

Research Ethics Policy and Procedures

Owner: Pro Vice-Chancellor for Research and Knowledge Exchange

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1. General principles

- 1.1. The University is committed to the maintenance of high ethical standards in the research undertaken by its staff and students, whether supported directly by the University or funded by external sources. The University recognises its obligation to ensure that research undertaken under its auspices is conducted to appropriate standards and conforms to generally accepted ethical principles and practices.
- 1.2. The University believes that ethics review and approval are important for the following reasons:
 - 1.2.1. to enhance the quality of research;
 - 1.2.2. to protect the rights and welfare of participants and minimise the risk of physical and mental discomfort, harm and danger from research procedures;
 - 1.2.3. to ensure the proper, fair, and proportionate collection, storage and processing of personal data in accordance with data protection regulations and the University's Data Protection compliance policy (Appendix 1);
 - 1.2.4. to protect the welfare of researchers and their right to carry out legitimate investigations;
 - 1.2.5. to minimise the potential for claims of negligence made against the University, its researchers and any collaborating individual or organisation;
 - 1.2.6. to ensure the reputation of the University and sponsors for the research it conducts.

- This policy applies to all academic and administrative staff, and all students conducting research projects and related activities as part of undergraduate, postgraduate or short course taught or research programmes. This includes: all research projects involving members of academic and administrative staff, full or part-time, including honorary staff at London Metropolitan University, and every research project conducted by postgraduate research students enrolled/registered at, and/or supervised by staff at, London Metropolitan University (except where the research project, Principal Investigator and/or postgraduate research student is based or enrolled/registered elsewhere and where the research project has been approved by an equivalent ethics committee/panel following a comparable level of ethics review).
- This policy should be read in conjunction with the University's Code of Good Research Practice and the University's policy on research misconduct and dealing with allegations of misconduct in research, which is contained within the Code.
 The Code provides guidelines on the issues involved in the proper conduct of research and on the standards expected.
- In terms of the University's policy on research misconduct, any member of staff or postgraduate research student who conducts research projects without ethics review and approval may face an investigation of research misconduct and may be subject to disciplinary procedures.
 - 1.3. This policy does not refer directly to broader questions of ethical behaviour within the University in areas other than research. Statements relating to the University's ethics and values more broadly construed are embedded within its mission statement and policies in such areas as admissions, international relations and human resources.

2. Ethics management structures

2.1. The University Research Ethics Sub-Committee is a sub-committee of the Research and Knowledge Exchange Committee. Under delegated authority from the Board of Governors, Academic Board, and the Research and Knowledge Exchange Committee, the University Research Ethics Sub-

Committee serves to develop, monitor and oversee the implementation of policies, guidelines and procedures devised to ensure that research at the University is conducted according to ethical principles.

- 2.2. The University Research Ethics Sub-Committee also provides advice, guidance and support to academic staff supervising research projects and related research activities conducted as part of taught undergraduate, taught postgraduate or taught short course programmes, who are responsible for ensuring that these projects and activities conform to accepted ethical principles and practices. The University Research Ethics Sub-Committee may, at its discretion, draw on appropriate expertise from one or more nominated external representatives.
- Research Ethics Review Panels (RERPs) are formally constituted sub-committees of the University Research Ethics Sub-Committee based within, and supported administratively by, each of the University's Schools. The Research Ethics Review Panels take responsibility for conducting formal ethics reviews of research projects requested by University staff and postgraduate research students. The Research Ethics Review Panels also provide advice, guidance and support to academic staff supervising research projects and related research activities conducted as part of taught undergraduate, taught postgraduate or taught short course programmes, who are responsible for ensuring that these projects and activities conform to accepted ethical principles and practices.
 - 2.3. Research Ethics Review Panels are chaired by suitably qualified academic staff members and membership is drawn from staff with research ethics expertise. Research Ethics Review Panels may also draw on staff from within the School concerned and from other Schools to provide an appropriate range of expertise in research and/or ethics.
 - 2.4. The University Research Ethics Sub-Committee meets at least three times a year.
 - 2.5. The Research Ethics Review Panels meet at least once a year and at other times conduct business by correspondence or arrange additional meetings, as required.

3. Ethics review procedures

- The University Research Ethics Sub-Committee and its Research Ethics Review Panels do not, under normal circumstances, review and approve research projects and related research activities conducted as part of taught undergraduate, taught postgraduate or taught short course programmes, but provide advice, guidance and support to academic staff supervising such projects and activities, who are responsible for ensuring that these projects and activities conform to accepted ethical principles and practices.
 - 3.1. Before research projects conducted by staff or postgraduate research students can proceed, they are required to undergo ethics review and receive ethics approval from the University Research Ethics Sub-Committee's Research Ethics Review Panels.
- Exceptionally, if a **funded** staff research project requires external approval, then submission to the University Research Ethics Sub-Committee's Research Ethics Review Panels is not required. The research lead must complete a Research Ethics Deferral Declaration which is logged by the RERP (emailed to the Chair) prior to submission of the funding application. External approval refers to approval by a research ethics committee outside the University, i.e. an NHS REC or an equivalent body, such as another UK university research ethics committee. However, all study documentation and the final ethical approval letter must be logged by the RERP. The proposed research project cannot proceed until these documents have been received by the Research Ethics Review Panel, and the Panel has confirmed that the level of research ethics review and approval involved meets or exceeds the standards required by the University. Where these standards have not been met, the Research Ethics Review Panel may require that an additional research ethics application be submitted to the Panel and/or to an appropriate external UK- or country-specific research ethics service.
 - 3.1.1. This exception is not applicable to level 3-6 student projects where RERP approval is always required, and before any external ethical review if that too is required.

- 3.2. The University's research ethics review and approval procedures require the completion and submission of a Research Ethics Review Form to the relevant Research Ethics Review Panel. The Form should be completed by either the member of staff responsible for the research project (whether as Principal Investigator or grant-holder) or the postgraduate research student concerned (in full consultation with all staff and students involved in the proposed research project; in the case of postgraduate research students, this includes their supervisors).
 - 3.2.1. The researchers must supply to the RERP, all associated documents put in front of the research participants; such as materials to be used and the questions (or a sample thereof) to be asked.
- 3.3. The Research Ethics Review Panels may approve the research project as described; request additional clarification or modification of the research project to ensure that this complies with accepted ethical principles and practice; or withhold ethics approval.
- 3.4. If no ethical concerns are identified by the Research Ethics Review Panel, the research project can proceed.
- 3.5. If difficulties with approval arise, the Research Ethics Review Panel will consult formally in writing with the applicant responsible for the research project and seek to resolve these difficulties. If agreement or resolution cannot be reached, the decision of the Research Ethics Review Panel Chair/Deputy Chair is binding. Where there are matters of concern at the level of the Research Ethics Review Panel, these should be referred to the University Research Ethics Sub-Committee.
- 3.6. Research Ethics Review Panels will endeavour to initiate correspondence with applicants responsible for research projects in which potential ethical concerns have been identified within ten working days (two weeks) from the receipt of the Research Ethics Review Form.
- Research Ethics Review Panels will endeavour to complete the review of Research Ethics Review Forms within twenty-five working days (five weeks) from

the receipt of the form, provided that satisfactory clarifications and required adjustments are received within a week of feedback on the original application having been sent out.

4. Research ethics approval

- 4.1. Research ethics approval can be granted for a maximum of 4 years or for the duration of the proposed research (whichever is shorter), on the understanding that:
 - 4.1.1. the researcher has accurately and honestly completed all the questions on their Research Ethics Review Form and included other relevant documentation; and that the proposed research, once approved, is conducted in line with the information provided in the Form and in any related research ethics applications;
 - 4.1.2. the research complies with UK legislation governing research (including that relating to health and safety, human tissues and data protection);
 - 4.1.3. the researcher complies with the University's Code of Good Research Practice; the researcher will inform their Research Ethics Review Panel of any changes to the proposed research that alters the answers given to questions in the Research Ethics Review Form or the information provided in any related research ethics applications (particularly where these changes would require a revised research ethics application to be submitted to an external research ethics committee and/or to the most appropriate School-specific Research Ethics Review Panel);
 - 4.1.4. and the researcher will apply for an extension to their ethics approval if the research project continues beyond four years.

Appendix (1): Data Protection and Handling

I. The nature of data;

The General Data Protection Regulation 2016 (GDPR) and Data Protection Act 2018 (DPA) recognises that everyone has the right to the protection of their personal data. Central to data protection is the concept of personal which includes any information relating to an identified or identifiable living person.

Such data includes names, addresses, email addresses, or other means that could be used to identify a living individual. It also refers to these personal identifiers being linked to other data which could be used in such a way as to identify an individual. Examples of these types of data are ethnicity, sexual orientation, religious beliefs, trade union membership, and genetic data derived from biological samples. Researchers should be aware that outliers in small cohorts may be identifiable. However, if data are fully anonymised and an individual cannot be identified, then the Act and Regulation does not apply, since the information stored is no longer defined as personal data (for more information see 'Identifiability, anonymisation and pseudonymisation')

To ensure proper compliance, the responsibilities of the users of personal data must be understood. Users of personal data include data controllers (the University) and data processors (generally the Principal Investigators). Almost all use of personal data, from collection and recording to retrieval and dissemination, storage, and finally erasure or destruction, constitutes "processing", with significant accountability required.

The University (data controller) determines the purposes and means of the processing of personal data. Data processors (usually the Principal Investigators) are a separate legal entity. They process personal data on behalf of the University. Data processors must assist the University where relevant, for example, in a potential personal data breach notification or in considering a Data Protection Impact Assessment (DPIA). It should be noted that the agency to which testing or data manipulation is outsourced becomes the data processor (refer to University GDPR Policy).

II. Special protection of personal data;

If personal information needs to be collected and stored it must be rigorously protected. The data processor must, by law,

- complete a Data Protection Impact Assessment (DPIA)
- determine whether data will need to be transferred to a different jurisdiction and what international transfer measures need to be taken
- determine how data will be stored and whether it will need to be encrypted
- consider making a <u>data management plan</u> which will help with the required DPIA and ensure that <u>participant information and consent forms are clear and</u> transparent

III. Our life of data statement;

The university is committed to storing personal data only for as long as it is needed for the duration of research project for which the data was collected. Processes by which the data will be erased will be set out clearly and transparently as part of the consent process presented to the study participants. Data processors are accountable for personal data being correctly disposed of.

IV. A commitment to periodic review of the reasons for preserving data;

The university is committed to periodic audits, undertaken by the Research Office, of all personal data stored for the purposes of research and to ensure that data is properly expunged or otherwise destroyed when the research project, for which it was collected, has terminated.

V. Data handling and retention;

Data stored as part of a publication or public resource, in the library, and no longer being processed for research purposes, will pass into the ethical jurisdiction of London Metropolitan Special Collections and Archives.

Appendix (2) Resources:

Concordat to Support Research Integrity

Code of Practice for Research: Promoting Good Practice and Preventing

Misconduct - UK Research Integrity Office

Recommended Checklist for Researchers - UK Research Integrity Office

Procedure for the Investigation of Misconduct in Research - UK Research

Integrity Office

NHS Health Research Authority – <u>Governance arrangements for research</u> ethics committees: 2020 edition

ESRC Framework for Research Ethics – UK Research and Innovation

NHS Health Research Authority- Research Ethics Service and Research Ethics Committee

Clarke, N., Vale, G., Reeves, E.P. et al. GDPR: an impediment to research?. Ir J Med Sci188, 1129–1135 (2019). https://doi.org/10.1007/s11845-019-01980-2

Applying GDPR in research

Identifiability, anonymisation and pseudonymisation

Information Commissioner's Office guidance for organisations