Task & Finish Group: IOE REC Review Processes for 'Very Low Risk'[i] Research

Recommendations

v1. September 2023

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Executive Summary

1. This Task & Finish Group was convened to scope possible adaptations to current formal IOE REC review processes for certain types of 'very low risk' research, in the context of concerns about the ethical and practical appropriateness of existing processes.
2. 'Very low risk' research is defined relative to the low risk projects that IOE REC is currently authorised to process.
3. The Group evaluated current staff research activities across departments for which existing processes may need adapting, reviewed established research ethics principles and relevant ethical guidelines, and developed recommendations that are pragmatic, adaptable to changing environments and norms, while maintaining the highest standards of ethical research conduct.
4. The Group recommends the following three-tier approach to ethics review in future:
    a. **Tier 1:** Extremely low risk research, which does not involve human research participants (i.e. 'subjects'), only 'authors'; or involves only publicly available organisation-level data; and where the topic of research is not considered ethically complex/sensitive; and there are no project-specific requirements for local ethical approval, to be covered by an optional 1-page self-assessment checklist, which is not formally evaluated by IOE REC.
    b. **Tier 2:** Very low risk research, where there is ambiguity over whether participants count as 'authors' or 'subjects'; or aggregated data is not publicly available or requires registration with/approval from an institution that is not another UK HE institution; or the topic may be ethically complex/sensitive; or there are project-specific requirements for local ethical approval; or the work already has ethical approval from a UK HE institution, to be covered by an obligatory 1-page self-assessment checklist, checked by one REC reviewer and filed.
    c. **Tier 3:** All other low risk research involving new data collection from human participants as 'subjects'; and/or which compounds multiple features from Tier 2, to go through full-ethics review as per current IOE REC processes.

Context

Currently, all staff 'research' activities require formal Research Ethics Committee (REC) approval at the IOE. While this was established in order to provide rigorous oversight of all such activity, a number of concerns have arisen:

1) The definition of research used by the IOE REC seems to go significantly beyond the Frascati definition of research thereby increasing the scope of what the committee needs to review, and going beyond what many other ethical bodies suggest is reviewed;
2) The current guidance for staff regarding which projects do and do not require ethical approval does not fully reflect this more encompassing definition of 'research', as it states that only research projects "which collect or use data from human participants" are required to seek ethical approval. This means that there is a potential contradiction between the guidance and the expectations. It is vital that clear guidance is available on which activities are and are not required to apply for ethical approval from the IOE REC.
3) The current process creates an administrative burden on both staff researchers and IOE REC committee members, particularly in the context of 'very low-risk'* research, which do not currently require separate approval elsewhere at UCL. The process is therefore inconsistent with the Provost's recent call to make work more efficient at UCL.
4) Given the administrative burden, and time-consuming nature of completing a form that is more complex than necessary, and the ambiguity between written guidance and expectations, staff researchers could potentially avoid REC submission entirely, particularly for 'very low-risk' research, thus creating a compliance problem for IOE relative to other parts of UCL with a lighter touch process.

The current Task & Finish Group was therefore formed (see membership details below) to scope possible adaptations to current formal IOE REC review processes for 'very low risk' research[ii, iii].

Group Membership

- Zsófia Demjén (Chair) (CCM)
- David Bann (SRI)
- Olga Cara (EPS)
- Claire Crawford (DLL)
- Leda Kamenopoulou (PHD)
- Lindsey Macmillan (DLL)
- Bernardita Munoz Chereau (DLL)
- Karen Schucan Bird (SRI)
- Samuel Sims (DLL)
- Rachel Wilde (EPS)

Method

The group proceeded as follows:

1. Scoped current staff research activities across departments for which existing processes may need adapting and engaged with departmental heads/Heads of Research and wider staff to seek views on current processes for reviewing 'very low risk' research

2. Examined commonalities across the above activities (bottom-up approach)
3. Reviewed established research ethics principles (specifically the Belmont Report, Beauchamp & Childress, 2001), ethical guidelines of relevant professional organizations (specifically, BERA, BAAL, BPS, BSA, AoIR), as well as current UCL and IOE guidance (top-down approach)
4. Developed recommendations that aim to be pragmatic, adaptable to changing environments and norms, while maintaining the highest standards of ethical research conduct.

Results

Examples of 'very low risk' research

Across IOE departments the activities that were identified as potentially benefiting from an adapted IOE REC process included the following:

a. Evidence-synthesis: systematic and non-systematic reviews of published research, rapid reviews, literature summaries etc.;
b. analyses of publicly available specifications for digital apps, and other products;
c. analyses and comparisons of word usages in existing general language corpora available to researchers;
d. discourse analysis of policy texts or transcripts of meetings of government, available to the public via official sources;
e. multimodal analysis of publicly available texts, produced by public entities rather than individuals (e.g. organisational websites);
f. discourse analyses of news media articles collected from Nexis, and literary analyses of published works of literature;
g. (secondary) analysis of administrative data on organizations made publicly available by government, academic or other bodies for research or accountability purposes, or for general public consumption (e.g., aggregate School Census Data);
h. (secondary) analysis of pseudonymized individual-level survey or administrative data made available for research (e.g., cohort studies housed at IOE or individual-level administrative data provided by government departments) where accessing the data involves applying for approval from the data holder

These activities could result in a range of outputs, including academic publications, time-sensitive responses to consultations, provision of evidence to select committees, blog posts, media interviews, and so on.

Common characteristics of 'very low risk' research that should not warrant ethical review

The type of activity alone was not seen as a useful way of differentiating between work that definitely needed full ethics review and work that could potentially benefit from alternative approaches. Instead, the nature of the data, its availability and processes for accessing it were identified as key determiners. The types of work listed above were united by one or more of the following (letters in brackets refer to the examples listed above):

1. absence of human participants (b, c, g)
2. content produced by humans but explicitly for wide public consumption (a, d, e, f)
3. data gathered from human participants but pseudonymized and made available specifically for the purposes of research, where appropriate ethical and access permissions are in place (h).

A distinction between 'authors' and 'subjects' (AoIR 2002, see Appendix I for further details) is signaled in point 2 above. This is important for some types of research, e.g. research using internet content. Generally, research involving 'authors' would count as very low risk, while research involving 'subjects' would not.

Exceptions: characteristics of very low risk data/research that potentially warrant ethics review: However, there may be some circumstances when even the kinds of work listed above would benefit from ethics review. Example scenarios include but are not limited to: the topic of research being sensitive in some way, potentially posing a greater risk even in the case of pseudonymized data or to the researcher themselves (e.g. vicarious trauma), research being conducted or data being collected in countries with significantly different ethical standards from the EU/UK, or if the work involves more participatory collaborations with people with lived experience.

Recommendations

Based on the above, the group recommends that the IOE REC adopts a three-tier approach to ethics review, with responsibility for deciding which Tier a project fits into resting with the lead researcher (but based on clear IOE REC guidance)[iv].

Tier 1 (extremely low risk research):

- There are no research participants (i.e. 'subjects') at all, or only 'authors' (identifiable or not); or
- the data is at organisation level and is made publicly available without restrictions by a recognised official body and explicitly for accountability, research or public consumption; and
- the topic of research is not considered ethically complex/sensitive by the staff conducting the research; and
- there are no project-specific requirements for local ethical approval.

→ Optional 1-page self-assessment checklist including basic information about the work (project title, RQs, data sources and confirmation of above criteria). Ideally this will be a web form to make completion efficient. This is not 'reviewed' or submitted to IOE REC, but can be completed and submitted to Worktribe, if the system requires evidence of ethical considerations for release of funds. It is optional since 1) general ethical advice for this type of research can be placed on the IOE/UCL website and 2) completing these forms in all cases is not considered to be a good use of public resources unless it is required. REC Processing time: 0 days.

Tier 2 (very low risk research):

- Ambiguity on whether participants count as 'authors' or 'subjects'; or
- Administrative data on organizations not made available by a recognized official body; or
- Topic may be ethically complex/sensitive; or
- There are project-specific requirements for local ethical approval; or
- Administrative or pseudonymized survey data where access requires registration with/approval from an institution that is not another UK HE institution (i.e. the funder or data holder, e.g. the UK Data Service); or

- Research already has ethical approval from a UK HE institution or other body providing an appropriate ethics review

→ Obligatory 1-page self-assessment checklist (same as above) submitted to REC for checking and filing (with just one reviewer), along with any existing approvals, where relevant. REC Processing time: 2 working days.

Tier 3: (low risk research) All research involving new data collection from human participants as 'subjects' and/or which compounds multiple features from Tier 2.
→ Full-ethics review as per current processes. REC processing time: 10 working days.

Tiers 1-3 are illustrated with example case studies of research projects in Appendix II.

Key Principles

To determine which Tier is appropriate for a given piece of work, we recommend that the IOE REC provides clear guidance based on key principles underpinning the tiered approach. These key principles are as follows:

1. Are data collected from human participants as 'subjects'? In line with latest ethical guidance, this should be a starting point, but is NOT sufficient as a criterion on its own: some research involving human participants may still be considered 'very low risk' as outlined above. It is also not to be understood as a binary distinction, but rather as a cline, involving consideration of the distinction between 'subjects' and 'authors' as outlined in Appendix I. An example of this cline from 'no subjects' to clearly involving 'subjects' in terms of data sources would be:

Tier 1	Tier 2	Tier 3
software specifications, company websites, publicly available statistics, newspaper articles	(anonymous) reader comments on news articles, existing pseudonymized personal data with access restrictions, blog/vlogs belonging to anonymous individuals or public personae	online forum or social media contributions by private individuals, interviews or questionnaires with selected participants

2. Who is making the data available? This also relates to the distinction between 'subjects' and 'authors' discussed above, which in turn relates to the purposes for which content is made available and the size of the expected audience. This is again to be understood as a cline from content most obviously shared for wide public consumption to content least so:

Tier 1	Tier 2	Tier 3
Governments, health/ educational/academic institutions, NGOs, large commercial organizations, news outlets	anonymous or identifiable public individual, anonymous individual in a personal capacity	identifiable private individual in a personal capacity

3. What processes are needed for accessing the data? In many cases accessing a dataset for secondary analysis requires scrutiny of the proposed project from the data holder or funder, which makes further ethical review unnecessary. A key consideration here is whether existing permissions to use the data explicitly cover its intended use.

4. Is the topic being studied/discussed sensitive, distressing or controversial? Even with no human participants, there can be risks to the researcher in dealing with distressing data and these need to be considered when deciding which Tier a piece of work falls into.
5. Are there any specific requirements for the project itself? For example, are there institutional administrative requirements to have a locally approved ethics application (as is the case with the release of funds for some funded projects), or is an institutional ethics application required for data access in the first place?

Along with the three Tiers, we recommend a self-referral option for Tiers 1 and 2 that can be triggered by the lead researcher, should they feel, for whatever reason, that they would benefit from going through a full ethics process.

To make both the tiered and the self-referral approach smoother, we recommend a digital form that reveals sections to complete as they become relevant based on previous responses. This would significantly reduce the administrative burden on the IOE REC and would also be more transparent for researchers about which sections are and are not required for completion in different situations.

Finally, in the interest of improving both the efficiency and the status of ethics reviews, the group recommends moving towards expert reviews, i.e. reviews by colleagues with expertise in the subjects and methods in question. There are two potentially complementary ways of achieving this: recognizing ethics reviewing explicitly in workload allocations according to the number of reviews per term committed to; and/or reviewers who are hired and paid for this role.

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[i] Please note: 'very low risk' is a problematic term here. According to UCL's authorisation of local research ethics committees the IOE REC is only authorised to review low risk applications; anything high risk has to be escalated to UCL REC. For the purposes of these recommendations, 'very low risk' should be understood as relative to the officially low risk projects that IOE REC is authorised to deal with.

[ii] In line with UCL policies, the group makes a distinction between ethical research conduct as captured by UCL's Academic Integrity policy and the new UCL Code of Conduct for Research, and research ethics procedures. The group assumes that all researchers are bound by and act according to the principles of Academic Integrity and the UCL Code of Conduct and therefore confines itself to recommendations that pertain to the ethics review process specifically.

[iii] The group is aware of guidance currently in development regarding information collected as part of research impact, public engagement and/or knowledge transfer activities, particularly any activities that involve 'two-way communication'. Responding to this is out of scope for this group, as guidance has not yet been finalized. However, we recommend that a separate Task & Finish Group be set up to map how the data principles outlined in these Recommendations (see page 6 onwards) apply to research impact, public engagement and/or knowledge transfer activities. This new group should consider distinctions between, for example, feedback collected regarding the activity itself (e.g. for improving similar future events) vs. feedback on research being presented (e.g. for inclusion in research outputs as stakeholder contributions).

[iv] These recommendations should be regularly reviewed and informed by ethical developments in 'very low risk' domains and research practices, e.g., evolving debates about ethical considerations in systematic reviews. For example, in future IOE REC might want to evaluate whether Tier 2 research could be handled in the same way as Tier 1 given existing safeguards (e.g. academic code of conduct), researcher administrative load and REC capacity.

Appendix I - On the subject of human participants

As noted in our recommendations, the presence/absence of human participants is central in macro ethical principles, e.g. the Belmont Report, and guidance offered in existing literature (e.g. Hunter 2018) and professional guidelines on the subject of ethical research (e.g. BERA, AoIR, BAAL, etc.). Most professional guidelines, and indeed the Belmont Report, assume direct human participants in the traditional sense of interviewees, respondents to questionnaires, or patients receiving different types of treatments. However, special reference is made in more recent guidelines of some organizations to internet-based research, in which the crucial question of 'Are there human participants?' becomes more difficult to answer. Even where it is possible to make a clear distinction, the Association of Internet Researchers (AoIR) explicitly argues against using this criterion as the single 'litmus test for whether or not one needs to undergo ethical review before conducting research'. They propose a useful distinction between human participants as 'subjects' and as 'authors'. 'Subjects' here refer to the more traditional type or 'human participants' covered by typical ethics guidance, or, in internet-based research, participants 'in small chatrooms, MUDs or MOOs intended to provide reasonably secure domains for private exchanges'. 'Authors', on the other hand, are defined as humans who generate content (i.e. data) specifically for wide public consumption (e.g., e-mail postings to large listserves and USENET groups; public webpages such as homepages). If the data being collected is content produced by 'authors' then there are much lower expectations, if any, of privacy and no expectations of informed consent, etc.

Appendix II - Example Case Studies

The following case studies are designed to illustrate how the three-tier REC process might apply in different contexts

Case Study 1 – Corpus linguistic investigation of contemporary representations of obesity in a UK media corpus.
Data: articles on obesity from two UK broadsheets and two UK tabloids published between 2018 and 2022. Articles sourced from Nexis database available via the UCL library.
Method: Corpus-based discourse analysis of collocation patterns and concordance lines of 'obesity' and 'obese' with comparisons between newspaper types.
Purpose: To produce a journal article and accompanying blog post on the extent to which current media discourses around obesity might contribute to the stigmatization of the condition.
This project involves authors, not subjects, because data is written to be widely read and is made available for public consumption by established news outlets. Topic does not relate to sensitive or controversial issues, or topics likely to be triggering to researchers. No restrictions of data use and no project-specific requirements to have local ethical approval.

➔ Tier 1.

Case study 2 – study of how physical activity relates to depression using secondary data analysis.
Data: millennium cohort study, housed in UCL IOE. Individuals gave data on their physical activity and their depression symptoms. Researchers analysed the correlations between these anonymized data. Participants consented and ethical approval was provided for this study for use in secondary data analysis (see link).
While health is examined, this was not considered an ethically complex/sensitive topic, but the obligatory 1-page form should be submitted to demonstrate that intended data use was considered consistent with the original ethical approvals obtained at primary data collection.

➔ Tier 2.

Case study 3 – study of the consequences of cousin marriages on offspring health using secondary data analysis.
Data: Born in Bradford cohort study, housed in the University of Bradford. Researchers examined how cousin marriages could impact on offspring health (the child's birth weight and early developmental milestones). Participants consented and ethical approval was provided for this study for use in secondary data analysis; data were anonymised and minimised.
While the health outcomes were not considered controversial, the link with cousin marriages was considered to be ethically complex/sensitive (there was a compounding of Tier 2 criteria) and full REC review would help the researchers navigate this.

➔ Tier 3.

Case Study 4 – summary of evidence on the impact of childcare and early education for a policy briefing note

Purpose: a non-systematic review of the literature on the impact of childcare and early education on children, families and the wider economy.
'Data': published research studies and thus only involving human participants under the very widest definition of human participants and as authors rather than subjects.
Topic is not sensitive or likely to be triggering to researchers. No restrictions on 'data' use and no project-specific requirements to have local ethical approval

➔ Tier 1.

Case Study 5 – analysis of what explains variation in the take-up rates of early education entitlements across local authorities

Purpose: to understand why take-up rates of the early education entitlements - 'free' early education for all 3-4 year olds and disadvantaged 2-year-olds in England – vary so widely across local authorities.
Data: publicly accessible data published by government departments, non-governmental organisations and other public bodies at local authority level.
No human participants. Topic is not sensitive or likely to be triggering to researchers. No restrictions on data use and no project-specific requirements to have local ethical approval

➔ Tier 1.

Case Study 6 – analysis of how take-up of early education entitlements varies across groups

Purpose: to understand why take-up rates of the early education entitlements vary across groups defined on the basis of individual characteristics, e.g. low family income, ethnicity.
Data: pseudonymised data shared via a trusted research environment (secure data facility). Permission from the data owner sought and granted prior to access, with results subject to approval before removal from the secure environment to prevent inadvertent disclosure.

Application to access the data reviewed and granted by the data owner. Topic is not sensitive or likely to be triggering to researchers. No project-specific requirements to have local ethical approval.

➔ Tier 2.