Good Research Practice Guidelines

The Sanger Institute guidelines on Good Research Practice reflect our commitment to a research culture founded on honesty, integrity and respect in order to create an open environment of creative exchange of ideas and views. These guidelines are designed to lay out the Institute's expectations with respect to Good Research Practice and the behaviours which support our research culture. The guidelines also highlight the importance of compliance with Institute research policies and all relevant regulatory and/or legal requirements, including contractual requirements, funder terms and conditions and ethical norms. Equality and diversity are integral components of Good Research Practice and we expect researchers to give consideration to equality and diversity in all aspects of their work including experimental design.

There is no absolute set of rules that researchers can follow to ensure Good Research Practice. These guidelines outline the principles that underpin Good Research Practice and include behaviours we expect from all researchers at every level.

We expect all researchers to behave with honesty and integrity, and respect fellow staff, students, collaborators, research participants, animals and the environment.

This policy will be reviewed every three years unless changes are required due to changes in legislation, regulations or the expectations placed upon us by research funders.

We welcome all feedback on the content of the guidelines or ideas for embedding Good Research Practice in our research. Please contact directorsoffice@sanger.ac.uk.

1. Defining Good Research Practice

Research at the Sanger Institute must uphold the highest standards of integrity and rigour and demonstrate respect in all areas of work. It must be conducted in accordance with all applicable ethical and legal regulation, and Institute policy. In order to achieve this the Institute expects all those involved in research to understand their responsibilities, and the Institute has a responsibility to provide the necessary support. We define Good Research Practice within four pillars:

1. Research ethics, integrity and reporting
2. Respect, ethical behaviour and professional standards
3. Training, mentoring and leadership
4. Research visibility and impact

These four pillars are consistent with broader expectations placed on all staff, whether engaged in research or not, to demonstrate honesty, integrity and respect. Senior staff should also support staff development, including their own, engage with the Institute through committee membership, and create an environment where views, from concerns to new ideas, will be actively listened to and acted upon.

1.2 Research ethics, integrity and reporting

The Sanger Institute expects high standards in the design, conduct and reporting of its research. These expectations include accepting personal responsibility for the integrity of the research and reporting, and ensuring appropriate experimental design; balancing scientific need and rigour with ethical safeguards.

Researchers should be familiar with the legal, ethical and regulatory requirements associated with their research, as well as relevant internal research policies. Steps should be taken to recognise and mitigate

risks associated with research and minimise any adverse impact on people, animals or the natural environment. Any possibility of the use of research outputs for harmful purposes should be recognised, consideration given to whether the research is justified and steps taken to minimise the risk.

Planning for necessary agreements and approvals is a key part of ethical research and good research design. Agreements and ethics approvals must be fully in place and active prior to research commencing.

Clear and accurate recording and documentation of research is a cornerstone of good research practice. Researchers must take responsibility for ensuring the accuracy of the research record and for ensuring that they fulfil all ethical and regulatory obligations. Honest mistakes happen, but researchers must be willing to correct the public research record.

Reproducibility is a critical aspect of experimental design and researchers are responsible for ensuring that others are able to reproduce or replicate their results by providing sufficient methodological information and/or making data sets available to other researchers.

The Institute provides a process for reporting concerns of academic misconduct and how any resulting investigation must be run. This is available to all staff on Fred and on the website.

1.3 Respect, ethical behaviour and professional standards

Researchers should be honest in all their actions and in their responses to the actions of others. Honesty and transparency are necessary across the entire spectrum of research related activity including, but not limited to, research planning, mentoring, collaboration, and sharing and distribution of research outputs. Being open, listening to and acting on concerns or even criticism is a key aspect in developing an open and transparent research culture.

Collaboration is at the heart of the scientific strategy of the Sanger Institute. Researchers are expected to foster a culture of openness and creativity, and encourage exchange of ideas and partnerships both within and beyond the Institute.

Researchers should acknowledge the contributions of others. Issues of authorship, recognition and intellectual property rights should be discussed and agreed at the earliest opportunity and decision making should be transparent and documented where necessary.

Our professional research support services (Grants, Legal, Ethics and Governance, and Health and Safety) are critical for good research practice. Their role is to safeguard our reputation as a trusted source of excellent science and support researchers to meet their legal and ethical obligations. Researchers should seek advice from them where necessary, in a timely manner, and recognise their role in supporting research integrity.

Researchers should be cognisant of real or potential conflicts of interest; these can be financial or otherwise. It is individuals' own responsibility to declare conflicts of interest, and register them in accordance with GRL policy.

1.4 Training, mentoring and leadership

We are committed to developing the next generation of scientists and scientific leaders, recognising that many of these roles will be outside academic research groups.

All researchers are responsible for ensuring that they have the necessary skills and training to carry out their research. Researchers with management or supervisory responsibilities are responsible for

ensuring that their staff or students have appropriate training and understand their responsibilities with respect to the research they are undertaking.

In fostering a culture of good research practice based on the principles outlined in this document, all researchers are encouraged to engage in training and activities beyond the immediate remit of their research, for example, management training, public engagement or enterprise and innovation. Students and early career researchers should be allowed and encouraged to develop a broad skill set that will ensure they develop good practice with respect to research integrity and support their future careers.

Excellent scientific leadership requires skills and behaviours beyond those needed for good research. Researchers should seek personal development and training throughout their careers to support the development of leadership skills, inclusive and professional behaviours and ensuring awareness and good practice regarding equality and diversity.

1.5 Research visibility and impact

Sanger Institute researchers should strive to maximise the impact of their research by considering the best approach to distribution of their research outputs and resources. To this end the Institute has policies on open access publishing, translation and IP and sharing software. Where resources have been developed using Institute core funding, researchers are encouraged to make resources available to the research community. Researchers should bear in mind that while open access and open source will often be preferable there may be situations, particularly with respect to sustainability, where licensing of research outputs may be more suitable.

Translation, public engagement and policy engagement are activities that increase the impact of research. The Institute allows researchers time to participate in these and recognises the importance of these activities.

2   Academic Misconduct

Allegations of academic misconduct are rare, but the Sanger Institute takes them very seriously. We are committed to ensuring that all allegations of academic misconduct are investigated thoroughly, fairly and in a timely manner. Failure to conform to the standards of honesty, integrity, and respect outlined in this document or which egregiously breaches of regulation, legislation or the internal research policies (below) could be considered academic misconduct. There is a fuller definition of academic misconduct and defined procedure for handling an allegation of academic misconduct and running an investigation available on Fred.

All staff at the Sanger Institute are required to report any concerns about possible misconduct. Staff can informally resolve an issue if the suspected misconduct is basic or minor and the staff member feels comfortable doing so. If the problem cannot be resolved informally or is too serious it must be handled using the formal process.

3   Other Research Policies

The Sanger Institute has a number of other policies covering the research undertaken at the Institute. Some of these policies will also affect research undertaken by collaborators or within collaborations. Institute researchers are expected to know what Institute policies, and regulatory and legal requirements apply to their research and ensure compliance. The Legal, Ethics and Governance Office – legal@sanger.ac.uk and ethicsandgovernance@sanger.ac.uk - is always available to provide advice on research regulation, research ethics, and contractual and legal requirements and researchers are

strongly encouraged to discuss all new projects with them. Research policies and guidelines are available in full on Fred.

3.2 Animals in Research

In order to use animals in research, all staff must comply with all relevant Wellcome Sanger Institute policies and the Animals (Scientific Procedures) Act (as amended). The Animals in Scientific Procedures Policy outlines the measures that are required to be taken at the Sanger Institute in order to fulfil these requirements and also covers the provision of facilities for housing animals. A supplement to this Policy covers the specific area of the use of animal admixed embryos in research.

All staff must commit to and accept responsibility for the humane care and welfare of the laboratory animals they use in their research. In cases where the use of laboratory animals is the only practicable technique staff will, as a minimum, comply with all the requirements of the Animals (Scientific Procedures) Act (1986) (as amended)(A(SP)A) and with all applicable guidance issued by the Home Office.

Staff wishing to use animals in research will need the appropriate training and licences before being able to commence work. Staff should be aware that many funders have additional requirements where animals are being housed and used in facilities outside the Institute. The Ethics and Governance Office can advise and support staff working with animals - ethicsandgovernance@sanger.ac.uk.

3.3 Use of Human Materials

When working with human materials researchers must comply with the Human Tissue Act (2004). The Use of Human Materials guidelines outline the measures required for researchers to fulfil these requirements; including the need for research participant consent, Research Ethics Committee (REC) review and HRA approval where appropriate. Confidentiality is an important issue in the use of human material in GRL's activities. GRL expects researchers to typically use linked or unlinked anonymised samples and GRL personnel should not, under any circumstances, attempt to identify the individual donors of these samples. Any proposed use out with these recommendations should be discussed with the Ethics and Governance Office ethicsandgovernance@sanger.ac.uk.

3.4 Use of Stem Cells

Research using human induced Pluripotent Stem Cells (iPSC) and human Embryonic Stem Cell (hESC) lines is not covered by the Human Fertilisation and Embryology Act (2008). Nevertheless, there are some restrictions on use that researchers should be aware of. Where the intention is to create iPSCs, researchers must have ethical approval from a Research Ethics Committee (REC) and where possible donor consent. Commercially available iPSCs are exempt from these requirements, although researchers should make best efforts to ensure that such lines were created ethically. Use of hESC lines requires approval from the UK Stem Cell Steering Committee. This includes for importation or exportation of hESC lines and accessing from or depositing hESC lines into the UK Stem Cell Bank. The Institute's Use of Human Material Policy and the Human Tissue Act (2004) will also apply to the collection and use of human samples for the generation of iPSC or hESC. Researchers intending to create iPSC or use hESC should discuss this with the Ethics and Governance Office.

3.5 Use of Genetic Resources (Nagoya Protocol)

The Nagoya Protocol covers access and utilisation of plants, animals, fungi and microbes (termed 'genetic resources') in commercial and academic research and development. It covers any material containing functional units of heredity (e.g., genes and DNA) or their derivatives (e.g., cell lines, proteins, lipids, enzymes) from overseas countries. Basic and applied research, including genetic modification are within scope of the Nagoya Protocol. Legislation varies across countries; researchers

should contact the Ethics and Governance Office – nagoya@sanger.ac.uk - before importing genetic resources from outside the UK, even if they have previously imported samples from the same country.

3.6 Data Protection

Personal data is any information identifying a living individual or information relating to a living individual that can be identified from that data alone or in combination with other identifiers GRL can reasonably access. This includes any research data that allows identification of a living individual. Researchers should be aware that pseudonymised data is no longer automatically out of scope of Data Protection legislation in the UK.

Researchers using personal data must adhere to the following principles, laid out in UK law:

a) Processed lawfully, fairly and in a transparent manner.
b) Collected only for specified, explicit and legitimate purposes.
c) Adequate, relevant and limited to what is necessary in relation to the purposes for which it is processed.
d) Accurate and where necessary kept up to date.
e) Not kept in a form which permits identification of individuals for longer than is necessary for the purposes for which the data is processed.
f) Processed in a manner that ensures its security using appropriate technical and organisational measures to protect against unauthorised or unlawful processing and against accidental loss, destruction or damage.
g) Not transferred to another country without appropriate safeguards being in place.
h) Made available to data subjects and data subjects allowed to exercise certain rights in relation to their personal data.

Researchers handling identifiable human data, highly sensitive data or data with the potential to cause harm in the event of a breach must speak to the Legal Team before commencing research – legal@sanger.ac.uk.

3.7 Data Sharing Policy

The Sanger Institute is completely committed to sharing its data, as well as the resources and materials it produces. Rapid and open data sharing strategically supports the Institute's mission by enabling research and accelerating translation. The Data Sharing policy requires that researchers share their data as widely and effectively as possible with the following considerations:

- Data should be deposited in accessible repositories, wherever possible. For human data, these repositories will typically have managed access. Dataset accession numbers must be included in any publications.
- Researchers must always protect the privacy and confidentiality of research participants. Access to human data sets will usually be managed, although this may vary according to the consent given by participants. Conditions for access must be transparent.
- Researchers should be appropriately credited for their contribution to data generation.
- In certain circumstances, it may be appropriate and necessary to delay sharing of data to allow for intellectual property protection in order to ensure that the data is used for benefitting health.

3.8 Human Data Security Policy

All projects involving Human Genetic Data must be assigned to one of four data security levels prior to the start of data processing (and ideally prior to receipt or generation of data). The assignment should be carried out by the project PI and should be re-assessed at least once a year to ensure that it remains

appropriate. If a project contains distinct datasets that would fall into multiple levels, there are two choices: the entire project can be assigned to the highest applicable level, or the Human Genetic Data can be divided into multiple projects, each of which contains data only at the assigned level or below. Advice and guidance on technical solutions for protecting human data can be obtained from the Head of IT security: nc8@sanger.ac.uk.

3.9 Publication Policy

The Sanger Institute requires researchers to publish research either in open access journals or in journals that allow deposition of the article within six months of publication in the Europe PubMed Central (PMC) repository. Researchers should be aware that third party funders may have additional publication requirements, which must be adhered to as part of the funding terms and conditions. We encourage researchers to consider sharing in pre-print archives such as BioRxiv or publishing on platforms such as Wellcome Open Research. The Library, library@sanger.ac.uk can answer any questions on the publication policy and is available to offer advice and support on all forms of open access publishing.

The Sanger Institute is a signatory to the San Francisco Declaration On Research Assessment (DORA). At the Institute level, we use a broad definition of research excellence that seeks to encompass a range of outputs including and beyond publication. Our criteria for hiring and promotions are explicitly based on scientific merit of publications, not the journals in which they were published. In assessing research quality we consider all research outputs and a broad range of impact measures. We will consider the potential for gender and racial bias, and the potential to disadvantage early career researchers if using metrics. If we use metrics we will be transparent and explicit about which metrics we are using, why, and the methodologies behind them.

3.10   Software Policy

Software under GRL copyright that directly supports published work authored by GRL employees (e.g. software implementing methods described in a methods paper or software presented in an application note) must be released publicly using an acceptable free software license by the time of the related publication at the very latest. Useful and potentially reusable software under GRL copyright that represents a substantial portion of the analysis and/or processing that went into producing results presented in a research paper should also be released publicly using an acceptable license by the time the research paper is published.

For information about licensing options please contact the Translation Office: innovation@sanger.ac.uk. Questions about software release can be discussed with the Head of Scientific Computing: tjrc@sanger.ac.uk

3.11   Translation Policy

The Sanger Institute conducts both basic and translational research, and has a proud heritage of achieving impact through rapid dissemination of research findings, data and materials. Further development of scientific discoveries for human health benefit sometimes requires different approaches and activities.

The process for deciding how we utilize our resources and capabilities for developing translatable science and eventually what model will be adopted is regulated via the following structures/groups:

- Technology Translation Office
- Translation Committee
- Board of Management
- GRL Executive
- GRL Board

Researchers interested in translating their research should contact the Translation Office: innovation@sanger.ac.uk.

3.12 Conflict of Interest

All researchers should declare and manage any real or potential conflicts of interest. They should also be aware of the impacts the perception of conflicts may have. A conflict of interest is any situation in which personal interests, or loyalties to another person or body, may, or may appear to, unduly influence or affect a decision. They may be financial or non-financial and can arise in all aspects of research.

The Legal Team - legal@sanger.ac.uk- can advise researchers on managing any potential or real conflict of interest.

4. Funder Requirements

When a grant or third party award is applied for and accepted by GRL, there is then an obligation on GRL to perform the research and comply with the funder's terms of award. As a result GRL is taking on the reputational risk of delivering the project and the legal, ethical and financial obligations of the agreement. This policy aims to ensure that such obligations are recognised and managed appropriately. It covers the whole range of activities related to third party awards performed by any staff member whether permanently or temporarily employed, associate faculty or other person applying for or delivering a grant, contract, donation or funding agreement from a funder, donor or collaborator.

For more information about complying with funders' terms of award and advice on applying for grants and fellowships please contact grantsoffice@sanger.ac.uk.

5. Other important policies

A complete list of Institute policies can be found on Fred

Employment policies
Dignity at Work (Bullying and Harassment)
Disciplinary policy (excluding Academic Misconduct)
Grievance Policy

ICT Acceptable Use Policy
Outside Activities Policy
Travel Policy
Whistleblowing policy

6. Revision History

V4 09/02/21 updated hyperlinks to Fred