Research Ethics Policy

Policy Category:	General
Subject:	Policy on the Ethical Conduct of Research Involving Human Participants
Approving Authority:	Academic Board
Responsible Officer:	Senior Vice-President (Operations)
Responsible Office:	Research Governance, Ethics and Integrity and College Research Ethics Committee
Related College Procedures:	Academic Misconduct Procedure Security Sensitive Research Procedure
Related College Policies:	International Regulations Policy Disclosure of Interest Policy Safeguarding Policy Health, Safety, Welfare and Fire Safety Policy
Effective Date:	06/03/2024
Supersedes:	New
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1. Purpose & Scope

1.1 Research Ethics is a globally recognised set of principles governing the way research involving human participants, their tissue or data, is designed, managed and conducted in order to safeguard the dignity, rights, health, safety, and privacy of those involved.

1.2 King's College London is committed to ensuring its researchers adhere to ethical standards to protect both participants and researchers and to ensure the conduct of research is ethical. Ethical research is honest, rigorous, transparent, respectful and protects participants.

1.3 In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. KCL's review processes are intended to ensure this whilst remaining sensitive to the needs of researchers.

1.4 The University is committed to providing a competent, rigorous and robust process of ethics review that is proportionate to the potential risk and, where a high risk is identified, assesses that risk against the benefits to the public good. The research ethics process requires researchers to consider and manage ethical issues such as the management of risk, protection of confidentiality and the process of informed consent, in order to ensure the dignity, rights, safety and wellbeing of participants are central to any research study. Research should be initiated and continued only if the anticipated benefits justify the risks involved.

1.5 Where research involves human participants or their data, research funders will generally only fund research that has ethical clearance, and many publishers will not accept results of such research for publication if it has not been granted ethical clearance. As such, researchers may need to present evidence of ethical clearance in order to publish their results to the wider research community.

1.6 This policy should be read in conjunction with the UK Research Integrity Office (UKRIO) Code of Practice for Research and reflects the principles and commitments outlined in the funder-endorsed Concordat to Support Research Integrity.

1.7 The purpose of this policy is to:

(i) Set out the principles, responsibilities and requirements for all research involving human subjects conducted under the auspices of King's College London staff, students, or affiliates.
(ii) Provide KCL staff, students, and affiliates with a clear understanding of the ethical review process operated by King's College London; and
(iii) Support a culture of academic freedom and high ethical standards by providing a framework for review which subjects research proposals to a level of scrutiny that is in proportion to the risk of harm or adverse effect to participants, researchers, the University and to society as a whole.

1.8 The policy applies to all KCL staff, students and affiliates conducting KCL sponsored research activities involving human subjects (including those with visiting or honorary contracts and students on placements), whether or not the research is conducted on the University's premises or using the University's facilities.

1.9 Third parties (for example staff of other institutions working with King's College London students or on University premises) are expected to adhere to the University's ethical standards of research.

2. Principles of Ethical Research

The following ethical principles apply to all research which involves human participants:

2.1 **Research should aim to maximise benefits for individuals and society and minimise risk and harm**: Research involving human participants is ethically acceptable only when the potential benefits of the project justify any risks involved in participating. Benefit encompasses direct impacts on involved parties and broader contributions to knowledge and society. Maximizing research benefits should be paramount in ethical considerations during research development. Ethical studies exhibit a positive risk-benefit ratio, where risks are minimized and justified by expected benefits for participants or society. Where risks arise as an unavoidable and integral element of the research, robust risk assessment and management protocols should be developed and complied with.

2.2 **The rights and dignity of individuals and groups should be respected**: Research should be designed and conducted in a way that respects the rights, interests, values, dignity and, if possible, autonomy, of participants (including individuals, groups and communities). The research community has a role to play in promoting safe environments which are free from exploitation, abuse and bullying, and harassment for all involved.

2.3 **Wherever possible, participation should be voluntary and appropriately informed**: Primarily, this principle implies that researchers should obtain the informed consent of all participants in their research. 'Informed consent' requires that the potential participant should be given all information relevant to making an informed decision about participation and that once the participant has reached a decision, no information should be given which has the potential to materially change that decision (see further details under section 3).

2.4 **Participants should be free to withdraw from the research after providing their consent:** Researchers must allow and enable participants to withdraw at any stage of the research

process for any or no reason. It must be as easy as possible for participants to do this, without any impediment, and without causing them any detriment. Wherever possible (i.e. wherever data is collected identifiably), this principle includes giving participants the ability to withdraw their data from the study within a reasonable timeframe after it has been collected.

2.5 **All participants should be selected and treated fairly in all aspects of their research involvement**: Researchers should ensure that their selection of target participant groups is guided by scientific need and the appropriate distribution of burdens, rather than perceived ease of recruitment. Individuals should neither be unreasonably excluded from the possibility of freely participating in research, nor should unnecessary additional burdens be placed on already significantly burdened groups or individuals, and never on individuals whose ability to bear the additional burdens of the research is in doubt.

3. Informed Consent

3.1 Informed consent is one of the founding principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with sufficient information about what it means for them to take part and give consent before they enter the research.

3.2 Consent should be obtained before the participant enters the research (prospectively), and there must be no undue influence on participants to consent. The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to.

3.3 The process of informed consent should ensure that research participants are provided with all the relevant information they need in order to decide if they would like to participate in a study. It is therefore important that information given to participants, before obtaining their informed consent to take part, is clear and concise and gives adequate and appropriate information about the research, to allow participants to make a meaningful choice about whether or not to take part.

3.4 For the most part, potential participants should be provided with an information sheet and given the opportunity to ask any questions about the study. They can then give informed consent by completing a consent form based on this information sheet which is then returned to the researcher as evidence of informed consent.

3.5 The Research Ethics Office provides General Data Protection Regulation (GDPR) compliant templates which are in line with the highest standard of informed consent set by GDPR. However, there will often be cases in which researchers may feel that it is more appropriate to simplify the information provided to participants in a proportionate way depending on the target demographic and the nature of the research. In such cases, researchers must justify, in their ethics application, why a simplified version of the information sheet is more appropriate and how informed consent will still be ensured.

3.6 It is recognised that there are instances when it may be more appropriate to provide a verbal or brief written overview to potential participants instead of a written information sheet, with a link to more detailed information if appropriate. Such instances include, but are not limited to, interviewing professionals, instances where it is not culturally appropriate or when participants are approached in a busy environment (i.e., on a busy street) and it is impractical to expect participants to read a written document. Researchers wishing to employ a verbal consent mechanism are required to provide an adequate and appropriate justification, in their ethics application, why written consent is not appropriate. For online research with relatively straightforward ethical issues, such as simple online surveys or tasks where no personal or sensitive data is collected, participants' informed consent may be implied by their completion of the survey or task instead of having a separate consent process. It is still important to provide participants with the information they need to make an informed decision about whether or not to complete the survey or task.

3.7 It is recognised that the determination of the information required to obtain 'informed consent' is a matter of judgement. Provision of some information may be burdensome to participants and/or detrimental to the integrity of the research. In all cases researchers must provide a strong justification, in their ethics application, for the degree of information provided, to demonstrate that the process they propose is appropriate and ethical. *This justification would then be considered by the relevant Research Ethics Committee or Panel to ensure its use is appropriate and will not place participants at any undue risk, with appropriate safeguards and mitigations in place.*

3.8 For research categorised as minimal risk where participation is completely anonymous, the researcher is responsible for determining the level of information that should be provided to participants to qualify as informed consent. This should be measured against the complexity of the project and the time commitment of participation and must consider any additional risk as a result of limited information being provided to participants. In such cases, at a minimum, participants should be informed about the purpose of the research and that their anonymous data, which cannot be withdrawn once submitted, may be used for a King's College London research output. Justification for this determination must be documented when registering a project as minimal risk.

4. University Requirements for Ethical Clearance

4.1 Research activity requiring ethical clearance

4.1.1 The College stipulates that all research involving human participants and/or their tissue or data (where the data is identifiable and not in the public domain) requires ethical clearance prior to the commencement of data collection. This is to ensure that the rights, dignity and well-being of those involved are protected.

4.1.2 Whilst there is no universally agreed definition of 'research', it is generally accepted that research is undertaken to attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This process of systematic inquiry entails collection of data; documentation of critical information; and analysis and interpretation of that data/information, in accordance with suitable methodologies set by specific professional fields and academic disciplines.

4.1.3 Human participation in research incorporates all forms of primary data collection from humans (i.e., interviews, questionnaires, focus groups, observations, taking/using materials from humans, invasive/intrusive procedures, administering substances/products, physical activities, or collecting data from humans in any form) where the data being collected is primarily to be used as research data.

4.1.4 Projects involving the analysis of previously collected data (including human tissue) and/or the collection of existing data that has not previously been used for research purposes before (such as data taken from private social media groups) will require ethical clearance if the data being accessed is identifiable and not available in the public domain. The use of fully anonymous existing datasets and data that are freely available in the public domain does not require ethical clearance.

4.1.5 Where a project does not involve human participants or human subject data, it is usually the case that ethical clearance from the KCL College Research Ethics Committee (CREC) will not be required. However, there may be exceptional cases where a research study does not strictly involve human participation (for example, excavating a burial ground, site-specific environmental monitoring) but does raise associated ethical issues with respect to the potential social and/or environmental implications of the research activities, and how these may impact on humans. In such cases ethical clearance would be required should there be clearly identifiable potential for the research activity to cause an impact/change with respect to particular individuals or communities.

4.1.6 The remit of CREC is to provide ethical review for research only. It is the responsibility of the researcher (and their supervisor where appropriate) to determine if their work is research or if it is a non-research project. If the work is deemed not to be research, then ethical clearance is not required from KCL.

4.1.7 CREC and its devolved review committees are primarily tasked with assessing the overall ethical soundness of proposed research projects rather than reviewing methodology and design aspects of projects in detail, unless such aspects present ethical concerns such as exposing participants to unnecessary risks and burdens. Research proposals that are obviously methodologically flawed and unlikely to yield worthwhile outcomes, thus potentially wasting participants' time or endangering them, may be considered unethical.

4.1.8 The above requirements for KCL ethical clearance apply to all research activity conducted by KCL staff, students, or affiliates for KCL sponsored projects. This includes KCL projects taking place overseas that may have been through local ethical review, or projects that involve collaboration with other institutions who may have their own processes.

4.2 Sponsor responsibilities for obtaining ethical clearance

4.2.1 Ethical clearance must be obtained through KCL where it has been determined that KCL is the lead sponsor for the research project. KCL will normally act as research sponsor for projects where the Chief Investigator or Lead Investigator is employed by the University, the University takes prime responsibility for managing the research and associated funding, and/or the project is forming part of a KCL educational qualification (KCL student research).

4.2.2 Where external staff or organisations are involved in the development or management of a research project, it may be more appropriate for another organisation to act as sponsor, or to enter into a co-sponsorship arrangement.

4.2.3 Where it has been determined that another UK organisation is the lead sponsor for a research project and will therefore be obtaining ethical clearance for the project, additional ethical clearance from KCL is not required, provided any involvement of KCL researchers in human subject data collection is included in the ethical clearance obtained by the sponsoring organisation. However, in some cases funders may insist that ethical clearance is obtained locally from each collaborating organisation.

4.2.4 Sponsorship arrangements should be established between institutions prior to the submission of an ethics application.

4.2.5 If KCL is not the lead sponsor of a research project, but the lead organisation does not have a recognised procedure for obtaining ethical clearance, KCL researchers involved in the project may request an ‘ethical opinion’ from CREC. If granted, an ethical opinion will be given with the proviso that KCL are not the sponsoring institution and therefore cannot provide insurance and indemnity for the research project. In such cases, researchers should contact the KCL Insurance team to establish if KCL’s general insurance policies cover their personal involvement in the project.

4.3 Ethical review of KCL led projects conducted overseas

4.3.1 KCL sponsored research carried out overseas must uphold the University’s ethical standards while also being cognisant of the local civil, legal, financial and cultural conditions. Any research that would require ethical review when carried out in the UK should similarly be subject to appropriate ethical review when carried out overseas.

4.3.2 Research projects which are conducted in a country outside of the UK must be reviewed according to UK standards to ensure that our researchers are abiding by the principles and legislation governing UK research. Therefore, KCL sponsored studies will require review by CREC even if ethical clearance has been received in the host country. This is to ensure that KCL research overseas is conducted to a consistently and appropriate ethical standard as ensured through the well-established KCL process, and in acknowledgement of the fact that the standard of ethical review processes in countries outside of the UK varies greatly.

4.3.3 Many countries require local ethical approval or registration of research projects, and some require specific research visas. Researchers are expected to refer to international guidelines and conform to relevant local regulations for the country or countries where the research is taking place.

4.3.4 It is the researcher's responsibility to find out what the local overseas requirements are, including any data protection requirements, and include this information in the ethics application when you submit to CREC. All regulatory procedures of the host country must be complied with, including any requirements for research ethics clearance. If researchers do not abide by the local rules of the host country, this will invalidate the ethical approval from KCL, may be subject to investigation for research misconduct and may run the risk of legal action within the host country.

4.4 Non KCL led overseas studies involving KCL researchers

4.4.1 Where KCL researchers are involved in a study that is sponsored and led by an overseas Higher Education Institute (HEI) (i.e. the Lead Investigator belongs to an overseas HEI), ethical clearance can typically be obtained by the overseas sponsoring institution, providing the standard of the institution's ethics review process is equivalent to that of KCL's.

4.4.2 Researchers should consult with the KCL Research Ethics Office to establish if the overseas ethical clearance meets the required standard. If it is determined that this is not the case, additional ethical clearance will need to be obtained from KCL prior to commencement of data collection.

4.5 Service Evaluation/Audit

4.5.1 Service Evaluation is undertaken to benefit those who use a particular service and is designed and conducted solely to define or judge current service. Participants will normally be those who use the service or deliver it. It involves an intervention where there is no change to the standard service being delivered (i.e. no randomisation of service users into different groups). This type of project does not require ethical approval, but may require local approvals from participating organisations (i.e. NHS Trusts, schools etc) It is the responsibility of the researcher to ensure any required permissions are in place.

4.5.2 It is possible to use data collected from participants during a service evaluation for later research as long as:

(i) The data is completely anonymous.
(ii) It is not possible to identify participants from any resulting report.
(iii) Use of the data will not cause damage and/or distress.
or
(iv) Where data is identifiable, the Consent from the data subjects allows for the data to be used for the new research purpose and the appropriate level of ethical clearance has been obtained.

4.5.3 Audit is defined as an assessment of the level of service being provided against a set of predetermined standards. This generally involves the analysis of existing data and the results of this analysis usually being used/distributed locally in order to effect change to improve/change the level

of service currently being provided. This type of project does not require ethical approval, but may require local approvals from participating organisations (i.e. NHS Trusts, schools etc) It is the responsibility of the researcher to ensure any required permissions are in place.

4.6 **Research Involving Animals**

4.6.1 CREC is responsible for the ethical review of projects involving human participants and their data only. Research involving animals is not under the remit of CREC. The ethical requirements and review of projects involving animals is the responsibility of the KCL Animal Welfare & Ethical Review Board (AWERB).

4.7 **Taught Course Practicals**

4.7.1 Where human participant data is being collected for a taught course practical* as part of a learning module, ethical clearance is only required if the activity falls into the 'high risk' criteria.

4.7.2 For taught course practicals that do not require high risk ethics review, module leaders should complete a Taught Course Practical Checklist and upload a signed copy within the OPAMA (Online Programme and Module Approval) system when submitting for module approval.

4.7.3 Where students are conducting individual research projects in which the activity does not fall within the learning aims and objectives of the course but is instead a stand-alone research project for which each student has their own specific aims and objectives, then an individual ethics application must be made for CREC ethical clearance, regardless of the risk level of the project.

** A taught course practical is classified as an activity involving human participants which falls within the learning aims and objectives of the course, which has the principal goal of practising research methods.*

4.8 **Research which has already received ethical approval by a Research Ethics Committee (REC) at another organisation**

4.8.1 If an ongoing non-KCL sponsored study has received ethical approval from a different Institution and the study is being transferred to KCL due to personnel change or departure, the study must be submitted through the University's Transfer of Sponsorship process within the Research Ethics Management Application System (REMAS) in order for KCL to accept lead sponsorship of the study and for indemnity to be confirmed. However, if recruitment and data collection has already been completed under an existing ethical approval before the project transfers to King's, no further action is required regarding ethical clearance. If applicable the researcher should discuss the transfer of associated funding with the KCL Pre-Award team.

4.8.2 As part of the Transfer of Sponsorship process, the Principal Investigator (PI) will be asked to provide an outline of the study as well as details of the original ethical approval and associated recruitment documents.

4.8.3 KCL will, where possible, accept the approval provided by the original Institution, however the University reserves the right to request further ethical review if there is any concern around the standard of the existing approval, or if any changes have been made to the previously approved protocol that require ethical review.

4.8.4 Recruitment and/or data collection must not take place until KCL sponsorship has been confirmed by the Research Governance Office.

4.9 **Health and Social Care Research requiring external clearances under the Health Research Authority (HRA)**

4.9.1 In the UK, there are a number of regulators with a remit for activities related to health and social care research (the HRA) or to health research only (the Human Fertilisation and Embryology Authority, the Human Tissue Authority and the Medicines and Healthcare products Regulatory Agency. Applications to all key approval bodies are made through a single UK-wide Integrated Research Application System provided by the HRA. The HRA also oversees the NHS and Social Care Research Ethics Committees.

4.9.2 Although not an exhaustive list, ethical review will typically be required through a Research Ethics Committee acting on behalf of the HRA in the following circumstances:

(i) National Health Service Research Ethics Committee (NHS REC) review will be required for any research that involves recruitment of participants who are identified from or because of their past or present use of NHS services, research involving adults lacking capacity, invasive research involving prisoners, a Clinical Trial of an Investigational Medicinal Product or where the research falls under legal requirements for NHS REC review. Legal requirements include the Human Tissue Act 2004, Mental Capacity Act 2005 and the Ionising Radiation (Medical Exposure) Regulations 2017.

(ii) Social Care Research Ethics Committee (SC REC) review will be required for research projects involving Social Care service users or social care projects funded by the Department of Health involving adult social care service users.

4.9.3 Study-wide management review by the HRA (called HRA or NHS approval) is generally required for any research utilising substantive NHS staff, NHS facilities or NHS premises as research sites. HRA approval is separate from ethical approval, therefore studies requiring HRA approval will need to additionally obtain ethical approval as required (for example from an NHS REC, SC REC or via REMAS.)

4.9.4 The Governance Arrangements for Research Ethics Committees(GAfREC), the HRA ethics decision tool and the HRA decision tool outline in more detail the types of research that will require approval under the Health Research Authority and/or the NHS REC or SC REC.

4.9.5 If a project has been ethically approved by the NHS Research Ethics Committee or Social Care Research Ethics Committee, additional ethical clearance from KCL is not required.

4.9.6 Some studies will fall outside of the review requirements of the UK Department of Health's Research Ethics Service, but instead require KCL research ethics clearance, but will also require HRA approval. In such instances the researcher will be required to submit and ethics application to KCL through REMAS and also an Integrated Research Application System (IRAS) application to the HRA.

4.9.7 Researchers should consult the 'What approvals and decisions do I need' page on the HRA website for more information.

4.10 **Research requiring external ethical review from the Ministry of Defence Research Ethics Committee (MoDREC) or the HM Prison & Probation Service (HMPPS)**

4.10.1 Ministry of Defence Research Ethics Committee (MoDREC) Review:

4.10.1 i) MoDREC ethical review will be required for Research that is funded or sponsored by the Ministry of Defence and some types of research that involves MoD staff.

4.10.1 ii) Prior to final review by MODREC, scientific and technical rigour must be obtained through assessment by a Scientific Advisory Committee (SAC)

4.10.1 iii) Researchers should consult the 'Ministry of Defence Research Ethics Committee' page on the gov.uk website for more information on both SAC and MoDREC review.

4.10.2 **HM Prison & Probation Service (HMPPS) Review:**

4.10.2 i) All researchers wanting to conduct research with staff and/or offenders in prison establishments, the Probation Service regions or within HM Prison and Probation Service (HMPPS) Headquarters are required to formally apply for research approval to the HMPPS National Research Committee (NRC).

4.10. 2 ii) Researchers should consult the 'HM Prison & Probation Services' webpage on the gov.uk website for more information.

4.11 Research Conducted without ethical clearance

4.11.1 Obtaining ethical clearance prior to the commencement of a research study involving human participants and/or their data is a mandatory requirement of King's College London.

4.11.2 Failure to obtain ethical clearance prior to commencement of a study could put the research participants at risk of harm. It is expected therefore that all studies that require ethical clearance have that clearance in place before the research begins.

4.11.3 To begin recruitment or data collection for a research project requiring research ethics clearance without having first obtained the appropriate ethical clearance will be considered a breach of ethics and, depending on the circumstances, research misconduct. Such breaches will typically be dealt with under the Colleges 'Policy and Procedure for Research Conducted Without the Appropriate Ethical Clearance' and will likely result in the requirement to destroy all relevant raw data, with restrictions being placed on a researcher's ability to publish their research findings.

5 Roles and Responsibilities

5.1 College Research Ethics Committee (CREC)

5.1.1 CREC is the over-arching committee responsible for advising on and informing the development of the College's research ethics policy, procedures, and application system.

5.1.2 CREC develops, establishes, and reviews the procedures for the examination of proposals for research which involves human participants and materials derived from human participants, which are to be carried out by KCL staff, students and affiliates, except where the proposal for such research has been or will be examined by a research ethics committee acting on behalf of the UK Health Research Authority.

5.1.3 The review of studies that fall under the remit of CREC are undertaken by either a Research Ethics Subcommittee (RESC) for high-risk projects, or the Research Ethics Office and a Research Ethics Panel (REP) for low-risk projects, in line with CRECs proportionate review process.

5.1.4 CREC manages its membership and operates in line with its Terms of Reference.

5.2 Research Ethics Subcommittees (RESCs)

5.2.1 Three RESCs operate under authority delegated to them by the CREC and are accountable to that Committee.

5.2.2 The RESCs are responsible for ensuring that research involving human participants that has been determined to be 'high risk' is carried out safely and with considered consent and respect for the autonomy and privacy of the research participants, and in accordance with the ethical principles set out in the Declaration of Helsinki and other relevant guidelines.

5.2.3 In addition to ethical review, the RESCs, in conjunction with the Research Governance Office, will ensure that relevant legal requirements, such as compliance with data protection legislation and University protocols on records management, are complied with.

5.2.4 Health RESCs are responsible for reviewing high risk applications from the following Faculties/Institutes:

(i) Faculty of Life Sciences & Medicine
(ii) Institute of Psychiatry, Psychology & Neuroscience
(iii) Faculty of Natural, Mathematical & Engineering Sciences
(iv) Faculty of Dentistry, Oral & Craniofacial Sciences
(v) Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care.

5.2.5 The Social Science, Humanities and Law Research Ethics Sub-Committee (SSHL RESC), is responsible for reviewing high risk applications from the following Faculties/Schools:

(i) Faculty of Social Science & Public Policy
(ii) The Dickson Poon School of Law
(iii) Faculty of Arts & Humanities
(iv) King's Business School
(v) King's Academy
(vi) Global Institutes
(vii) Central Departments

5.2.6 The RESCs manage their membership and operations in line with their Terms of References (ToRs).

5.3 **Research Ethics Panels (REPs)**

5.3.1 Discipline specific REPS operate under authority delegated to them by CREC and are accountable to that Committee. The Panels are as follows:

(i) Biomedical Sciences, Medicine, Dentistry and Natural & Mathematical Sciences REP
(ii) Psychiatry, Nursing & Midwifery REP
(iii) Education and Business REP
(iv) Arts and Humanities REP
(v) Security Studies REP
(vi) Law, Politics & Economics REP
(vii) Geography, Global Institutes & the Policy Institute REP

5.3.2 REP members are responsible for ratifying the reviews of low-risk staff and PhD/MPhil student applications following an initial review carried out by the Research Ethics Office (REO), offering amendments or changes in light of their disciplinary expertise. Activity is conducted virtually within REMAS.

5.3.3 REP members also help to improve engagement with ethics within departments by:

(i) promoting awareness and understanding of the ethical approval process among colleagues when appropriate, and

(ii) supporting the REO with the development of discipline specific ethics training and guidance.

5.4 **Research Ethics Office (REO)**

5.4.1 It is the responsibility of this central research ethics team to set policies and standards in the area of research ethics and to support Faculties/Schools with the delivery of those standards via training and guidance, and through the development and maintenance of the online system REMAS.

5.4.2 The REO is also responsible for providing administrative support to the CREC and its supporting RESCs and REPs, including maintaining membership in line with the relevant ToRs.

5.5 **Research Governance Office**

5.5.1 The Research Governance Office (RGO) provides support for KCL sponsored research submitted through the REMAS system and/or the IRAS system for HRA/NHS/Social Care REC approvals, on matters pertaining to local and national policy or associated legislation.

5.5.2 The RGO provides this support via ad hoc advice, training, issuing guidance and process implementation.

5.5.3 The RGO performs parallel reviews with the Research Ethics Office on research applications submitted through REMAS and will provide project specific expert research governance advice, typically in relation to the following:

(i) Data protection requirements under the UK General Data Protection Regulation and the Data Protection Act 2018.
(ii) Requirements relating to the storage and collection of tissue under the Human Tissue Act/Human Tissue Authority.
(iii) Regulatory approval routes
(iv) Research Sponsorship
(v) Issues of Research Insurance
(vi) Risk Assessments
(vii) Safety reporting
(viii) DBS checks

5.6 **Researchers**

5.6.1 It is the responsibility of staff, student and affiliate researchers and their supervisors to plan and conduct their research within the parameters of ethical practice and with integrity in accordance with the UK Research Integrity Office (UKRIO) Code of Good of Practice for Research.

5.6.2 Prior to commencement of data collection, staff and student researchers must:

(i) Recognise their responsibility to conduct research of appropriate ethical standards and ensure that any ethical implications of the research have been given proper consideration.
(ii) Be aware of KCL policies and procedures relating to good practice in research and make sure that their research complies with these policies and procedures, seeking guidance from the Research Ethics Office when necessary.
(iii) Establish if ethical clearance is required for their research and ensure this is sought and received prior to the commencement of recruitment of participants or data collection.
(iv) Ensure that any applications for ethical review are complete, well-written, contain all the supporting documentation and will be conducted in accordance with all UK and University policy and legislation (including GDPR).
(v) Work with the Research Governance, Ethics and Integrity team to ensure that they have the necessary training, resources and support to carry out their research.

5.6.3 During the course of data collection, staff and student researchers must also:

(i) Ensure that data collection is conducted in line with their ethically approved protocol and seek a formal modification to the existing ethical clearance for any planned or unexpected but necessary change to the approved methodology or supporting documentation, including extensions to the window of data collection.
(ii) Inform the Research Governance, Ethics and Integrity Team of any adverse event (i.e., an event which had not been foreseen in the application and was disadvantageous to one or more participants), protocol deviations or ethics breaches.

5.6.4 Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the cultural,

economic, psychological, physiological, political, religious, spiritual, and social consequences of the research for the human participants involved.

5.7 Supervisors

5.7.1 Research supervisors are responsible for overseeing their students' research conduct. This includes the development of an ethics applications and providing or directing to relevant advice and guidance as appropriate.

5.7.2 Supervisors must come to an agreement with their students about the scope, research questions, design and methods of the research.

5.7.3 Supervisors are responsible for advising their students if ethics clearance is likely to be required, what ethical considerations may arise in a research project, and how these may be addressed.

5.7.4 Supervisors must ensure that their students do not commence research without having the appropriate ethical clearance and any other required approvals in place.

6 Research Ethics Procedure

A copy of the Research Ethics Procedure can be found on the ethics webpages and are subject to change.

7 Research Governance matters which impact research ethics

7.1 Processing of Personal Data

7.1.1 Personal data is any information relating to an identified or identifiable natural person. These data have statutory protection under the GDPR2016 and the UK Data Protection Act 2018.

7.1.2 Researchers must comply with data protection law when collecting and processing personal data. Where personal data is processed in jurisdictions outside the European Economic Area, they should be handled to the standards prescribed by UK data protection law.

7.1.3 Under this legislation any personal data collected must be processed fairly and lawfully. Among other things researchers are required to issue a privacy notice to their research participants, which explains the purpose(s) for which the data are being collected, the lawful basis for processing the data, who the data will be disclosed to, and the rights of the individuals in respect of their personal data.

7.1.4 All KCL recruitment document templates are UK GDPR compliant. Where researchers wish to deviate from following KCL templates, this should be justified in their ethics application.

7.1.5 Researchers must ensure that personal data are kept secure and are not disclosed to unauthorised persons. This is important for all personal data but particularly applies in the case of special category sensitive personal data, which include information about an individual's: race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

7.1.6 Under UK Data Protection legislation, as a registered data controller, King's College London has an obligation to maintain accurate records that reflect current processing activities at the University.

7.1.7 It therefore is a mandatory requirement that all staff and students planning to collect and store any personal data as part of a King's sponsored study must register this processing activity in one of two ways:

(i) By submitting an ethics application through REMAS, researchers can complete an integrated data management plan in order to register processing activity.

(ii) Where external ethical approval has been obtained or the processing of personal data does not require CREC ethical clearance, personal data processing can be registered through the College's Kings Data Protection Register (KDPR).

7.2 **Insurance**

7.2.1 Most KCL sponsored research projects are automatically covered by the University's general insurance or the College's Clinical Trials and Research Projects Involving Human Subjects Insurance Policy once ethical clearance has been granted. However, there are some specific exclusion criteria that apply that researchers are required to consult with to establish if the proposed activity can be automatically covered by the policy or not.

7.2.2 If the activity meets any of the policy's exclusion criteria as outlined in REMAS, researchers must contact the College's Insurance Officer to confirm if KCL are able to provide insurance for the research. Without this confirmation KCL insurance cover will not apply and researchers will therefore be personally liable for any claims that may arise from the project.

7.3 **Risk to the Researcher**

7.3.1 Researchers need to take responsibility for all risk assessments associated with their projects, this extends beyond potential risks to participants and includes any potential risks to the researcher or their wider research team.

7.3.2 Researchers are therefore required to complete a Departmental Risk Assessment Form prior to commencing data collection if their study involves any of the following -

(i) The study places the researcher at any risk greater than that encountered in his or her daily life (e.g. research work alone or in dangerous circumstances)
(ii) Data collection outside of the UK, other than your home country
(iii) The administration of food substances (risks of allergic reactions, choking, food hygiene etc)

7.3.3 Whilst CREC may recommend that a Departmental Risk Assessment Form is completed as a condition of granting ethical clearance, this process is managed locally by departments and supported by the KCL Health and Safety Services team.

7.3.4 Local departmental risk assessment requirements can vary; therefore researchers should familiarise themselves with their local risk assessment procedures at an early stage in their research development and ensure that completed risk assessment forms have been signed off by either the researcher's supervisor (for students) or the researcher's Head of Department (for staff) that prior to the arrangement of any travel or recruitment.

8 Reporting

8.1 CREC reports to the College Research Committee on an annual basis and subsequently to Academic Board. Any policy developed by CREC is therefore approved through Academic Board.

8.2 CREC also reports annually to the Audit, Risk and Compliance Committee.

9 Enforcement

Non-compliance with this policy or associated policies, procedures and guidance, is an infringement of King's regulations and will be investigated in accordance with the appropriate university regulations.

10 Review

This policy will normally be reviewed every three years.

11 Sources and further reading

British Psychological Society Code of Ethics and Conduct
Available at:
https://explore.bps.org.uk/content/report-guideline/bpsrep.2021.inf94

UK Research Ethics Office Research Ethics Support and Review in Research Organisations
Available at:
https://ukrio.org/wp-content/uploads/Research-Ethics-Support-and-Review-in-Research-Organisations-UKRIO-ARMA-2020.pdf

Economic and Social Research Council (ESRC) Framework for Research Ethics
Available at:
https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/framework-for-research-ethics/

The Concordat to Support Research Integrity
Available at:
https://www.universitiesuk.ac.uk/sites/default/files/field/downloads/2021-08/Updated%20FINAL-the-concordat-to-support-research-integrity.pdf