Community Healthcare System

Central Institutional Review Board
901 MacArthur Blvd., Munster, IN 46321
Phone: 219-836-6862

EXPEDITED REVIEW DETERMINATION
(Form Date 1/2019)

The Administrative staff will review the Protocol Submission Form, Abbreviated Protocol Submission Form, or the Request to Renew a Research Study and/or any supporting documents related to the protocol to assess whether it qualifies for Expedited Review.

The Administrative staff will document their findings on the Check List and file it with the acknowledgment letter to the investigator and the supporting documents in the protocol binder.

The Administrative staff will refer the request to the Chair or Co-Chair of the CHS CIRB if an expedited status appears unclear. (Reference: Policy IRB 7.4 Expedited Review)

Protocol title:
Investigator:

☐ **Continuing review of non-research Humanitarian Use Device (HUU) using the expedited procedure**. IRBs are responsible for initial as well as continuing review of the a HUD. For initial review of a HID IRBs are required to perform their review at a convened meeting (21 CFR §56.108). For continuing review, IRBs may use the expedited review procedures (21 CFR §56.100)

Additional criteria for research involving prisoners (Check if "Yes" or "N/A". Must be checked)
☐ The research is minimal risk and the prisoner representative concurs with this determination.
☐ N/A: No prisoners as subjects.

Minor Modifications: 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 subjects.
☐ All added procedures fall into categories (1) – (7) below.☐ N/A No procedures added.
☐ 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. (Must be checked)

Initial Review, Continuing Review or Modifications (Check if "Yes")

☐ (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[i] from healthy, non-pregnant adults who weigh >110 pounds where the amount drawn is <550 ml/8 week period and collection occurs at most 2 times/week[ii].

☐ (2)(b) Collection of blood samples 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 (at most 50 ml or 3 ml/kg/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 means.

☐(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.

☐(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.

☐(7)(a) Research on individual or group characteristics or behavior

☐(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 the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects (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.

☐(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.

Additional Items That May Be Reviewed by Expedited Review unless otherwise specified by the sponsor: (Check all that apply)

☐Minor changes to consents providing the revisions, documentation or clarifications do not indicate or result in a change to the protocol, consent or investigator brochure that would affect the rights and welfare of the study

subjects or change the risk/benefit ratio. Examples may include; administrative changes, typographical corrections.

☐Minor amendment changes in previously approved research during the period for which approval has been authorized by the CHS CIRB. Examples may include: Any decrease in the amount of

- ☐Removing/not implementing approved procedures, where there is no adverse effect on participants, e.g., dose reduction, removing approved survey questions, decreasing the amount or removing a blood draw, removing a physical test, etc.);
- ☐Minor working/clarification revisions to survey measures, recruitment materials, etc. where the meaning/substantive content does not change;
- ☐Removing research assistants or other staff whose roles are not related to overall project oversight;
- ☐Title change; addition or deletion of co-investigators; extending accrual of subjects or number of subjects.

☐Recruitment/advertisements for research

NOTE: Refer to CHS CIRB Policy IRB 7 "Guide to Creating and Submitting Recruitment Materials to the CHS CIRB"

☐Any protocol revision that entails more than a minimal risk to the subjects must be reviewed by the full CHS CIRB.

_____ Expedited Status
_____ Refer to CHS CIRB Chair
_____ Refer for full CHS CIRB Review

_____ _____
Signature of Reviewer Date

_____ _____
Signature of Chair Date
(if applicable)

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