GOOD RESEARCH PRACTICE POLICY

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Approved by	Research Governance Committee	
Applicable to	All LSHTM staff and students, including the MRC Unit the Gambia at LSHTM, and the MRC/UVRI and LSHTM Uganda Research Unit, as well as research collaborators	
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	V2: 2010	*Amended and approved*
	V1: 2010	*Approved by Council*
	V1: 2009	*Agreed by Senate*
Related Policies & Procedures	See references and links in section 222	

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Please note that this document:

(i) will be updated to take account of revised/new supporting policies and procedures and/or their website location. The most up to date version of this Policy will be available on the LSHTM website;

(ii) refers to other LSHTM policies and procedures. These are listed, with appropriate links in Section 22. These may be internal locations, which are only accessible to staff and students.

1. Scope

1.1 This Policy applies to all staff, students and honorary staff conducting research involving the London School of Hygiene and Tropical Medicine (LSHTM) including the MRC Unit the Gambia at LSHTM, and the MRC/UVRI and LSHTM Uganda Research Unit. It is expected that all collaborative research partners should be made aware of this policy, and it is the responsibility of each Principal Investigator to undertake this. This group to whom the Policy applies are to be named collectively in this document as 'researchers'.

1.2 Research is defined as "a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, culture, society, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction" (REF 2021). Research is the attempt to derive generalisable new knowledge, and includes studies that aim to generate hypotheses, as well as studies that aim to test them.

1.3 This policy applies to all research, as defined above, regardless of funding source. This policy applies to all stages of research, from design, conception, conduct, analysis, and publication/dissemination.

1.4 LSHTM expects the principles, policies and procedures set out in this Policy to be understood, observed, and followed by all researchers.

2. Purpose and Overview

2.1 LSHTM has a broad research governance framework which comprises a range of principles, policies, procedures and guidelines that regulate research at LSHTM. The Good Research Practice Policy provides the over-arching element that combines all elements of this framework. The Policy is supported by more detailed policies, procedures and guidelines including: investigating allegations of research misconduct, ethical review, health and safety, safeguarding, grant management, management and confidentiality of data and records, intellectual property, and working with the private sector.

2.2 Research conducted under LSHTM's auspices must be undertaken to the highest standards in accordance with good research practice. All research must be conducted in compliance with this Good Research Practice Policy.

2.3 This Policy has been developed in accordance with national guidance including: the Concordat to Support Research Integrity from Universities UK, Research Councils UK, UKRI, Wellcome Trust, and the UK Research Integrity Office.

2.4 All staff and students at LSHTM, including the Units, are responsible for their own awareness and compliance with this policy. In addition, the Principal Investigator/team leader/manager are responsible for their group's awareness and compliance.

3. LSHTM Research Environment: Principles

3.1 'Excellence' in research is a key LSHTM value and is supported by seven principles which underpin the research environment at LSHTM, and should be understood and observed by all researchers:

- **Honesty** – in relation to own research and that of others, including ensuring the accuracy of data and results, conveying valid interpretations, acknowledging the contributions of others, and neither engaging in misconduct nor concealing it

- **Rigour –** conducting the research in line with prevailing norms and standards, using appropriate methods for the study question, adhering to an agreed protocol where relevant, in drawing suitable conclusions and interpretations with respect to the fidelity of the data, and communicating the results of the study

- **Integrity** – complying with all relevant legal and ethical requirements, declaring any potential or actual conflicts of interest relating to research and where necessary taking steps to resolve them

- **Transparency, Co-operation & Open Communication**– promoting the open exchange of ideas, research methods, data and results and their discussion, scrutiny and debate, subject to any considerations of confidentiality. As well, declaring potential competing interests at all stages of the project, in reporting the data methodology, analysis and making the results widely available

- **Safety, care and respect**– ensuring the rights, safety and wellbeing of all involved in research (i.e., research participants (whether human or animal), researchers, and others), and ensuring that the potential or benefits of the study justify the risks. As well, ensuring that the environment and cultural objects are respected

- **Accountability** – recognising that ultimate accountability is to the general public and research should be conducted and reported always with this in mind. Ensuring research undertaken complies with any agreements, terms and conditions relating to the project, ensuring proper governance. Following the requirements and guidance of any professional bodies of which those involved in the research are members

- **Training and skills** – ensuring that those engaged in the research have the necessary skills, training and resources to carry out the research, and report and resolve any unmet needs identified.

3.2 LSHTM is committed to providing a research environment that develops good research practice and nurtures a culture of research integrity.

3.3 LSHTM is responsible for ensuring arrangements are in place which embed these principles within the broad research governance framework (see 2.1, above) and also supports researchers in adhering to them. Honest errors, notwithstanding due to ignorance, should not be penalised; efforts should be made to learn from mistakes to prevent them recurring.

3.4 The elements of good research practice are set out in the remainder of this document.

3.5 LSHTM aims to provide an inclusive research, education and working environment reflected through a community that everyone feels a part of, which is safe, respectful, supportive and enables all to reach their full potential. To achieve this, we have committed to a number of guiding principles (within our EDI strategy), these include:

- Ensuring LSHTM values and expected behaviours reflect respect for all and are clearly communicated, understood and enacted in all our interactions at all levels and regardless of job role.
- Working in partnership with our students, staff, and other stakeholders enabling a range of perspectives to be heard, recognising the global and diverse cultural contexts in which we work.
- Embedding equity, diversity and inclusion in all that we do and recognising it as a School-wide responsibility.

3.6 All researchers at LSHTM should expect to work in a supportive research environment, and in turn, are encouraged to promote practices that allows good quality research to thrive. LSHTM will provide guidance and work to create and maintain a culture of research that supports all staff in Good Research Practice.

4. Research Involving Human Participants

4.1 LSHTM and researchers have specific responsibilities for human research participants, in particular to ensure their rights, safety and wellbeing, to obtain full informed consent, as appropriate, to maintain confidentiality inasmuch as possible and to follow good practice principles in relation to the management of data. All research involving humans must be conducted in compliance with this Policy and related ethical, legal and good practice documents which regulate such work.

4.2 For the avoidance of doubt, 'human participant' includes: a person either alive or dead, their data, and/or their tissue/material (including DNA/RNA, cells, organs, parasite-infected human cells) that may be collected or stored from a previous research project.

4.3 To ensure the appropriate measures are in place to safeguard the rights, safety and wellbeing of research participants, all research projects undertaken by staff or students involving humans, their tissue and/or their data ***must*** undergo ethical review before the research project begins. Approval must be obtained from both the LSHTM Research Ethics Committee (REC) as well as all other UK/overseas ethical review and regulatory bodies, where appropriate. Peer/scientific review should also be sought as good practice, before submitting for ethical review.

4.4 LSHTM supports all activities and efforts to safeguard participants, staff, and the community before, during, and after a research project. Safeguarding in research is defined as: "preventing and addressing any sexual exploitation, abuse, or harassment of research participants, communities and research staff, plus any broader forms of violence, exploitation and abuse such as bullying psychological abuse and physical violence" (UKCDR 2020). LSHTM will not tolerate any actions or activities that breach safeguarding guidelines or appear to breach these guidelines. All staff engaged on a research project, whether by LSHTM directly, or through local collaborators, have a duty of care for research participants.

4.5 Failure to obtain full permission to start the study, including ethics approval, will be considered as research misconduct.

4.6 All participants in research should expect researchers to act within this Policy and the other aspects of LSHTM's Research Governance framework.

4.7 All research projects involving the collection or use of human tissue must comply with the Human Tissue Policy.

4.8 All research is expected to be conducted in compliance with LSHTM's Standard Operating Procedures for research.

4.9 Clinical trials[1] are expected to be conducted in compliance with the principles of ICH Good Clinical Practice R2 (2016), as amended.

Ethical Review

4.10 All research involving humans, their tissue and/or their data (i.e., through observation, questioning, examination, interviews, focus group discussions, specimen collection, specimen use or intervention) **must** be reviewed and be approved by one of LSHTM's RECs. This includes secondary data analyses except when data is fully in the public domain (i.e., freely available without requiring any form of registration, e.g., on the internet, in public archives or other grey literature). The REC is responsible for assuring that all research involving human participants conducted by LSHTM staff and students, or on LSHTM premises, or with whom LSHTM is closely involved (i.e., researchers) conforms to the highest ethical standards. This applies to research undertaken in the UK and overseas.

[1] WHO definition of clinical trial: "a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. this definition includes Phase I to Phase IV trials".

4.11 All ethical reviews must take place before the study starts. LSHTM's Research Ethics Committees will not review a study retrospectively. Data collected prior to receiving ethics approval will not be admissible to be used in any publication, thesis or other part of the research project and will be destroyed under the supervision of the Head of Research Governance and Integrity.

4.12 All staff and students who act in the role of co-investigator must submit to the LSHTM REC, as well as to all other appropriate ethical and regulatory bodies. All applicants to the LSHTM REC must have undergone training in the ethics of research on human participants in the past 3 years.

4.13 Approval must also be obtained from one of the Research Ethics Committees to amend or extend a study which has previously received Research Ethics Committee approval.

4.14 Researchers must ensure that the ethics committees are informed of serious issues that arise during the project (e.g., protocol violations and serious adverse events).

4.15 In addition, proposed studies must also gain approval from regulatory and other ethical review bodies where necessary, both in the UK and overseas, before the start of a research project.

4.16 LSHTM's Research Ethics Committee approval is contingent on local approval also being obtained, where relevant.

4.17 Further information and the full procedures can be found on the Research Ethics Committees webpage, and in their Terms of Reference.

5. Research involving animal subjects

5.1 LSHTM has a specific policy on the use of animals in biomedical research with which all research involving the use of animals must comply with.

5.2 Achieving some of the aims in LSHTM's Mission requires the use of animals for research into the causes, treatment and prevention of infectious diseases of global importance. Animal research will focus on:

- defining the basic mechanisms of how pathogens cause disease
- developing new diagnostics to detect pathogens or monitor treatment or prevention
- developing new chemotherapeutic drugs to combat infection
- developing novel vaccines to prevent infection

5.3 Researchers will conduct research involving animals in accordance with the highest standards of humane care and treatment. Researchers will act in accordance with the 3Rs concept of replacement, reduction and refinement through the development, validation and adoption of appropriate alternatives to the use of animals in order to eliminate, or if not, reduce the need for animals in biomedical research. *In vitro* alternatives to whole animal experiments should be used wherever possible. Due to the complexity of the infection

process and the need to rigorously evaluate candidate diagnostics, drugs and vaccines for protective efficacy, it may still be necessary for *in vivo* studies to be performed.

5.4 Research involving animals should only occur where:

- no other non-sentient alternative is available
- the research proposed is peer reviewed, of the highest scientific quality and likely to provide knowledge critical for improving human health
- the investigations are performed using the smallest number of animals to guarantee a statistically valid and biologically meaningful result (thus reducing the number of times each experiment must be performed).

5.5 All animals obtained for research will be purpose bred at establishments licensed by the Home Office or other international regulatory agencies and subject to inspection and approval by the Named Veterinary Surgeon. All research involving animals in the UK is governed by the Animals (Scientific Procedures) Act 1986 which controls how animals are obtained, housed and treated. All Researchers who perform experiments with animals will undergo an approved training course, have appropriate experience in the procedures required, hold a Personal license and operate under the additional guidance of a Project license awarded by the Home Office.

5.6 Compliance with this legislation will be actively and rigorously monitored at several complementary levels.

5.7 Studies carried out by LSHTM staff at laboratories and other locations *overseas* should be designed, organised and carried out to the same ethical standards as work in the UK.

5.8 All animal-based research will be subject to review by the LSHTM Animal Welfare and Ethical Review Board (AWERB) that includes independent experts in ethics and animal welfare who are not members of LSHTM staff. The panel reviews before and during research to ensure compliance with the best possible standards of animal care.

Ethical Review

5.9 LSHTM requires that all research involving animals undergoes ethical review via the Animal Welfare and Ethical Review Board (AWERB), and personal and project licensing issued by the Home Office, as well as expectations and requirements for research on animals conducted overseas. All projects involving the use of animals, regardless of where the project takes place, should be reviewed by an appropriate AWERB.

5.10 Researchers should consider the opportunities for reduction, replacement and refinement of animal involvement (the three Rs), at an early stage, in the design of any research involving animals. Where the research question cannot be addressed without the use of animals, investigations must be performed using the smallest number of animals to provide a statistically valid and biologically meaningful result.

6. Compliance

6.1 Research must be approved and conducted in accordance with:

- LSHTM's research governance framework including this Policy and the principles (see 3. above)
- LSHTM's policies and Standard Operating Procedures. Other LSHTM policies that may impact on research and should be read, include (but not limited to):
  - Data Protection Policy
  - Research Data Management Policy
  - Records Management Policy
  - Information Management and Security Policy
  - Freedom of Information Policy
  - Health, Safety and Wellbeing policy
  - Whistleblowing Policy
  - Open-access Publishing Policy
  - Declaration of Interests Policy
  - Safeguarding and Security Screening Policy
- Ethical, legal, professional and policy requirements which regulate work (e.g., health & safety, data confidentiality requirements, research involving humans or animals), in the UK and in any other country in which Researchers are based or in which the research is being conducted;
- Standards of research practice set out by professional bodies, and scientific and learned societies;
- Requirements including contractual requirements of the relevant funding bodies, and
- Standards and guidelines of the relevant funding bodies.

6.2 Researchers are expected to be aware of and adhere to all regulations and standards of good practice governing their research activities in the country where the research will take place. This includes, but is not limited to:

- The ICH Good Clinical Practice (R2) guidelines detailing the conduct of clinical trials
- All ethical guidelines, including but not limited to
  - the World Medical Association's Declaration of Helsinki (1964, as amended (currently 2013))
  - CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016), as well as other established standards in biomedical research.
  - In addition, the Interventions and Observational A ethics committees comply with the US Federal Policy for the Protection of Human Subjects (also known as the Common Rule, i.e., 45 CFR part 46). The Interventions committee complies with the Food and Drug Administration regulations on Protection of Human Subjects (21 CFR 50) and on Institutional Review Boards (21 CFR 56).
- All local, in-country regulations and requirements required by the Sponsor and host institution, for example (but not limited to):
  - Medicines and Related Products Act 2014, Republic of The Gambia

- National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014, Uganda
- Uganda National Council for Science and Technology (UNCST) 2014. National Guidelines for Research involving Humans as Research Participants. Kampala, Uganda: UNCST
- Uganda National Council for Science and Technology (UNCST) 2016. Research Registration and Clearance Policy and Guidelines. Kampala, Uganda: UNCST

As LSHTM is regulated as a UK Higher Education Institution, LSHTM policies (including this policy and the Human Tissue Policy) and procedures have been devised to ensure that research adheres to:

- the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended)
- the Human Tissue Act 2004
- the Data Protection Act 2018 (General Data Protection Regulation (GDPR), incorporated into UK legislation (for research projects only)
- the UK Policy Framework for Health and Social Care Research (2017) (formerly the Research Governance Framework for Health and Social Care (2005))
- Nagoya Protocol

Links to these documents are available on the regulatory documents section of the LSHTM website, RGIO intranet page, and/or in the reference section of this policy.

6.3 The Research Governance and Integrity Office (RGIO) is responsible for the operational oversight of all human research conducted by LSHTM staff, doctoral or MSc student, and where LSHTM is taking the role of Sponsor for any interventional study, clinical trial or health-related research undertaken in the UK. The RGIO ensures that the study meets the standards detailed in 6.2 and will act as the final compliance check before the study can start. The RGIO can request amendments to the study protocol or other documentation to bring the study in line with the standards detailed in 6.2. The activities of the RGIO are overseen by the Research Governance Committee.

6.4 In conjunction with the insurance office within the Finance department, the RGIO ensures that the study has appropriate indemnity in place for the lifetime of the project. All clinical trials where LSHTM is the named legal Sponsor must be reviewed by the insurance brokers for LSHTM for costing of a local insurance policy prior to submission of the grant application. Interventional trials will typically require a policy per territory.

6.5 Freedom of Information requests are managed by Legal Services who will respond to such requests on behalf of LSHTM.

7. Research misconduct

7.1 Researchers must not engage in any act which may constitute research misconduct.

7.2 Research misconduct may involve (note this list is not exhaustive):

- Fabrication – making up data results or other outputs and presenting them or recording them as if they are real
- Falsification – inappropriately manipulating research processes, or changing or omitting data
- Plagiarism – appropriation of other people's material without giving proper credit in proposing, performing or reviewing research, or in reporting research results
- Failure to meet ethical, legal and professional obligations, such as:
    - Not observing legal, ethical and other requirements for research with humans or animals, or for the protection of the environment
    - breach of duty of care including failing to obtain informed consent
    - breach of confidentiality, misuse of personal data including inappropriate disclosures of the participant identity or the improper handling of privileged or private information on individuals collected during the research.
    - improper conduct in peer review of research proposals, results or manuscripts for publication
    - deception in proposing, carrying out or reporting results of research
- Failure to follow approved and accepted research protocols/procedures, including:
    - Not obtaining appropriate permissions prior to the start of the study (i.e., relevant ethics committee approvals/favourable opinions and regulatory authority approvals)
    - Not exercising due care in carrying out responsibilities for, or avoiding unreasonable risk or harm to:
        - humans
        - animals used in research
        - the environment
- Misrepresentation/mismanagement of:
    - data including suppression of relevant results or data and/or primary materials. This includes knowingly, recklessly or negligently presenting flawed interpretations
    - inappropriate claims to authorship or attribution of work and denial of authorship/attribution to persons who have made an appropriate contribution
    - interests including failure to declare competing interests of researchers or funders
    - qualifications, experience, and/or credentials
    - publication history, through undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts (self-plagiarism)
- Improper dealing with allegations of misconduct, including failing to address possible infringements, such as attempts to cover up misconduct and reprisals against whistle-blowers, or failing to adhere appropriately to agreed procedures in the investigation of alleged research misconduct.

- Engaging in Questionable Research Practices (QRPs) can also be defined as research misconduct. QRPs are defined as actions that violate traditional values of the research enterprise and that may be detrimental to the research process. Examples of QRPs include: selective outcome reporting, selective reporting of (dependent) variables, failure to disclose experimental conditions, rounding down the p-value.

7.3 Research misconduct includes acts of omission as well as acts of commission. Misconduct does not include honest errors and differences in interpretation of data, results or methodology.

7.4 Researchers, as well as all other staff and students, have a responsibility to report suspected cases of research misconduct in accordance with LSHTM's policy and procedure for investigating research misconduct, as well as LSHTM's Whistleblowing policy. Informal discussions or queries should be directed to the Head of Research Governance and Integrity in the first instance.

7.5 Allegations of research misconduct will be investigated in accordance with LSHTM's procedure for investigating allegations of research misconduct.

7.6 Allegations of student research misconduct will be investigated in accordance with the academic regulations.

7.7 Concerns may also be raised in accordance with LSHTM's Whistleblowing policy which covers raising concerns about malpractice or impropriety, and includes:

- Financial malpractice or impropriety or fraud;
- Failure to comply with a legal obligation or with the regulations of LSHTM;
- Dangers to health and safety or the environment;
- Academic or professional malpractice;
- Miscarriage of justice;
- Improper conduct or unethical behaviour;
- Serious conflict of interest without disclosure;
- Criminal activity (not covered by the above), and
- Attempts to conceal any of the above.

7.8 Researchers found to have engaged in misconduct will face penalties commensurate to the type and level of misconduct committed. This may include sanctions, correcting the research record, and reporting any action to regulatory and statutory bodies, research participants, funders or other professional bodies as circumstances, contractual obligations and statutory requirements dictate. Further details are provided in the procedure for investigating allegations of research misconduct. Researchers will be provided with the appropriate support when reports are made to professional and/or statutory bodies.

7.9 The Research Governance and Integrity Office will report incidents of misconduct to the Research Governance Committee, as well as a summary to the Audit and Risk Committee

on an annual basis. A narrative statement will be published on the RGIO page of the LSHTM website.

8. Conflicts of Interest

8.1 Conflicts of interest can be defined as conditions where professional judgement concerning a primary interest (e.g., conducting or reporting research) may be, or appear to be, unduly influenced by a secondary interest (e.g., financial gain). Conflicts of interest can arise due to financial, academic, personal, political, religious, legal, ethical, moral or other personal interests. Attention should be given to potential conflicts as well as actual conflicts of interest.

8.2 Researchers must fully disclose any personal interest that could lead to an actual or potential conflict of interest at the earliest possible time and in accordance with LSHTM, funder or any other external party's policies and regulations. If a researcher is in doubt over whether a personal interest could lead to an actual or potential conflict of interest, immediate guidance should be sought from the Head of Legal Services and/or Research Governance and Integrity Office. Steps need to be taken to resolve any such conflict of interest at the earliest possible stage and usually before approval for conducting a particular research project can be granted.

8.3 It may be necessary not to grant approval for a particular project of a researcher or to limit or discontinue such a project or the involvement of the researcher where there is an actual or potential conflict of interest which could undermine or discredit the researcher, LSHTM and its reputation, the research or research outcomes, or could in any other way be in breach of relevant LSHTM, funder or any other external party's policies or regulations in regards to conflicts of interest.

9. Confidentiality

9.1 Researchers must ensure the confidentiality of personal information relating to research participants, and that the research fulfils any legal requirements, in particular, is in compliance with the Data Protection Act 2018 and GDPR. If there are problems with ensuring compliance, contact the Data Protection Officer as soon as possible (dpo@lshtm.ac.uk).

9.2 Prior to publication or depositing data in a central depository, data should be fully anonymised, unless with prior agreement via full informed consent. This process should include: removing all personal identifiers (name, initials, date of birth, post code etc) as well as removing other types of identifiers where it may be possible to identify a participant, e.g., very rare diagnosis, name of organisation.

9.3 Researchers should ensure that informed consent includes the provision of sharing data, including in a public central depository, and for any potentially identifiable activities in a publication.

10. Health and Safety

10.1 All staff, students and visiting workers of LSHTM are required to comply with LSHTM's health and safety procedures whether they are working on behalf of LSHTM, at one of its principal sites, or remote from LSHTM's premises.

10.2 LSHTM's Health, Safety and Wellbeing Policy can be found on the intranet. Various procedures related to this which relate to research are also available, such as:

- Laboratory guidance and procedures
- BioRisk
- Genetically Modified Organisms
- Chemical Safety
- Radiation Safety
- Travel guidance and safety
- Occupational Health

10.3 The principal objective of all safety procedures is to control hazards. This is best achieved by preventing the hazard from arising; whenever possible, therefore, the research method, material or organism presenting the least hazard should be chosen. Wherever hazards still remain, appropriate measures must be taken to control those hazards.

10.4 All new staff are required to complete a safety induction with records held by the Health and Safety Department.

10.5 All research involves a degree of risk to participants and to researchers. All researchers should complete a risk assessment for their project so that they are aware of the potential risks and have plans in place to mitigate these risks. Adverse Events, Adverse Incidents and Serious Adverse Events may occur on any project, and it is the Principal Investigator (PI)'s responsibility to monitor and act upon them.

11. Research Design and Methodology

11.1 Suitable research design and methodology should be employed to ensure that key study questions can be appropriately and adequately be answered. This includes, but is not limited to the following:

- Research should aim to add to the existing knowledge of the subject, or confirm reproducibility of existing data, or develop methods for research into the question
- Research design should be appropriate to the study question and addresses sources of bias

- A clear and detailed research plan or protocol should be produced setting out the design and conduct of the study, including how records will be gathered, analysed and managed, and how and in what form relevant data will eventually be made available to others. Consideration should be given to how data may be reused in the future, including sharing it with collaborators, other researchers or through open access.
- Use of an appropriate statistical method to analyse the data
- Sufficient resources available to undertake the proposed research. This includes the knowledge, experience and education of all study team members to undertake the tasks assigned to them.

11.2 As part of the process of designing the research, the proposal should examine all the potential risks and ethical issues, how data will be collected, what techniques and instruments will be used and how, and how records will be analysed.

11.3 All researchers are recommended to make use of independent / scientific / peer review as best practice.

11.4 All clinical trials and all research taking place in the UK, must have a nominated legal Sponsor, i.e., the organisation responsible for the initiation, management and/or financing of research. The Sponsor ensures that the research plan is suitable and meets all regulatory, ethical and other standards of good practice, and has ultimate oversight on the conduct of the research. The RGIO undertakes this role at LSHTM, and may delegate responsibility to counterparts within the Units, as necessary.

11.5 Any research undertaken by LSHTM may be subject to audit by the RGIO, to ensure that it is carried out in accordance with all LSHTM policies and procedures, and all ethical and legal requirements. Researchers are expected to cooperate with the audit of their research projects.

11.6 Care should be used to ensure that research data is not misused by groups intent on nefarious activities.

12. Management of Research Assets, including Data, Code, Samples and Records

12.1 The following principles should be applied to manage assets used in research. This includes research data, software code, samples and records, irrespective of the form in which they are held (physical, digital) and/or their source (produced or collected by a project, transferred from another institution).

- Research assets must be obtained, stored, managed, and used in accordance with the agreed design of the project and in compliance with legal, ethical, regulatory, funding, contractual, LSHTM, and other requirements;

- Projects that are creating or capturing new research assets, such as data or samples, must create a Data Management Plan prior to the commencement of research and ensure it is reviewed and updated at appropriate intervals during the project lifecycle;

- Researchers must keep full, clear and accurate records sufficient to allow others to access, understand, verify and replicate their research. Relevant documentation will include information on procedures applied, approvals granted, sources used and results obtained (including interim and negative results);

- Research assets must be stored securely in a manner that ensures the confidentiality of information, protects against data loss and corruption, and complies with relevant legal, ethical and other requirements;

- Research assets must be stored in a manner that enables prospective and retrospective audit;

- Research assets collected as part of international projects or through collaborating organisations/sites must be maintained in accordance with relevant policies and procedures and research agreements;

- Research assets (excluding samples originating from humans) must be stored in an appropriate form and retained for a minimum of 10 years following project completion or the publication date (whichever is longest), in accordance with LSHTM's Records Retention and Disposal Schedule. A shorter retention period may be applied, if mandated by a third party, and will require ethics approval to undertake this;

- Samples originating from humans must be stored in an appropriate form in line with the consent obtained. In order for samples to be retained following project completion, explicit consent must be in place for storage for future unspecified research. Where consent was project-specific, samples must be destroyed following project completion;

- Research assets collected and stored by staff for projects originating from LSHTM are the intellectual property of LSHTM (see 14). Staff are not permitted to remove the primary copy when leaving LSHTM. Secondary copies may be taken with appropriate written permission from the department;

- Samples originating from humans remain the property of the donor, and consent for storage may be revoked at any time. Where possible, samples should remain in their country of origin and/or be returned following project completion.

- Doctoral and MSc students should clarify intellectual property rights and custodianship of data, samples, records and other research assets that they produce or acquire for use in research, since it may vary depending upon the source

and associated agreements. They must also be retained in accordance with other relevant requirements (e.g., LSHTM, legal, ethical, funding body, professional body);

- Projects should consider the need to share research assets that substantiate research findings at the earliest opportunity, taking appropriate steps to address ethical, legal, and contractual and other requirements that may act as a barrier to wider access (See section 17 on Openness).

All staff and students must abide by LSHTM information security policy and supporting documents.

13. Financial Management and Accountability

13.1 LSHTM's Financial Regulations sets out policy and procedures relating to research activity, including: project proposals; costing and pricing; contract terms and conditions; acceptance of offers and signature of contracts; budgeting; collaborators and sub-contracts; project expenditure; overspends; claiming and invoicing; credit control; grant closure; and publication of research. The Financial Regulations also set out specific responsibilities, including for: Deans of Faculty; Heads of Department; Budget Holders/Principal Investigator; and Research Operations Office.

13.2 LSHTM has also prepared guidance to support overseas-based staff and partners by setting out LSHTM's expectations for financial and other management arrangements of LSHTM grants held fully or in part overseas.

13.3 When developing budgets and managing funds, researchers and administrators should uphold the principle of using funds to achieve the greatest benefits possible within the scope of the research project.

13.4 LSHTM retains responsibility for funds it distributes to collaborators for research projects and will undertake due diligence on collaborators, as necessary. All researchers, including collaborators, must ensure that they abide by the bribery and anti-fraud policy.

13.5 Where LSHTM is a sub-awardee, funds must be managed in accordance with LSHTM's financial regulations, and any additional requirements stipulated by the prime grant recipient.

14. Intellectual Property

14.1 IP (Intellectual Property) means all research results and data generated through research programmes conducted at LSHTM (including with third party collaborators), as well

as all other outputs of work, such as teaching materials, and all intellectual property rights associated with or arising from such results and outputs.

14.2 In order to fulfil its charitable mission, LSHTM must support successful application of the outcomes from its research activities and capabilities to ensure the widest benefit to society and the economy. IP generated from innovation and translation must also be managed effectively so that, in order to maximise its impact, appropriate industrial partners can be attracted to progress the development and commercialisation of products and services arising from academic discoveries made at LSHTM. LSHTM is therefore responsible for ensuring research outputs and inventions originating at LSHTM are translated and/or disseminated in a manner consistent with LSHTM's mission and status as a socially responsible higher education and research institution. Any revenue generated from commercialisation of LSHTM IP is invested back into fulfilling LSHTM's mission through funding further research and/or education, as well as into supporting further technology transfer activities.

14.3 Commercialisation of Intellectual Property generated by LSHTM staff will typically be handled via Chariot Innovations – LSHTM's wholly owned subsidiary company which has been established for this purpose.

14.4 LSHTM works in compliance with the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity" (Nagoya Protocol). The Nagoya Protocol governs access to non-human genetic resources and traditional knowledge. Researchers are required to exercise due diligence to ascertain that genetic resources or traditional knowledge have been accessed according to the Nagoya Protocol and keep this due diligence for 20 years after the end of utilisation.

14.5 Further information on Intellectual Property can be found in the LSHTM IP Policy.

15. Decision Making

15.1 For the purposes of transparency and good record-keeping, all formal discussion/decision making meetings (including those concerning budget and publication) should be minuted. A record of other important decisions made outside formal meetings should also be kept. Where a project involves external partners, all those with a stake in the decision should be involved in discussions and decision-making.

16. Research Collaborations

16.1 LSHTM conducts research in collaboration with many other organisations throughout the world. LSHTM staff must make every effort to ensure that collaborative research and projects are conducted reasonably and equitably, including through fair contractual arrangements. Where collaborators have relevant procedures for good research practice,

LSHTM will follow such collaborator procedures in addition to this LSHTM Policy, as required by the collaborator, and to the extent possible.

16.2 LSHTM is in the process of developing additional guidance on equitable research collaborations, building on initiatives throughout the institution and existing published guidance (see resources in section 22). All staff are encouraged to familiarise themselves with principles of fair partnership and engage in equitable partnership practice at all stages of the research lifecycle. This includes working to overcome barriers imposed by internal and external policies and procedures and acting with the interests of all partners in mind.

16.3 The LSHTM Research Office has developed guidance to support staff and students in making decisions about whether and how to engage with external partners for consultancy or research, including who the lead partner should be.

16.4 LSHTM does not accept funding from, nor works with the tobacco industry.

16.5 LSHTM researchers are encouraged, inasmuch as possible, to involve the community, the public, patient groups, etc in the development of the research idea and plan to ensure that the research meets the needs of the local community, the general public, and patients.

17. Openness

17.1 LSHTM is committed to ensuring that there is a research culture of openness, which includes:

- Researchers discussing their work with other scientists and with the public through scholarly exchange of ideas and the submission of work to peer review;
- Providing access to information on ongoing and completed research, subject to appropriate scientific review and subject to any confidentiality restrictions;
- LSHTM will add approved research projects to an accessible section of the website, with the expectation that Principal Investigators will endorse this unless there is a good reason not to
- Publishing findings in a timely fashion in a peer-reviewed journal or in other reputable publications that enables broad access to research findings, where feasible. Use of open access publication methods are particularly encouraged;
- Publishing in an accessible format to inform policy and practice;
- Disseminating research results through open access publishing where possible.
- Ensuring results are in the public domain as soon as practicable, but no later than 12 months following completion of the project. This includes adding results to all clinical trial registers (eg clinicatrials.gov or ISRCTN) and the EU Clinical

Trials Register in compliance with various regulations and good practice guidelines. The registry number should be included in the abstract for ease of finding the results.

- Sharing data, samples and other information that underpins research findings through a managed repository or enclave in a manner appropriate to the content. Researchers should ensure that their data is recorded in 'LSHTM Data Compass', LSHTM's institutional repository for research data.

18. Publication

18.1 LSHTM is committed to ensuring the observance of good publication practice, which includes the following principles:

- The duty to publish and disseminate research and research findings accurately and without selection that could be misleading (including adverse findings);

- Results should be published in a timely fashion, in peer reviewed journals where appropriate, and presented at scientific meetings;

- Results should be published in accordance with the funding agreement;

- The duty to declare any potential or actual conflicts of interest in relation to the research when reporting findings at meetings or in publications;

- A publication which is substantially similar to another publication from the same research, must contain appropriate references to the other publication to ensure the reader is aware that the results may be disseminated elsewhere;

- A research paper must not be submitted simultaneously to more than one potential publisher (duplicate submission) unless this is acknowledged to all publishers to whom the paper is submitted;

- Anyone listed as an author on a paper must have made a significant intellectual or practical contribution to the work and/or take responsibility for a particular component of the study, including its accuracy. All authors are responsible for the content of the paper and should be able to identify their own contribution. Authorship should follow the conventions of the International Committee of Medical Journal Editors or similar guidance appropriate to the field of study. "Honorary" or "gift" authorship (i.e. for those that do not fulfil criteria of authorship) is unacceptable;

- The contribution of formal collaborators, funders, sponsors, and all others who significantly assisted the research – but who do not qualify for authorship - should be properly acknowledged;

- All sources of information and data used in the research must be clearly acknowledged;

- Research findings should not be reported to the public media before they have been peer-reviewed by experts in the field of research. Except in exceptional circumstances, it is undesirable to make research findings available to the public media in advance of publishing the findings in a scientific journal or as a formal scientific report. Pre-prints are acceptable when timely dissemination of results is required (eg which impact on pandemic response). Open science principles should be followed;

- All press releases including for partners, funders, journals should be discussed with the Press Office prior to publication. Collaborators must be appraised of this principle;

- It is advisable to address publication and authorship issues at an early stage of the project, and to document agreed decisions. PIs must ensure that where appropriate all research project staff, including external partners have the opportunity to contribute to the publication process and be appropriately recognised for their contribution.

18.2 LSHTM recognises the benefits of open access publishing as a means to ensure that research results are disseminated as widely as possible. Researchers should deposit their Author Accepted Manuscript in 'LSHTM Research Online', LSHTM's institutional repository for research publications, immediately upon acceptance to ensure availability via the Green open access publishing route and eligibility for the Research Excellence Framework (REF). Researchers are also encouraged to include costs for Gold open access publishing as part of grant proposals. Library, & Open Research Services (LAORS) manages funds for UKRI and Wellcome funded researchers.

18.3 It is also important to note the requirements of particular funders, noting however, that if a project is deemed to be research, findings should be publicly disseminated and not be subject to censor from the funder. Contractual clauses should be scrutinised to ensure that this is not prohibited. Exceptions may occur in the case of commissioned research.

18.4 MSc projects are held by the Library for seven years. PhD theses are held by the Library permanently.

19. Training

19.1 LSHTM is committed to ensuring that staff and students undertake appropriate training to enable them to carry out their research activities appropriately, safely and effectively. Researchers are expected to undergo appropriate training in order to carry out their duties and to develop their knowledge and skills throughout their career, repeating and updating their training where necessary to ensure that skills are kept up-to-date.

19.2 No research activity should be carried out by any individual who does not have the necessary skills and experience to do so. It is the responsibility of managers and supervisors, and researchers themselves to identify particular training needs which may be identified through formal mechanisms, such as annual Performance & Development Reviews (PDRs), and informal mechanisms.

19.3 The Talent and Educational Development programme provides a range of training opportunities, in addition to other local training provision (e.g. Faculty/Department level training). It may be necessary to identify other/specialised training to meet some needs, for example if doctoral students undertake teaching, they will need to participate, at the least, in the introduction to learning and teaching workshop which is aligned to the Researcher Development Framework. LSHTM is signatory to the Concordat to Support the Career Development of Researchers and is committed to supporting researcher to engage in a minimum of 10 days professional development (pro rata) per year.

19.4 The Talent and Educational Development run an LSHTM-wide annual programme of training, for example the Transferable Skills Programme, for doctoral students and including Equity, Diversity and Inclusion workshops. The programme includes a range of short workshops, training sessions and online resources. In addition, doctoral students have access to training run by the Bloomsbury Postgraduate Network plus other provision organised locally by their Faculty/Department.

19.5 An important aspect of achieving equity in research partnerships is to strive towards all partners having equal capacity to manage and deliver research. Time and resources should be dedicated towards capacity strengthening where needed and welcomed, and opportunities sought for mutual exchange of learning.

20. Roles and Responsibilities

20.1 LSHTM has arrangements in place for the management and supervision of research, which provides for particular roles and responsibilities. Managers provide direction and leadership for research activities and through doing so are responsible for promoting and supporting a culture of good research practice in accordance with this Policy.

20.2 Key roles and responsibilities include:

- Director – overall responsibility to Council for the academic and financial affairs of LSHTM.

- Deputy Director and Provost – works alongside the Director and Deans of Faculty in the development and implementation of LSHTM's Research Strategy and developing research collaborations.

- Unit Directors – responsible for all activities within the MRC Units.

- Deans of Faculty – manage the Faculty such that it undertakes relevant research to the highest standards and manage the Faculty's financial resources effectively and in accordance with LSHTM's Financial Regulations and the requirements of research and other sponsors.

- Heads of Department – manage the Department such that it undertakes relevant research to the highest standards and manage the Department's financial resources effectively and in accordance with LSHTM's Financial Regulations and the requirements of research and other sponsors.

- Principal Investigators (PIs) - have academic, managerial, financial and ethical responsibility for their research projects/programmes. All research projects/programmes must have clear management and supervision arrangements, which are understood and observed by all researchers involved in the project/ programme. PIs' (or project leader) responsibilities include emphasising adherence to current safety practices and ethical requirements, the adoption of systematic research methods, good record keeping, sharing of data within the research team and openness in discussion, including identification of potential conflicts of interest, and encouraging good communication between colleagues, peer review of work, and timely publication.

- Pro-Director for Education- has overall responsibility for taught courses and the research degree programme.

- Faculty Research Degree Directors – have oversight of research degrees in their faculty.

- Department Research Degree Co-ordinators – oversee the progress of all doctoral students in their department.

- Supervisors (*for doctoral/taught course students*) – oversee and support doctoral/MSc students for all aspects of their study/project.

- Ethics Committee Members, including the Chair(s) - undertake review free from bias and influence, provide advice to the researchers on all aspects of welfare and safety of research participants, check and ensure that all information given to the research participants is clear and easy for them to understand, honest and does not have a negative impact on the participant's autonomy. Review projects annually, as well as safety and protocol deviation reports

20.3 Everyone has a responsibility to embed equity, diversity and inclusion in all that we do and recognising it as a School-wide responsibility (See 3.5).

20.4 LSHTM is a signatory to the Declaration on Research Assessment (DORA) which aims to improve how researchers and outputs of research are evaluated.

21. Dissemination

21.1 This Policy will be provided to all new staff, and both MSc and doctoral students as part of induction packs and addressed as part of induction arrangements. Staff awareness of this Policy will be encouraged through email from time to time.

21.2 Further information on research integrity and the implementation of this Policy may be sought from the Head of Research Governance and Integrity (rgio@lshtm.ac.uk). The Head of Research Governance and Integrity is the first point of contact for all queries on research integrity.

22. References, Links and Further Reading

LSHTM references

3. Research Environment
EDI Strategy: https://www.lshtm.ac.uk/aboutus/organisation/governance/equity-diversity-and-inclusion/edi-strategy-and-reports

4. Research Participants
Human Tissue policy: https://www.lshtm.ac.uk/research/research-governance-integrity/human-tissue
Policy and Procedure for review of research proposal quality: https://lshtm.sharepoint.com/Research/Strategic-Research/
Safeguarding information and policy: https://www.lshtm.ac.uk/aboutus/organisation/governance/safeguarding
Anti-bullying and harassment policy: https://www.lshtm.ac.uk/sites/default/files/Anti-Bullying-Harassment-Policy.pdf
SOPs for Research, including audit guidance for clinical trials: https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx
LSHTM Research Ethics Committees Membership and Terms of Reference: https://www.lshtm.ac.uk/aboutus/organisation/governance/committees

Research involving animal subjects
Use of animals in biomedical research: https://www.lshtm.ac.uk/research/research-governance-and-integrity/animal-research
Animal research policy: https://www.lshtm.ac.uk/research/research-governance-and-integrity/animal-research

Compliance

LSHTM's policies and Standard Operating Procedures:
https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx
LSHTM Data Protection Policy: https://www.lshtm.ac.uk/sites/default/files/data-protection-policy.pdf
LSHTM Records Management Policy: https://lshtm.sharepoint.com/Services/Information-Management/Pages/records-management-policy.aspx
Information Management & Security at LSHTM:
https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security
LSHTM's Freedom of Information Act Policy:
https://www.lshtm.ac.uk/sites/default/files/Freedom_of_Information_Policy.pdf
LSHTM policy on Health and Safety:
https://lshtm.sharepoint.com/Services/Safety/Pages/policy.aspx
Whistleblowing Policy:
https://www.lshtm.ac.uk/sites/default/files/whistleblowing_policy.pdf
LSHTM Open Access Policy:
https://www.lshtm.ac.uk/sites/default/files/open_access_policy.pdf
Policy on Declaration of Interests: https://lshtm.sharepoint.com/Services/Human-Resources/Documents/Declaration-of-Interest-Policy.pdf#search=conflict%20of%20interest
Safeguarding information and policy:
https://www.lshtm.ac.uk/aboutus/organisation/governance/safeguarding

7. Research Misconduct
LSHTM's policy and procedure for inquiring into allegations of research misconduct:
https://www.lshtm.ac.uk/sites/default/files/allegations-of-misconduct-policy.pdf
Whistleblowing Policy:
https://www.lshtm.ac.uk/sites/default/files/whistleblowing_policy.pdf
RGIO research integrity page: https://www.lshtm.ac.uk/research/research-governance-integrity/research-integrity

8. Conflict of Interest
Financial Conflict of Interest for US HHS/PHS funded research:
https://lshtm.sharepoint.com/sites/assets/policies/Documents/Financial%20Conflict%20of%20Interest%20Policy.pdf#search=conflict%20of%20interest
Policy on Declaration of Interests: https://lshtm.sharepoint.com/Services/Human-Resources/Documents/Declaration-of-Interest-Policy.pdf#search=conflict%20of%20interest

9. Confidentiality
LSHTM Data Protection Policy: https://www.lshtm.ac.uk/sites/default/files/data-protection-policy.pdf
Information on Data Protection at LSHTM:
https://lshtm.sharepoint.com/Services/Information-Management/Data/Pages/default.aspx

10. Health & Safety
LSHTM policy on Health and Safety:
https://lshtm.sharepoint.com/Services/Safety/Pages/policy.aspx

11. Research Design and Methodology

Prevent**:** https://www.lshtm.ac.uk/aboutus/organisation/governance/prevent-duty
LSHTM SOP on risk assessment: https://lshtm.sharepoint.com/Research/Research-Governance/PublishingImages/Pages/standard-operating-procedures-(sops)/LSHTM-SOP-015-02_Risk%20Assessment_18.12.19_v2.0_Final.pdf
Safety risk assessment:
https://lshtm.sharepoint.com/Services/Safety/Documents/Intranet%20Site/Biorisk%20Arrangements%202020.pdf

12. Management of Research Data and Samples

Human Tissue policy: https://www.lshtm.ac.uk/research/research-governance-integrity/human-tissue
Information Management & Security at LSHTM:
https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security
LSHTM Records Management Policy: https://lshtm.sharepoint.com/Services/Information-Management/Pages/records-management-policy.aspx
Information on Records Management at LSHTM:
https://lshtm.sharepoint.com/Services/Information-Management/Pages/records.aspx
LSHTM Research Data Management Policy:
https://www.lshtm.ac.uk/sites/default/files/research_data_management_policy.pdf
Information on Research Data Management at LSHTM:
https://lshtm.sharepoint.com/Research/Research-data-management/

13. Financial Management

LSHTM financial regulations: https://lshtm.sharepoint.com/Services/Finance/
Support for Management of Overseas Research Grants:
https://lshtm.sharepoint.com/Services/Research-Operations/Pages/default.aspx
LSHTM due diligence policy: https://lshtm.sharepoint.com/Services/Research-Operations/Documents/LSHTM%20COLLABORATOR%20DUE%20DILIGENCE%20AND%20MONITORING%20POLICY.pdf
Anti-bribery conduct:
https://www.lshtm.ac.uk/sites/default/files/Anti_Bribery_Conduct_Policy_Procedures.pdf
Anti-bribery policy:
https://www.lshtm.ac.uk/sites/default/files/Anti%20Bribery%20Policy%20and%20Guidance%20on%20Gifts%20and%20Hospitality.pdf
Anti-fraud policy: <link to be included>
Guidance for working with external partners: <link to be included>

14. Intellectual Property

LSHTM Intellectual Property Policy:
https://www.lshtm.ac.uk/sites/default/files/School_Intellectual_Property_Policy.pdf

16. Research Collaborations

LSHTM Statement on working with the tobacco industry:
http://www.lshtm.ac.uk/research/researchgovernanceandintegrity/researchgovernance/index.html
GHD equitable partnerships tool <link to be provided>

17. Openness
LSHTM's Freedom of Information Act Policy:
https://www.lshtm.ac.uk/sites/default/files/Freedom_of_Information_Policy.pdf
Information on Freedom of Information at LSHTM:
https://lshtm.sharepoint.com/Services/Information-Management/Pages/foi.aspx
LSHTM Open Access Policy:
https://www.lshtm.ac.uk/sites/default/files/open_access_policy.pdf

18. Publication
Information on Open Access publishing at LSHTM:
http://www.lshtm.ac.uk/library/specialist_services/open_access/index.html
Good Publication Practice Standard Operating Procedure:
https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx

19. Training
TED: https://lshtm.sharepoint.com/Services/TED/
Professional Development:
https://lshtm.sharepoint.com/Services/TED/Pages/profe_index.aspx
Transferable Skills Programme: https://lshtm.sharepoint.com/Teaching-and-Support/Pages/transferrable-skills.aspx
Researcher Development CPD:
https://lshtm.sharepoint.com/Services/TED/Pages/Researcher-Development-CPD.aspx
Training courses on Research Ethics, Good Clinical Practice, Working with Human Tissue, and Good Research Practice can be found at:
https://open.lshtm.ac.uk/course/index.php?categoryid=6

20. Roles and Responsibilities
Doctoral Degree Handbook: https://www.lshtm.ac.uk/study/new-students/msc-research-students/regulations-policies-and-procedures
MSc Project Handbook: https://lshtm.sharepoint.com/students/Pages/masters-students.aspx
Doctoral supervisors' handbook: <link to be included>
Student disciplinary procedures:
https://www.lshtm.ac.uk/sites/default/files/student_disciplinary_procedure.pdf
DORA: https://www.lshtm.ac.uk/research/research-publications-and-research-data

External references

Career Development
The Concordat to Support the Career Development of Researchers (2019):
https://www.vitae.ac.uk/policy/concordat

Vitae Researcher Development Framework: https://www.vitae.ac.uk/researchers-professional-development/about-the-vitae-researcher-development-framework

Bloomsbury Postgraduate Network: http://courses.grad.ucl.ac.uk/bloomsbury/

Definition of Research

REF (2021) Assessment framework and guidance on submissions:
https://www.ref.ac.uk/publications/guidance-on-submissions-201901/

Collaborations

Commission for Research Partnerships with Developing Countries:
http://www.naturalsciences.ch/organisations/kfpe

UKCDR Equitable Partnerships hub, a portal to access resources in this area:
https://www.ukcdr.org.uk/guidance/equitable-partnerships-hub/

COHRED Research Fairness Initiative
https://rfi.cohred.org/

COHRED Fair Research Contracting
https://www.cohred.org/frc/

TRUST Global Code of Conduct for Research in Resource Poor Settings
https://www.globalcodeofconduct.org/

KFPE Guide for Transboundary Research Partnerships
https://kfpe.scnat.ch/en/11_principles_7_questions

CCGHR Partnership Assessment Tool
https://cagh-acsm.org/en/our-work/country-partnerships/partnership-assessment-tool

BRIDGE guidelines for good epidemiological practice in global health
https://www.kit.nl/project/bridge-bridging-research-integrity-and-global-health-epidemiology/

Good Publication Practice

'Guidelines on Good Publication Practice' produced by the Committee on Publication Ethics (COPE) - https://publicationethics.org/core-practices

International Committee of Medical Journal Editors:
http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two

Open Science Principles
Open Science Training Handbook, at: https://open-science-training-handbook.gitbook.io/book/open-science-basics/open-concepts-and-principles

Research Integrity and Good Research Practice Guidelines
Concordat to Support Research Integrity (2019): https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/the-concordat-for-research-integrity.aspx

European Code of Conduct for Research Integrity (2011): https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

UK Research and Innovation Policy and Guidelines on Governance of Good Research Conduct: https://epsrc.ukri.org/about/standards/scimisconduct/ukripolicy/

UKRIO Code of Practice for Research: https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research-original-2009-format.pdf

Wellcome Trust (2018) Good Research Practice guidelines: https://wellcome.ac.uk/funding/guidance/good-research-practice-guidelines

RCUK (2017) RCUK Policy and Guidelines on Governance of Good Research Conduct: https://www.ukri.org/files/legacy/reviews/grc/rcuk-grp-policy-and-guidelines-updated-apr-17-2-pdf

Singapore Statement on Research Integrity: https://wcrif.org/guidance/singapore-statement

Montreal Statement on Research Integrity: https://wcrif.org/montreal-statement/file

Research Regulations and Guidelines
International Council for Harmonisation for Good Clinical Practice Guidelines (R2, 2016): https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

Declaration of Helsinki (2013): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016): https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

US Federal Policy for the Protection of Human Subjects (45 CFR part 46):

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html#:~:text=The%20HHS%20regulations%2C%2045%20CFR,D%2C%20additional%20protections%20for%20children.

Food and Drug Administration regulations on Protection of Human Subjects (21 CFR 50) and on Institutional Review Boards (21 CFR 56): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

Medicines and Related Products Act 2014, Republic of The Gambia: https://www.mca.gm/

National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014, Uganda https://www.nda.or.ug/ndpa-act-regulations/

Uganda National Council for Science and Technology (UNCST) 2014. National Guidelines for Research involving Humans as Research Participants. Kampala, Uganda: UNCST https://www.uncst.go.ug/

Uganda National Council for Science and Technology (UNCST) 2016. Research Registration and Clearance Policy and Guidelines. Kampala, Uganda: UNCST https://www.uncst.go.ug/

Medicines for Human Use (clinical trials) Regulations (2004), as amended: http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Human Tissue Act (2004): http://www.legislation.gov.uk/ukpga/2004/30/contents

Data Protection Act (2018): http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted

UK Policy Framework for Health and Social Care Research (2017): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Nagoya Protocol: https://www.cbd.int/abs/

Safeguarding

UKCDR: Guidance on Safeguarding in International Development Research (2020): https://www.ukcdr.org.uk/resource/guidance-on-safeguarding-in-international-development-research/

UKRI: Preventing harm (safeguarding) in research and innovation policy (2020): https://www.ukri.org/wp-content/uploads/2020/10/UKRI-050920-PreventingHarmSafeguardingInResearchAndInnovationPolicy.pdf

NIHR Safeguarding guidance (2020):
https://www.nihr.ac.uk/documents/nihr-safeguarding-guidance/25744?pr=

International development research funders' statement on safeguarding:
https://www.ukri.org/about-us/policies-standards-and-data/international-development-research-funders-statement-on-safeguarding/

DFID Enhanced Due Diligence: Safeguarding for external partners:
https://www.gov.uk/government/publications/dfid-enhanced-due-diligence-safeguarding-for-external-partners

Appendix 1: UKRIO checklist (available at https://ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf)

UKRIO Recommended Checklist for Researchers

This Checklist by the UK Research Integrity Office lists the key points of good practice for a research project and is applicable to all subject areas. More detailed guidance is available in our *Code of Practice for Research*.

Before conducting your research, and bearing in mind that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research:

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it? ☐
2. Is your research design appropriate for the question(s) being asked? ☐
3. Will you have access to all necessary skills and resources to conduct the research? ☐
4. Have you conducted a risk assessment to determine:
   - a whether there are any ethical issues and whether ethics review is required; ☐
   - b the potential for risks to the organisation, the research, or the health, safety and well-being of researchers and research participants; and ☐
   - c what legal requirements govern the research? ☐
5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant? ☐
6. Will your research comply with all requirements of legislation and good practice relating to health and safety? ☐
7. Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves animals, human participants, human material or personal data? ☐
8. Will your research comply with any monitoring and audit requirements? ☐
9. Are you in compliance with any contracts and financial guidelines relating to the project? ☐
10. Have you reached an agreement relating to intellectual property, publication and authorship? ☐
11. Have you reached an agreement relating to collaborative working, if applicable? ☐
12. Have you agreed the roles of researchers and responsibilities for management and supervision? ☐
13. Have all conflicts of interest relating to your research been identified, declared and addressed? ☐
14. Are you aware of the guidance from all applicable organisations on misconduct in research? ☐

When conducting your research:

1. Are you following the agreed research design for the project? ☐
2. Have any changes to the agreed research design been reviewed and approved if applicable? ☐
3. Are you following best practice for the collection, storage and management of data? ☐
4. Are agreed roles and responsibilities for management and supervision being fulfilled? ☐
5. Is your research complying with any monitoring and audit requirements? ☐

When finishing your research:

1. Will your research and its findings be reported accurately, honestly and within a reasonable time frame? ☐
2. Will all contributions to the research be acknowledged? ☐
3. Are agreements relating to intellectual property, publication and authorship being complied with? ☐
4. Will research data be retained in a secure and accessible form and for the required duration? ☐
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