Good Research Practice: external version of guideline

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 not only for excellence in our research but also for honesty and integrity in the way it is carried out, for openness and co-operation, and for 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.

All researchers are also required to comply with the relevant ICR policies.

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 • Mental Capacity Act 2005 • Human Tissue Act 2004: www.legislation.gov.uk/ukpga/2004/30/contents • UK Policy Framework for Health and Social Care Research: https://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
Health and safety	• Health and Safety at Work etc. Act 1974: http://www.legislation.gov.uk/ukpga/1974/37 • Control of Substances Hazardous to Health Regulations 2002
Research integrity	• Concordat to Support Research Integrity: www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf • Code of Practice for Research (UK Research Integrity Office): http://ukrio.org/publications/code-of-practice-for-research/; checklist: http://ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf
Governance, accountability and transparency	• Data Protection Act 1998: www.legislation.gov.uk/ukpga/1998/29/contents • Anti-bribery and anti-corruption laws • Concordat on Openness on Animal Research: www.understandinganimalresearch.org.uk/policy/concordat-openness-animal-research/

2. Responsibility and leadership

Overall responsibility for good research conduct rests with the ICR's Executive Board.

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

The ICR has a formal procedure for submitting and authorising grant applications that includes review by a scientific member of the Executive Board. Only members of ICR Faculty can apply for grants as Principal Investigator.

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

The ICR Animal Welfare Advisory and Review Body (AWERB) reviews all proposed research involving animals.

3. Ethical practice in Research

Research involving human participants

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

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

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

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 1998, EU General Data Protection Regulation and common law duty of confidentiality.

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

Researchers must follow the joint ICR/Royal Marsden policy on the Removal, storage, use and disposal of human tissue for research. The ICR and The Royal Marsden 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, but retention of human tissue for future undefined research after an ethically approved project is complete requires a licence.

The ICR and The Royal Marsden keep a record of all tissue collections stored on their premises, both collections stored under their licence and tissue stored for a specific ethically approved project.

Research involving animals

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 Chief Executive Officer.

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.

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, animal care staff and lay people (some of whom are independent of the ICR) and 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 an 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. The 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.

4. Health and safety

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

Hazardous work activities must be risk assessed, and accidents, near misses and environmental incidents must be reported promptly.

5. Data, samples and equipment

Ownership

Researchers are encouraged to seek 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.

Researchers are urged to consider how the project's research data are to be preserved for the benefit of future researchers beyond the life cycle of the project.

Record keeping

Researchers are required to 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. The Secure 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

ICR researchers are expected to 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. The ICR subscribes to the Universities UK Concordat to Support Research Integrity.

Researchers are expected to understand and apply the following principles:

- Plagiarism, deception, or the fabrication or falsification of results, are regarded as serious disciplinary offences.
- Cases of suspected misconduct, should be reported 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 (PDF, 253KB).
- Research staff must declare and manage any real or potential conflicts of interest, both financial and professional. The ICR's detailed policy on Declaration of Conflicts of Interest and Competing Financial Interests is available publicly.

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 has signed up to the principles of the RCUK, 2008 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.

Only those individuals who hold ‘Institute recognised supervisor status’ are eligible to act as primary and back-up supervisors for research degree students.

8. Intellectual property

The ICR has internal policies on the management of any intellectual property arising from our research and any substantial interactions with industry.

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 are asked to 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 are required to check their funder’s open access policies and make sure the publisher's open access policies enable them to comply with the 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.
- 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.

Authorship

Responsibility for determining the inclusion of authors on a paper and the order in which the authors' names appear lies 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 he or she is familiar with the contents of the paper and can identify his or her 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 authors deem it appropriate.

The granting or acceptance of 'guest' or 'honorary' authorship on ICR papers or on behalf of ICR researchers is unethical and is not permitted. The ICR has a procedure for resolving disputes over authorship rights. 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.

10. Openness

Whilst recognising the need for researchers to protect their own academic and, where appropriate, their intellectual property rights, the ICR encourages researchers to be as open as possible in discussing their work with other researchers and with the public. Researchers are however advised to 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. 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 the ICR undertakes scientific and clinical research that is focussed on the needs of patients, carers and the public. Researchers are asked to encourage and support cancer patients and representatives to work alongside them and health professionals and make meaningful contributions in key areas such as research prioritisation, management and dissemination.

The Public & Patient Involvement (PPI) strategy of the Biomedical Research Centre at The Royal Marsden and the ICR aims aim to involve patients and the public at every stage of the research cycle, ensuring that we carry out research that reflects issues considered important and relevant to those potentially affected by it.
The strategy seeks to involve and engage patients in six main areas:

- Prioritisation and input into research ideas
- Input into study design
- Training (researchers, trainees and support staff)

- Training (patient involvement representatives)
- Information outlets
- Events.

Those involved in clinical research are asked to consider how best to incorporate these principles into their research and can seek advice from BRC staff and via the MRC's Clinical Research Governance documents on how to do so.

12. Monitoring and audit

Research staff are expected to co-operate with both internal and external monitoring and audit visits. Regulatory authorities such as the MHRA, Human Tissue Authority and NHS Digital have the right to audit research. Research funding organisations may also request to undertake an audit of research they are supporting.