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Code of Ethical Conduct in Research Policy

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Research Ethics Policy

Effat University EU Policy #: EU 10007
UC Decision #: Exp#3/13.Dec.2016/2.6-10 (EU Policy No. EU 10007)
Developed: 14 April 2009
Effective Date: 14 December 2016 Revised:13 December 2016

Policy Statement

Purpose

The principal goals of the research ethics policy are to:

- Increase the knowledge of those engaging in research, or considering doing so, as to the various ethical issues involved through and in conjunction with Effat University, and promote responsible conduct of research.
- Raise awareness regarding local and international standards with regard to promoting responsible conduct of research.
- Ensure that research is conducted in accordance with universal ethical standards while taking into consideration core Islamic values, and the laws of the Kingdom of Saudi Arabia. Also, the Implementing Regulations of the Law of Ethics of Research on Living Creatures at the National Committee of Bioethics (NCBE), Effat University's Code of Ethical Conduct (Tarbawwyat), and other national and international laws were considered.
- Ensure that all research conducted at Effat University is consistent with the Research and Ethical Guidelines.
- Provide appropriate protection for researchers, research participants, and Effat University

This includes:

- Research on Human Participants and Other Living Creatures Policy
- Misconduct in Research Policy
- Informed Consent Policy

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Research on Human Participants & Other Living Creatures Policy

Scope

All research conducted at Effat University involving human participants must be submitted to the Research Ethics Institutional Review Committee (REIRC) for review and approval, or to be determined exempt from the need for review.

Responsible Party

The Chairperson of the REIRC.

Definitions

Research may be usefully defined as a class of activities designed to develop or contribute to generalizable knowledge. Encompasses basic research, applied research, and research training activities in areas such as biomedical, and life science, natural sciences, engineering, humanities and arts, and social and behavioral science.

A *human participant* is 'a living individual about whom an investigator (whether professional or student) obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

***Intervention*:** Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

***Interaction*:** Communication or interpersonal contact between investigator and participant.

***Private Information*:** 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 (for example, a medical record).

***Identifiable Information*:** Information that is individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information).

GENERAL

All university policies fall within a hierarchy of laws and rules. University policies are subject to compliance with bylaws and regulations instituted by higher governing authorities as follows:

- The Ministry of Higher Education
- The King Faisal Foundation
- Effat University Founders' Board
- Effat University Board of Trustees
- The University Charter and Bylaws
- The National Association for Accreditation and Academic Assessment (NCAAA)
- Effat University Policies and Procedures

Policies

I.- Policy Statement

Any study that involves intervening upon people (e.g., a complex intervention involving educational sessions), interacting with them (e.g., conducting an interview or administering a questionnaire), or collecting identifiable private data (e.g., abstracting data with identifiers from a medical record) for the purpose of contributing to generalizable knowledge must be submitted to the REIRC.

II - Application Process

The committee meets once a month except in the months of July and August. Submission of applications for review by a REIRC are to be received by the chairperson 3 weeks prior to its meeting date by email at REIRC@effatuniversity.edu.sa. An email notification will be sent by the chairperson to researchers whose projects will be reviewed by either the REIRC or the chairperson.

III - Applications

Applications should include: (See Appendix 3 & 4)

- Name of faculty or staff members and/or student(s) conducting research
- College, department, and major (or affiliation)
- Research Advisor (required for students)
- Research proposal including:
- Purpose of the research
- The significance of the research and its benefits to the academic community and society as a whole
- Identified targeted population of participants with identified characteristics (if relevant)
- Identification of research materials and instruments (questionnaires and interview questions), as well as discussion of appropriate steps taken to ethically use them (if relevant)
- Explanation of proposed methodologies and analysis to be utilized

- Identified plan to secure confidentiality of participants (if relevant)
- Identified risks and potential negative consequences to participants, community, or humanity (see checklist previous section)
- Copy of informed consent (see requirements for consent forms);
- Identification of debriefing and follow up services available (if relevant)
- Identification of potential conflicts of interest, as well as plan to minimize risk associated with these conflicts should they occur (if relevant)
- Identification of any outside organization, institution, or individual parties that will be collaborating with the applicant.

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Misconduct in Research Policy

Purpose

To define and provide procedures for addressing allegations of misconduct in research. The university requires that intellectual honesty and the highest ethical standards in research be maintained and relies primarily on the acceptance of responsibility by each member of the university community to adhere to professional standards of conduct in all research activity. In cases where allegations of Research Misconduct arise it is the policy of the university to inquire into and, if necessary, investigate, suspend, report, and resolve promptly and fairly all instances of research misconduct.

Scope

This policy applies to all Effat employees, faculty, staff and students conducting research. This policy applies equally to all research activity, whether carried out solely with university resources, sponsored or non-sponsored, or with or without assistance of outside funds. The director of the research and consultancy institute the responsibility to report research misconduct to sponsoring agencies as deemed necessary.

Responsible Party:

Director of the Research and Consultancy Institute

Definitions

Allegation - A claim of fact by oral, written or other evidence, which the complainant claims to be able to prove or provide sufficient evidence of instances of research misconduct. Any oral or written statement or other evidence of one or more apparent instances of research misconduct.

Complainant - A person who in good faith makes an allegation of research misconduct. The role of the complainant is limited. Once the complainant has made an allegation of research misconduct, that person does not participate in the proceeding other than as a witness or to provide data related to the allegation.

Inquiry - A preliminary collection, examination and evaluation of all relevant facts, records and evidence conducted by the director of the research and consultancy institute The purpose of the inquiry is to conduct an initial review, and gather information to determine whether an allegation of research misconduct has substance and warrants an investigation. An inquiry does not require a full review of all the evidence related to the allegation. All reasonable and practical steps shall be promptly taken to obtain custody of all research records and evidence.

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Investigation - A formal examination and evaluation of all relevant facts by the Director of the Research and Consultancy Institute to determine, based on a preponderance of evidence, whether research misconduct has occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct.

Research - Any systematic investigation, including research development, testing, and reporting, designed to develop or contribute to generalizable knowledge. Encompasses basic research, applied research, and research training activities in areas such as biomedical, and life science, natural sciences, engineering, humanities and arts, and social and behavioral science.

Research Misconduct - Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest errors or honest differences in interpretations or judgments of data. A finding of research misconduct is made if (a) there is significant departure from accepted practices at Effat University; (b) misconduct is committed intentionally, knowingly, and (c) the allegation to be proven of the evidence.

Respondent - A person against whom an allegation of research misconduct is made.

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I. Policy Statement

Effat University is responsible for the integrity of the research conducted at the university. The university has procedures for the inquiry and investigation of allegations of research misconduct with due care to protect the rights of those making the allegations, those accused, and the university. The university has explicit procedures for addressing incidences in which there are allegations of misconduct in research.

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II. Research Scope

This policy applies to allegations of research misconduct and research misconduct involving: (i) applications, proposals for support and research for extramural or intramural research, research training or activities related to that research or research training, such as dissemination of research information; (ii) all extramural or intramural research, research training programs and activities that are related to research or research training; and (iii) plagiarism of research records produced in the course of research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, reported, or any research record generated from that research.

III. Confidentiality

A. Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding.

B. Except as may be otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research participants might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding. The outcome or recommendation after an inquiry or investigation to the Dean of Graduate Studies and Research is only shared with the respondent.

IV. Determination of Action

The complainant notifies the Dean of Graduate Studies and Research of the alleged misconduct. The Dean will investigate and notify the legal office and the Provost. The Provost will install an ad hoc disciplinary committee to investigate.

The Dean of Graduate Studies and Research will provide a recommendation and transmit to the Provost the final determination report prepared by the Director of the Research and Consultancy Institute. At the beginning of the committee's investigation, the respondent will be notified of the complainant's identity, shown the documents and evidence supporting the allegation, and given fifteen (15) days to respond in writing to the Director of the Research and Consultancy institute.

The committee will prepare a non-binding recommendation to the Provost and or to the legal office, after which a formal decision is communicated to the respondent.

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Informed Consent Policy

Purpose

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for participants in research. This requirement is founded on the principle that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected. It requires that prospective research participants be given the opportunity to choose what shall or shall not happen to them and thus necessitates adequate standards for informed consent.

Scope

This policy applies to all research conducted at Effat University involving human participants.

Responsible Party

Chairperson of the REIRC.

Definitions

A *human participant* is 'a living individual about whom an investigator (whether professional or student) obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

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Identifiable Information: Information that is individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information).

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I- Policy statement

The informed consent process involves three key features: (1) disclosing to potential research participants information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained.

II-Disclosing information

The informed consent process is the critical communication link between the prospective human participant and an investigator, beginning with the initial approach of an investigator to the potential participant (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study. The informed consent process should be an active process of sharing information between the investigator and the prospective participant. The exchange of information between the investigator and prospective participants can occur via one or more of the following modes of communication, among others: face-to-face contact; mail; telephone; video; or fax.

III-Facilitating understanding

Prospective participants should be provided with ample opportunity to ask questions and seek clarification from the investigator.

IV-Voluntariness of participation

The prospective participants should be in a position to freely decide whether to initially enroll in the research, or later, to withdraw or continue participating in the research. The informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective participants or their legally authorized representatives adequately understand the research so that they can make informed choices.

V-Waiver of informed consent

Waiver of the consent requirement may be applied in certain circumstances where no foreseeable harm is expected to result from the study and a requirement of individual informed consent would make the conduct of the research impracticable, the REIRC may waive some or all of the elements of informed consent

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VI-Informed Consent Process

Send participants at least one week before the date of their participation an explanation of your study and materials that they need to understand the study and the consequences of their participation. Have participants sign the informed consent form (see Appendix 5) prior to commencement of their participation.