

Walsh University
INSTRUCTIONS for Application to Use Humans in Research

To protect the rights, well being and privacy of individuals, all research using humans as subjects conducted by the faculty, staff, and students must be reviewed and approved by the University Human Subject Review Committee in accordance with Federal Regulations (45 CFR 46, as amended). The chair, HSR Committee, serves as Reviewer to conduct preliminary review of the research protocol and to determine the legal aspect of risk and level of review required.

INSTRUCTIONS

- 1) The Application for Approval must be completed in detail. (See the attached application checklist.) Only typed or word processed forms will be accepted. Attach copies of consent forms, questionnaires, surveys, data collection forms, interview questions and so on. **Please submit one hard copy with all appropriate signatures and send one electronic copy of the entire application (including attachments) to the chair of the committee.**
- 2) Advisor's signatures are required on HSR applications for student research.
- 3) Submit the Application for Approval and required attachments to the Chairperson, Human Subjects Review Committee, 2020 East Maple St., North Canton, OH 44720
- 4) Your project will be reviewed and placed in one of the following categories:

Level I Exempt Review	Approved as no risk, you may begin immediately upon receiving approval from the HSR Chair. If you are a student, written approval will be sent to both your advisor and you.
Level II Expedited Review	Approved as minimal risk; you may begin the project after receiving written approval from HSR Committee. If you are student, written approval will be sent to both your advisor and you.
Level III Full Review	Your project deals with sensitive issues, special populations or is considered high risk. You may be invited to attend the meeting to answer questions the Committee may have about your project.
- 5) Allow adequate time for review and approval. The Human Subjects Review Committee meets on the second Friday of each month. Reviews are to be received by the previous Friday to be considered at the next meeting. **For some academic courses, alternative submission and review dates may need to be arranged with the course coordinator. The course coordinator will inform you of the submission date. Exceptions can also be made for approval needed for grant applications.**

- 6) For all levels of review, a response from the HSR Committee will be sent to the primary investigator within 5-7 workdays of the meeting date. The response will indicate that (1) no revisions are required and the project is approved or (2) revisions are required. If you are a student, written approval will be sent to both your advisor and you.
- 7) If revisions are required, the revised Application for Approval and any additional material requested needs to be resubmitted to the HSR. Responses to revision submissions will be made within 5-7 business days from the date of resubmission.
- 8) Projects involving other facilities. The Human Subjects Review Committees of both Walsh University **and** the involved facilities must approve projects of Walsh University faculty or students to be done at other facilities. If the facility does not have a Human Subjects Review Committee, appropriate approval must be obtained from official of the facility. Copies of the report from other facilities must be submitted to the Human Subjects Committee of Walsh University.

CONSENT FORMS

Consent forms must be typed on departmental letterhead that is available from the department secretary. Contact information including the names and phone numbers of the investigator(s), the HSR contact, and the faculty advisor, if the principal investigator is a student, must be on the consent form. Please follow the sample consent forms included in the Walsh University Human Subjects Review Policy carefully touching on each point. Also consider the attached informed consent checklist. A copy of the consent form must be given to each subject. Signed consent forms must be kept on file with Faculty Advisor/Researcher for a period of three years beyond the end of the project.

Consent Obtained Orally: When consent information is to be presented orally, a transcript must be provided to the HSR Committee and a witness must be present when the transcript is read to the subject. The subject and the witness are to mark or sign the transcript indicating they were present and heard the oral information. The subject must also mark or sign agreeing to be in the project.

PROPOSAL FOR EXTERNAL FUNDING

Proposals for external funds that include humans used as subjects in research should be reviewed prior to submission so that notification of HSR approval can be included with the proposal.

CHANGES TO AN APPROVED NON-EXEMPT PROJECT

Changes to an approved project that affect the subject must be approved before the initiation of the revised research. A copy of the revised portion of the protocol must be submitted for review.

EQUIPMENT

If unusual equipment is to be used, include qualifications of the operator.

CHECKLISTS FOR THE APPLICATION AND INFORMED CONSENT DOCUMENT

Yes	No	N/A	
			Is the cover sheet completed and secured all signatures?

Yes	No	N/A	Does the project application include:
			A description of the research area and the project purposes, objectives, Research questions, or Hypotheses?
			The university/college/department affiliation?
			Descriptions of the subject characteristics and how the subjects will be used?
			Copies of all questionnaires, data collection forms, and a description of all tests?
			A discussion of the risks, benefits, and privacy safeguards?
			A description of data collection methods and maintenance of records considering confidentiality and anonymity?
			A description of the disposition of data and audio/video data records?
			A statement about special subject populations?

Yes	No	N/A	Does the Informed Consent Statement:
			Introduce you and your research?
			Provide the subject with a brief, understandable explanation of the research, including the purposes of the study and the reason for the study?
			Explain the risks/discomforts and benefits of the study?
			Explain the anonymity and/or confidentiality guarantee of the investigator?
			Describe the expected duration of the subjects' involvement in the study?
			Describe the financial costs and/or remuneration for the subjects if applicable?
			Mention that participation is voluntary and that the subject may withdraw at any time without prejudice?
			Include a statement regarding the policy of the University concerning compensation and medical treatment for injuries occurring during or caused by participation in the study.

			Include a statement and information for contacting the investigator and the Walsh University IRB (and the faculty advisor if necessary)?
			Provide a phone number where the subject may contact you for further information?
			Provide a signature and date block for the subject, guardian, and witness (if needed) to complete?
			If a signed consent form is not needed for procedural or substantive reasons, include a statement and your alternative procedure for obtaining consent.