**Saint Louis University**

**Institutional Review Board**

**Tips for Choosing the Appropriate IRB Application/Form**

Before beginning any research study involving human subjects, you must submit your study for IRB review and determination. If you are uncertain that IRB review is required for your project, you can complete and submit the [SLU IRB Human Subjects Determination Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/hsr_determination_form.docx). Decisions on whether IRB review is required for activities can only be made by the SLU IRB.

Once you have determined that IRB review is needed, you will need to select and prepare the appropriate IRB application/form. To do this, you must determine:

* [Which type of review your study qualifies for](#Review_Type) (Exempt, Expedited, or Fullboard review).
* [Which type of application/form you should choose](#Application_Type) (Biomedical Research or Social, Behavioral, and Education Research).

***Which type of review does my study qualify for?***

The type of review your project will need will depend on the level of risk your study imposes on participants, and whether certain regulatory criteria are met. It is important to know which type of review your study qualifies for **before** starting the submission process as exempt review applications are not transferrable to non-exempt review applications. There are three types of review:

* + [**Exempt Review**](#Exempt_Review): studies that involve minimal risk and can be justified under one or more of the 6 exempt categories used at SLU. These studies typically involve non-sensitive, non-interventional research.
  + [**Expedited Review**](#Expedited_Review): studies that involve minimal risk and can be justified under one or more of the 7 expedited categories. These studies are less restrictive than exempt counterparts, but still must meet certain requirements.
  + [**Full Board Review**](#Full_Board_Review): studies involving more than minimal risk, vulnerable populations, or those that did not qualify as exempt or expedited. These studies must be submitted by the published submission deadlines.

1. **Exempt Review:**

* “Exempt” does NOT mean that your research doesn’t need IRB review. All exempt studies are initially reviewed by the IRB. After its review, the IRB will determine its exempt status. If a study qualifies for exempt then it is exempt from continuing IRB review.
* A determination of exempt does NOT permit you to make changes in your study at any time without IRB review. You MUST alert the IRB to any and all changes in your study before they can be implemented.
* Only certain types of research qualify for exempt review. If your research does not fit into one or more of the categories listed below, it will not qualify for exempt review and you cannot use the form designated for this type of research.
* To request exempt review, use the Exempt Application for Biomedical or Social, Behavioral, and Education research in [eIRB](https://eirb.slu.edu/).

**Exempt Category Considerations:**

* All research activities must fall under one or more of the exempt categories and must be properly justified (i.e., meet all the requirements or restrictions listed).
* ***Prisoner*** subjects cannot be directly targeted as subjects and can only be included in research aimed at a broader subject population that only incidentally involves prisoners (e.g., data from a large medical chart review incidentally includes data from a prisoner).
* The use of ***children*** as subjects varies according to the regulations and local SLU policy.
  + Research involving survey or interview procedures with children is not permitted at the Exempt review level.
  + Children may not be included in categories 1 (per SLU policy), 2 (limited), or 3 as specified below in each specific category.

**Exempt Categories:**

All study procedures must fall into one or more of the following exempt categories:

**Category 1.** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

* Note: Use of children as subjects is not currently allowed at SLU. This restriction may be lifted when capacity to meet the regulatory requirements has been confirmed. Researchers proposing to use children as subjects in this category will be considered on a case by case basis.

**Category 2.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

* + 1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;
    2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
    3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.
* Note: Children may not be included as subjects in this category except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. Children may not be included in projects under 2(iii).

**Category 3.** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

* Note: Children may not be included in this category.

**Category 4.** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available;
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is restricted under [HIPAA], for the purposes of “health care operations” or “research” as those terms are defined [by HIPAA] or for “public health activities and purposes” as described under [HIPAA]; or
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with the E-Government Act, if all the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act.
   * + - This category only applies to the *re-use* of data and specimens that were or will be collected for *nonresearch purposes* or from previously approved research studies other than the proposed research study.
         * The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens.
         * **No contact between the investigator and subject is allowed.** If an investigator wants to collect information/specimens directly from research subjects, then the study will need to be approved under the Expedited categories or Fullboard review.
       - Examples of publicly available information: driver's license and court records.
       - Note: If data are to be submitted to the FDA or held for inspection by the FDA in support of a new product or use, please use the Biomedical Expedited/Full form.

**Category 5.** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of Department or Agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

* + - * Public benefit or service programs, including procedures for obtaining benefits or services under those programs;
      * Possible changes in or alternatives to those programs or procedures; or
      * Possible changes in methods or levels of payment for benefits or services under those programs.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting agreements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

**Category 6.** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Category 7.** Category 7 is new with the revisions to the Common Rule (implemented January 21, 2019). It will be implemented at SLU when capacity to meet the regulatory requirements has been confirmed.

**Category 8.** Category 8 is new with the revisions to the Common Rule (implemented January 21, 2019). It will be implemented at SLU when capacity to meet the regulatory requirements has been confirmed.

1. **Expedited Review:**

* To receive an expedited review, a study must be minimal risk and all research activities must fall into one or more of the categories of expedited review (listed below).
* Expedited research does not have to go before the full board before it can be approved. After it is approved, it is then reported to the board.
* Note that expedited and fullboard studies share the same application/form. To request expedited review, complete the “Expedited Paragraphs” tab within the application/form.

**Expedited Categories:**

All study procedures must fall into one or more of the following expedited categories:

**Category 1**: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a). Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b). Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a). From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b). From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

\**Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."*

**Category 3:** Prospective collection of biological specimens for research purposes by non-invasive means.

Examples:  (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un-cannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

**Category 4:** Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:  (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual

**Category 5:** 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

**Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 7:** 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

1. **Full Board Review:**

* Studies requiring IRB review that do not qualify for exempt or expedited review are reviewed by the full (convened) board.
* Studies submitted for full board review must be submitted by the [published deadlines](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/meeting_dates_deadlines.pdf) in order to be reviewed at a specific convened meeting.
* Note that expedited and fullboard studies share the same application/form. Fullboard studies should not complete the “Expedited Paragraphs” tab of the form.

***Which type of application/form should I choose?***

In some studies it is not clear whether the Biomedical or Social, Behavioral & Education application should be used; the IRB typically accepts either. However, studies submitted on Exempt applications that need Expedited or Fullboard review will be returned and the correct form will need to be completed.

1. **Biomedical Research**: select for studies that need Expedited or Fullboard review and are medical in nature (involve clinical procedures, biomedical research design, biospecimens, etc.).
2. **Biomedical Research- Exempt**: select for studies that qualify for Exempt review and are medical in nature, such as retrospective medical chart reviews.
3. **Social, Behavioral & Educational Research**: select for studies that need Expedited or Fullboard review and are not medical in nature, such as research involving surveys or interviews.
4. **Social, Behavioral & Educational Research- Exempt**: select for studies that qualify for Exempt review and are not medical in nature, such as research involving surveys or interviews.

\*\*Every investigator on a study must complete Human Subjects training. Please see the [IRB website](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb-process/submit-irb-application.php) for instructions on completing training.