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|  | Diagram  Description automatically generated | **FORM: Expedited Review[[1]](#footnote-1)** |

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| --- | --- | --- | --- |
| **Date:** |  | | |
| **FHIRB #:** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Principal Investigator:** |  | | |
| **Study Title:** |  | | |

**Instructions:**

If you are requesting a minimal risk determination, complete sections A and B and attach this workhseet to your submission in Hutch IRB. Contact the Institutional Review Office at IRO@fredhutch.org if you have questions about the Expedited categories or minimal risk research in general.

Note: This worksheet supports the IRB in determining if the research fits into one or more regulatory Expedited categories. The formal determination, including the appropriate regulatory Expedited category or categories, will be communicated to the investigator in an approval letter.

1. **Expedited Review Research Categories -** Check the appropriate checkbox(es) below to indicate under which category the research activity may fit[[2]](#footnote-2). ***Check all that may apply.***

**1) The research study involves a Clinical study 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, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml[[3]](#footnote-3) in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[[4]](#footnote-4), considering the 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[[5]](#footnote-5).

**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 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.

Note: Nasal swabs that go beyond the nares, and nasal-pharyngeal swabs, are considered invasive and do not fit in this Expedited category. However, the fully convened IRB could consider a request for a minimal risk determination for research involving one of these procedures.

Note: Biopsies, including skin biopsies, are considered invasive and do not fit in this Expedited category. However, the fully convened IRB could consider a request for a minimal risk determination for research involving the collection of extra biopsy material during a clinical biopsy procedure that a patient is undergoing as part of their standard medical care.

**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**.

Note: 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 retrospective materials (data, documents, records, or specimens) that have already been collected for any purpose (e.g., clinical or research purposes); and/or research involving materials that 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 46.104(d)(4). This listing refers only to research that is not exempt.

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

Note: WA state law (RCW 9.73.030) requires that some type of consent or notification occur for transmission or recording of private communications. The IRB cannot approve the recording of private communications without the prospective consent or notification of all individuals to be recorded.

**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 46.104(d)(2). This listing refers only to research that is not exempt.

1. **Background/Applicability — If you selected categories 1-7 above, or if you are otherwise requesting a minimal risk determination that does not fall into the Expedited Categories, check to confirm all the criteria in this section apply to your research project.**

This research activity presents no more than minimal risk to research participants.

Note: If the research involves only procedures listed in categories 1-7 above, the Institutional Review Board (IRB) may review through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. *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.*

This research activity does not involve the identification of the research participants and/or their responses that would reasonably place them at risk of criminal or civil liability or be damaging to their 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.

This research activity does not involve classified information[[6]](#footnote-6) involving research participants.

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Notes:

* The Expedited Categories in the list apply regardless of the age of subjects, except as noted.
* Categories 1 through 7 above pertain to both initial and continuing IRB review
* IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**Expedited Categories 8 and 9 below apply only to Continuing Review of research originally reviewed through a convened “Full review” meeting**

**8)** Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related procedures; and (iii) the research remains active only for long-term follow-up[[7]](#footnote-7) of subjects; or

(b) where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB for the particular site has identified any additional risks from any site or other relevant source; or

(c) where the remaining research activities are limited to data and laboratory analysis.

**9)** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Modifications to Minimal Risk Research:**

When minimal risk research is modified, the Expedited reviewer must confirm that:

* The research activities (or remaining research activities) present no more than minimal risk to human subjects (N/A if the research falls into Category 8.b. above).
* The research (or remaining research) falls into one of the Expedited Categories described above.

1. This document satisfies AAHRPP elements I-9, II.2.F-II.2.F.3, II.5.A. [↑](#footnote-ref-1)
2. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. [↑](#footnote-ref-2)
3. Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. Per Huron correspondence with OHRP dated October 2019. [↑](#footnote-ref-3)
4. Children are defined in the HHS regulations as "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." [↑](#footnote-ref-4)
5. Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure. [↑](#footnote-ref-5)
6. Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, “Classified National Security Information,” December 29, 2009. [↑](#footnote-ref-6)
7. Long- term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long- term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk. [↑](#footnote-ref-7)