UCSC Ethics Review Committee (UCSC-ERC)

Procedure and Guidelines

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Important Information

Who can apply?

Staff members and students (undergraduate or graduate) of UCSC.
Note: A study shall involve at least one permanent academic staff member of UCSC.

What type of studies qualifies for applying?

Research that pertains to computing and includes human participants, or research that holds substantial socio-cultural and political implications or conflicts of interest.

Please note that UCSC-ERC does not assess studies that involve clinical trials or animals. Applicants must seek ethical approval for such research from an appropriate and specialized ERC, such as the Medical Faculty ERC of UoC. Any study that has received ethical approval from an external ERC must inform the UCSC-ERC by submitting copies of the relevant documentation.

What type of studies that typically do not require ethical clearance?

- Analysis of pre-existing data obtained from public sources or published literature.
- Surveys or questionnaires that do not collect any identifying information from participants and are entirely anonymous. However, if there is any potential risk to participants or sensitive questions are asked, ethical review may still be needed.
- Studies conducted solely for educational purposes as part of classroom assignments or teaching activities, especially if they involve minimal risk and do not aim for generalizable knowledge.
- Evaluations of programs or interventions carried out for the purpose of assessing their effectiveness, without the intent to contribute to generalizable knowledge. However, ethical considerations should still be taken into account when interacting with participants.
- Studies that collect data from participants through anonymous online platforms, where participants cannot be identified. However, if there are potential risks to participants, a review is still advisable.

Note: The UCSC-ERC is not permitted to pre-determine whether an ethical review is necessary. The responsibility lies with the research entity to decide whether to submit an initial application.

How to submit your application?

The applicant has the option to either submit an initial application for smaller studies, such as undergraduate projects with negligible ethical implications, or directly proceed with the detailed application for studies with significant ethical ramifications. Following the assessment of the initial application, the committee will determine whether to request a detailed application.

Submitting the initial application

- Duly completed initial application form
- Checklist of contents, signed by the Principal Investigator (or supervisor in the case of a supervised student project)
- Information sheets, consent forms, assent forms and data collection booklets/forms/questionnaires, where necessary in all three languages. Please note it is mandatory to include the following at the bottom of the information sheet: "*This project has been approved by the Ethics Review Committee, University of Colombo School of Computing. You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112581245 extension xxx (between 9am and 4pm) or by sending an email to ethics@ucsc.cmb.ac.lk*".

- A brief curriculum vitae of each investigator (note: providing a comprehensive account of any prior experience pertaining to similar studies conducted by the investigator, if applicable, is necessary)
- Other related documents as applicable
- A receipt for the appropriate payment to the accounts department

Submitting the detailed application

- Duly completed detailed application form
- Checklist of contents, signed by the Principal Investigator (or supervisor in the case of a supervised student project)
- The detailed research protocol, which must be correctly numbered and paginated
- Information sheets, consent forms, assent forms and data collection booklets/forms/questionnaires, where necessary in all three languages. Please note it is mandatory to include the following at the bottom of the information sheet: "*This project has been approved by the Ethics Review Committee, University of Colombo School of Computing. You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112581245 extension xxx (between 9am and 4pm) or by sending an email to ethics@ucsc.cmb.ac.lk*".
- Ethics approval from sponsoring country or country of the overseas investigator (if any)
- A brief curriculum vitae of each investigator (note: providing a comprehensive account of any prior experience pertaining to similar studies conducted by the investigator, if applicable, is necessary)
- Other related documents as applicable
- A receipt for the appropriate payment to the accounts department

Note: All the above documents must be submitted as a soft copy (PDF format) and a hard copy. The title of the research project must be displayed as a heading at the top of the front page on each of these documents.

Applicable Fees

- Externally funded project: Rs. 10,000/=
- Non-funded or internally funded staff project: 5,000/=
- Postgraduate student project: Rs. 5,000/=
- Undergraduate student project (external): Rs. 3,000/=
- Undergraduate student project (internal): Free

Note: Fees once paid will not be refunded.

When and where to submit your application?

- To the Postgraduate, Research & Project Division of UCSC during the working days/time and by attaching as PDF documents to ethics@ucsc.cmb.ac.lk

- The deadline for receiving the completed application is 12 noon on the last working day of each month, by which time the complete application must be received at the office.

The Reviewing Process

The lead investigator presents the complete research proposal to the ethics review committee (ERC). The ERC conducts an initial screening to ensure the proposal meets all submission requirements and is comprehensive. In cases of incomplete submissions, the proposal may be returned to the researchers for further revision. There are instances when the committee may suggest that the researchers approach a different ERC if the study falls beyond the scope of UCSC-ERC.

The committee then assigns one or more reviewers to meticulously analyze the research proposal, focusing on ethical considerations, potential risks to participants, adherence to ethical guidelines, procedures for informed consent, data privacy measures, and other pertinent ethical aspects. Reviewers offer feedback and recommendations to the researchers, prompting them to make any necessary revisions to address ethical concerns and improve the proposal.

Certain proposals, particularly those involving vulnerable groups or intricate ethical dilemmas, may warrant a comprehensive review by the entire ethics committee. Following the resolution of any concerns and implementation of required revisions, the proposal undergoes a final evaluation, where the committee decides whether to grant full approval, approve with minor adjustments, request significant revisions, or reject the proposal outright.

Upon approval, the committee issues an ethical clearance certificate, affirming that the research has undergone rigorous ethical scrutiny and has been deemed ethically sound. In specific cases, the ethics review committee may mandate continuous monitoring of the research to ensure ongoing compliance with ethical standards, necessitating regular progress reports from the researchers.

The ethics review committee meticulously maintains records of all reviewed proposals, decisions made, and correspondence pertaining to each study, ensuring a comprehensive and organized review process. The duration of the review process typically ranges from one to three months.

The approval and the ethical clearance certificate

- This is an official letter issued by the ERC to researchers or principal investigators (PIs) indicating that their research proposal has been reviewed and found to be ethically acceptable. This certificate serves as evidence that the study has met the ethical standards and principles necessary to protect the rights, safety, and well-being of the research participants.
- The certificate includes the following information: Study Title, Principal Investigator, Institutional Affiliation (where the research is conducted), Approval Reference Number, Dates (the date of approval/clearance and the validity period), Conditions/Requirements (if any, enforced by the ERC), Reviewing Committee Information, Expiration Date, and Signature of the Chair.

- This certificate is **valid only for one year from the date of approval/clearance**. This approval relates to the ethical content of the study only, and the investigator/s are responsible to obtain any other relevant approval.
- If the study is continued for a period beyond one year, the applicant is required to furnish an annual progress report for the year and an application for the extension of approval by a further year. The ERC will issue such extension after consideration of the progress report and any other information it may require from the applicant for this purpose.

Appendices

Appendix 1: The Initial Application Form

❖ Project Information:

- Title of the Project:
- Details of the Investigators (Title/Name/Designation/Affiliation/Role/Signature):
- Contact Details of the Investigators (Mobile/Email/Address):
- Funding Details (Sources/Amounts):
- Study Setting (Timeline/Venue/Collaborations):
- Date of Submission:
- Checklist of the List of Documents Submitted:

❖ Project Summary:

- Brief Description of the Project:
- Objectives and Goals of the Project:
- Methodologies and Techniques Used:

❖ Ethical Considerations:

- Explanation of Ethical Issues Addressed in the Project:
- Potential Risks to Participants, Data, or Society:
- Measures Taken to Mitigate Identified Risks:

❖ Informed Consent:

- Description of the Informed Consent Process for Participants:

- How Participants' Consent will be Obtained and Documented:
- Procedures to Ensure Participants' Understanding of their Rights and Participation:

❖ Data Privacy and Security:

- How Data will be Collected, Stored, Handled, and Shared:
- Measures to Ensure Data Privacy and Security:
- Data Retention and Disposal Policy:

❖ Anonymity and Confidentiality:

- How Participant Identity will be Protected:
- Procedures for Handling Any Identifying Information:
- Steps Taken to Ensure Confidentiality of Data:

❖ Potential Conflict of Interest (Commercial/Financial/Intellectual/Other):

- Disclosure of Any Potential Conflicts of Interest:
- How Identified Conflicts will be Managed:

❖ Compliance with Laws and Regulations:

- Assurance of Compliance with Relevant Laws and Regulations:
- Identification of Specific Legal Requirements:

❖ Review of Previous Ethical Approvals (if applicable):

- Information on Similar Projects Approved by Other Ethics Committees:
- Explanation of Changes Made Based on Previous Feedback:

❖ Participant Recruitment and Selection:

- Description of How Participants will be Recruited and Selected:
- Criteria for Participant Inclusion and Exclusion:

❖ Researcher Training:

- Details on How Researchers Involved will be Trained on Ethical Considerations and Guidelines:

❖ Risk-Benefit Analysis:

- Assessment of Potential Benefits of the Project Compared to the Risks Involved:

- ❖ Protocol for Handling Ethical Issues:
  - Outline of Procedures for Addressing and Resolving Ethical Issues:
  - Outline of Procedures for Maintaining Equipment Safety:
- ❖ Documentation and Reporting:
  - Requirements for Maintaining Records:
  - Obligations for Reporting Adverse Events or Deviations from the Approved Protocol:
- ❖ Declaration and Signatures

Appendix 2: General Ethical Guidelines

1. Obtain informed consent from all participants before collecting any data. Participants should be fully informed about the purpose of the study, the nature of the data being collected, how the data will be used, potential risks and benefits, and their rights to withdraw without penalty.

2. Protect participants' privacy by ensuring that their personal information and responses are kept confidential. Anonymize or pseudonymize data whenever possible to prevent re-identification. Clearly communicate how data will be stored, who will have access to it, and how long it will be retained.

3. Collect only the data that is necessary to address the research question. Avoid collecting excessive or irrelevant information that could compromise participants' privacy.

4. Participation in the study should be voluntary, and participants should not be coerced, pressured, or incentivized to participate against their will.

5. If the study involves vulnerable populations (such as children, prisoners, or individuals with cognitive impairments), take additional measures to ensure their rights and well-being are protected. Obtain informed consent from legally authorized representatives when necessary.

6. If the study involves any form of deception, such as withholding information about the study's true purpose, it should be justified, and participants must be fully debriefed and informed about the deception after their participation.

7. Implement robust data security measures to protect participants' data from unauthorized access, breaches, or misuse. This includes secure storage, encryption, and access controls.

8. Be transparent about the research process, methodology, and potential conflicts of interest. Communicate findings accurately and avoid misrepresenting results.

9. Adapt the approach to respect participants' cultural backgrounds.

10. Clearly communicate to participants who owns the collected data and whether and how it will be shared. Obtain additional consent if data sharing is planned beyond the original scope of the study.

11. Ensure the accuracy and reliability of the data collected. Adhere to appropriate research methodologies and data collection techniques.

Appendix 3: Terminology

'Research ethics' refers to the moral principles guiding research from its inception through to completion and publication of results.

'Human subject' is a living individual about whom an investigator (whether professional or student) conducting research obtains, (1), Data through **intervention** or **interaction** with the individual, or, (2), Identifiable **private information**.

'Human participant' is defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and fetuses, human tissue and bodily fluids and human data and records (such as but not restricted to medical, genetic, financial, personal, criminal or administrative records, and test results including scholastic achievements).

'Clinical trial' is any research study that prospectively assigns human participants or groups of humans to one or more health-related **interventions** to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. (WHO-ICTR definition).

'Intervention' includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **'Interaction'** includes communication or interpersonal contact between investigator and subject. **'Private information'** involves information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record).

'Risk' is defined as the potential physical or psychological (e.g., participant's personal social status, privacy, personal values and beliefs, and personal relationships) harm, discomfort or stress to human participants that a research project may generate.

'Minimal risk' refers to the likelihood and extent of harm or discomfort expected in the research, which does not exceed that commonly encountered in daily life or during routine physical or psychological examinations or tests.

'Research Ethics Committee (REC)' or 'Ethics Review Committee (ERC)' is a multidisciplinary, independent body responsible for reviewing research proposals involving human participants to ensure that their dignity, rights, and welfare are protected.

Appendix 4: Ethical Principles

The four ethical principles set out by the British Psychological Society to be used as a tool when someone wants to make reasoned judgments about research ethics: respect for the autonomy and dignity of persons, scientific value, social responsibility, and maximizing benefits and minimizing harm.

The following research types have been categorized as involving **more than minimal risk** to research subjects:

- Research involving vulnerable groups (e.g., children aged 16 and under);
- Research involving potentially sensitive topics (e.g., participant's sexual behavior and their ethnic status);
- Research involving a significant and necessary element of deception;
- Research involving access to records of personal or confidential information;
- Research involving access to potentially sensitive data through third parties;
- Research that could induce psychological stress, anxiety or humiliation or cause more than minimal pain (e.g., repetitive or prolonged testing);
- Research involving invasive interventions (e.g., hypnotherapy) that would not usually be encountered during everyday life;
- Research that may have an adverse impact on employment or social standing;
- Research that may lead to 'labeling' either by the researcher or by the participant (e.g., 'I am stupid');
- Research that involves the collection of human tissue, blood, or other biological samples.

However, in instances where an element of risk is an unavoidable element of the research design, a detailed case outlining the cost-benefit analysis and the risk management protocol should be submitted to the Ethics Committee.

Apart from the ethical principles discussed above, the following procedures are required to be followed in ethical research:

Valid consent: Researchers must ensure that each research participant provides informed consent based on a sufficient understanding of the research procedures. Additionally, participants should retain the freedom to withdraw or modify their consent and request the deletion of data during the data collection phase. However, the specific form of consent required (e.g., ticking a box, written consent, audio-recorded verbal consent, implied consent, etc.) varies depending on the research's nature, subject matter, and the characteristics of the participants (e.g., individuals under 16 years of age and those with impaired capacity to consent).

Confidentiality: The researcher must ensure the protection of information acquired from and concerning a participant during an inquiry, unless explicitly agreed upon beforehand (this is also mandated by legislation, including the Data Protection Act). In publications, information confidentiality is preserved by separating the data from personal details.

Giving advice: In the event that a researcher identifies any physical or psychological issues in a participant that the participant appears to be unaware of, it is the researcher's ethical responsibility to communicate the problem to the participant and assist them in accessing suitable professional support.

Deception: It is advisable to refrain from deceiving participants regarding the purpose and nature of the research whenever possible. However, in cases where certain aspects of the investigation must remain confidential until the conclusion of data collection (especially in psychological experiments), the deception can be disclosed at a later stage. Nevertheless, if participant reactions are expected to result in discomfort, objection, or anger, such deception is unsuitable for the research.

Debriefing: After concluding the data collection, the researcher must engage in discussions and furnish participants with any essential information to mitigate potential harmful consequences, including negative emotions and misunderstandings.

Ethical practices in the use of medical devices

Every medical (or related) device carries inherent risks contingent upon specific circumstances, which may only become evident through extensive market experience. Hence, the risk assessment of a medical device is conducted based on the possibility of the device posing a hazard (potentially leading to adverse events) that could result in safety issues and harm (WHO-MDR). In practical terms, the process of risk assessment is intricate, relying on the expertise of healthcare professionals and safety-oriented design engineering. Various regulatory authorities have classified medical devices into distinct classes, considering their perceived potential hazards. For example, the U.S. Food and Drug Administration (FDA) has categorized medical devices into three regulatory classes, each requiring different levels of control to ensure device safety and effectiveness: Class I – general controls, Class II – general controls and special controls, and Class III – general controls and premarket approval.

- **Class I** devices present the minimal level of risk for harm, therefore, they have the lowest level of regulation including good manufacturing practice and labeling;
- **Class II** devices require special controls including guidance documents, special labeling requirements, mandatory performance standards, and post market surveillance;
- **Class III** devices require the most stringent regulation because they include devices that support or sustain human life.

There are several areas of hazard that are considered when classifying medical devices: the degree of invasiveness, duration of contact, the body system affected, and local versus systemic effects (WHO-MDR). For instance, an invasive device is considered to have higher potential hazard than an equivalent non-invasive device.