

**ST. VINCENT HOSPITAL RESEARCH & REGULATORY AFFAIRS
EXPEDITED RESEARCH CATEGORIES FORM**

DIRECTIONS: This form is to be neatly typed and submitted to the IRB when the investigator is contemplating the initiation of a research project which, in the investigator's judgment, qualifies for expedited review by the IRB. Items 1-7 are the categories which may qualify for expedited review. **Research Proposal Summary Form must be submitted with this form.**

IRB Study Number:

Research Proposal Title:

APPLICABILITY:

- (A) Research activities that: (1) present no more than minimal privacy, psychological and/or physical risk to human subjects, *and* (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of the subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) The standard requirements for informed consent and authorization (or their waiver, alteration, or exception) apply regardless of the type of review.

Check the appropriate category(ies) that applies to your research project:

- 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 312) 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.

- 2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, as follows:
 - (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts withdrawn 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.

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3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
- (a) Hair and nail clippings in a nondisfiguring 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) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax 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.
4. Collection of data through noninvasive 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 subject's 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 echocardiography;
 - (e) moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.
5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for nonresearch 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. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.** Check below, as appropriate.
- The data, documents, or records do NOT include health information.
- No authorization from the subject or waiver of authorization from the IRB is required.
- The data, documents, records, or specimens include identifiable health information.
- You must either obtain authorization from the subject or receive a waiver of authorization from the IRB. NOTE: The waiver of authorization should be requested under Section XIII of the Human Subject Research Statement.
- The health information is de-identified. (Note: to be considered "de-identified," either all identifiers must be removed or sufficient number of identifiers removed to be statistically de-identified. See the list of eighteen identifiers below.
- De-identified data must have the following data removed:
- Name
 - All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip codes if the geographic unit of combining all the same three initial digits contains more than 20,000 people
 - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated in a single category of age 90 or older.

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- Telephone numbers
 - Fax numbers
 - Electronic mail addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web universal resource locators (URLs)
 - Internet protocol (IP) address numbers
 - Biometric identifiers, including finger and voice prints
 - Full face photographic images and any comparable images; and
 - Any other unique identifying number, character, or code.
6. Collection of data from voice, video, digital or image recordings made for research purposes. If the data collected is considered individually identifiable health information, the data must be protected from inappropriate use and disclosure. Either an authorization must be obtained from the subject or a waiver of authorization must be obtained from the IRB.
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 exempt.***

If the data collected is considered individually identifiable health information, the data must be protected from inappropriate use and disclosure. Either an authorization must be obtained from the subject or a waiver of authorization must be obtained from the IRB.