GOOD RESEARH CONDUCT POLICY
Version. 1

FOR

ADROIT BIOMEDICAL AND BIO-ENTERPRENEURSHIP RESERCH SERVICES

(ABBRS)

P. O. Box 112139 NAGURU-KAMPALA

P. O. Box 112139 NAGURU-KAMPALA
Email: grants@abbrs-uganda.org

Prepared by: Administration

Reviewed by: Ethics & Legal

Approved by:

Board of Directors

Practice Guidelines

ABBRS's Guidelines on Good Research Practice are developed to articulate the importance of integrity and rigour in all research carried out at and in partnership with the institution. These guidelines are informative, rather than prescriptive. They aid researchers in helping them to determine how to apply the baseline standards set by ordinances and regulations of the ABBRS, as well as by wider legal and contractual requirements and ethical norms, to the concrete situations which face them in everyday practice of research. The practice of research will require adherence to principles of ethics and integrity that may vary in their details according to the type of research undertaken. Thus, these general guidelines may need to be supplemented by other research-related policies, guidelines, and principles.

Links to additional guidance provided by funders, and other organisations may apply and will be available in the library for reference. This policy will be routinely reviewed every three years unless earlier revision is required due to a major change in the legislation, regulations and guidance that govern good research practice.

1.1 Introduction

The ABBRS is committed to conducting its business in accordance with the seven principles identified by the Committee on Standards in Public Life -selflessness, integrity, objectivity, accountability, openness, honesty, and leadership ABBRS expects all those that are engaged in research to observe these principles irrespective of the sources of their funding, or their area of research. Researchers should make efforts to understand and meet the expected standards of integrity and good practice relevant to their work.

To facilitate such efforts, this document provides guidelines on good practice in research. It is intended for all staff at ABBRS. Research involving humans, human tissue, personal data, and animals raises specific ethical issues, which must all be addressed.

1.2 Funder requirements

Research funders cannot be prescriptive about individual approaches taken by researchers to solving particular research problems. However, funders can reasonably expect ABBRS and the attached researchers to ensure that an adequate policy framework exists that promotes and circulates good research practice, that emphasises integrity and rigour in research, and that facilitates the development of a culture in which the following general principles can be understood and observed. Compliance with the Concordat is a condition of receipt of funding.

Many funders have published their own policies on the Governance of Good Research Conduct and Guidelines on Good Research Practice. A list of relevant policies and guidance from various funders will be provided to the researchers so that they adhere to these guidelines. Researchers should ensure that they are aware of and abide by all policies and guidelines that apply to their research.

Research Councils and charities fund for public benefit, and in the case of charities within their charitable objects and impose certain obligations and restrictions on the use of their funds, for example a requirement to disseminate research findings, and a proscription on funding research for the purpose of direct commercial or private gain.

Researchers should be aware of these obligations and seek advice where required. Researchers should report any significant changes in the direction of funded research to the funder or any other

relevant body. Best practice would be to discuss any change in direction of the research with the funder prior to its implementation. Most funding agreements will provide a mechanism for handling this process. ABBRS' Research Operations Office will provide guidance on funder requirements and funding agreements.

1.3 Integrity

All individuals involved in research at ABBRS are expected to observe the highest standards of integrity, honesty, and professionalism in respect of their own actions in research and in their responses to the actions of others. ABBRS is committed to upholding the commitments outlined in the ABBRS' Concordat to Support Research Integrity. This requires those involved in research to abide by national and international standards of research integrity and to embed good practice in every aspect of their work. A summary of the standards to which researchers are expected to adhere is provided in the ABBRS's Statement on Research Integrity. All researchers should be aware of their responsibilities under the Concordat.

The primary responsibilities of researchers are:

- Take personal responsibility for ensuring that you act in accordance with the principles of the Concordat
- Understand and maintain the expected standards of rigour and integrity relevant to your research
- Understand and comply with ethical, legal, and professional frameworks, obligations and standards as required by statutory and regulatory authorities, and by employers, funders, and other relevant stakeholders
- Design, conduct and report research in ways that embed integrity and ethical practice throughout
- Ensure that your research is subject to appropriate and active consideration of ethical issues
- Collaborate to maintain a research environment that encourages research integrity
- Declare conflicts of interest and act to manage them

The expectation to uphold the highest standards of integrity applies to the whole range of research work including, but not limited to:

- designing studies and experiments;
- generating, recording, archiving, analysing, and interpreting data
- sharing data and materials
- applying for funding; presenting and publishing results
- training new researchers, staff, and students; and
- peer reviewing the work of other researchers.

The direct and indirect contributions of colleagues, collaborators and others should be acknowledged. ABBRS expects research results to be checked for accuracy and consistency by the researchers responsible for them before being made public. Researchers must be able to explain and justify how results were reached.

2.1 Research Misconduct

Allegations of misconduct in research are rare but ABBRS takes them very seriously. ABBRS is committed to ensuring that allegations of misconduct in research are investigated with all possible

thoroughness and vigour. All members of ABBRS, and individuals permitted to work in ABBRS, have a responsibility to report any incident of misconduct, whether this has been witnessed, or is suspected. Those participating in or running investigations into allegations of research misconduct are expected to act in good faith and according to ABBRS policy. ABBRS's definition of research misconduct and approach to managing these issues is described in detail in the ABBRS's policy on Misconduct in Research.

2.2 Conflict of interest

Researchers should declare and manage any real or potential conflicts of interest, both financial and professional. ABBRS's Financial Regulations contain further information on the declaration of personal interests. Researchers should ensure that they abide by any conflict-of-interest requirements of funders or that are otherwise relevant to their research. In particular, researchers should be aware of terms and conditions and the specific requirements of the funders such as European Union and US Public Health Service

3. Openness

Whilst recognising the need for researchers to protect their own intellectual property rights (IPR), ABBRS encourages researchers to be as open as possible in discussing their work with other researchers and with the public. The aim in disseminating charity funded or ABBRS research is to increase knowledge and understanding: its purpose should not be primarily to seek publicity for the researcher, for ABBRS or for the funder.

ABBRS is committed to disseminating research as widely as possible, whilst affirming freedom to choose the location and nature of publication. In keeping with this commitment, ABBRS supports its staff in making their research available through Open Access. Where research funders include Open Access requirements as a condition of grant funding, researchers are expected to ensure that they comply with such requirements.

Once research findings have been published, ABBRS expects researchers to make available all the 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, confidentiality considerations, and any intellectual property rights in them. Many funders will have data sharing policies that must be abided by where appropriate.

Funders recognise 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.

4. Professional Guidance and Legislation

Where available, the ABBRS expects researchers to observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies. All researchers should be aware of the legal requirements, which regulate their work including health and safety legislation, the data protection legislation, and the Freedom of Information Act.

5. Leadership and Co-operation

Heads of departments and their senior colleagues 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. Efforts should also be made to foster an environment where research is conducted in accordance with good research practice and to ensure that all those involved in research are made aware of these guidelines and related policies and guidelines . Senior researchers should make particular efforts to help new members of the scientific community to understand and adopt best practice. Within a research group, responsibility to ensure that good research practice is maintained throughout the research process ultimately lies with the group leader.

6. Supervision

ABBRS wishes to ensure that appropriate training and direction of research and supervision of researchers is available. Training in supervisory skills is provided as part of the ABBRS's overall staff development programme. ABBRS also provides guidance for supervisors and the Code of Practice. Senior researchers should guide ad supervise junior researchers at all stages of their research process, including outlining or drawing up a hypothesis, preparing applications for funding, the design of experimental or research protocols, data recording and data analysis, and writing the thesis.

7. Training

ABBRS offers many trainings to enable junior researchers and new researchers to understand and adopt best practice in research as quickly as possible. Senior researchers should encourage junior researchers to attend relevant courses as part of their overall career development. Researchers should also be aware of training offered locally and guide colleagues appropriately

8. Primary Data, Samples and Equipment

8.1 Ownership and responsibilities

There should be clarity at the outset of the research programme as to the ownership and use of, where relevant:

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

The responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee) should be made clear at the commencement of any project. Any research collaboration agreement relating to the research should contain clauses describing any necessary arrangements.

8.2 Research data

Research data should be generated using sound techniques and processes and accurately recorded in accordance with good research practices by those conducting the research. When collecting personal data, researchers must comply with data protection legislation. All research data must be

managed and curated effectively throughout its lifecycle to ensure integrity, security and quality and where possible to support new research and research data sharing. Data stored locally on a computer should be backed-up. Electronic files containing personal data should be encrypted or password protected and access to them should be limited to as few people as possible. It is of paramount importance that confidentiality, where required, is maintained. Retention periods for research data will vary according to specific contractual requirements and the nature and sensitivity of the research. Most funders consider a minimum of ten years after the completion of a project to be an appropriate period. However, research based on clinical samples or relating to public health may require longer storage to allow for long-term follow-up to occur. Researchers should adhere to guidance provided by funding bodies, professional guidance, local policies, as well as ABBRS requirements as set in ABBRS' Research Data Management policy.

Manual research records, as defined in the ABBRS Research Data Management Policy Framework, should be handled in line with funder policies and the ABBRS Statement of Records Management Practice and Master Records Retention Schedule. This means that researchers should – in line with funder policies and as appropriate for their disciplinary norm – destroy transient manual research records as necessary and, as far as possible, digitise those required for longer-term retention periods, including to share with a wider research lab/group or to comprise their core underlying data to evidence any particular research output. Where manual research records cannot be digitised and remain necessary for compliance with funder policies, regulations and/or ethical requirements or need to be kept evidencing the integrity of the research, they should be retained in manual form for as long as required by funders, regulators, or disciplinary norms. Some manual research records, like electronic ones, may be suitable for permanent preservation in the ABBRS archives, where they may be used for future research.

8.3 Record keeping

Researchers should keep clear and accurate records of the procedures followed and the approvals granted 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 the conduct of the research, the results obtained, or inventorship on patentable inventions.

9. Dissemination and publication of results

ABBRS 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. Dissemination will normally be a requirement of research council and charity funding. ABBRS tries to ensure that any funders who do not require dissemination understand that researchers must have freedom and funders should not discourage publication nor the dissemination of research or research findings. Funding agreements will normally require funders to be informed of any potential publication or dissemination of the research findings. This will enable the funder in question to have adequate time and accurate information to protect any arising intellectual property or to plan their own public relations, in conjunction with the ABBRS. Publicity may be important to industrial funders and to fund-raising charities and is important to the ABBRS itself. Advice on press releases and publicity can be obtained from the ABBRS's Communications Office. Arrangements and responsibilities for the publication of results should be considered when planning a study and should ideally be agreed by all investigators at the outset. These should be revisited where role and contributions change over the life cycle of the study. Such discussions might include authorship, authorisation for the content of papers, and the intended place of publication.

Researchers should consider the following guidance 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.

- Research should normally be peer reviewed prior to it being published, publicised, or disseminated. If research is placed in the public domain before peer review has been undertaken, it is good practice to make this clear in any publicity.
- Funding sources should normally be acknowledged in any publication or publicity.
- Results of research should be published in an appropriate form.
- Anyone listed as an author on a paper 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. Honorary authorship is not good practice.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be both specified and properly acknowledged.
- Researchers should make every effort to ensure that research is disseminated in a responsible manner, in such a way that results are not overstated. The Research Communications team can provide advice on research dissemination.

Similarly, in accordance with the Concordat on Openness on Animal Research, where research has been conducted using animal models, this should be clearly stated in press materials and news stories. Examples of good publication practice can be found in the Committee on Publication Ethics guidelines "Code of Conduct", the International Committee of Medical Journal Editors Recommendations and on the Nature web site.

10. Intellectual Property

ABBRS carries out research for public benefit and not for direct commercial or private gain. Public benefit may arise from education, i.e., the gain of knowledge that is placed in the public domain, or in the case of biomedical research improvement in the treatment or care of patients or in the prevention or cure of diseases. Although the ABBRS cannot carry out research solely for the purpose of commercial gain, commercial benefit from the exploitation of the results of research may be subject to expectations of funders, accrue to their inventor(s), ABBRS and, by agreement, to the funder of the research. Commercialisation may also be the most effective means of disseminating research results and accruing public benefit. Good Research Practice.

11. Ethical practice

All research carried out at the ABBRS must comply with relevant legal, regulatory, professional, and ethical requirements and standards. Researchers should be familiar with and know how to access such requirements including ABBRS ethical guidance and policies. Researchers who are unsure whether such requirements apply to their projects should seek advice. Researchers should work to ensure that, throughout the lifecycle of their investigations, ethical issues relating to their research projects are identified and managed. Ethical issues should be interpreted broadly and may encompass areas where regulation and approval processes exist as well as areas where they do not. All appropriate licences, permissions and approvals must be in place before research starts and be updated as necessary if plans change.

11.1 Ethical practice in research involving human participants, human tissue and personal data

All research involving human participants or personal data carried out by ABBRS employees or on ABBRS premises must abide by departmental and faculty research ethics policies and the ABBRS's Policy on the Ethics of Research Involving Human Participants and Personal Data. Researchers are required to consider the ethical risk of any procedure within a research project which involves human participation or personal data, consulting the relevant Faculty, Department, School and ABBRS policies and personnel before any work is undertaken. Advice must be sought in case of doubt. Where the need for formal review is identified, reasonable and proportionate independent ethical review must be carried out prior to research work commencing.

Guidance and details of the ABBRS's research ethics review system, including contact details for research ethics committees will be provided to those intending to apply for ethical approval. The ethical issues that researchers encounter in their work may vary according to the type of research they undertake. As such, researchers should familiarise themselves with the ethical guidance relevant to their subject area or issued by their department or funder. The ABBRS's research integrity website provides information on many of the key guidance documents. There are some particular considerations that will apply to certain types of research involving human participants, human tissue, or personal data: Those undertaking social research involving human participants may find it particularly useful to consult the ESRC's Framework for Research Ethics, compliance with which is compulsory for ESRC-funded research. Most research involving NHS patients, staff or facilities will come under the Research Governance Framework for Health and Social Care and will require review by a National Research Ethics Service (NRES) Committee. Some other research will also require NRES Good Research review for legal and policy reasons. In some cases, it may be also appropriate to seek the views of relevant patient groups.

Those undertaking research at the Clinical settings should be familiar with and comply with the research governance information must comply with the Human Tissue and Act. This regulates the removal, storage, and use of human tissue – defined as material that has come from a human body and consists of, or includes, human cells. Guidance on the act and links to further information is provided here. Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of data protection legislation.

ABBRS reminds researchers of the importance of obtaining necessary regulatory approval from bodies such as:

- Human Fertilisation and Embryology Authority
- Gene Therapy Advisory Committee.
- Medicine Healthcare Regulatory Authority

11.2 Research involving animals

ABBRS and its funders require that research involving animals should have been subject to the following (through the appropriate bodies):

- Ethical Review Process
- Home Office licence application.

Researchers are required by law to consider the opportunities for Reduction, Replacement and Refinement of animal involvement in research – the principle of "The Three Rs". The ABBRS recommends that researchers refer to the relevant national guidelines on the appropriate and

ethical use of animals in research. Publications using data acquired from animal research must follow the principles of the ARRIVE Guideline (Animal Research: Reporting In Vivo Experiments.) All animal research should be conducted in compliance with ABBRS Animal Welfare Policy, Codes of Practice and Procedures. In accordance with the Concordat on the Declaration of Openness in Animal Research, there is a requirement to support the ABBRS' goal of appropriate openness and transparency with respect to our use of animals.

11.3 Research misuse, non-proliferation, and dual-use research

Researchers must consider any risks that their research will generate outcomes that could be misused for harmful purposes when setting up research collaborations, communicating results. risks exist, they must seek advice and take active steps to minimise them. Researchers must also comply with all legal requirements relating to non-proliferation and dual-use, particularly export controls. ABBRS will develop a policy for handling export control matters which is available, together with guidance for researchers, on the Research Operations Office website.

12. Patient and consumer involvement

Researchers should consider and be aware of the active involvement of patients and consumer groups in research and in the dissemination of research findings. Where possible, and most often for studies involving patients and volunteers, researchers should engage with service-users, carers, representative groups and other stakeholders and beneficiaries in the design, conduct, analysis and reporting of research. It is important that researchers in the biomedical areas consider the impact any publication of research findings may have on patients with the condition under investigation, those involved in their care, those involved in the research and on consumer groups.

13. Collaboration

Research is increasingly collaborative, involving individuals from different disciplines and from international institutions. In establishing research collaborations researchers should be mindful of the ABBRS's policies and guidelines, as well as funder, legal and regulatory requirements, and ensure that research partners and their employing institutions are able to meet the required standards of research conduct. There needs to be clear agreement on and articulation of the standards and frameworks that will apply to collaborative work. This is particularly important in relation to the provenance of intellectual ideas and ownership of research outcomes as well as the specific conditions under which these may be shared. All parties should be clear about their respective roles and responsibilities within the collaboration, which should be set out in any formal collaboration agreement. The Research Operations Office can advise and shall have various model agreements for use in such collaborations. Guidance on research integrity in collaborative research is provided by the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations.