London South Bank University

Ethics Code of Practice for Research Involving Human Participants

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Section 1: Overview

1.1. Introduction and scope

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 it. 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 Division and the 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
- General Data Protection Regulation 2016
  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.

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 (if they have one or equivalent) 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.

1.2. Structure of the LSBU Ethics system for Staff and postgraduate research

University Ethics Panel (UEP)

Research conducted by LSBU staff, and doctoral and MRes researchers falls under the remit of the University Ethics Panel and the associated Schools' Ethics Panels.

The University Ethics Panel comprises a Chair of Ethics, A Vice Chair, the Chair of each School Panel (see below), and an independent member who is not an employee of LSBU.

The UEP delegates the majority of day-to-day decision-making around ethics applications to the Schools' Ethics Panels. However, it does consider applications that are deemed to be of high risk (as identified during the application process). The UEP also conducts reviews of the work of the SEP's to identify and share good practice; periodically updates the code of practice to keep in line with developments in the field; and manages any other ethical issues that arise in research and enterprise at the university. It also reviews and ratifies approvals granted by the collaborating universities where LSBU researchers are collaborators, or where such universities wish to recruit from LSBU staff or students.

The UEP reports to the LSBU Academic Board once a year.

School Ethics Panel

A School Ethics Panel is established in each School to support the application of the university's code of practice at School level.

Each School Ethics Panel (SEP) has responsibility for:

- Reviewing all Staff and Doctoral/MRes research applications except high risk projects that are judged to require UEP-level review, as well as collaborations between School Staff and institutions where ethics is granted by another institution;
- Record keeping, management and communication via the online management system, HAPLO;
- Increasing staff and student awareness and expertise around ethical issues within the School;
- Deciding whether to approve or reject applications and to require revisions to be made.

SEPs may also adopt other responsibilities, such as within-school data storage auditing or management of taught-program research (i.e. undergraduate student projects and MSc research) at their discretion.

The membership of each SEP will be determined by the School.

1.3. 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 it may be that professional and employer's insurance cover would be provided by LSBU, and Public Liability cover would be provided by the third party. Any insurance related to specialist research, if required, would need to be agreed by both parties and covered in the research contract. Please check the current insurance schedule for details.

The items below are not covered by the LSBU's standard insurance. 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). There are specific conditions when this work is insured (depending on how tissue is collected and processed, please speak to School ethics lead or UEP and see https://www.hta.gov.uk/sites/default/files/migrated_files/HT_Act_Licensing_flowchart_FINAL_201305210156.pdf)
- where an Association of the British Pharmaceutical Industry (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. There are specific conditions under which such work is insured (around, for instance, food science, please speak to School ethics lead or UEP)

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.

1.4. 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 of 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.

Section 2: Potential ethics exemptions

2.1. Online personal data and social media/internet research

Typically, the use of online personal data and social media is *not* exempt from LSBU ethics oversight. However, it is also an area where principles of ethical research are being developed, and case by case consideration is key. Schools' Ethics Panels will therefore be a key source of guidance, but will be in turn guided by the following principles.

Identifiable and potentially identifiable social media personal data, whether held on computer or in hard copy, closed-circuit television (CCTV), audio or video recordings, or email, are subject to the General Data Protection Regulation (GDPR), as set out in the Data Protection Act (DPA), 2018.

The temptation with information obtained on social media may be to say "but the data is public", but this overlooks "fair processing" which is the principle that those providing data must know what is happening to it, as a key principle of personal data processing. As a ground rule within any research project, special consideration is required to personal information that is "*likely to cause substantial damage or substantial distress to a data subject*" (DPA 2018, c.12, PART 2, CHAPTER 2, Section 19). It is therefore best practice to obtain consent from individual users when processing identifiable personal information. For children under the age of 13 consent is required from the parent or guardian (see also Consent).

Personal data should be recognised here as different from expert information from journalists, politicians, academics, and other public figures, who are named in their social media accounts. When acting as experts in their field, their work (whether tweets or full blogs), should be given full recognition, and cited as any other publication. However, when the data are unrelated to the subject expertise, personal data (such as images of their private life, or personally sensitive information) should be anonymised.

2.2. Use of secondary 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; publicly 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 (but see 2.1. Online personal data and social media/internet research).

The use of secure (e.g. not in public domain) data which are not and cannot be anonymous or NHS data should be submitted for review, and evidence that adequate permissions to use the data are in place should be provided.

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 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.

Any research which involves the subject of terrorism should be approved by the UEP, following procedures laid down in the LSBU Prevent policy.

2.3. Getting ethical approval from external agencies including the NHS

Health Research Authority (HRA) approval

HRA Approval is for all project-based research that involves NHS organisations in England. It brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that researchers only need to submit one application.

Do I need NHS REC approval? – Applicants are advised to use the online tool to establish whether they are required to submit an application for REC approval.

http://www.hra-decisiontools.org.uk/ethics/

Research support – A vast array of information and support is available from the HRA online services.

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

If your research project involves accessing confidential patient information without consent in England and Wales, you will need to additionally apply to the Confidentiality Advisory Group (CAG) (https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/).

If your project is eligible for HRA Approval there are five main steps that should be completed in the following order:

- Complete a draft research application form on the Integrated Research Application System (IRAS);
- Prepare and submit your proposal and study documents for submission on HAPLO for internal UEP review, using the NHS related research option;
- Contact the LSBU member of the Finance team responsible for providing LSBU approved insurance (currently the Category Manager, or your procurement officer) to inform them of your intended submission and the LSBU NHS research sponsor (please contact HSC SEP for details);
- Book your application in through the Central Booking Service (see https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/;
- E-submit your applications in IRAS having included the feedback from the LSBU ethics panel.

Approval from other Universities

Usually LSBU will accept ethical approvals from other universities. However, an SEP chair's action approval should be sought via Haplo. A request for a chair's approval should include the original approval letter and supporting documents.

2.4. Teaching activities and academic audit

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

- The data are 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 are used only for learning and teaching purposes or for evaluation of a course, programme, or service.

Routine academic audit that is expected of all course and module leaders is also exempt. Audit or service 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).

Where teaching and learning activities are used as the subject matter of research (e.g., data are collected from the VLE for the purpose of research publication), then a full ethics application should be submitted and approved before the start of data collection.

Section 3: Routine study issues

3.1. Vulnerable individuals and Disclosure and Barring Service (DBS)

Certain groups are potentially vulnerable and extra care and steps must be taken for their safeguard when securing their participation in research. Vulnerability can take different forms and may arise due to age, disability, marginalisation, abusive relationships, or personal or professional relationships where participants may feel coerced to participate. The Safeguarding Vulnerable Groups Act 2006 also lists a number of factors which signal vulnerability as an adult, including

- is in residential accommodation,
- is in sheltered housing,
- receives domiciliary care,
- receives any form of health care,
- is detained in lawful custody,
- by virtue of an order of a court, is under supervision per Criminal Justice Act 2003 sections regarding community sentences;
- receives a welfare service of a prescribed description,
- receives any service or participates in any activity provided specifically for persons who has particular needs because of his age, has any form of disability or has a prescribed physical or mental problem. (Dyslexia, dyscalculia and dyspraxia are excluded disabilities),
- has payments made to him/her or to an accepted representative in pursuance of arrangements under Health and Social Care Act 2012, and/or
- requires assistance in the conduct of own affairs

In cases involving potentially vulnerable groups special care must be taken to ensure: a) active consent, rather than solely the consent of a gatekeeper; b) the researchers in contact with the participants have obtained a disclosure from the Disclosure and Barring Service (DBS) prior to commencing the research project; c) information is given about possible negative effects or lack of benefits from their involvement with the research where these may be expected.

Where the research involves participants covered by the Mental Capacity Act 2005 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 at the time of writing is the Social Care Research Ethics Committee: http://www.screc.org.uk/.

Resources:

Regarding DBS, the level of disclosure 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.

Regarding research with potentially vulnerable people, more information is available from the ESRC funding page https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/frequently-raised-topics/research-with-potentially-vulnerable-people/

3.2. Participant recruitment, selection and rewards

Applications for ethical approval should include full details of the recruitment and selection of participants and any questionnaires 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 Panel.

Staff or students may form part of a research sample. Students in close contact with staff or student researchers should not normally be recruited, to avoid the risk of (actual or perceived) coercion from someone in a position of influence on their study or careers. In such cases, anonymising whether or not participants have taken part is a possible mitigation strategy.

Global (whole organisation) 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 Division and Course Director. When recruiting outside of the university, email policies of the organisations with potential participants must be followed.

If requests to specific individual participants (as opposed to groups) are required by the research, the reason for this should be explained in the application for ethical approval, and issues of (see also 3.3. Anonymity and 3.4. Consent).

Coercion (perceived or actual) should not be used to persuade people to participate in a research study. Careful study advertising, separation of information about participation and gatekeepers or those with power or influence over participants should be considered as ways of mitigating coercion (see additional info in 3.4. Obtaining consent).

Any payment made to participants should be proportionate to the study and the risk of undue influence on participation decisions should be considered. Such payment can be in the form of cash or vouchers and the researcher must be able to explain the payment choice. Participants should not need to spend/engage in activity to redeem an incentive (i.e. buy X to get 10% off) and commercially funded research should not reward participants with vouchers solely redeemable with the funder. Academic rewards in the form of course credit (such as the Division of Psychology Research Participation Scheme) 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 the School Ethics Panel.

A note on sample sizes: Studies should be powered amply to detect differences between conditions or relationships between variables reliability (i.e. at power =>.80) for quantitative studies. Evidence of power analysis should be provided. For qualitative studies, it should be reasonable to expect sufficient data is collected will produce good insight and, ideally, saturation. Underpowered samples are unlikely to produce *beneficence* (see 1.1. for more on beneficence).

3.3. Anonymity, confidentiality and General Data Protection Regulation (GDPR)

Anonymity and confidentiality are cornerstones of both good data management and research ethics. *Anonymity* is achieved when no-one, including the research team, can identify who data are associated with. Care must be taken to ensure that a combination of different data fields cannot be combined to identify a participant. Data are considered *pseudo anonymous* when a key file (e.g., a spreadsheet) links participant codes (used in a main separate datafile) with personal identifiable information. Names, emails, IP addresses, physical addresses, phone numbers are all examples of personal identifiable information which renders data non-anonymous.

Personal data are considered *confidential* when it is not shared beyond a specified group of people (e.g., the research team).

As a guiding principle, data should be collected anonymously or made anonymous as soon as practicable. Non-anonymous data and key files should be stored under a double-lock system (e.g., on a password-protected server in a password-protected file, or in a locked filing cabinet in a locked office). Where data cannot be made anonymous it should be used only for the purposes that participants have opted in for, and be held for the least amount of time possible.

Regardless of whether data are anonymous or not, it should be made clear to participants how data will be stored, for how long and in what form. It should also be made clear what are the scope and limits of confidentiality. This is usually outlined in the Participant Information Sheet, and participants consent to such processes in the Consent form. If anonymous data is to be archived (e.g., in a data repository), the process and access rights should be made clear to participants.

General Data Protection Regulation (2016)

All data, especially personal data collected, stored, used, archived or destroyed in the conduct of research with human participants (both research and enterprise investigations) must comply with the General Data Protection Regulation (GDPR) 2016 and the Common Law duty of confidentiality. Research data that has been properly anonymised is not subject to these legal requirements.

Researchers should be familiar with and abide by the GDPR and employ the practices outlined above, but should also bear in mind a number of exemptions if data is being processed for historical, statistical and scientific research purposes. Exemption is triggered when the following conditions are met:

- The data is not processed to support measures or decisions with respect to particular individuals, and
- The data is not processed in such a way that substantial damage or distress is, or is likely to be, caused to data subjects.

If the above conditions are met:

- The principle of data protection that information should only be obtained for one or more specified and lawful purposes becomes exempt: further processing of personal data for research purposes will not be regarded as incompatible with the purposes for which it was obtained
- The principle of data protection that information should not be kept for longer than necessary for the purpose(s) collected for becomes exempt: material can be kept indefinitely if the personal data is being kept for research, history and statistics. However, participants

should actively consent to this.

- Research data is exempt from the subject access provisions, if data is processed in compliance with above conditions and the results of the research/any statistics are not made available in a form that identifies any individual participant.

Additional guidance for Health and Social Care research

- The new EU General Data Protection Regulation (GDPR). For health and social care research, the GDPR Regulation is not very different from the previous Act and the Health Research Authority will not be adding to the existing effective safeguards. In particular, Research Ethics Committee (REC) approval and the legal gateway for processing confidential patient information on the advice of the Confidentiality Advisory Group (CAG) will continue, as will the other common law provisions. A summary of the key changes for all data processing (not just research) is available from the Information Governance Alliance.
- All guidance will be kept up to date in light of relevant national and European guidelines and the Data Protection Act 2018.
- Researchers should comply with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)
- Researchers may need an NHS research passport (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/research-passport/)
- The Health Research Authority (HRA) has published detailed guidance about operational arrangements that researchers and organisations may need to put in place. This operational guidance was produced for researchers and study coordinators on the implications of the GDPR for the delivery of research in the UK GDPR guidance
- Please see up to date guidance available from the HRA website https://www.hra.nhs.uk

3.4. Obtaining consent

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 or not to consent to participate. Consent should be obtained in writing. Where this is not possible, and the researcher should clearly outline why this is the case, consent can be obtained orally. In such circumstances, usual practice is that it should be tape-recorded or witnessed by at least one other observer. There should always be auditable evidence of consent.

Coercion

Research participants can be compensated for their time and involvement. However, the value of the compensation should not be such it unduly influences their decision to participate, or to take risks that they otherwise would not (all proposed payments to participants, including non-monetary payments, must be approved by the relevant ethics panel). This can be seen as coercion by inducement, in the same way that the below examples can be seen as consent being influenced by fear of penalties or of expectation of benefits:

- Participants may be dependent on the researcher (or sponsor or gatekeeper), for example: students or employees;
- Participants may be 'detained' such as: in a residential care home, prison, detention facility, psychiatric ward under section.

In such circumstances the researcher should be particularly careful when getting consent as there could be factors impacting on the individual's ability to freely and voluntarily give this. Incentives should not benefit the end-user of the research (i.e., a study commissioned by an online retailer should not be incentivised by vouchers redeemable solely at that retailer).

LSBU staff or students may be invited to volunteer to take part in research, taking into consideration the sensitive issue of coercion. The University recognises that it is normally reasonable for students to be recruited to take part in research but that they should not be recruited by (or for research done by) their current module lecturers. Teaching exercises where one of the primary objectives is to enable students to make their own observations does not fall into this category.

The components of informed consent are:

Information

Prior to participation in any research, the prospective participant should be informed of the details of the project in which they are considering participating. This should give an overview of aspects of the research and how it is being conducted which could reasonably impact their decision to participate or not. This may include, but not be limited to:

- The purpose of the research: background/aims, how long it will run for
- The data collection, usage and storage methods
- What the individual will be asked to do and the time involved
- Any potential risks or benefits that may arise from participation
- How as a participant they will be safeguarded
- Why they have been asked to participate and the overall number of people that are planned to be recruited

- How, and to who, to complain or raise concerns/dissatisfaction regarding the research
- Arrangements for participants who are content to be contacted in the future (these should be well-specified and explicit consent for this should be sought).
- Whether, how and when participants can withdraw their participation (during and after taking part in the research).

This information should be provided to the potential participant in the research information sheet, which should accompany the request for consent.

Consent

Voluntary consent must be obtained from participants before the research begins. There are certain circumstances where this may not be possible or appropriate (see 3.9. Deception; 3.10 Observational Research) in which case there are additional considerations that the researcher must address.

During the research, a participant has the right to withdraw up to the point agreed in the information sheet, without having to give a reason. This period should be as long as practicably possible. Participants should be made aware that in circumstances where the findings have already been published the right to withdraw cannot realistically be exercised – nor where withdrawal will impact aggregate, anonymised data sets. If, at any point, the researcher believes that a participant has doubts that they still consent to participation s/he should explicitly clarify this with participant. Any participant that wants to withdraw should always have the opportunity, if they wish, to have a private discussion as to their reasons why.

There may be circumstances where the potential participant does not/cannot be considered to fully appreciate the implications of participation. For, example:

- Pre-competent children[1]. In which case the researcher has a legal duty to obtain consent from the parent or legal guardian. Children in such circumstance should *also* consent.
- An adult without the capacity to consent. In which case, consent cannot, in law, be given on their behalf – other than in certain clinical situations.

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.

Consent forms include personal data and as such must be stored securely in a double-lock system so as to guarantee confidentiality of participation. They should be kept for at least 5 years following data collection. Storage lengths, disposal arrangements etc should be made clear in the participant information sheets.

3.5. Debriefing

After participant data has been gathered, and especially in cases where any deception or withholding of information has occurred, participants should be provided with an appropriate verbal and written debriefing. The debriefing should include a statement or clarification of the research aims and objectives, an explanation of how the data will be used and reference to supporting

[1] GDPR puts the default age at which a person is no longer considered a pre-competent child at age 16, but it allows member states to adjust that limit to as low as age 13.

organisations if there is any likelihood of distress associated with participating in the research. In some circumstances where the research aims and objectives were clearly communicated in the participants information sheet, a verbal debriefing may suffice.

3.6. Medical history and seeking medical advice

Research involving patients/ NHS and categorised as high risk 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.

Where appropriate, participants should be asked about their previous medical history and asked to give permission for 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 via Haplo 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.

See also guidance on *3.8. Safeguarding and adverse events.*

3.7. Public and Patient Involvement and ethical oversight

Public and Patient Involvement (PPI) includes NHS patients and members of the public who are consulted about a plan of research prior to, during, or after the research has been undertaken.

PPI potentially includes activities such as:

- Members of the public or NHS patients acting as research partners (the application may require approval, but the involvement of the PPI members in the research project team would not);
- as part of the process of identifying research priorities;
- part of project governance groups such as project advisory or steering group;
- consulting / commenting on study materials such as patient information sheets or advertising materials;
- assisting with the interpretation and dissemination of findings.

Our position on PPI draws on the National Research Ethics Service (NRES) and INVOLVE who advise that conducting PPI does not require ethical oversight:

"The active involvement of patients or members of the public does not generally raise any ethical concerns for the people who are actively involved, even when those people are recruited for this role via the NHS. This is because they are not acting in the same way as research participants. They are acting as specialist advisers, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore, ethical approval is ***not needed for the active involvement element*** *of the research, (even when people are recruited via the NHS), where people are involved in* ***planning or advising*** *on research e.g. helping to develop a protocol, questionnaire or information sheet, member of advisory group, or co-applicant."*

However, ethical approval should be sought when;

- Members of the public or NHS patients are participants in the research itself;
- Members of the public or NHS patients are researchers or collect data as part of the research process.

For more information and guidance on PPI, please see:

https://www.rds-london.nihr.ac.uk/wpcms/wp-content/uploads/2018/10/RDS_PPI-Handbook_2018_WEB_VERSION.pdf

3.8. Safeguarding and adverse events

Safeguarding

Everyone involved in research ethics should be aware of, and comply with, LSBU's Safeguarding Policy. Research should also ensure work is risk-assessed and review the 3.1. Vulnerable Populations.

Adverse Events

Alongside the responsibilities of safeguarding, researchers at LSBU have a responsibility to report adverse events associated with research.

An adverse event is a negative physical or psychological outcome which may possibly be linked to participation in a research study. Typically, an event would be considered adverse if it is of a level of severity that would lead one to seek medical or professional help (e.g., to a GP or Accident and Emergency department or seeking mental health professional support).

Projects where adverse events are likely should have a clear process for identifying and handling the events, for example who events are reported to, who is responsible for reporting them to the SEP/UEP and other panels (such as steering or safety panels) and providing contact information external to the project for participants to report events if appropriate. Reporting processes should be made clear to participants and all members of the research team.

Researchers must be aware that adverse events should be reported on Haplo via http://research.lsbu.ac.uk/ by going to the relevant project and clicking on the 'report adverse event' button. Additionally, adverse events can be reported directly to the School Ethics Panel or University Ethics Panel as appropriate. SEP or UEP will examine the reported adverse effects and advise on revisions to the project and may require project activity to be suspended while these are enacted. The SEP or UEP reserves the right to withdraw ethical approval temporarily or permanently in the advent of adverse events. Failure to report adverse events can be considered non-compliance with this code of practice.

3.9. Deception

Although the idea of deceiving research participants may be seen as inappropriate, there are many instances where clearly indicating the purpose of the research to participants in advance of data collection would influence participants' responses and behaviour. As deception contradicts the principle of informed consent, its use in research should be carefully considered and only used when it is absolutely necessary to the running of the study and there is no deception-free alternative.

Deception can refer to the deliberate withholding of information as well as deliberately giving misinformation. Researchers should seek to supply as full information as possible to research participants. However, in some cases an essential element of the research design would be compromised by full disclosure to participants at the outset, which justify the withholding of information or misinformation. The reasons for this should be clearly stated in the ethics application. Deception should only take place where it is essential to meet the research aims, where the research objective has strong scientific merit and when there is an appropriate risk management and harm alleviation strategy. Where any deception or withholding of information has occurred, participants must be debriefed as soon as possible following data collection. In some cases, additional retrospective consent (after the deception has been revealed) may help to ensure that the research is, and is seen to be, properly ethically managed. In these cases, following debriefing, participants' consent to use of their data, publication or other dissemination should be sought. Researchers should be prepared for refusals and subsequent withdrawal of participant data. Deception should never be used if physical pain or emotional distress are likely to occur.

3.10. Observational research

Wherever possible, participant information sheets should disclose as much information about a research study as is possible. However, in some cases, full disclosure is not possible. A situation where full disclosure (and even consent) is not possible is in some forms of observational research.

Observational research involves researchers recording the behaviour of participants in either a field or laboratory-based setting. When consent for a study involving an observational element can be reasonably obtained (for instance, when people are taking part in the lab-based study which involves some unobtrusive observation) then it should be. In other cases, the assumption should be that the observation is essentially a form of deception and should be treated as such.

In field studies, observational research is likely to be covert and participants may not consent or be debriefed as part of the research process. In such cases, researchers should follow the British Psychological Society's guidance on observational studies:

'Studies based on observation in natural settings must respect the privacy and psychological wellbeing of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in public situations where those observed would expect to be observed by strangers. Additionally, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.' British Psychology Society Code of Human Research Ethics (2014, pg. 25).Wherever possible, and when the balance of benefit to the participant is in favour of it, participants should be debriefed, and request to use the data should be sought.