

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

GUIDELINES ON GOOD RESEARCH PRACTICE

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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 these guidelines will be available on the School website;*
- (ii) refers to intranet locations, which are only accessible to staff and students.*

Guidelines on Good Research Practice, September 2010, Version 2

1. Background

1.1 LSHTM has a broad research governance framework which comprises a range of principles, policies, procedures and guidelines that regulate research at the School. The Guidelines on Good Research Practice provide one element of this framework. The Guidelines are supported by more detailed policies, procedures and guidelines including for investigating allegations of science misconduct, ethical review, health and safety, grant management, research management and confidentiality of data and records, intellectual property, and working with the private sector.

1.2 Research conducted under LSHTM auspices must be undertaken to the highest standards in accordance with good research practice. These Guidelines set out the framework for good research practice.

1.3 These Guidelines have been developed in accordance with national guidance including from RCUK and the UK Research Integrity Office.

2. Application

2.1 These Guidelines apply to anyone conducting research involving the School including staff, students, honorary staff and collaborative research partners. This group to whom these Guidelines apply are to be known in this document as 'Researchers'.

2.2 The School expects the principles, policies and procedures set out in these Guidelines to be understood and observed by all Researchers.

3. LSHTM Research Environment: Principles

3.1 'Excellence' in research is a key School value and is supported by six 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, acknowledging the contributions of others, and neither engaging in misconduct nor concealing it
- **Integrity** – comply with all relevant legal and ethical requirements, declare any potential or actual conflicts of interest relating to research and where necessary take steps to resolve them
- **Co-operation** – promote the open exchange of ideas, research methods, data and results and their discussion, scrutiny and debate, subject to any considerations of confidentiality
- **Safety** – ensure the safety of all involved in research (i.e. Researchers, research subjects, patients, participants and others)
- **Accountability** – recognise that ultimate accountability is to the general public and research should be conducted and reported always with this in mind. Ensure research undertaken complies with any agreements, terms and conditions relating to the project, and ensure proper governance and transparency. Follow the requirements and guidance of any professional bodies of which those involved in the research are members

- **Training and skills** – ensure 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 The School is responsible for ensuring arrangements are in place which embed these principles within the broad research governance framework (see 1.1, above) and also supports Researchers in adhering to them.

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

4. **Research Subjects**

Research involving human subjects

4.1 LSHTM and Researchers have specific responsibilities for human research subjects, in particular to ensure their well-being, to retain confidentiality on their involvement and to follow principles in relation to management of data. All research involving humans must be in compliance with these Guidelines, related policies and procedures and ethical, legal, policy and other requirements which regulate such work.

4.2 All research proposals involving human subjects must be reviewed and approved by the LSHTM's Ethics Committee, which is responsible for ensuring the research will conform to the highest ethical standards. Approval must also be obtained from other UK/overseas ethical review and regulatory bodies where appropriate.

4.3 All participants in a research undertaking should expect Researchers to act within these guidelines and the other aspects of the Research Governance Framework.

Research involving animal subjects

4.4 The School has a specific policy on the use of animals in biomedical research which can be found at http://intra.lshtm.ac.uk/support/research/policy_on_the_use_of_animals_in_biomedical_research.pdf . In summary:

4.5 Achieving some of the aims in the School'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

4.6 Researchers will conduct research involving animals in accordance with the highest standards of humane care and treatment. Purpose bred laboratory rodents and insects will be the only species used. 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.

4.7 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).

4.8 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 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.

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

4.10 All animal-based research will be subject to review by an Ethical Review Panel that includes independent experts in ethics and animal welfare who are not members of School staff. The panel reviews before and during research to ensure compliance with the best possible standards of animal care.

5. Compliance

5.1 Research must be approved and conducted in accordance with:

- LSHTM research governance framework including these Guidelines and the principles (see 3., above);
- LSHTM policies and procedures;
- ethical, legal and policy requirements which regulate work (e.g. health & safety, data management and 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.

5.2 Researchers are expected to be aware of and adhere to all regulations governing their research activities.

6. Research misconduct

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

6.2 Misconduct in research may involve:

- fabrication
- falsification
- misrepresentation of data and/or interests and/or involvement
- plagiarism

- failures to follow appropriate research protocols/procedures or to exercise due care in carrying out responsibilities for:
 - avoiding unreasonable risk or harm to:
 - humans
 - animals used in research
 - the environment
 - the proper handling of privileged or private information on individuals collected during the research.

Misconduct in research may involve acts of omission as well as acts of commission.

6.3 Researchers, as well as all other staff and students, have a responsibility to report suspected cases of research misconduct in accordance with the LSHTM's policy and procedure for investigating scientific misconduct.

6.4 Allegations of staff research misconduct will be investigated in accordance with LSHTM's policy and procedure for investigating allegations of scientific misconduct.

6.5 Allegations of student research misconduct will be investigated in accordance with the student disciplinary procedures.

6.6 Concerns may also be raised in accordance with LSHTM's *Public Interest Disclosure Policy and Procedure*; see

http://intra.lshtm.ac.uk/personnel/policies/public_interest_disclosure_policy_and_document.pdf This covers raising concerns about malpractice or impropriety, which includes:

- financial malpractice or impropriety or fraud;
- failure to comply with a legal obligation or with the regulations of the School;
- 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. Conflicts of Interest

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

7.2 Researchers must fully disclose any actual or potential conflicts of interest, in particular to managers, supervisors, funding bodies and publishers. Steps should be taken to resolve the conflicts of interest where possible.

7.3 A record must be retained of all actual or potential conflicts of interest, and any actions taken to resolve the conflicts.

7.4 It may be necessary to limit or discontinue the work of a Researcher where there is a serious conflict of interest which could undermine or discredit the research or research outcomes.

8. **Confidentiality**

8.1 Researchers must ensure the confidentiality of personal information relating to research participants, and that the research fulfils any legal requirements, in particular compliance with the Data Protection Act 1998.

8.2 Prior to publication or depositing data in a public depository, data should be fully anonymised. 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, eg very rare diagnosis, name of organisation.

8.3 Further information on confidentiality is available from:

- LSHTM's *Information Management & Security Policy*
<http://intra.lshtm.ac.uk/committees/isag/imspolicy.pdf>
- Ethics Committee guidance
<http://intra.lshtm.ac.uk/committees/ethics/ethic-guide.pdf>

Further information on the Data Protection Act 1998 is available from
<http://intra.lshtm.ac.uk/dataprotection/>

9. **Ethical Review**

Research involving human subjects

9.1 All research proposals involving observation, questioning, examination, specimen collection or intervention with human subjects must be referred to, and approved by, LSHTM's Ethics Committee (the only exceptions are studies using data fully in the public domain). The Ethics Committee is responsible for ensuring that all research involving human subjects conducted by LSHTM staff and students, or on LSHTM premises, or with which LSHTM is closely involved (that is Researchers) conforms to the highest ethical standards. This applies to research undertaken in the UK and overseas.

9.2 Further information and the full procedure can be found at <http://intra.lshtm.ac.uk/committees/ethics/>. It should be noted that special importance is attached to procedures for obtaining informed consent from participants.

9.3 Approval must also be obtained from the Ethics Committee to amend or extend a study which has previously received Ethics Committee approval.

9.4 In addition, proposed studies must also gain approval from regulatory and other ethical review bodies where appropriate, both in the UK and overseas.

Research involving animals

9.5 LSHTM's policy on the use of animals in biomedical research can be found at http://intra.lshtm.ac.uk/support/research/policy_on_the_use_of_animals_in_biomedical_research.pdf, which includes requirements for ethical review, and personal and project licensing issued by the Home Office.

9.6 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.

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 and safety procedures can be found at <http://intra.lshtm.ac.uk/safety/>. The information includes requirements relating to research, such as:

- risk assessment, including to comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH)
- research supervision, including for MSc summer projects
- occupational health
- storage and use of human tissue
- laboratory safety (pathogens, radiation, transport of material)
- travel safety
- off-site working

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 will be required to complete a health and safety induction with records held by the Safety Manager.

11. Management of Research Data/Samples and Records

11.1 The following principles apply to maintaining research data/samples and records:

- data/samples and records must be collected, used and stored in accordance with the agreed design of the project and in accordance with legal, ethical, regulatory, funding body and LSHTM requirements;
- Researchers must retain clear, full and accurate records, including procedures followed, approvals granted during the research process, sources used and results obtained (including interim results);
- data/samples and records, including electronic data and records, must be maintained securely, in accordance with requirements concerning anonymity and confidentiality;
- data/samples and records must be stored in such a way as to permit prospective audit if necessary (guidance for clinical trials can be found at <http://intra.lshtm.ac.uk/trials/sops/index.html>);
- data/samples and records collected as part of overseas studies or through collaborating sites must be maintained in accordance with relevant policies and procedures and research agreements;
- research records must be retained for a period of at least 10 years following the publication they relate to or in accordance with other relevant requirements (e.g. legal, ethical, funding body, professional body) – see LSHTM research records retention and disposal schedule;
- data/samples and records collected/stored by staff for studies originating from LSHTM are the property of LSHTM, and staff are not permitted to remove primary data/samples and research records when leaving LSHTM. Copies may be taken with appropriate

written permission. (For further information see policy on records management for staff leaving the School);

- ownership of data/samples and records used by research degree students, or MSc students for projects, will depend on the source and associated agreements for use, collection and storage. They must also be retained in accordance with other relevant requirements (e.g. LSHTM, legal, ethical, funding body, professional body);
- MSc projects are held by the Library for seven years. PhD theses are held by the Library permanently.

11.2 Further guidance can be found in:

- ITD *Good Scientific Practice* guidance – includes lab-specific information
- Records management for staff leaving the School
- Information on records management at LSHTM can be found at <http://intra.lshtm.ac.uk/recordsmanagement/>
- LSHTM research records retention and disposal schedule <http://intra.lshtm.ac.uk/recordsmanagement/2.%20Research.pdf>
- LSHTM's *Information Management & Security Policy* <http://intra.lshtm.ac.uk/committees/isag/imspolicy.pdf>

11.3 Other specific requirements are described in relevant policies and procedures (e.g LSHTM requirements for clinical trials <http://intra.lshtm.ac.uk/trials/> , or for research using human tissue <http://intra.lshtm.ac.uk/support/research/humantissueact.html> , or external requirements such as by the NHS).

11.4 Any Freedom of Information requests must immediately be brought to the attention of the Archivist & Records Manager. Further information on Freedom of Information can be found at <http://intra.lshtm.ac.uk/foi/index.html>

12. Financial Management and Accountability

12.1 LSHTM's Financial Regulations sets out policies and procedures relating to research activity <http://intra.lshtm.ac.uk/support/finance/FinancialRegs.pdf> , 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: Heads of Faculty; Heads of Department; Budget holders/Principal Investigators; and, Research Grants & Contracts Office.

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

<http://intra.lshtm.ac.uk/support/research/overseasguidance.html>

13. Intellectual Property

13.1 LSHTM's intellectual property policy can be found: http://intra.lshtm.ac.uk/support/research/intellectual_property_policy.pdf

14. Decision Making

14.1 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.

15. Research Partnerships

15.1 LSHTM conducts research with many partner organisations throughout the world. LSHTM makes every effort to ensure that partnerships are conducted reasonably and equitably, including through contractual arrangements. Collaborative partners will be expected to undertake research involving LSHTM in a manner consistent with these guidelines. Partners will also have relevant guidelines to which their staff will be under a duty to conduct research. LSHTM will follow partner guidelines in addition to these LSHTM Guidelines, as required by the partner.

15.2 Guidelines published by the Commission for Research Partnerships with Developing Countries can be found at http://www.kfpe.ch/key_activities/publications/guidelines/guidelines_e.php
These guidelines set out principles for establishing and maintaining research partnerships with partners in developing countries.

15.3 LSHTM guidelines on working with the private sector can be found at <http://intra.lshtm.ac.uk/support/research/private-sector.pdf>

15.4 LSHTM's policy on not working with the tobacco industry or undertaking research supported by that industry can be found at http://intra.lshtm.ac.uk/support/research/policy_on_contact_with_the_tobacco_industry.pdf

16. Openness

16.1 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 (although the need to protect research interests is recognised), in particular through scholarly exchange of ideas and the submission of work to peer review;
- declaring any real or potential conflict of interest at the outset, or as soon as it is recognised or identified;
- free access to information on research being conducted and on the findings of the research, once these have been subjected to appropriate scientific review and subject to any confidentiality restrictions;
- publishing findings in a timely fashion in a peer-reviewed journal or in other reputable publications and presenting results at scientific meetings (it is recognised that publication of results may be delayed pending protection of intellectual property rights);
- publishing in an accessible format to inform policy and practice;

- disseminating research results through open access publishing where possible.

17. Publication

17.1 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, preferably 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;
- 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. “Honorary authorship” (i.e. for those that do not fulfil criteria of authorship) is unacceptable;
- the contribution of formal collaborators, financial 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. Where a significant amount of another piece of work is used in the publication there must be permission from the relevant individual(s);
- 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;
- all press releases should be reviewed by the research team and discussed with the Press Office before they are released to the media, and 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 Researchers have the opportunity to contribute to the publication process.

17.2 Further information on good practice can be found in the 'Guidelines on Good Publication Practice' produced by the Committee on Publication Ethics (COPE) - <http://publicationethics.org/static/1999/1999pdf13.pdf>

17.3 LSHTM's policy on open access publishing is available at http://intra.lshtm.ac.uk/support/research/open_access_publishing.pdf. Essentially LSHTM recognises the benefits of open access publishing as a means to ensure that research results can be disseminated as widely as possible. Researchers should include costs for open access publishing as part of grant proposals.

17.4 It is also important to note the requirements of particular publications (e.g. timing to review study data).

18. Training

18.1 LSHTM is committed to ensuring that staff and students undertake any necessary training to enable them to carry out their research activity appropriately 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 training where necessary to ensure that skills are kept up-to-date.

18.2 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; training needs may be identified through formal (including annual appraisals) and informal mechanisms.

18.3 The Staff & Educational Development Programme provides a range of training opportunities for staff (<http://www.lshtm.ac.uk/staffdev/>), 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.

18.4 The Quality and Management Team co-ordinates School-wide training opportunities for research degree students in an annual programme of workshops and a range of online resources (http://intra.lshtm.ac.uk/edu/researchdegrees/professional_development/index.html). In addition research degree students will have access to other, possibly external, training provision via their Faculty/Department.

19. Mentoring

19.1 LSHTM has a mentoring policy for probationary lecturers/senior lecturers, and mentors can also provide guidance on good research practice. See: http://intra.lshtm.ac.uk/personnel/promotions/probationary_review_procedures_for_lecturers/senior_lecturers.pdf

http://intra.lshtm.ac.uk/personnel/promotions/guidance_on_the_role_of_the_probationary_mentor.pdf

20. Management and Supervision

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 these guidelines.

20.2 Key roles and responsibilities include:

- Director – overall responsibility to Council for the academic and financial affairs of LSHTM.
- Deputy Director (Research) – works alongside the Director and Heads of Faculty in the development and implementation of LSHTM's Research Strategy and developing research collaborations.
- Heads 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 the School'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 the School'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.
- Dean of Studies 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 research degree students in their department
- Supervisors (*for research degree/taught course students*) – oversee and support research degree/MSc students for all aspects of their study/project. Further information and guidelines can be found in the Research Degrees Handbook (http://intra.lshtm.ac.uk/registry/RD_handbook/index.htm) or in the relevant MSc Course Handbook and MSc Project Handbooks, the Teachers' Handbook (<http://intra.lshtm.ac.uk/edu/taughtcourses/staffresources/teachershandbook.pdf>), the Teaching Policies and Codes of Practice (http://intra.lshtm.ac.uk/edu/taughtcourses/staffresources/tpols_cop_1_2_3_5.pdf), and information for research degree supervisors (http://intra.lshtm.ac.uk/edu/researchdegrees/staff_resources/supguidance.html).

20.3 Further information covering specific management/supervisory health and safety responsibilities can be found in LSHTM's health and safety procedures (<http://intra.lshtm.ac.uk/safety/>), and financial responsibilities are set out in the financial regulations (<http://intra.lshtm.ac.uk/support/finance/FinancialRegs.pdf>).

21. Dissemination

21.1 These guidelines will be provided to all new academic staff, professional support staff where relevant, and research degree students as part of induction packs and addressed as part of induction arrangements. MSc students will be alerted to the guidelines within the project handbook. Staff awareness of these guidelines will be encouraged through email from time to time.

Agreed by Senate November 2009

Approved by Council March 2010

Amended September 2010