London South Bank University Ethics Code of Practice and Application Process for Research Involving Human Participants (July 2016)

1. Introduction

London South Bank University is committed to maintaining the highest standards of research governance. All staff, students and those wishing to conduct research with members of our university community must adhere to this Code. The Code sets out the conduct that is expected and indicates the sanctions that will be applied should individuals be found to have deliberately circumvented or ignored this code. We acknowledge that we have a range of professional associations and groups with differing ethical traditions and guidance. This professional Code upholds the principles of:

Autonomy – every individual has the right to think independently and act freely to decide to participate, continue or withdraw from a research study without hindrance. This includes researchers ensuring that participants are fully informed prior to their giving consent to participate, maintaining confidentiality and respecting their decisions.

Beneficence - research must have value to individuals, groups, communities or to add to the knowledge base. It is unethical to conduct research that cannot be demonstrated to be of benefit or have a purpose.

Non-Maleficence – participants and researchers should be protected at all times. Associated risks and how these will be minimised must be considered and articulated.

Justice – all research is conducted fairly and with respect for the human rights of all involved.

It is the duty of every researcher, supervisor, line manager, Head of Department and Executive Dean of each School to ensure compliance with all legal obligations in relation to each research project being undertaken within their jurisdiction and approved by the School Ethics Panel. This includes compliance with:

- Human Rights Act 1998: http://www.legislation.gov.uk/ukpga/1998/42/pdfs/ukpga_19980042_en.pdf
- Data Protection Act 1998: http://www.legislation.gov.uk/ukpga/1998/29/pdfs/ukpga_19980029_en.pdf
- Mental Capacity Act 2005: http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf
- Health and Safety at Work etc. Act 1974 and related Regulations: http://www.hse.gov.uk/legislation/index.htm

- Freedom of Information Act 2000: http://www.legislation.gov.uk/ukpga/2000/36/pdfs/ukpga_20000036_en.pdf

The University expects researchers to acknowledge in their application which set of professional or regulatory body, or disciplinary association, ethical guidelines they have used to prepare their application, and intend to follow in their research practice (see Appendix 4).

Researchers must also ensure that they are aware of and meet any specific, general, contractual or ethical requirement of any UK Government Department, Local Authority, Research Council or research funder in relation to the proposed research.

Where researchers are working with an external agency, they must specify in their application in what ways that agency's ethics code is consistent with LSBU's and, where there are significant differences, what measures will be put in place to ensure that LSBU's requirements are met.

2. Scope of this Code of Practice

This Code relates to all research investigations involving human participants as well as animals where applicable. It includes both funded commercial research as well as non-funded.

Where students are acting as investigators, they must be under the active supervision of a member of staff who will be designated as the Supervisor. The Supervisor is responsible for ensuring that students are made aware of and observe relevant ethical guidelines. The Supervisor is responsible for ensuring that the student has carried out a risk assessment of his/her project which should be signed off by the Supervisor.

Supervisors will be responsible for ensuring that applications are submitted on the appropriate form and that this Code of Practice is adhered to.

For applications from members of University staff to the School Ethics Panel (SEP) prior approval by the Dean or the Dean's nominee is required. The Dean's approval is in the nature of permission to do the research, having regard to any demands it may make on the School's resources. It is not approval of the ethics of the research proposal.

2.1 Additional Points

- Staff or students who wish to carry out biological investigations on participants outside University premises must obtain written ethical approval from any collaborating organisation as well as the School Ethics Panel. These details must be attached to the application form.
- Where Investigators are seeking or have obtained funding from sources outside the University, or are entering into other commitments with third parties, they should make clear to those third parties that the proposed project is conditional on gaining approval from the School Ethics Panel.

- Staff or students who wish to carry out research within a National Health Service organisation or with patients under the care of the National Health Service or with people under the care of a Social Care organisation must abide by the Research Governance Framework for Health and Social Care, Second Edition (last modified 09/2008): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962. Where this involves seeking ethical approval via the National Research Ethics Service (NRES), that approval should be obtained before applying for LSBU ethical approval. It is not a substitute for LSBU approval (see Section 5).
- Investigators who are not University employees or students and who wish to carry out investigations on human participants on the University premises are required to conform to the University's Code of Practice. They should submit their proposals to the University Ethics Panel for approval and must attach proof of appropriate insurance and indemnities that benefit the University together with evidence of any ethical approval already obtained. Due weight will be given to any existing ethical approvals.
- All proposals for investigations involving contact with human body fluids should adhere to the Code of Practice for the Handling and Disposal of Human Bodily Fluids: https://www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf LSBU is not licensed under the HTA so all our research has to comply with the above Code of Practice for Research with consideration of the Licensing Exemptions: https://www.hta.gov.uk/policies/licensing-exemptions
- Although animal research does not take place on London South Bank University premises the School Ethics Panel should be notified of collaborative research using animals which involves London South Bank University employees or students. Evidence of compliance with the Animals (Scientific Procedures) Act 1986 should be submitted in such cases.
- All proposals seeking approval for investigations involving the use of hazardous substances or ionising radiation (e.g. x-rays) should specifically highlight this within their ethical approval application form and set out detailed measures for ensuring the health and safety of investigators and participants in compliance with relevant legislation and the University Health and Safety Policy. Investigators and Supervisors are reminded that radioactive material can only be purchased through the office of the University's Radiological Protection Officer. ***Investigations involving ionising radiation must comply with the Ionising Radiation Regulations 1999. The University's Radiological Protection Adviser must be consulted before ethical approval is sought for such investigations. The Microbiological Safety Adviser must be consulted before ethical approval is sought for any microbiological investigation.***
- Generic applications are not normally considered for ethical approval. Reference may be made to related projects that have already obtained approval and their relationship to the current application. Supporting documentation should still accompany the applications (see Appendix 1 for process details).

2.2. Academic Audit

Classroom activities that involve learning or practising research or other techniques are exempt from applying for ethical approval if:

- The data is stored securely either electronically and/or in hard copy for learning purposes and destroyed after an appropriate interval in accordance with the university's data retention policy.
- The data obtained is used only for learning and teaching purposes, or is an evaluation of a course or programme.

Routine academic audit that is expected of all course and unit leaders is also exempt. Audit or evaluation differs from research in that the main purpose of data collection is to monitor and improve a particular service delivery (rather than with the intention of using data to understand a situation more generally or develop a concept).

3. School Ethics Panel

A School Ethics Panel has been established in each School in order to support the application of this Code at School level. University Ethics Panel review is required for selected applications (see Appendix 1 for details).

Each School Ethics Panel (SEP) has responsibility for:

- Delegating to the School Divisional Panels the review of applications from master's and undergraduate students, or from members of staff if the project is for an undergraduate or master's course that the member of staff is undertaking in the School.
- Review of all other staff and Doctoral research applications except for those judged to require University Ethics panel level review (see Appendix 1 for details of these exceptions) and collaborations between School staff and institutions where ethics is granted by another institution.
- Record keeping, management and communication.
- Increasing staff and student awareness of ethical issues within the School.

Each SEP has authority to decide whether to approve or reject applications and to require amendments to be made. Each also is responsible for the on-going review of the ethical practice of all research conducted in their School.

The membership of each SEP will be determined by the School. It is strongly advised that a Departmental Health and Safety Coordinator be involved to advise on associated health and safety issues.

4. Insurance

Insurers accept that research is part of the normal activities of a university. Consequently the University's liability insurances will in general cover incidents arising out of the proper conduct of research. Policy terms, conditions and exclusions will apply. Clinical research requiring a clinical trials authorisation from the Medicines & Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 is not covered by the University's existing policies. Insurers will require full details of the proposed research in order to quote for cover. Cover must be obtained before the research commences. The University's insurer may be contacted in the first instance via the Corporate Procurement Unit.

Research activity must be covered by a contract between the parties which will include responsibilities with regard to liability. For example, if work is being carried out by LSBU staff on a third party's site then professional and employers insurance cover would be provided by LSBU, Public Liability cover by the third party. Any specialist research related insurance, if required, would need to be agreed by both parties and covered in the research contract. Please follow the link for our standard Combined Liability Insurance http://www.lsbu.ac.uk/__data/assets/pdf_file/0005/15782/combined-liability-insurance.pdf.

The items below are not covered by the University's standard insurances. It may be possible to obtain cover for an additional premium. Insurers will require full details of the proposed research. Requests for additional specialist cover should be directed to the Corporate Procurement Unit in the first instance. Please do this in advance of making an ethics application.

- Research being conducted in the USA, Canada or places subject to their jurisdiction.
- Research subjects who are pregnant or are under 5 years of age
- Hepatitis
- Creutzfeldt-Jakob Disease
- Genetic engineering
- The process of conception
- Studies involving human tissue as described in the Human Tissue Authority Act
- 2004(http://www.hta.gov.uk)
- where an ABPI indemnity is not in place for research sponsored/funded by a pharmaceutical company (or equivalent)
- where the substance under investigation has been designed, manufactured or modified by the University

Researchers are reminded that insurance cover is not a substitute for carrying out appropriate risk assessments or for getting all necessary ethical approvals into place before commencing fieldwork.

5. Approvals from External Research Ethics Committees

Where a research study has or is required to have approval from a Research Ethics Committee approved by the UK Research Ethics Committees Authority or the Medicines and Healthcare Products Regulatory Agency then London South Bank University Ethics Panel (UEP) approval is likely to be granted providing the following conditions are met:

- The same documentation supplied to the external Research Ethics Committee must be supplied along with evidence that any amendments required by that Committee have been made to its satisfaction; and
- Evidence of financial indemnity for the University must also be supplied along with evidence that appropriate insurance is in place.

If these papers are not supplied, the project will not be approved and a full application must be made instead.

Researchers are reminded that fieldwork must not commence until LSBU ethical approval has been given.

6. Non-compliance with this Code

The University reserves its position on dealing with breaches of this Code or failure to comply with it. Carrying out research without the necessary ethical approval is likely to prejudice insurance cover and may also prejudice funding or other commitments from third parties.

It should also be noted that participation as an investigator in a clinical trial without having secured ethical approval may expose the University to unnecessary liability and is a criminal offence under the Medicines for Human Use (Clinical Trials) Regulations 2006.

Retrospective ethical approval for investigations is not normally granted. Failure for staff and students to comply with this Code may constitute academic misconduct and data collected may not be allowed to be used. In extreme circumstances civil or criminal liability may arise.

Appendix 1. Submitting Research Proposals for Ethics Approval

MPhil/PhD students, Professional Doctorate students and members of staff undertaking investigations including human participants that are not part of an undergraduate or taught master's degree (including research sponsored by funders or commercial organisations) must apply for ethical approval.

Applications can be assessed either by the School Ethics Panel or by the University Ethics Panel depending on their type. Schools have differing numbers of application requests and therefore have different processes to ensure effective management of ethics applications.

Approval authority level	Application type	Email your application to
School Ethics Panel (SEP)	Fulfils requirement for a Light Touch Review marked 'No' to all of the points on the checklist	School
School Ethics Panel (SEP)	Full review where you have ticked 'Yes' to at least one of the points on the Light Touch Review checklist	School
School Ethics Panel (SEP)	Applications where we are a partner in a project where ethics approval has already been given by another University	School
University Ethics Panel (UEP)	NHS sponsored research	ethics@lsbu.ac.uk plus copy to your School-based email
University Ethics Panel (UEP)	Research covering any of the following topics: -Terrorism and radicalisation -Administration of substances altered at LSBU	ethics@lsbu.ac.uk plus copy to your School-based email
University Ethics Panel (UEP)	Research that requires additional insurance cover over and above university standard	ethics@lsbu.ac.uk plus copy to your School-based email
University Ethics Panel (UEP)	Applications from external researchers to undertake research with LSBU students or staff	ethics@lsbu.ac.uk plus copy to your School-based email

The standard reference information required to support an ethics application is available from:

- Staff intranet Key Documents REI category http://policy/default.aspx
- School Doctoral student Moodle sites
- School ethics contact information

The Ethics document set includes:

1. Code of Practice
2. Ethics Application Form
3. Light Touch Review
4. Participant Information Sheet and Consent Form

Appendix 2. Points for Special Consideration when Preparing your Application

Applicants are advised to consider the following issues carefully as they prepare their applications. Please use the standard university participant consent and information forms provided.

2.1. Consent to Participate

Researchers have an obligation to protect participants from any possible harm and to preserve their rights. This includes providing potential participants with enough and appropriate information about the research project for them to make an informed decision whether to participate. In some sorts of research, however, it is not appropriate or possible for full information to be provided. Where this is the case, the reasons should be explained in the application for ethical approval.

Voluntary consent must be obtained from participants before the research begins, except where this is not feasible or appropriate such as participant observation in public settings. Each participant must be given details of the nature, object and duration of the proposed research, unless this is inappropriate or not possible. The participant should be told what the research will involve as well as the potential risks. Consent should usually be obtained in writing. If implied or verbal consent will be sought, justification must be given in the application for ethical approval. Researchers are advised to indicate to the Committee how they will record having obtained non-written consent.

Where applicable, participants must be informed and advised about any foreseeable risks to health to which they may be exposed. Safeguards regarding communicable diseases and personal safety should be taken to protect the participant, the researcher and others involved in the work, where appropriate. Where there might be a risk of causing distress including the discussion of sensitive issues, this must be clearly identified along with sources of support that would be available to the participant.

Participants must be free to withdraw from the research at any stage without having to give a reason, and should be told they have this right. An opportunity should be provided for participants to discuss privately their wish to withdraw. Where participants are students, they should be informed that non-participation or subsequent withdrawal will have no effect on their course marks.

Where partial information or concealment of the purpose of the study is necessary, participants should not be exposed to any risk, such as unexpected anxiety or distress, lowering of self-esteem, or any form of psychological or physical harm. ***Participants should be given as much information as possible as to the scope of the research. Where placebos are to be used in a drugs trial, for example, it must be clearly explained to participants that this is part of the process of effective monitoring of the impact of the trial drug.*** Upon completion of the participants' involvement, researchers should normally provide a debriefing explaining the full purpose of the

study. If this is not appropriate, the reasons why must be explained in the application for ethical approval.

2.2. Vulnerable Individuals and Disclosure and Barring Service (DBS)

Certain groups are vulnerable and extra care and steps must be taken when securing their participation. Such groups include adults with a physical or mental incapacity, people with learning disabilities, and people under the age of 18. It may be appropriate to obtain permission from the person with authority or legal responsibility for the participant. However, all such arrangements are governed by the Mental Capacity Act 2005. Social care research carried out in England that involves adults lacking capacity is required to be reviewed by 'a recognised Appropriate Body' under the Mental Capacity Act and the only committee recognised by the Secretary of State for this purpose is the Social Care Research Ethics Committee: http://www.screc.org.uk/.

Supervisors must ensure that investigators whose research will bring them into contact with children or vulnerable adults have obtained a disclosure from the Disclosure and Barring Service (DBS) prior to commencing their research project. The level of disclosure required will depend on the degree of contact, but is likely to be an Enhanced Disclosure because of the position of trust in which the researcher is likely to be. Further advice may be obtained from the DBS https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/210857/DBS_Framework_Document.pdf or the University's Lead Counter signatory (the University Secretary) and the University's policies which are available from http://extranet.lsbu.ac.uk/hr/Policies%20Procedures%20%20Forms/Forms/AllItems.aspx

Application forms may be obtained from HR. Persons applying for a DBS are advised first to read the notes of guidance published on the DBS website. The University complies with the DBS Code of Practice.

The University will not normally accept a DBS issued by another Registered Body.

The School Ethics Panel reserves the right to turn down any application or to withdraw approval previously granted, if in its opinion a DBS indicates that the researcher and/or supervisor is not a suitable person.

2.3. Participant Recruitment, Selection and Rewards

Applications for ethical approval should include full details of the selection of participants and any questionnaire to be used in the selection process should accompany the application. If the questionnaire is drawn from a battery of pre-validated tests, it is helpful to indicate the source to the Committee.

Wherever possible, researchers should recruit participants via a notice or if verbally, through a group approach. If requests to specific individuals are required by the research, the reason for this should be explained in the application for ethical approval.

Staff or students may be invited to volunteer to take part. Students in close contact with staff or student researchers should not normally be recruited. They may feel vulnerable to pressure from someone in a position to influence their careers. It is recognised, however, that it is normally reasonable for students to be recruited to take part in teaching exercises where one of the primary objectives is to enable them to make their own observations.

Global recruitment emails are prohibited by the University's Email policy. However, university staff lists can be accessed with the approval of line managers and student group lists with the approval of the appropriate Head of Department and Course Director. When recruiting outside of the university, email policies of the organisations with potential participants need to be followed.

Coercion (perceived or actual) should not be used to persuade people to participate in a research study.

Any payment made to participants normally should only be for expenses, time, inconvenience or discomfort. Researchers must decide for themselves whether such payment should be in the form of cash or vouchers, and must be able to defend that decision. Academic rewards in the form of course credit can be given for students where the process has been agreed within the School and is overseen. All proposed payments to participants including course credit must be approved by either the School Ethics Panel.

2.4. Medical History and Seeking Medical Advice

Research involving patients/ NHS is categorised as high risk and is referred to UEP for assessment rather than for School review. It may require a suitably qualified healthcare professional to be responsible for an investigation or to be in attendance when certain procedures are carried out, or require that facilities for emergency medical care should be at hand.

The School Ethics Panel may, in certain cases, require that participants be medically screened before taking part in an investigation. This may incur an additional cost and the School Ethics Panel will need to be satisfied that sufficient funds are available for this purpose.

Where appropriate, participants should be asked about their previous medical history and asked to give permission to the investigator to contact their doctor and to authorise the doctor to release any relevant details of their medical history. Sufficient time should be allowed to permit participants to consult their doctor before they agree to participate in the investigation.

Participants should be strongly advised to report any unusual or unexpected signs and symptoms after the research study to the researcher and to their own doctor as soon as possible.

Any adverse or untoward event affecting a participant during or after a research study should be communicated initially to SEP as soon as possible, since there is an obligation that LSBU inform its insurers, and following on this – with the individual's consent – to inform the participant's doctor. Applications for SEP approval should state and justify their stance on giving feedback to participants about any medical conditions revealed through screening and/or participation in the research.

2.5. Data Management and Storage

Data, and especially personal data, collected from investigations must comply with the Data Protection Act 1998.

The researcher should keep full records of all procedures carried out in an appropriate form for review by the School Ethics Panel, and – where relevant – keep a register of participants. Details of how this information will be used, stored and the length of time held should be included in the application form.

2.6. Location

The locations of investigations should be appropriate to the type of study and the risk involved. The School Ethics Panel may, at its discretion, request an inspection of the proposed premises.

Online or web based research is increasing. Particular care needs to be taken with ensuring anonymity and confidentiality of information obtained.

2.7. Safeguarding

Appropriate action must be taken to safeguard the participants' health and to respect their privacy and psychological wellbeing. If a participant drops out of a research study the researcher should take reasonable steps to find out if any harm has come to the individual as a result of participation in the study and take appropriate action.

Caution should be exercised in any cases where a participant seeks advice from the researcher as a result of participation in a research study and the Participant should generally be guided to appropriate professional advice.

If any potential participant, or their legal representative, is unwilling or unable for any reason to give his/her informed consent that person must not be included as a participant in the research.

Appendix 3. Use of Secondary / Archival data

The Economic and Social Research Council (ESRC), Medical Research Council (MRC) and NHS all have guidelines on the use of secondary data, and we advise all researchers considering the use of such data to consult these alongside with the guidelines below (which draw on these sources, in particular ESRC guidance). Secondary data includes: archival data; publically available and secure datasets which exist already; and potentially also material available from media and other sources (e.g. newspaper articles, blogs etc.).

Much use of existing online data does not need formal School Ethics approval. In particular, *anonymised records and data sets that exist in the public domain do not require ethical review*. Specific examples include Office for National Statistics or the UK Data Archive data. These sources contain data where appropriate permissions have already been obtained and where it is not possible to identify individuals from the information provided. Published biographies, newspaper accounts of an individual's activities and published minutes of a meeting would not be considered 'personal data' or sensitive personal data requiring ethics review, nor would interviews broadcast on radio, television or online, and diaries or letters in the public domain. Information provided in forums or spaces on the internet and web that are intentionally public would be valid to consider 'in the public domain', but care should be taken to ensure anonymity is ensured at the point where the data are harvested.

The use of secure (e.g. not in public domain) data which is not and cannot be anonymous or NHS data should be submitted for a *light touch review*, and evidence that adequate permissions to use the data are in place should be provided. In addition – when data has been collected by a third party, but it is not clear (or reasonable to assume) that those providing it understood it may be used for research purposes, a light touch review should be submitted.

In addition, the use of NHS data with patient identifiable information obtained without explicit consent also needs NHS approval via the Confidentiality Advisory Group, for section 251 approval.

Appendix 4. Regulatory, Professional and Specialist Group Ethical Guidelines and Codes

The University expects applicants to acknowledge which set of professional or regulatory ethical guidelines they have used to prepare their application for review and to guide their research practice. It is very important that applicants familiarise themselves with the guidance that relates to their professional group prior to completing their application as each has been produced by ethical experts within each tradition.

Examples of key professional association or regulatory ethical guidelines include:

- Association of Business Schools Ethical Guidelines
  https://charteredabs.org/wp-content/uploads/2015/06/Ethics-Guide-2015-Advice-and-Guidance.pdf

- Association of Social Anthropologists of the UK and Commonwealth
  http://www.theasa.org/ethics.shtml

- British Computer Society
  http://www.bcs.org/upload/pdf/conduct.pdf

- British Educational Research Association *Revised Ethical Guidelines for Educational Research (2011)*
  https://www.bera.ac.uk/wp-content/uploads/2014/02/BERA-Ethical-Guidelines-2011.pdf

- British Psychology Society: *Code of Ethics and Conduct (August 2009)*
  http://www.bps.org.uk/system/files/Public%20files/aa%20Standard%20Docs/inf94_code_web_ethics_conduct.pdf

- British Society of Criminology: *Statement of Ethics (2015)*
  http://www.britsoccrim.org/documents/BSCEthics2015.pdf

- British Sociological Association: *Statement of Ethical Practice for the British Sociological Association*
  http://www.britsoc.co.uk/media/27107/StatementofEthicalPractice.pdf?1467114696745

- College of Occupational Therapists: *Code of Ethics and Professional Conduct (2015)*
  https://www.cot.co.uk/sites/default/files/publications/public/CODE-OF-ETHICS-2015.pdf

- Institute of Engineering and Technology (IET): *Rules of Conduct (2012)*
  http://www.theiet.org/about/governance/rules-conduct/index.cfm

- Institute of Career Guidance: *The Code of Ethics for Members of the Institute of Career Guidance*
  http://www.thecdi.net/Code-of-Ethics

- Institute of Business Ethics: *Ethical Values and Codes* http://www.ibe.org.uk/ethical-values-and-codes/102/52
- General Social Care Council *Codes of Practice for Social Care Workers* http://www.scie.org.uk/workforce/files/CodesofPracticeforSocialCareWorkers.pdf?res=true
- National Health Service National Patient Safety Agency: National Research Ethics Service http://www.nrls.npsa.nhs.uk/
- Royal College of Nursing: *Research Ethics: RCN Guidance for Nurses* https://www.rcn.org.uk/professional-development/publications/pub-003138
- Social Policy Association http://www.social-policy.org.uk/downloads/SPA_code_ethics_jan09.pdf
- Social Research Association: *Ethical Guidelines* http://the-sra.org.uk/wp-content/uploads/ethics03.pdf
- World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (latest revision: October 2008)* http://www.wma.net/en/30publications/10policies/b3/17c.pdf

The above list is not exhaustive.