to publish the outcomes of the research.
 - Understand that in some cases research might be in collaboration with a commercial partner.
 - Provide written informed consent, unless alternative means have been approved by the appropriate Ethics Committee.
- 7.8 In circumstances where the participant is legally incapable of providing consent or is a child, the researcher should obtain consent from the participant's legal guardian (as distinct from next of kin) in line with best practice as defined by the RCSI Ethics Committee. In this regard see also Section 7.7 above.

For such consent to be valid, the researcher must also:

- Explain to participants in language that they can understand what they are being asked to do;
- Seek their agreement to take part in the research;
- Ensure that their best interests are protected.

7.9 Unobtrusive observation raises ethical questions regarding informed consent and invasion of privacy. Researchers must satisfy the RCSI Ethics Committee that the gain in knowledge justifies the risk to the human dignity of the participants.

7.10 It is recognised that, in addition to expenses, financial or other inducements to participate may be necessary in order to carry out some kinds of research. Care must be taken to ensure that any such inducements are modest and do not constitute an undue inducement to persuade people to act against their better judgement. It should also be approved by the relevant Ethics Committee.

Avoidance of Harm

7.11 Studies should be designed to minimise potential risks and maximise potential benefits to research participants, and ensure that benefits to participants and society outweigh the risks.

7.12 Participants in research must be selected in a fair way. This means that, in general, stigmatised/vulnerable groups may not be selectively targeted to participate in research with potential risk, and privileged groups may not be selectively targeted to participate in potentially beneficial research. Focus on specific population groups is essential for certain research programmes. In these cases, justification of this focus within the ethics approval process is required. Fair selection also requires that, as far as possible, those who bear the risks of research must be in a position to enjoy its benefits.

7.13 Research must be conducted to the highest possible health and safety standards, safeguarding research participants, collaborators, and the general public. Research must adhere to current safety practices and legal requirements.

7.14 Researchers working with children must complete RCSI's Garda Vetting process and comply with relevant guidelines.

8. DATA MANAGEMENT

General

8.1 Issues may arise concerning the ownership, recording and storage of information. However, it is recognised that not all research generates outcomes which can be described as "data". The principles below must be applied as relevant. Researchers working with data have a responsibility to familiarise themselves and comply with the *RCSI Data Protection Policies*.

Ownership of Data

- 8.2 The researcher must, at the outset of the research programme, clarify any issues regarding the ownership of results and of data/samples used or created in the course of the research as directed by *RCSI's Intellectual Property Policy* and the *National Intellectual Property Protocol 2016*. Any such issues must be resolved before the research commences.

Record Keeping

- 8.3 Throughout their work, researchers are required to keep clear and accurate records of research procedures followed, reagents used and results obtained, including interim results. Doing so is necessary, not only as a means of demonstrating proper research practice, but also in case of subsequent queries about either the conduct of the research or the results obtained. Record keeping is also important for the protection of intellectual property rights.
- 8.4 Numbered and logged laboratory notebooks must be kept, and each key document and any changes should be signed and dated.

Data Storage

- 8.5 Data generated in the course of research must be kept securely in paper or electronic form, as appropriate, and back-up records must always be kept for data stored on a computer. Data must be stored in such a way that permits a complete retrospective audit, if necessary, and records must be monitored regularly to ensure their completeness and accuracy.
- 8.6 RCSI expects data to be securely held for a minimum period of ten years after the completion of a research project, in line with general audit requirements. Some funding bodies may require data to be kept for longer periods. It is the responsibility of the Principal Investigator to ensure that data retention meets with the requirements of the funding body in such cases.
- 8.7 If Principal Investigators leave RCSI, for whatever reason, before the required period of data retention expires, they have a responsibility to ensure that the data are securely held by RCSI.
- 8.8 If postdoctoral researchers or postgraduate students leave RCSI, for whatever reason, before the required period of data retention expires, they must leave all research records (for example, laboratory books) with the Principal Investigator.

9. DISSEMINATION

Academic Freedom and Protection of Intellectual Property

- 9.1 RCSI supports the freedom to publish research findings in compliance with *RCSI's Intellectual Property Policy*.
- 9.2 Should external funders exert pressure to suppress results which they perceive to be detrimental to their interests, RCSI will take whatever action it deems necessary and possible to support freedom of expression.

- 9.3 In negotiating contracts with external funders, the right to publish the results should be protected. It is the responsibility of the Office of Research and Innovation, on behalf of RCSI, in consultation with the individual researcher, to ensure that adequate terms have been agreed.
- 9.4 There may be occasions when a legitimate request for deferral of publication is made (for example, where an industrial partner wishes to safeguard intellectual property). RCSI expects that the period of deferral should not normally exceed six months.
- 9.5 RCSI regards appropriate protection of intellectual property rights (IPR) as important. Researchers must clarify issues of IPR at the outset, particularly in the case of collaborative research, and they should pay due regard to refraining from publication or disclosure until it is clear that any necessary protection has been secured.

Publication Practice

- 9.6 Researchers must make all reasonable attempts to present their research to the academic community through peer-reviewed papers, books, presentations or other suitable media and, where appropriate, to the public. Research of suitable quality should be published and/or made available in a form that is appropriate to the particular discipline concerned and the target audience. Most academic journals give detailed guidance to authors on format and rules concerning issues such as redundant or secondary publication.
- 9.7 Researchers must ensure that experiments included in publications are repeated a minimum of three (3) times or in line with best practice according to the research subject matter involved.
- 9.8 Where research participants have been involved, it may be appropriate to inform them of the outcome of the study.
- 9.9 Where applicable, authorisation for publication of results must be sought from the Principal Investigator. Authorisation should cover both the content of the publication (integrity of results, adequacy of internal peer review, appropriate protection of intellectual property rights, appropriate authorship) and the intended place of publication.
- 9.10 In general, except where there is an alternative contractual arrangement, research findings must not be reported in the public media before they have been reported to a research audience of experts in the field of research - preferably by publication in a peer-reviewed journal or in an authored book, published by a reputable publisher.
- 9.11 While describing research inevitably involves the use of discipline-specific terms, it is always good practice to use as clear and accurate language as possible, without recourse to unnecessary jargon. Clarity is particularly important when communicating with a lay audience.
- 9.12 Researchers must include in their publications a statement declaring any conflicts of interest (cf. Para. 6.15-19).

9.13 Researchers should avoid artificial proliferation of publications.

10. PROCEDURE IN THE EVENT OF SUSPECTED RESEARCH MISCONDUCT/DISPUTES

10.1 Complaints of possible infringements of the RCSI Code of Research Conduct, and requests for the resolution of research integrity related disputes, should be made in writing and addressed to the Research Integrity Officer as per *RCSI Procedure for the Investigation of Misconduct in Research*.

REFERENCES

European Code of Conduct for Research Integrity

(https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf)

EU Clinical Trials Directive (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf)

EU Clinical Trials Regulation (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)

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<https://www.medicalcouncil.ie/News-and-Publications/Reports/Guide-to-Professional-Conduct-and-Ethics-8th-Edition-2016-.pdf>

National IP Protocol 2016 (<http://www.knowledgetransferireland.com/ManagingIP/KTI-Protocol-2016.pdf>)

National Policy Statement on Ensuring Research Integrity in Ireland (<http://www.iaa.ie/wp-content/uploads/2014/06/National-Policy-Statement-on-Ensuring-Research-Integrity-in-Ireland-2014.pdf>)

RCSI Conflict of Interest Policy (<http://staff.rcsi.ie/administration-and-support/human-resources/policies-and-procedures/attachment/conflict-of-interest-policy-final-27-06-17>)

RCSI Data Protection Policies <http://staff.rcsi.ie/administration-and-support/records-management/about-data-protection/policies-procedures>

RCSI Intellectual Property Policy <http://staff.rcsi.ie/wp-content/uploads/2012/10/RCSI-Intellectual-Property-Policy-2017-FINAL.pdf>

RCSI Procedure for the Investigation of Misconduct in Research <http://staff.rcsi.ie/wp-content/uploads/2018/12/RCSI-Procedure-for-the-Investigation-of-Misconduct-in-Research.pdf>

RCSI Research Ethics website (http://www.rcsi.ie/Research_Ethics)

RCSI Researcher Handbook (<http://staff.rcsi.ie/wp-content/uploads/2012/11/Researcher-Handbook.pdf>)

World Health Organisation Handbook for Good Clinical Research Practice – Guidance for Implementation

http://apps.who.int/iris/bitstream/handle/10665/43392/924159392X_eng.pdf?sequence=1&isAllowed=y

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APPENDIX A

Role of Research Integrity Officer (RIO).

According to the National Forum on Research Integrity Position Paper on ‘Research Integrity Officer Role and Reporting’ the RCSI RIO (and nominated alternate) will have the following responsibilities:

- Assisting RCSI to put in place appropriate policies regarding adherence to principles of research integrity and a published procedure for the investigation of allegations of research misconduct against either staff or students, in accordance with the staff and student disciplinary codes;
- Advising RCSI on the provision of Research Integrity training for both staff and students, but not be personally involved in delivering that training;
- Assisting RCSI in the processing of any instances of allegations of research misconduct against staff or students, namely:
 - receiving any allegations of misconduct in research;
 - taking, in liaison with appropriate colleagues if required, the decision as to whether the allegations pertain to research misconduct based on the definitions in the National Policy Statement on Ensuring Research Integrity in Ireland, and if not, which alternate route RCSI should take to address the allegations, e.g. direct referral to RCSI’s disciplinary or other internal processes;
 - initiating RCSI’s procedure for investigating allegations of misconduct in research;
 - collating the information record of the investigation and subsequently reporting on the investigation with internal contacts and external organisations where appropriate;
 - reporting to the National Forum Secretariat, on an annual basis, the number of investigations carried out by RCSI, the number upheld and an overview of the types of misconduct observed.

The RCSI RIO will not be involved in deciding whether individual allegations of research misconduct should be upheld. This decision will be made via RCSI’s process for investigating allegations of misconduct in research. While the RIO will initiate and coordinate the process, they shall not personally participate in any investigation panels/process nor seek to influence the work or findings of said panels/process.

The RCSI RIO should generally be:

- an individual within the organisation with significant knowledge and experience of research, but not the CEO/Registrar, Director of Research or the Human Resources Director;
- have the appropriate competence, training and mandate to perform the role, including the authority to resolve conflicts that do not merit a full investigative proceeding;
- have the links to appropriate higher level authorities within the organisation.

To allow for cases where the appointed RIO has a potential conflict of interest with the complainant or respondent or is otherwise involved in the case, RCSI should also have a formally nominated alternate to whom allegations can be brought to directly, or be referred by the RIO. In addition, to facilitate a “no-wrong-door” approach for reporting of allegations, RCSI should inform all staff that any person who brings an allegation of misconduct in research to them should instruct the complainant, in confidence, to bring the allegations to the RIO or their alternate.

The term of appointment of a Research Integrity Officer will typically be between 3 and 5 years and will not normally be held on a full time basis.