International University for Graduate Studies

Policy on Research Ethics Involving Human Participants and Personal Data

University Research Ethics Committee Overview

IUGS is committed to the conduct of academic research that meets the highest standards quality and of human subjects protections and safeguards and works to ensure that all research activities undertaken by University staff or students that involves human subjects or personal data are safeguard the dignity, rights, health, safety, and privacy of participants, researchers, students and third parties. The Committee comprises three University Deans.

Policy on the Ethics of Research Involving Human Participants and Personal Data

I. **Policy Statement**

A. The University is fully committed to the advancement of high quality academic research and to ensuring that all research activities undertaken by University employees, or on University premises, involving human participation or personal data are undertaken in a way that safeguards the dignity, rights, health, safety, and privacy of those involved. This commitment extends to participants, researchers, students and third parties.

B. The University expects its staff members, students, or any other person conducting research under the University's auspices to abide by the University's expectations in research practice described in this policy and to take all reasonable steps to ensure that ethical conduct of research involving human participants and personal data is observed at all times. To facilitate this, the University will, through the *Research Ethics Chair and Committee* and all other relevant means:

- Foster a research culture that embraces the principles set out in this Policy as well as all obligations set out in any relevant legislation governing the protection of the dignity, rights, safety and privacy of those involved in research;
- Provide clear and easily accessible guidance on best ethical practice and regulatory requirements;
- Offer support and training to staff and students and any others engaged in University research projects to maintain awareness and high ethical standards;
- Conduct an ethical review process for each proposed research study that evaluates the level of ethical risk the study represents and decides on approval of the study from an ethical standpoint;
- Take appropriate action where there is evidence that the University's policy is not being followed.

II. **Guiding Principles**

A. The University recognises that ethical issues raised by research vary across disciplines and that Schools will necessarily have differing approaches to ethical review. Set out below are the guiding principles that the University expects its researchers to abide by; subject specific guidance must be obtained by researchers from their Department or School:

- **Any potential risk of harm to those involved in or affected by research must be minimised** in all instances and all participants must be warned in advance about any potential risks of harm, however slight these might seem. The definition of risk is found in Appendix 1.
- **Researchers are required to consider the ethical risk of any procedure within a research project which involves human participation or personal data**, consulting the relevant Faculty, Department, School and University policies and personnel, before any work is undertaken. Advice must be sought in case of doubt.
- Where more than minimal risk is identified, **reasonable and proportionate independent ethical review** must be carried out prior to research work commencing.
- **Risks which become apparent during research require immediate full consideration** and the relevant Head of Department/Chairman of Faculty Board, as well as the relevant Research Ethics Committee must be consulted forthwith.
- **Researchers must respect the participant's right to withdraw from research** at any time without adverse consequences to the participant.
- Except where the nature of the research or participants makes this impossible, **free and informed consent and a confidentiality statements must be obtained from all participants, in research** at an appropriate point in the research process (usually the beginning). Participants and research staff should be informed of the purpose, methods and intended use of the research. The University will provide the student researcher an "Informed Consent and Confidentiality Template" they can use to draft their own document for submission. In some cases obtaining signed informed consent and/or confidentiality documentation actually decreases the likelihood of maintaining confidentiality by the simple fact that a subject will have minimal contact with the research study and their signature on a document will be the only evidence of their participation. In such cases, a decision may be made to waive the requirement for signed forms.
- Research must be designed, reviewed and undertaken in a way that maintains **academic independence, integrity and quality**.
- Research methods and the process of ethical review should be **open, independent and transparent**.
- **Research must comply with all current legislative requirements**.
- **University sponsored research carried out overseas must uphold the University's ethical standards.** Research must also be cognizant of local expectations, practices and laws, without compromising University standards.
- **Confidentiality of information given by participants, and the anonymity of subjects, must be respected** at all times and documentation protected accordingly.
- **Research evidence should be retained for peer review**, subject to conditions imposed by legal and funder regulations
- While anonymisation of stored research data is encouraged, it should be recognised that this does not always guarantee privacy and consequently every effort should be made to ensure **effective protection of stored data.**

III. University Ethical Review Process

A. The University is committed to providing a rigorous and independent ethical review process that is proportionate to the potential risk. See Appendix 1, below.

B. The University recognises that in some cases review by the full Research Ethics Committee may not be necessary. However, it expects all students embarked on research involving human

participants or personal data will consider the ethical risks of their work and will seek guidance from their Faculty member.

C. The student researcher is responsibility to assure that any proposal that also requires review by any external entity (e.g., a hospital's Institutional Review Board or a governmental agency) refer their study to that entity as early as possible in the review process. The University will assist in this process when feasible by writing a letter stating that the University Research Committee has approved the study, but the responsibility remains with the researcher. If the student needs such secondary approval and cannot get it, the student will, of course, have to identify some other means for conducting their research.

D. A student researcher may appeal the decision Research Ethics Committee makes on any of the following grounds:

> That there existed material circumstances relating directly to the case of which the reviewing committee was not aware; that procedural irregularities or misunderstandings occurred in the review process, which were of such a nature as to cause reasonable doubt as to whether the Committee would have reached the same conclusion had the irregularities not occurred; and, that there is demonstrable evidence of prejudice, bias, or inadequate review.
>
> If the University Research Ethics Committee are of the view that a complaint does not fall within any of the grounds specified above, they may dismiss the complaint and inform the complainant accordingly.

E. Complaints, or expressions of concern about research ethics at the University, can also be made to the University Research Ethics Committee.

F. To ensure a consistency of standard and approach, the University Research Ethics Committee will file an annual report regarding the review process.

IV. Areas of responsibility for ethical review

A. Both the individual researcher and the University have responsibilities to ensure the ethical conduct of research.

B. Individual researchers must take personal responsibility for the conduct of their research. The University expects researchers to familiarise themselves with this policy and any additional guidance the University may establish, as well as any subject specific material related to their profession's ethical standards. Researchers undertaking a project that involves human participation or personal data that requires ethical review may not begin their research project until approval has been obtained. The student must seek advice from their Dean or Faculty in cases of doubt.

C. It is the Dean's responsibility to ensure that their students are comply with this policy and any accompanying guidance.

D. It is the Dean's responsibility to ensure that all staff members and students and any other researchers with access to the University's resources are aware of this policy and also to ensure the effective implementation of the ethical review process in their academic programs.

E. The Research Ethics Committee is responsible for ensuring that proposals referred to them receive valid, sufficiently comprehensive, independent and timely ethical review.

F. The University Research Ethics Committee has overall responsibility for the implementation of this policy. It will also offer advice on best practices in research ethics training. The Committee will report to the University Administration annually and will recommend any changes considered necessary in light of experience.

V. Application of the policy

This policy will apply to all staff members and students, as well as to other persons engaged in a University-led research project who, as a condition of being granted access to University resources, have agreed in writing that this policy will apply to them.

VI. Policy review

As part of the University's commitment to ethical research, this policy will be reviewed every three years, or more frequently in the event of a major policy change by a significant stake-holder or the identification of a significant weakness in the existing policy.

Appendix 1. Definition of Risk and the Decision Process

The concept of risk in human subjects research is divided into three broad categories. These categories are derived from the United States Department of Health and Human Services[1]. The categories, and decision processes are as follows:

- **Exempt Review**. (but must still be submitted for human subjects review) when there is no risk to subjects: Reviewed by one Committee Member who notifies the full Committee. Records are stored in the student's file.

  Examples of Exempt Categories:

  1. Education research
  2. General opinion surveys, interviews, educational tests, public observations (that do not involve children)
  3. Studies of public officials
  4. Analysis of previously-collected, anonymous data
  5. Public benefit or service programs
  6. Consumer acceptance, taste, and food quality studies
  7. Surveying teachers, nurses, or doctors about a technique or an outcome
  8. Interviewing managers about a management style or best practice
  9. Conducting a focus group about an experience or an opinion of a community program
- **Expedited Approval.** There is minimal risk to subjects. An expedited review procedure may be carried out by the Committee chairperson or by one or more experienced reviewers designated by the chairperson from among Committee members. In reviewing the research, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. Disapproval will require a decision of the full Committee. Whenever a Committee member intends to make an expedited approval he/she will first notify the full Committee of the research proposal under review for which he/she is intending to make the expedited decision.

  Examples of minimal risk for expedited approval:

  1. Any studies involving physically invasive methods, clinical studies of drugs or medical devices, collection of biological specimens for research purposes by noninvasive means
  2. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected for non-research purposes and will be reused for the research study
  3. Collection of data from voice, video, digital, or image recordings made for research purposes
  4. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies (if the study would put the subjects at any kind of risk of exposure to criminal or civil liability or be damaging to the

[1] Basic HHS Policy for Protection of Human Research Subjects
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/

subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality, then full committee review is required (and would likely not be granted)

- **Full Committee Review.** Note that IUGS, because it is an International University with students who may be from, and conduct studies in numerous countries, must be especially sensitive to international standards of conduct. IUGS is therefore especially sensitive to studies taking place internationally, particularly in countries which may have little or no provisions for protection of human subjects, or where subjects may be at physical, psychological or legal risk.

  Examples of higher risk for full committee review:

  1. Studies using "vulnerable populations" and thus requiring extra protections: e.g., Children, prisoners, pregnant women, spousal abuse
  2. Studies requiring subjects to report on past traumatic experiences, substance use or abuse, criminal activity, or other personal experiences that subjects may not want to risk having disclosed
  3. Studies in which disclosed information could require mandatory legal reporting (e.g., child/elder abuse, etc.)
  4. studies involving forms of deception that raise risk to subjects or others
  5. Studies that could arouse a traumatic response in subjects, up to and including a PTSD-level reaction

In all cases, the final decisions are reported to University Administration for the University's records and for insertion in the student/researcher's file.