Ottawa University (OU) IRB Policy (Revised 6/1/2016)

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A. Executive Summary

The key changes and clarifications are as follows:

- IRB membership is defined according to the Code of Federal Regulations (See Appendix 1)
- As reflected in the attached forms, IRB application and review procedures differ according to the scope of the proposal. Two distinct forms allow applicants to submit a request for exemption from IRB review (**Form 1**) or to initiate a proposal for a human subject research project requiring IRB review (**Form 2**). A separate form documents requests for and approvals of protocol changes (**Form 3**) to initial proposals made with **Forms 1 or 2**. This change also simplifies the use of limited-scope human subject research as a Classroom Research Project (**Form 4**).
- Principal Investigators (PIs) on OU-IRB Applications must be full-time OU faculty; when others wish to conduct research, they must identify a full-time OU faculty person to sponsor the research as its Principal Investigator.
- Principal Investigators (PIs) who propose research projects that are part of their graduate studies at other institutions must provide confirmation of any relevant training in research ethics, as well as eventual IRB approval from their graduate studies home institution to complete their OU-IRB file.

The modified forms and procedures are designed to streamline the submission and review of research projects, as well as make them more accessible and useful to researchers.

B. OU-IRB Revised Policies & Procedures

The National Research Act was signed into law in July 1974. The act and resulting regulations (45 CFR 46) were developed to provide guidelines for human subject research and the use of human experimentation in medicine. The act's purpose was primarily to prevent unethical experimentation on human subjects, such as that conducted by Nazi war criminals and by the Tuskegee syphilis project. Since its passage, the act's enforcement has focused upon research conducted by or in conjunction with federal departments or agencies such as drug testing by the Federal Food & Drug Administration. However, the act is also highly relevant in higher education, whose mission it is to produce new knowledge through ethical investigation.

The Ottawa University (OU) Institutional Review Board (IRB) has oversight of research projects sponsored by or completed within the University structure that involve human subjects. These include faculty, student and non-academic research. Examples of non-academic research are data analyses of survey responses from alumni, or studies of University employees by outside agencies or institutional researchers. In every case, OU-IRB review is focused upon the psychological and physical welfare and safety of human subjects. This process is not a review of research practices or methodology; the OU-IRB's approval of a proposed project does not indicate an endorsement of the project's practices or methods.

The University's Institutional Animal Care and Use Committee (IACUC) will review applications for research related to vertebrate and invertebrate animals.

Structure of IRB Membership

Coordinator: The Director of Compliance will serve as the Coordinator of the IRB (Coordinator); the IRB operates on the authority extended by the Associate University Provost. The Coordinator will normally hold faculty rank within the University. The Coordinator's role is:

- To be the first contact for researchers, IRB members, and other university staff, students and faculty;
- To be responsible for the initial education of IRB members concerning the law and regulations, as well as any updates that affect the operations of the IRB;
- To serve as an *ex officio* member of the IRB;
- To appoint the IRB Chair and to nominate the IRB's remaining members.

The Coordinator does not vote on research project approvals and is required to attend IRB meetings *only* for the purpose of IRB member orientation and continuing education.

Faculty Chair for the IRB: The appointed Chair of the IRB must be a full-time member of OU's faculty. The Chair is responsible for the secure maintenance of IRB records. These records include all research application documents, the minutes of IRB meetings, and correspondence with members of the IRB or researchers. The Chair will also manage the logistics of meetings involving full IRB membership.

Diversity and Expertise of Membership (Compliance with 21 CFR 56.107): The Coordinator ensures that at least five persons, including the IRB Chair (but excluding the *ex officio* Coordinator her- or himself), serve on the IRB. IRB members chosen from among OU's faculty are nominated by the Coordinator and approved by their respective School Deans; selection will favor those who hold terminal degrees. To ensure diversity of backgrounds and appropriate expertise, the group's membership is designed with the following features:

- A combination of women and men, to guard against gender-biased decisions;
- Racial and cultural diversity;
- One OU faculty member from each of the three academic Schools (Arts & Sciences, Business, and Education) for a mix of disciplines or professions, to include multiple ethical paradigms;
- At least one OU faculty member representing the scientific disciplines and at least one representing the non-scientific disciplines;
- One OU faculty member representing the social and behavioral sciences (to accommodate the fact that most research proposals, historically, have concerned social science questions);
- Representation from multiple OU campus locations; and
- One external IRB member without professional affiliations with or family connections to OU.

If any member of OU's IRB has a conflicting interest in a research proposal, she or he will recuse her- or himself from the review process, except to provide information as requested by remaining members of the IRB. Where additional expertise is necessary for assessment of particular research proposals, the IRB may consult with other persons; however, outside consultants are not voting members of the IRB.

Terms: OU IRB members will each serve a term of three years. Any OU faculty person on the IRB may serve a second three-year term, with the approval of his or her School Dean.

Meetings: A meeting of the IRB may be called by any of its members at any time to discuss a specific research application or any other matters pertinent to the IRB. A quorum of five must participate in any IRB meeting to ratify decisions. The Chair will keep the minutes of all IRB meetings.

Security of Documentation: The IRB Chair, under the auspices of the IRB Coordinator, will keep all filed documentation in a secure electronic form. IRB documentation will be available to the project's original researchers, current members of the IRB, any administrator at the Associate Vice President level or higher, or any person given permission to review specific materials through a vote of the current IRB.

Resources on Ethics

Ottawa University values the ethical creation of knowledge; thus, OU recommends that researchers and instructors undergo ethics training related to human subject research. The National Institutes for Health and the Office of Health and Human Services provide helpful questionnaires, online learning modules, videos, and other materials:

- https://humansubjects.nih.gov/questionnaire
- http://www.hhs.gov/ohrp/education-and-outreach/online-education/index.html

The IRB Review Process

Overview: Ottawa University's IRB review process is designed to meet the requirements of all pertinent statutory and regulatory law, while best accommodating the general nature of research submitted to the OU-IRB.

All researchers gathering data about or from human subjects at Ottawa University must submit a request through the OU-IRB using **OU-IRB Form 1: Request for Exemption from IRB Review** or **OU-IRB Form 2: Research Project Approval Request**, and must use **OU-IRB Form 3: Protocol Amendments Request** to obtain IRB approval for any changes to an initial application. Upon receipt of the application documents, the Chair will determine if the proposed research project has been proposed through the appropriate channels, as exempt from IRB oversight, or as a project requiring either expedited or standard review.

Classroom Research: Ottawa University seeks to make the research process accessible to students and instructors, especially at the introductory level. Some **classroom research projects**, by virtue of their very limited scope, impact, and public exposure, do not require IRB review. When instructors assign projects that meet these conditions, the instructors act in the stead of the IRB, receiving applications from students, and approving projects that meet all of the conditions outlined in **OU-IRB Form 4: Classroom Research Project Approval Request**. While the OU-IRB provides Form 1 for classroom use by OU's faculty, it does not govern the application process for classroom research projects. This responsibility is left up to the course's instructor, as described on **OU-IRB Form 4.**

Projects with Exempt Status: Following the guidelines of 45 CFR 46.101, some projects are defined as exempt from IRB review. The determination of exempt status involves these steps:

1. To request approval of a project as "exempt," applicants submit **OU-IRB Form 1: Request for Exemption from IRB Review** (as well as any supporting documents, such as survey instruments) to the IRB Chair for verification of exempt status.
2. Once the Chair determines that the project is reasonably defined as exempt, the Chair electronically files all documents related to the exempt application and notifies all IRB members of the availability of the files.
3. Any IRB member may challenge the determination of exempt status within three days of receipt of access to the application files.
4. If challenged, the Coordinator will schedule a teleconference of the IRB membership.
5. If unchallenged, the Coordinator will notify the researcher of the project's exempt status.

The self-explanatory form elucidates all the nuances of exempt status, and will be updated as required by changes to federal regulations. If the IRB determines that the project does not qualify as exempt, the researcher may be redirected to submit **OU-IRB Form 2: Research Project Approval Request**.

Projects Requiring IRB Review: Following the guidelines of 45 CFR 46.101, some projects require IRB review. The IRB review involves these steps:

1. To request approval of a project that does not qualify as "exempt" and must undergo review by the full IRB, applicants submit **OU-IRB Form 2: Research Project Approval Request** to the IRB Chair, complete with supporting documents. Supporting documents will include:

   a. A consent form where appropriate,
   b. The project's data-gathering instruments (such as questionnaires),
   c. Any approvals of the project from other institutions (for example, where the project is undertaken to complete graduate research), and
   d. Evidence of the researcher's completion of human subject research ethics training (if required by the researcher's home institution).

   The full application will be submitted to the IRB Chair. The self-explanatory form elucidates all the nuances of human subject research requiring IRB review, and will be updated as required by changes to federal regulations.

2. The Chair determines whether the application will receive *expedited* or *standard* review.

Expedited Review Process: Following the guidelines of 45 CFR 46.110, some projects may receive expedited review. During an expedited review, the review process follows these steps:

1. The Chair makes an initial determination of approval or disapproval.
2. The Chair electronically files all documents related to the application and notifies all IRB members of the availability of the files, and of the initial determination of approval or disapproval.
3. If the Chair rejects the project or requires revision, the researcher may appeal to the full IRB for review, and a teleconference will be scheduled.
4. Any IRB member may challenge the Chair's assignment of the project for expedited review, contest the Chair's initial determination, request revisions to the project, or reject the application within three days of receipt of access to the application files.
5. If challenged, the Chair schedules a teleconference of the IRB membership.
6. If unchallenged, or once IRB membership agreement is achieved, the Chair notifies the researcher of the application's approval or rejection, with or without revisions. Normally, a researcher can expect to hear from the Chair within two weeks of submitting the application.

Standard Review Process (45 CFR 46. 103, 108, 109, 11): If the project is determined to require standard review:

1. The Chair, along with the IRB faculty member representing the academic school most closely related to the subject of the project, make an initial determination of approval or disapproval, or return the project to the researcher for revision.
2. The Chair electronically files all documents related to the application and notifies all IRB members of the availability of the files, and of the initial determination of approval or disapproval.
3. If the Chair rejects the project or requires revision, the researcher may appeal to the full IRB for review, and a teleconference will be scheduled.
4. Any IRB member may challenge the Coordinator and IRB member's initial determination, request for revisions to the project, or rejection of the application within three days of receipt of access to the application files.
5. If challenged, the Coordinator schedules a teleconference of all IRB members.

6. If unchallenged, or once IRB membership agreement is achieved, the Chair notifies the researcher of the application's approval or rejection, with or without revisions. Normally, a researcher can expect to hear from the Chair within two weeks of submitting the application.

Post-Approval Changes to a Project: After approval, a research project must be reconsidered by the IRB if it deviates from the original proposal or from the time allotted for its completion. The IRB may suspend and/or cancel research it deems to require further investigation. Researchers whose projects change during the course of a research investigation must submit **OU-IRB Form 3: Protocol Amendments Request**.

Appeals: A researcher may not appeal an adverse IRB decision if the proposed project was rejected due to inappropriate or unacceptable harm to human subjects.

Conflicts of Interest: Any question of a conflict of interest presented by an IRB member's review of a specific application will be addressed by the IRB Coordinator, by the IRB Chair, or at the request of any IRB members. An IRB member will recuse him- or herself from the decision-making process in such cases, except to provide information as requested by IRB members.

Notification to the University Community of the IRB's Role

The Coordinator will communicate the role of the IRB to the University each year. These communications will also include the responsibilities of anyone wishing to conduct human subject research. Documentation of these communications will be electronically filed by the Coordinator.

C. Flowcharts

IRB Flowchart for OU Students

I am an OU student who is planning research that involves human beings.	Is my project a Classroom Research Project with limited scope, impact, and public exposure?	**Yes**	I need to use **Form 4** and submit it to my instructor.	
		No, I am conducting *independent* research that meets the definition of research with human participants, but my project falls under one or more of the exemption categories specified on **Form 1**.	I need to use **Form 1** and submit it to my instructor for his or her endorsement as Principal Investigator. Then I need to submit the form to OU's IRB Chair.	If anything changes during the course of my project, I will need to submit **Form 3** to my instructor for endorsement as PI, and then to the IRB Chair for approval.
		No, I am conducting *independent* research that meets the definition of research with human participants, and my subjects are in vulnerable populations, *or* I'm investigating a subject that may be stressful for some, *or* participants may be at risk of psychological harm, etc.	I need to use **Form 2** and submit it to my instructor for his or her endorsement as Principal Investigator. Then I need to submit the form to OU's IRB Chair.	

IRB Flowchart for OU Faculty, Staff, and Affiliates

I am planning research that involves human beings.	Am I a full-time OU faculty person?	**Yes**	I need to submit the appropriate form (**Form 1** or **Form 2**) to the OU-IRB Chair. If anything changes during the course of my project, I will need to submit **Form 3** to the OU-IRB Chair for approval.
		No	I need to identify a full-time member of OU's faculty who will sponsor my project as its Principal Investigator (PI). My PI will submit the application to the OU-IRB Chair on my behalf.
	I am conducting this research as part of the requirements of a degree program at another institution.	In my OU-IRB application, I need to include any pre-existing approvals from the IRB at my graduate program's institution, as well as evidence that I have completed human subject research ethics training, if required by my program. If any subsequent IRB approvals or changes are issued by the IRB at my graduate program's institution, I must file documentation with the OU-IRB Chair.	

APPENDIX 1

21 CFR 56.107 - IRB membership.
Updated: April 2013

Title 21: Food and Drugs

CHAPTER I: FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A: GENERAL
PART 56: INSTITUTIONAL REVIEW BOARDS

Subpart B: Organization and Personnel
56.107 - IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991; 56 FR 29756, June 28, 1991; 78 FR 16401, Mar. 15, 2013]