HRP-313 | 2/2/2024

WORKSHEET: Expedited Review

The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. It does not need to be completed or retained.[1]

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1. **Humanitarian Use Device (HUD)** (Check if "**Yes**" or "**NA**". Must be checked)

☐ Continuing review of non-research HUD using the expedited procedure[2] ("**NA**" if not HUD) ☐ **NA**

2. **Additional Criteria for Research Involving Prisoners**[3] (Check if "**Yes**" or "**NA**". Must be checked)

☐ The research involves interaction with prisoners, is minimal risk, the prisoner representative concurs with this determination, and the prisoner representative must review the research[4]. (**"NA"** if no prisoners as subjects, no prisoner interaction, or for modifications that do not involve interaction with prisoners.) ☐ **NA**

Initial or continuing review must meet criteria set 3. Modifications can meet either criteria set 2 or 3.

3. **Minor Modifications** (Check if "**Yes**" or "**NA**". All must be checked)

☐ The modifications do not affect the design of the research.

☐ The modifications add no more than Minimal Risk to subjects.

☐ All added procedures fall into categories (1)-(7) below. ("**NA**" if no added procedures) ☐ **NA**

4. **Initial Review, Continuing Review, or Modifications** (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (**"NA"** if the research falls into category (8)(b))

☐ Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless

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[1] This document satisfies AAHRPP elements I-9, II.2.F-II.2.F.3, II.5.A.
[2] Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff Document issued on September 6, 2019 states, "For continuing review [of the HUD], an IRB may use an expedited review procedure in which a chairperson or one or more experienced reviewers carries out the review, similar to the expedited review procedure described at 21 CFR 56.110(b)."
[3] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative; OHRP Prisoner Research FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html.
[4] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18).

reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than Minimal Risk. (**"NA"** if the research falls into category (8)(b))

☐ The research is **NOT** classified[5].

☐ The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)**

- ☐ (1)(a) Clinical studies of drugs when an IND is not required.
- ☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh ≥110 pounds where the amount drawn is ≤550 ml[6]/8 week period and collection occurs at most 2 times/week.
- ☐ (2)(b) Collection of blood samples[7] by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (50 ml or 3 ml/kg,[8] whichever is less, per 8 week period), and the frequency with which it will be collected (at most 2 times/week).
- ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive[9] means.[10]
- ☐ (4) Collection of data through noninvasive procedures[11] (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.[12]
- ☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.
- ☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.

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[5] 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.

[6] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[7] Collection of blood samples from other adults and children may include a draw from an existing peripheral indwelling catheter; however, all draws from central lines are considered to be greater than minimal risk. *Per correspondence with OHRP dated April 2023.*

[8] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[9] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[10] 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) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base 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.

[11] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[12] 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.

☐ (7)(a) Research on individual or group characteristics or behavior[13].

☐ (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

For research approved on or after 1/21/2019, this does not include scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; this is deemed not to be research per 45 CFR 46. 102(l)(1).

☐ (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects[14]. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source[15].

☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (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.[16] [17]

[13] Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

[14] 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.

[15] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). OHRP 2018 Requirements FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html.

[16] Ibid.

[17] A nonsignificant risk (NSR) study that is determined to be minimal risk by a convened board would be eligible for expedited review for continuing review under Category 9 (per OC GCP correspondence from FDA dated January 2015).