Staff Ethics Application Form

Anyone conducting research under the auspices of the Institute (staff, students or visitors) where the research involves human participants or the use of data collected from human participants, is required to gain ethical approval before starting. This includes preliminary and pilot studies. Please answer all relevant questions in terms that can be understood by a lay person and note that your form may be returned if incomplete.

The guidelines on the IOE Research Ethics webpage provide support and advice. If you require further guidance or require an alternative format of this form, please contact the IOE Research Ethics team at ioe.researchethics@ucl.ac.uk.

Section 1 – Project Details

a. Project Title: Generative LLM-Based Tools for Health and Social Care Applications: Living Map and Critical Review
b. Principal Investigator (PI): James Thomas
c. Department: Social Research Institute
d. Research Centre (if applicable): EPPI Centre
e. Co-Investigators (Co-I):
    a. UCL-based Co-Is/Collaborators: Gareth Hollands; Dylan Kneale; Alison O'Mara-Eves; Ian Shemilt; Katy Sutcliffe
    b. Non-UCL Co-Is/Partners/Collaborators: N/A
    (Please enter Co-Is/Collaborators separated by a semi-colon. I.e. John Smith – Oxford University; Jane Smith – LSE; etc)

f. Start Date for data collection/systematic review/secondary analysis:
    - Data collection: N/A;
    - Systematic review: 1st January 2024;
    - Secondary analysis: N/A
g. End Date: 31st December 2025
h. Funder: National Institute for Health Research Policy Research Programme (Grant: PR-R6-0113-11003 - Reviews facility to support national policy development and implementation)
i. Funding confirmed? Yes ☒ No ☐
    If yes, please could you provide your Worktribe ID: 560250
j. Expedited review requested? Yes ☐ No ☒
    If yes, please give your reason for expedited review. **Note:** Expedited reviews are for exceptional circumstances only. Enter text
    Please see our guidance on how to request expedited reviews

k. Specify which professional code of ethics will be adhered to for this research: Social Research Association (SRA) Ethical Guidelines

l. Is this application a continuation of a research project that has already received ethical approval? Yes ☐ No ☒

If yes, provide details below (see guidelines) including the ethics reference number. N/A

m. Country fieldwork will be conducted in N/A - No fieldwork (systematic review)

If research to be conducted abroad please ensure travel insurance is obtained through UCL. ***Details can be found on the*** *UCL travel advice webpage*

n. Has this project been considered by another (external) Research Ethics Committee?

Yes ☐ External Committee Name: Enter text

Date of Approval: Enter text

No ☒ **If no, *continue to Section 2***

If yes: *Submit a copy of the approval letter with this application. Proceed to Section 9 - Attachments*

Section 2 – Research methods summary (tick all that apply)

☐ Interviews
☐ Focus groups
☐ Questionnaires
☐ Action Research
☐ Observation
☐ Literature Review
☐ Controlled trial/other intervention study
☐ Use of personal records
☒ Systematic review - **if only method used complete the below then go to Section 5.**
☐ Secondary data analysis - **if only method used complete the below then go to Section 6.**
☐ Advisory/consultation/collaborative groups
☐ Other, give details: Enter text

Please provide an overview of the project, focusing on your methodology. This should include some or all of the following: purpose of the research, aims, main research questions, research design, participants, sampling, data collection (including justifications for methods chosen and description of topics/questions to be asked), reporting and dissemination. Please focus on your methodology; the theory, policy, or literary background of your work can be provided in an attached document (i.e. a full research proposal or case for support document). *Minimum 150 words required.*

Aim: To empower key policy and other stakeholders with the enabling knowledge and skills needed to ask relevant questions, and make informed judgments, about the utility, reliability, and potential risks of generative large language model-based tools, when considering these for potential adoption for health and social care applications.

Research design: Evidence mapping and critical review (systematic review)

Participants: N/A - No human participants (systematic review)

Sampling: N/A - No human participants (systematic review)

Data collection: We will extract and code data from published research articles (reports) using a bespoke coding scheme (evidence map) and data extraction form (critical review) – please see also the attached protocol, which includes a pilot coding scheme (evidence map - section 2.2.1) and data collection methods (critical review - section 2.2.2)

Reporting: We have already produced a protocol for this project (attached) and we will also produce a final report based on the completed project (systematic review). Both of these documents will be published on the EPPI Centre website (http://eppi.ioe.ac.uk/) alongside other systematic reviews, related forms of evidence synthesis, and protocols previously produced for the NIHR Policy Research Programme Reviews Facility.

Dissemination: This project (systematic review) has been commissioned by the National Institute for Health Research Policy Research Programme (NIHR PRP) for the UK Department of Health and Social Care (DHSC). Key findings and implications for policy and practice will be directly disseminated to representatives of the DHSC and other key policy stakeholders, via the NIHR PRP Research and Development (R&D) Committee. This committee includes representatives of the DHSC, the Care Quality Commission (CQC), the National Institute for Health and Care Excellence (NICE), NHS England (NHSE), and the UK Health Security Agency (UKHSA).

Section 3 – Research Participants (tick all that apply)

Approximate maximum number of participants required: Enter text
Approximate lower age limit: Enter text
Approximate upper age limit: Enter text

☐ Early years/ pre-school
☐ Ages 5-11
☐ Ages 12-15
☐ Young people aged 16-18
☐ Adults - *please specify:*
☐ Unknown – *please specify*
☐ No participants

Click or tap here to enter text.

NB: Ensure that you check the guidelines carefully as research with some participants will require ethical approval from a different ethics committee such as the National Research Ethics Service (NRES) or Social Care Research Ethics Committee (SCREC).

Section 4 – Security-sensitive material

Security sensitive research includes: commissioned by the military; commissioned under an EU security call; involves the acquisition of security clearances; concerns terrorist or extreme groups.

a. Will your project consider or encounter security-sensitive material?
   Yes* ☐ No ☐

b. Will you be visiting websites associated with extreme or terrorist organisations?
   Yes* ☐ No ☐

c. Will you be storing or transmitting any materials that could be interpreted as promoting or endorsing terrorist acts?
   Yes* ☐ No ☐

d. Will your research involve personal data involving criminal convictions and offences?
   Yes* ☐ No ☐

* *Give further details in* ***Section 8 Ethical Issues***

Section 5 – Systematic reviews of research

a. Will you be collecting any new data from participants
   Yes* ☐ No ☒

b. Will you be analysing any secondary data
   Yes* ☐ No ☒

* *Give further details in* ***Section 8 Ethical Issues***

If your methods do not involve engagement with participants (e.g. systematic review, literature review) ***and*** *if you have answered* ***No*** *to both questions, please go to* ***Section 8 Attachments.***

Section 6 - Secondary data analysis (Complete for all secondary analysis)

a. Name of dataset/s Enter text
b. Owner of dataset/s Enter text

c. Are the data in the public domain?
Yes ☐ No ☐
If no, *do you have the owner's permission/license?*
Yes* ☐ No ☐

d. Are the data special category personal data (*i.e. personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation*)?
Yes* ☐ No ☐

e. Will you be conducting analysis within the remit it was originally collected for?
Yes ☐ No* ☐

f. **If no to above,** was consent gained from participants for subsequent/future analysis
Yes ☐ No* ☐

g. **If no to above,** was data collected prior to ethics approval process?
Yes ☐ No* ☐

* *Give further details in* ***Section 8 Ethical Issues***

If secondary analysis is only method used ***and*** *no answers with asterisks are ticked, go to* ***Section 9 Attachments.***

Section 7 – Data Storage and Security

Please ensure that you include all hard and electronic data when completing this section. *Guidance about data storage and security can be found on the UCL Research Data Management webpage*

a. **Data subjects -** Who will the data be collected from? Click or tap here to enter text.

b. **What data will be collected?** Please provide details of the type of personal or special category data to be collected Click or tap here to enter text.

c. **Is the data anonymised?** Yes ☐ No* ☐

Do you plan to anonymise the data? Yes* ☐ No ☐

Do you plan to use individual level data? Yes* ☐ No ☐

Do you plan to pseudonymise the data? Yes* ☐ No ☐

Guidance on anonymisation vs pseudonymisation can be found on Practical Data Protection Guidance Notices

d. Disclosure - Who will the results of your project be disclosed to? Enter text

Disclosure - Will personal data be disclosed as part of your project? Enter text

e. **Data storage** – Please provide details on how and where the data will be stored
Guidance can be found on Best Practice to Store and Preserve Data

Click or tap here to enter text.

f. **Data Safe Haven (Identifiable Data Handling Solution)** – Will the personal identifiable data collected and processed as part of this research be stored in the UCL Data Safe Haven (mainly used by SLMS divisions, institutes and departments)?

Yes ☐ No ☐

g. How long will the data and records be kept for and in what format?
Please note that the UCL Records Retention Schedule recommends research data is retained for 10 years after completion of the research.

Click or tap here to enter text.

Will personal data be processed or be sent outside the European Economic Area?
(If yes, please confirm that there are adequate levels of protections in compliance with GDPR and state what these arrangements are)

Yes ☐ No* ☐

Will data be archived for use by other researchers?

(*If yes, please provide details.*)

Click or tap here to enter text.

h. If personal data is used as part of your project, describe what measures you have in place to ensure that the data is only used for the research purpose (e.g. pseudonymisation and short retention period of data)
Click or tap here to enter text.

i. **Data sharing**. Will data be shared with other organisations, e.g. research partners or collaborators, funders, contractors or government departments?
Yes* ☐ No ☐

If yes to the above:

j. What is the name of the organisation (or type, if name not known) that data will be shared with: Enter text

k. Please provide a brief purpose for the data sharing:

Click or tap here to enter text.

l. **Please clarify** whether you will be the data controller or data processor:

Click or tap here to enter text.

m. Will a data sharing agreement be put in place?
Yes ☐ No ☐

* *Give further details in* ***Section 8 Ethical Issues***

Section 8 – Ethical issues

Please clearly state the ethical issues and any risks which may arise in the course of this research and how will they be addressed.

All issues that may apply should be addressed. Some examples are given below, further information can be found in the guidelines. *Minimum 150 words required.*

- Methods
- Sampling
- Recruitment
- Gatekeepers

- Informed consent
- Potentially vulnerable participants
- Safeguarding/child protection
- Sensitive topics
- International research
- Risks to participants and/or researchers
- Confidentiality/Anonymity
- Disclosures/limits to confidentiality
- Data storage and security both during and after the research (including transfer, sharing, encryption, protection)
- Reporting
- Dissemination and use of findings
- Impact, public engagement, and knowledge exchange activities

This project is classed as a systematic review, and it will therefore not have any human participants. This systematic review will use only information that is already in the public domain, in the form of published research. For these reasons, we have *not* identified any ethical issues or risks in relation to the conduct of this project with regards to any of the following stages of research (only a few of which are applicable to systematic reviews): methods; sampling; recruitment; gatekeepers; informed consent; potentially vulnerable participants; safeguarding and child protection; sensitive topics; international research; risks to participants or researchers; confidentiality and anonymity; disclosures and limits to confidentiality; data storage and security; reporting; dissemination and use of findings; or impact or public engagement. As well as adhering to SRA Ethical Guidelines (see also Section 1, item k above), we will also adhere to the UKRIO Code of Practice for Research (https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf).

Please confirm that the processing of the data is not likely to cause substantial damage or distress to an individual Yes ☒

Section 9 – Attachments

Please attach the following items to this form or explain if not attached. Please see our guidance and templates on informed consent and General Data Protection Regulation (GDPR)

- Information sheets, consent forms and other materials to be used to inform potential participants about the research *(List attachments below)* Yes ☒ No ☐

Protocol for the evidence map and critical review (systematic review).

If applicable/appropriate:

- Approval letter from external Research Ethics Committee Yes ☐
- The proposal ('case for support') for the project Yes ☐
- Full risk assessment (more information on IOE Research Ethics) Yes ☐

Section 10 – Declaration

I confirm that to the best of my knowledge the information in this form is correct and that this is a full description of the ethical issues that may arise in the course of this project.

Name: James Thomas

Date: 24th November 2023

Timescales

For receiving the Committee's decision following submission are as follows:

Standard –30 working days

Expedited – 15 working days

Please note that the above are guidelines for response times which will vary depending on the quality of the application and the number of applications being processed. All applications are assessed prior to forwarding to the Research Ethics Committee and **incomplete** applications will be returned for further detail.

Decisions

Approved: The research is fully approved and can commence immediately.

Revision required: The application is incomplete and/or raises concerns so further information and/or changes need to be made and submitted before full approval can be granted.

Rejected: The application is considered to raise fundamental concerns that means it cannot be approved by the committee.