THE INSTITUTE OF CANCER RESEARCH: ROYAL CANCER HOSPITAL

Good Research Practice Guidelines

1. Introduction

The Institute of Cancer Research, London, has a reputation as a world leader in the biology of cancer and its application to treatment built over more than 100 years of groundbreaking and rigourous research. In order to fulfil our mission to make the discoveries that defeat cancer, we strive for excellence in our research and are committed to honesty and integrity in the way it is carried out, to openness and co-operation, and to accountability to funding bodies and the public. We aim to provide the training required not only to develop new researchers but also to foster a culture of research integrity, openness and collaboration among both trainees and established researchers. Finally, we strive to do this within an environment that is as safe as possible for researchers, research participants and the wider public.

The Institute of Cancer Research (ICR) has developed Guidelines on Good Research Practice to emphasise the importance of integrity and rigour in all research carried out at, and in partnership with, the ICR, and to help ensure that all researchers are aware of their obligations with respect to proper scientific conduct.

This statement summarises good practice in research, signposting external references where applicable. It is intended mainly for external stakeholders such as funding bodies, patients and the general public. For ICR staff (including those with an honorary contract and visiting workers) and students carrying out research at or on behalf of the ICR, there is a more detailed internal guideline with links and contacts that can be viewed on the ICR intranet (Nexus).

Regulations and Guidelines

The ICR is committed to conducting its research in accordance with relevant laws, regulations and good practice guidelines as summarised in Table 1 below:

Table 1. *Laws, regulations and guidelines relevant to good research practice*

Category	Law, regulation or guideline and key external links
Human subjects research	• EU Directive for Clinical Trials: www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf • Medicines for Human Use (Clinical Trials) Regulations 2004: www.legislation.gov.uk/uksi/2004/1031/contents/made • Mental Capacity Act 2005: www.legislation.gov.uk/ukpga/2005/9/contents • Human Tissue Act 2004: www.legislation.gov.uk/ukpga/2004/30/contents • UK Policy Framework for Health and Social Care Research: www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
Animal research	• Animals (Scientific Procedures) Act 1986: www.legislation.gov.uk/ukpga/1986/14/contents • Animal Research: Reporting of *In Vivo* Experiments (ARRIVE) guidelines: www.nc3rs.org.uk/arrive-guidelines • Concordat on Openness on Animal Research: https://www.understandinganimalresearch.org.uk/regulation/concordat-openness-animal-research
Health and safety	• Health and Safety at Work etc. Act 1974: www.legislation.gov.uk/ukpga/1974/37 • Control of Substances Hazardous to Health Regulations 2002: www.legislation.gov.uk/uksi/2002/2677/regulation/7/made
Research integrity	• Concordat to Support Research Integrity: https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity • Code of Practice for Research (UK Research Integrity Office): ukrio.org/publications/code-of-practice-for-research/; checklist: ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf
Core Facilities Acknowledgement	• Recommended Guidelines for Authorship on Manuscripts: https://www.abrf.org/authorship-guidelines
Governance, accountability and transparency	• Data Protection Act 2018: www.legislation.gov.uk/ukpga/2018/12/contents/enacted • EU General Data Protection Regulation Directive: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL&from=EN • Anti-bribery & anti-corruption laws

2. Responsibility and Leadership

Overall responsibility for good research conduct rests with the ICR's Research Committee.

Heads of Division and Team Leaders are responsible for mentoring research staff within their Teams/Divisions and ensuring that staff and students in their teams adhere to good practice guidelines and relevant regulations.

The ICR has a policy for the approval and submission of grant applications, whether or not submitted through the ICR. The policy provides the ICR with a robust system for obtaining an overview of upcoming grant submissions, ensuring strategic relevance, high quality, and the greatest chance of success in an increasingly competitive environment for research funding. Only members of ICR Faculty, Honorary and Associate Honorary Faculty, and Principal Statisticians can apply for grants as Principal Investigator. Other staff, including Staff Scientists, Core Research Facility Managers and Post-Doctoral Training Fellows, may act as co-investigator on external research grant applications where there is an ICR Faculty member also listed.

For fellowships at independent team leader level, or posts of equivalent status, approval for the position must be obtained from the Faculty Recruitment and Progression Committee if the individual applying does not already hold ICR Faculty/Team Leader status. This process applies to both internal and external candidates.

There are separate procedures for approval of engagements with industrial sponsors. All contracts covering industrial support for research must be negotiated by the Business and Innovation Office.

The Research Committee reviews major programmes of research and advises on overall research strategy. Researchers are required to read the terms and conditions of a grant award and of a proposed industrial collaboration and ensure that they can meet the obligations before it is accepted. Grants and industrial contracts can only be signed by authorised signatories.

3. Ethical practice in Research

The Committee for Clinical Research (CCR) is a sub-committee of the Clinical Research Governance Committee of the Royal Marsden NHS Trust (RM) and the ICR, and is responsible for approving all clinical research proposals (see section 3.1).

The ICR Animal Welfare and Ethics Review Body (AWERB) reviews all proposed research involving animals (see section 3.2).

3.1 Research involving human participants:

3.1.1 The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. All research involving patients/users of the NHS, carers/relatives of NHS patients, access to data/organs of past/present NHS patients, NHS staff or carried out on NHS premises requires approval from an NHS Research Ethics Committee. All research involving human participants must be submitted to the Joint ICR/RM Clinical R&D office and must comply with the UK Policy Framework for Health and Social Care Research.

3.1.2 Additional regulatory approval must be obtained as required, for example:

- Medicines & Healthcare products Regulatory Agency (MHRA)
- Human Fertilisation and Embryology Authority
- Gene Therapy Advisory Committee.

3.1.3 Researchers must ensure the confidentiality, integrity, availability and security of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the Data Protection Act 2018, General Data Protection Regulation and common law duty of confidentiality.

ICR staff and students must abide by all ICR Information Governance and Information Technology policies in relation to storing, using, sharing and destroying sensitive information.

3.1.4 Researchers must follow the joint ICR/RM policy on the Removal, Storage, Use and Disposal of Human Tissue for Research.

ICR and RM both have site licences for 'storing human organs, tissues and cells for research purposes other than for a specific ethically approved research project'. Human tissue which is being stored for a specific ethically approved project does not require a licence. However, to continue to store human tissue consented for future undefined research (i.e. not for a specific project with ethical approval) or after an ethically approved project is complete, it will need to be stored under a licence.

ICR and RM keep a record of all tissue collections stored on their premises, both under their HTA licence and tissue stored for a specific ethically approved project. FreezerPro is the software the ICR and RM have chosen as centralised database for tracking sample collections.

3.2 Research involving animals

3.2.1 All biomedical research must comply with both the letter and the spirit of the Animals (Scientific Procedures) Act 1986 (the Act) - widely viewed as the most rigorous piece of legislation of its type in the world - which regulates any experimental or other scientific procedure applied to a protected animal that may have the effect of causing that animal pain, suffering, distress or lasting harm (a regulated procedure). The overall responsibility for ensuring compliance with the provisions of the Act is held by the Certificate Holder. This position is currently held by the ICR Chief Executive.

3.2.2 Before any regulated procedure is carried out it must be part of a programme specified in a project licence and carried out only by a person holding an appropriate personal licence. Applications for the grant of a project or personal licence are made to the Secretary of State for the Home Office. Copies of the application forms and notes on their completion are available on the Home Office website.

3.2.3 No application for a project licence can be made to the Home Office until it has been approved by the AWERB. The AWERB includes the Named Veterinary Surgeon, Named Animal Care and Welfare Officers, Named Training and Competency Officer, scientific staff members and lay people (some of whom are independent of the ICR). The AWERB scrutinises all proposals for their scientific and ethical justification of animal use. The AWERB also provides information and advice about ethical analysis, best practice in animal welfare and new developments in techniques that avoid animal use. This is in line with the aim of the AWERB to develop initiatives leading to the widest possible application of the '3Rs', namely:

- Replacement (of animals with non-sentient alternatives),
- Reduction (in animal numbers) and
- Refinement (of techniques to minimise pain and suffering).

Researchers must consider, at an early stage in the design of any research involving animals, the opportunities for Reduction, Replacement and Refinement of animal involvement. The ICR recommends that researchers should refer to the Guidelines for the welfare and use of animals in cancer research, Workman et al. British Journal of Cancer (2010) 102, p1551-1577. ICR is committed to enhancing public understanding of the need for animals in cancer research and has signed the Concordat on Openness on Animal Research.

3.3 Researchers should keep a record of all approvals granted during the research process.

4. Health and Safety

All research staff and students must undertake mandatory health, safety & environment (HS&E) induction training and must comply with the relevant HS&E Policies and Procedures.

Researchers must read and sign a copy of the Local Rules for the areas in which they work.

Hazardous work activities must be risk assessed. Typical laboratory risk assessments may include work with genetically modified organisms, unsealed radioisotopes, hazardous chemicals, clinical specimens and biological agents. DSE (Display Screen Equipment) workstation assessments are required for all researchers who use a computer for more than 1 hour per day.

Accidents, near misses and environmental incidents must be reported promptly online using the Alcumus website.

The HS&E team run a variety of training courses that are highly recommended or mandatory for certain roles and activities.

There is an HS&E Advisor allocated to each Division available to provide advice and assistance to researchers on health, safety and environment matters.

5. Data, samples and equipment

5.1 Ownership: There should be clarity at the outset of a research project as to the ownership, use, storage and disposal of:

- Data and samples used or created in the course of the research
- The results of the research
- Equipment paid for by funders.

Consideration should be given to how the project's research data is to be preserved for the benefit of future researchers beyond the lifecycle of the project.

The ownership of data generated using a core facilities equipment lies with the researcher and their research team. The responsibility of storage and management of data generated from a core facilities equipment lies with the research team and not the core facilities.

5.2 Record Keeping: Researchers should keep clear and accurate records of the procedures followed during the research process, including records of the interim results obtained as well as of the final research outcomes. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained. Properly maintained notebooks may be used in evidence when establishing ownership of inventions. The ICR has internal policies for the preservation of laboratory notebooks, records management, records retention and security of sensitive information.

Data generated in the course of research must be kept securely in paper or electronic format, as appropriate. Back-up records should always be kept for data stored on a computer.

The ICR's Data Storage Policy sets out the requirements for secure storage of ICR computer-based data and aims to protect the confidentiality, integrity and availability of ICR information resources in line with all relevant legislation, policy and standards.

6. Integrity and Financial Probity

Researchers must be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, including designing experiments, generating and analysing data, applying for funding, publishing results, and when peer reviewing the work of other researchers. The direct and indirect contributions of colleagues, collaborators and others should be acknowledged (see Section 10, Dissemination and Publication of Results). ICR subscribes to the Universities UK Concordat to Support Research Integrity.

Researchers are expected to understand and apply the following principles:

6.1 Plagiarism, deception, or the fabrication or falsification of results are regarded as serious disciplinary offences. The ICR Code of Practice for Plagiarism and Examination Offences applies to all students registered on any of the ICR's taught courses and research degrees.

6.2 Researchers are encouraged to report cases of suspected misconduct, and to do so in a responsible and appropriate manner. The ICR's approach to managing these issues is described in detail in the Procedure for the Investigation of Misconduct in Research.

6.3 Research staff must declare and manage any real or potential conflicts of interest, both financial and professional. The ICR's Business and Innovation Office Conflicts of Interest and Competing Financial Interests in Research policy provides a standard by which all ICR staff must abide.

Areas of potential conflict might include:

- Where researchers have an existing or potential financial interest in the outcome of the research;
- Where there is a private or private practice benefit significantly dependent upon the outcome of the research;
- Where the researcher's professional or personal gain arising from the research may be more than might be usual for research.

7. Training and Supervision

The ICR is committed to training its research staff and students to ensure they are aware of their responsibilities and have the required skills for their work and study. The ICR subscribes to the Concordat to Support the Career Development of Researchers.

All staff and students at the ICR are expected to undertake a series of mandatory training programmes during their probation period including health and safety, data protection and information management.

The ICR Code of Practice for the degrees of MPhil, PhD and MD (Res) detail the generic skills training which should be completed by students and how supervisors should assess and monitor students' training needs.

Only those individuals who hold 'Institute Recognised Supervisor Status' are eligible to act as primary and secondary supervisors for research degree students.

8. Intellectual Property

Researchers must inform the Business and Innovation Office of any intellectual property arising from their research or any substantial interactions with industry. Where the research is externally funded there may be a requirement to inform the funder.

9. Dissemination and publication of results

When publishing or disseminating their research or research findings including any plans they may have to publish or publicise research at conferences or on web sites, researchers should keep in mind that the first priority is benefit to patients, the general public and the scientific community. Researchers should adhere to the following guidance:

- Published ICR research should conform to the highest standards of reproducibility and robustness. This includes *inter alia* taking special care over choice of cell lines and use of chemical probes.
- Before deciding where to publish research researchers should check their funder's open access policies and make sure the publisher's open access policies enable them to comply with ICR's Open Access policy, and to meet any specific requirements the funder may have.
- The funder should be notified in advance when the research might be published.
- Before a paper is submitted for publication, research staff should consult the ICR's Policies and Practices on Intellectual Property.
- For each piece of published research, researchers must include a financial disclosure statement, even if this means stating that there were no competing financial interests and even if the journal does not require such a disclosure.
- All funding sources must be acknowledged in any publication or publicity.

The ICR is a signatory of the San Francisco Declaration on Research Assessment (DORA), which promotes the development of robust and time-efficient ways of evaluating research and researchers. In signing DORA, the ICR will no longer consider journal impact factors in decisions around the hiring and promotion of academic staff.

9.1 Authorship

Responsibility for determining the inclusion of authors on a paper and the order in which the authors' names appear with the senior (or corresponding) author.

A consensus on the authorship list should be reached as far in advance as possible, allowing for flexibility to accommodate the unpredictable nature of research. Anyone listed as an author should accept responsibility for ensuring that they are familiar with the contents of the paper and can identify their contribution to it. A person's status or position should have no influence on their inclusion or exclusion as an author. In the case of 'team science' projects it is recognised that all members of the team may have legitimate claims to authorship and these should be accommodated where the senior author(s) deem(s) it appropriate.

The ICR Core Facilities provide essential services for their users, and it is crucial to recognise their contributions to scientific advancement at the ICR. Therefore, it is ICR’s policy to recognise the contribution of Core Facilities to ICR research by authorship or acknowledgement in publications and presentations as outlined in the Facilities Acknowledgement Policy.

The granting or acceptance of 'guest' or 'honorary' authorship on ICR papers or on behalf of ICR researchers is unethical and is not permitted. Disputes over authorship rights should be resolved locally but where this is not possible anyone can refer a dispute to the Chair of the Research Committee who will determine who on the Research Committee should arbitrate. The decision of the arbitrator may be appealed to the Executive Board. Anyone suspected of deliberate or reckless misrepresentation of authorship may be subject to disciplinary procedures as described in the Procedure for the Investigation of Misconduct in Research.

The contributions of all others who directly assist or indirectly support the research should be both specified and properly acknowledged.

9.2 Image Integrity

Researchers should ensure that scientific images within publications, presentations or any other type of dissemination clearly and correctly represent research findings. Any manipulation of an image, or part of an image, that changes the interpretation of the data is misrepresentation of the original data and as such is a form of research misconduct. When publishing images, journal guidelines for permissible image processing should be followed. Any changes made to images should be clearly documented, and the original unprocessed image should be retained in all cases.

Further guidance on acceptable and unacceptable image processing is available from the UKRIO website.

10. Openness

Whilst recognising the need for researchers to protect their own academic and, where appropriate, their intellectual property rights (IPR), the ICR encourages researchers to be as open as possible in discussing their work with other researchers and with the public. Researchers should however be especially careful when discussing work that is not complete or has not been published and must not discuss work where confidentiality agreements are in place, or it has been agreed that a third party (e.g. funder) will own in full or part intellectual property arising from the research, until the appropriate publication approval process has been gone through, which will be set out in an industrial contract or in grant terms and conditions.

Researchers are encouraged to publish and present their work through the usual academic channels of peer-reviewed journals and conferences (see Section 9, Dissemination and Publication of Results). Where publication is not possible or would be unduly delayed, researchers are encouraged to use alternative platforms such as pre-print and post-publication peer review servers, the ICR website and reputable sharing sites, in order to make data, protocols, code, presentations etc. available to a wide audience. Researchers are also encouraged to make available 'negative', confirmatory and contradictory results where to do so might benefit the scientific community, patients or the general public.

11. Patient aspects / consumer involvement

Commitment to patient and public involvement is pivotal in making sure that ICR undertakes scientific and clinical research that is focussed on the needs of patients, carers and the public. Researchers should encourage and support cancer patients and representatives to work alongside them and health professionals and make meaningful contributions throughout all stages of research such as research prioritisation, management and dissemination.

The Public & Patient Involvement (PPI) Strategy of the joint RM/ICR Biomedical Research Centre (BRC) details how we involve patients as partners in our research and engage with the public to raise awareness of the clinical research we undertake. Involvement helps us to identify the issues most important and relevant to those directly affected by cancer and its treatments. Patients, carers and the public support us in every stage of our research by:

- Identifying important issues that could be addressed by research, such as treatment side effects
- Ensuring that the materials we produce for patients and the public, such as leaflets, are informative and easy to understand.

All researchers are strongly encouraged to involve patients in their work and the BRC offers support and advice on how to do this successfully. Further details about user involvement may be found in NIHR's Briefing notes for researchers.

12. Monitoring and Audit

Research staff are expected to co-operate with both internal and external monitoring and audit visits.

12.1 Internal Audit: The ICR Clinical Trials and Statistics Unit (CTSU) is responsible for providing monitoring and audit for clinical research projects at the ICR. In addition, there is internal audit of human tissue management.

12.2 External Audit: Regulatory authorities such as the MHRA, Human Tissue Authority and NHS Digital have the right to audit research. Research funding organisations/sponsors may also request to undertake an audit of research they are supporting.