Good Research Practice

The National Centre for Biological Sciences' Guidelines on Good Research Practice have been developed to emphasise the importance of integrity and rigour in all research carried out at and in partnership with the Centre. The policy covers integrity, openness, conflicts of interest, leadership, supervision & training, ethical practice, conducting the research, intellectual property and publications of research results.

1. General principles

The National Centre for Biological Sciences (NCBS) is committed to conducting its business in accordance with seven principles: selflessness, integrity, objectivity, accountability, openness, honesty and leadership. The Centre expects all those engaged in research to observe these principles, whether they are employees of the Institute, or students, and irrespective of the sources of their funding, or their area of research.

The Centre has an Honour code which states: “NCBS operates on a principle of trust. Most research materials are kept in accessible locations. Research at NCBS depends critically on colleagues being able to trust each others data. Hence, any form of cheating or falsification of data is totally unacceptable and will invite appropriate consequences. “

This document provides guidelines on good practice in research and is intended for all staff, including persons with honorary positions, and students carrying out research at or on behalf of NCBS. Research in the biomedical area involving humans and other animals raises specific ethical issues. These are addressed in Section 6.

2. Integrity

Researchers should 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 8, Dissemination and Publication of Results).

Researchers are accountable to society, their professions, the institutes where the research is taking place, the staff and students involved and, in particular, to the sponsor that is funding the research. Researchers are expected to understand and apply the following principles:

- Plagiarism, deception, or the fabrication or falsification of results is regarded as a serious disciplinary offence
- Researchers are encouraged to report cases of suspected misconduct, and to do so in a responsible and appropriate manner.

The Centre’s approach to managing these issues is described in detail in the policy document entitled "Misconduct in Research".

3. Openness

Whilst recognising the need for researchers to protect their own academic and, where

appropriate their intellectual property rights (IPR), the Centre encourages researchers to be as open as possible in discussing their work with other researchers and with the public. The aim in disseminating public-funded or Centre research is to increase knowledge and understanding: its purpose should not be primarily to seek publicity for the researcher, for NCBS or for the sponsor. Once results have been published, NCBS expects researchers to make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethical approvals and consents which cover the data and materials, and any intellectual property rights in them. Procedures for managing the transfer of materials in and out of NCBS are available on request.

Sponsors recognize that publication of the results of research may need to be delayed for a reasonable period pending protection of any intellectual property arising from the research. Any such periods of delay in publication should be kept to a minimum and this should normally be no more than six months. Researchers should be especially careful when discussing work that is not complete or has not been published, particularly if it has not undergone peer review. Exchange of confidential information by e-mail is not recommended especially if patent applications are anticipated.

4. Conflicts of interest

Conflicts of interest happen in all walks of life; scientific research is no exception. A conflict arises when a person's judgement concerning a primary interest, such as scientific knowledge, could be unduly influenced by a secondary interest, such as financial gain or personal advancement. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognise the fact and deal with it accordingly. Researchers must pay as much attention to perceived and potential conflicts of interest as to actual conflicts. How one is perceived to act influences the attitudes and actions of others, and the credibility of scientific research overall.

Conflicts of interest can occur at every stage of the research endeavour – from planning the research to disseminating and exploiting the results – and in many forms. Apart from financial interests, conflicts might, for example, be personal, academic, or political. Researchers should automatically ask themselves "Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?" If the answer is no, the interest must be disclosed and addressed appropriately, for example according to the policy of an employer, a peer-review body, or a journal.

The Centre’s approach to managing financial conflicts of interest is described in detail in the policy document entitled "Managing conflicts of interest".

5. Leadership

Senior colleagues at the Centre should ensure that a research climate of mutual co-operation is created in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered.

6. Supervision & Training

Although everyone involved in science must take personal responsibility for maintaining the highest standards of integrity, the head of a laboratory, who is necessarily a mentor

or supervisor of research, has special responsibilities. The laboratory head should ensure that personnel for whom he or she has responsibility, including associates, students, and technical staff, receive appropriate supervision and instruction. In particular, the laboratory head should teach and encourage careful scrutiny and interpretation of results, emphasizing the importance of and reliance on sound primary data.

Careful review and evaluation of all primary data by the laboratory head is necessary and cannot be delegated to others unless it is clearly understood that the individuals concerned are conducting research in a largely independent manner, for example in the case of certain senior visiting scientists or other senior research staff. It is inadvisable for the investigator to delegate these important functions.

The laboratory head must assume absolute responsibility for the validity of all communicated and published information from his or her laboratory and for the publication of the data that may ensue from work in the laboratory.

NCBS offers courses to enable students and new researchers to understand and adopt best practice in research as quickly as possible. Supervisors should encourage students and colleagues to attend relevant courses as part of their overall career development.

7. Ethical practice

The legal and ethical requirements relating to human participants, animals, and stem cell research should be familiar to each person involved in the study, and they should know to whom to turn for advice. Since ethical issues, guidance, or requirements often change, research teams must have effective arrangements for disseminating knowledge and documents. Each person should also know when changes may call for new ethical/regulatory approval and should be able to recognise unforeseen results or incidents that need to be reported and discussed.

7.1 Research involving human participants

NCBS and its sponsors require that all research involving human participants or human biological samples has approval from the Institutional Bio-safety and Bio-Ethics Committee. The mandate of the Committee is to:

- Conduct scientific review in respect of proposals that involve human subjects and samples
- Examine ethical issues involving human subjects and samples
- Examine and approve all proposals for research at NCBS in conformity with Department of Bio-Technology (DBT) and Indian Council of Medical Research (ICMR) Bio-Safety and Bio-Ethics rules and guidelines

7.2 Research involving animals

NCBS and its sponsors require that all research involving animals has approval from the Institutional Animal Ethics Committee. The mandate of the Committee is to:

- Conduct scientific review in respect of proposals that involve animals
- Examine ethical issues involving experimentation on animals

- Examine and approve all proposals for research at NCBS in conformity with the CPCSA Guidelines.

Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for Reduction, Replacement and Refinement of animal involvement "The Three Rs".

7.3 Research involving stem cells

NCBS is in the process of creating an Institutional Committee for Stem Cell Research and Therapy. The mandate of the Committee will be to:

- Conduct scientific review in respect of proposals that involve human stem cells
- Examine ethical issues involving experimentation with human stem cells
- Examine and approve all proposals for permissive stem-cell research at NCBS in conformity with the DBT/ICMR Guidelines.
- Examine and approve all proposals for creation of new human stem cell lines at NCBS
- Examine and approve the import/movement of established human stem cell lines into NCBS
- Examine and approve all proposals involving clinical trials of human stem cell lines at NCBS

8. Conducting the research

8.1 Use, calibration, and maintenance of equipment

Equipment used to generate data should be appropriately located, safe, suitable for the purpose, of appropriate design, and of adequate capacity. It should be calibrated and serviced regularly by trained staff so that performance is optimal and the results can be trusted. A designated person should be responsible for ensuring the proper use and maintenance of equipment and, where appropriate, for training staff in its use; when this is not possible, the users themselves should take on the responsibility. Records should be kept of calibration, servicing, faults, breakdowns, and misuse of equipment. There should be easily accessible instructions for the safe shutdown of equipment in case of emergency.

8.2 Hazardous processes and materials

Experiments should be conducted in accordance with local policies on training, and health and safety regulations and guidelines. Where appropriate, risk assessments should be prepared before the work is carried out. Where necessary, materials and equipment should be decontaminated according to specified health and safety practices including an approved risk assessment. Waste should be disposed of and recorded in accordance with these practices and the appropriate health, safety, and environmental regulations, and also in compliance with local rules for dealing with spillages. Where relevant, the appropriate authority should be notified. Staff should be properly trained and monitored so as not to endanger themselves, others, or the environment.

8.3 Standard operating procedures

Standard operating procedures (SOPs) should be documented for all routine methods

and for individual items of equipment to ensure that data are collected consistently and accurately. When there is more than one approved technique for any given procedure, all should be covered by SOPs. SOPs should be written in simple language, readily accessible, and ideally in a standardised format. They should be updated as necessary, and only the current version should be available. Written protocols are likewise essential for ensuring strict adherance to regulations/licences, for example in research involving animals.

8.4 Gathering and storing data

- Data should be stored in a way that permits a complete retrospective audit if necessary.
- Data should be stored safely, with appropriate contingency plans.
- Data records should be monitored regularly to ensure their completeness and accuracy.
- Data should be backed-up regularly; duplicate copies should be held on disc or tape in a secure but readily accessible archive. The Centre provides secure and archived storage for electronic data.
- Where feasible, a hard copy should be made of particularly important data.
- Copies of relevant software, particularly the version used to process electronic data, must be retained along with the raw data to ensure future access. Software updates must be logged and stored as new formats and media are adopted.
- Raw (original) data/images should be recorded and retained; this is especially important where data/images are subsequently enhanced. If possible, both original and enhanced data/images should be stored, along with provenance tracking to record every manipulation done to images or data. Overenhancement or over- interpretation of images is inappropriate.
- Special attention should be paid to guaranteeing the security of electronic data.
- Confidentiality is also important where there is potential for commercial exploitation.

8.5 Notebooks and electronic records

The following basic policies apply:

- All raw data should be recorded and retained in indexed laboratory notebooks with permanent binding, or in electronic laboratory notebooks which maintain a full logging system so that all edits and comments on any entry are recorded.
- Machine print-outs, questionnaires, chart recordings, autoradiographs, etc which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross- indexed with the main record. Similarly, any digital data that cannot be incorporated into physical or electronic notes must be fully referenced so that it can be easily accessed. Digital data should always be stored on lab or institution servers so that it is accessible to the lab and institute, and should have full backup and archival capabilities.
- Records in physical or electronic lab notebooks should be entered as soon as possible after the data are collected. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.
- Special attention should be paid to recording accurately the use of potentially hazardous substances (eg, radioactive materials) in both laboratory notebooks and any central logbooks.
- In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.
- Supervisors should regularly (monthly or as appropriate to the nature of the work) review and "sign-off" notebooks of researchers to signify that records are complete and accurate. Electronic lab notes should also be marked by the supervisor as having been

examined. Queries should be discussed immediately with the individual who recorded the data and any resultant changes to the records should be signed by both. In the case of electronic lab notes the changes must be logged by the system. Authentication of data collected and recorded electronically requires special consideration.

- All lab records should be placed in a standard location, known both to the laboratory head and to the Dean's office. This includes standard locations for electronic lab records on institute servers. This is mandated by the requirements that all results can be substantiated by the laboratory head and centre.
- All labs must have a policy for handover of original laboratory notes, and all supporting material, to the supervisor, at the time of departure/graduation of laboratory members. It is permissible and encouraged for a copy to be made for the departing laboratory member.

9. Dissemination and publication of results

NCBS encourages the publication of and dissemination of results of high quality research but believes that researchers must do this responsibly and with an awareness of the consequences of any such dissemination in the wider media. NCBS expects those it supports to play their part in disseminating balanced information on scientific advances and their potential implications for society to the health professionals and policy makers who will be involved in applying them, and to the wider public.

Researchers should take into account the following guidance when publishing or disseminating their research findings including any plans they may have to publish or publicise research at conferences or on web sites.

9.1 Publication policy

- The person with overall responsibility for the research programme should authorise publication of results; authorisation should cover both the content of the paper (integrity of results, adequacy of internal peer review, appropriate protection of intellectual property rights, appropriate authorship) and the intended place of publication.
- Open access and open source publishing of data is encouraged, to improve reuse of results and raw data. However, release of data on the internet must be approved by the leader of the research team, as this may compromise subsequent publication and intellectual property rights.
- All funding sources must be acknowledged in any publication or publicity.
- Research findings with substantial implications for clinical practice or which are likely to attract strong public interest should be drawn to the attention of the research funders before publication.
- Published reports should normally contain basic information about the ethical acceptability of the work and/or its legality, as well as information about the scientific method.
- Work should normally be published as a coherent entity rather than a series of small parts, unless there is a legitimate need to demonstrate first discovery by publishing preliminary data.
- Quality rather than quantity is paramount.
- Authors must not publish the same data in different journals.

9.2 Authorship

- Authorship of papers should include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper. Authors should have participated sufficiently in the research to take public responsibility for the content.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be both specified and properly acknowledged. Other contributions to the work should be acknowledged formally,

as should financial support from sponsors. Authors are responsible for obtaining written permission from persons acknowledged by name.

9.3 Correction of errors and retraction of published findings

- If an error is found that degrades the worth of published findings, the principal author must immediately discuss the matter with the research leader, with a view to notifying co- authors and publishing a correction as soon as possible setting out the basis of the reservations.
- Where the findings are found to be in serious doubt, a retraction should be published speedily.
- Where fraud is suspected, the procedure set out in the policy “Managing Research Misconduct” should be followed.

10. Commercial exploitation

NCBS has in place an Intellectual Property Management Office (IPMO) and a Technology Transfer Office (TTO) to develop and implement strategies and procedures for the identification, protection, management and exploitation of institutional intellectual property (IP).

The Centre’s policy on Intellectual Property Rights ensures that institutional intellectual property is used for the benefit of wider society, and that institutional inventors are rewarded appropriately. Researchers are strongly encouraged to inform the IPMO of any intellectual property rights that may arise from externally funded research and also inform the sponsor, if they so request. Full details of the NCBS’ approach to managing intellectual property are available on request.

Other Useful Sources of Information

- The Office of Research Integrity (ORI), USA.
- MRC-Good Research Practice
- University of Cambridge-Good Research Practice
- HHMI Policy on Research Conduct
- WT/DBT India Alliance- Guidelines on Good Research Practice