Institutional Review Board

Checklist: Expedited Review

Use For Initial Review, Continuing Review, or Amendments

NUMBER | HRP-313

Expedited submissions are reviewed by a single IRB member.	
IRB Number:	
Protocol Name:	
Investigator:	

In accordance with 45 CFR 46.110 and 21 CFR 56.110, an IRB may use the expedited review procedure to review certain kinds of research involving no more than minimal risk to human subjects and one or more procedures listed in Categories 1-9 below, and for minor changes to previously approved research. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by a convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b) and 21 CFR 56.108(c).

1. Additional Criteria for Research, if applicable

☐	The research is minimal risk and the prisoner representative concurs with this determination. ☐ *N/A, if there are no prisoners as subjects*.
☐	Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedure. If checking this, the rest of the form does not apply. Proceed to end "Approval" choices and your signature ☐ *N/A, not a HUD.*

2. Minor Amendments (check if "YES" or "N/A". All must be checked)

☐	The modifications do not affect the design of the research
☐	The modifications add no more than Minimal Risk to the subjects
☐	All added procedures fall into categories 1-7 below. Or ☐ N/A if no added procedures. If checking this, the rest of the form does not apply. Proceed to end "Approval" choices and your signature.

3. Initial, Continuing Review, or Amendments (Check if "Yes" or "N/A". All must be checked)

☐	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
☐	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 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. ☐ N/A if the research falls into Category 8
☒	The research is NOT classified. *Classified research is generally defined as research subject to a security classification established by a United States government agency.*

Research Categories: The following categories may also be reviewed through an expedited review procedure.
Categories 1-7 apply to initial or continuing review; Categories 8 and 9 apply to continuing review only.

☐	**Category 1 – Drugs or devices which do not require an IND or IDE** Clinical Studies of drugs and medical devices only when condition (a) or (b) is met. ☐ (a) Research on drugs for which an IND application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risk 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 IDE application (21 CFR 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 – Blood Samples** Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: ☐ (a) From healthy, non-pregnant adults who weight 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 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐	**Category 3 – Specimens (collected prospectively and by non-invasive means)**
	Prospective collection of biological specimens (excluding blood) for research purposes by noninvasive 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 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.
☐	**Category 4 - Data**
	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.
☐	**Category 5 – Materials (collected retrospectively or prospectively, depending on circumstance)**
	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 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.)
☐	**Category 6 – Voices, video, digital or image recordings**
	Collection of data from voices, video, digital or image recordings made for research purposes.
☐	**Category 7 – Individual or group characteristics or behavior; surveys; interviews, etc.**
	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 QA 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.)
☐	**Category 8 – Continuing review of research previously approved by the convened IRB**
	Continuing review of research previously reviewed and approved by the convened IRB as follows: ☐ (a) (i) The research at this site is permanently closed to the enrollment of new subjects; and (ii) All subjects at this site have completed all research-related interventions; and (iii) The research at this site remains active only for long-term follow up of subjects. ☐ (b) No subjects have been enrolled at this site and no additional risks have been identified anywhere; or ☐ (c) The remaining research activities at this site are limited to data analysis.
☐	**Category 9 – Continuing review of previously approved research not conducted under an IND or IDE**
	Continuing review of research previously reviewed and approved by the IRB as follows: (a) The research is not conducted under an investigational new drug application (IND) or investigational device exemption (IDE); and (b) The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk; and (c) No additional risks have been identified since IRB review at a convened meeting.

Approval Box

At this time I recommend the research be: (Please check one, and sign/date)

- ☐ APPROVED.
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office. *Note conditions below*
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full IRB Meeting. *Note conditions below*
- ☐ Do Not Recommend approval at this time. List Reasons.

(Convened board must agree by a vote if study is not approved.)

Comments Section:

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(Name) (Signature) (Date)