

Wichita State University Institutional Review Board (IRB) for the Protection of Human Subjects

Guidelines for Application for Approval of Research Involving Human Subjects

The purpose of advance review of research involving human subjects by WSU's IRB, and the requirement of informed consent, is to assure that the rights and welfare of subjects who participate in research conducted by WSU faculty, staff and students are protected and that the University is in compliance with federal requirements (Title 45 **Code of Federal Regulations**, Part 46).

When is Review Required? *All* research and research-related activities involving human subjects must be reviewed and approved by the IRB in writing *prior to* initiation of a project. Review by the IRB is required whether a project is conducted by faculty members, graduate students, undergraduate students, or staff. It is required whether the project receives external funding, internal funding, or no funding.

Who Should Complete the Application? This application should be completed by the principal investigator. If that is a student, the application must list the student's faculty sponsor as principal investigator and the student as co-principal investigator, and should be approved and signed by the named faculty sponsor.

What to Submit? One original of the completed, signed application and all supporting materials must be forwarded to the Office of Research Administration, Room 319 National Institute of Aviation Research Building, campus box #7. Supporting materials include, but are not limited to, informed consent forms, questionnaires, survey instruments, letters of approval from cooperating institutions, etc.

What are the Levels of Review?

Full

IRB review is required for all research posing greater than minimal risk to subjects. In addition, full review is required for all research activities involving vulnerable subject populations, including, but not limited to, pregnant women, prisoners, and psychiatric patients.

Expedited

IRB review is provided for research that presents no more than minimal risk to subjects, **and** involves only procedures listed in one or more of the following categories:

- X research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis);
- X collection of data from voice, video, digital, or image recordings made for research purposes;
- X research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;
- X clinical studies of drugs and medical devices only when a new drug application (21 CFR Part 312) is not required;
- X clinical studies on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing;
- X collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds;

- X collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings, teeth, excreta, and external secretions (including sweat and saliva);
- X collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves, and
- X continuing review of research previously approved by the convened IRB.

The expedited review procedures may not be used where identification of the subjects or their responses would place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.

Exempted review means exempt from full IRB review, for the following categories:

- X research involving normal educational practices;
- X research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior, unless the obtained information is recorded in such a manner that human subjects can be identified;
- X research involving the use of educational tests (cognitive diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior that is not exempt under the previous category if the subjects are elected or appointed public officials or candidates for public office;
- X research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens if these sources are publicly available, or if the information is recorded in such a manner that subjects cannot be identified, and
- X taste and food quality evaluation and consumer acceptance studies.

What is Informed Consent? Every researcher (faculty, staff, or student) at WSU must obtain the informed consent of any human subject used in research before involving that person in the research project. The investigator must ensure that the circumstances under which consent is sought will provide the subjects (or their representative) with sufficient opportunity to consider whether or not to participate. Informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", i.e. understandable to the people being asked to participate. The written presentation of information is used to document the basis for consent and for the subjects' future reference.

If the subject is a child or minor, an assent form must be signed to accompany the parent/guardian consent form.

Under certain circumstances, the use of written consent documents may be waived. All waivers must be approved by the IRB, and requests for waiver must be fully justified by the researcher when submitting an application to the IRB. Waiver of written consent procedures does not imply waiver of the researchers' responsibility to obtain consent from the subject. Wherever practicable, when a written informed consent form is waived, a cover letter should be submitted to subjects which outlines the purpose and procedures of the project including a statement indicating that completion of the survey and/or return of the questionnaire indicates consent to participate in the study.

Samples of a Consent and Assent form are found with the IRB Application