TITLE: Expedited Review		POLICY/PROCEDURE NUMBER: IRB 7.4	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
Date Originated:	8/13/02	Date Effective:	1/2021
Page 1 of 5			

	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:
The Code of Federal Regulations, Title 21, part 56, 56.110, allows an IRB to use an expedited review procedure for research studies that represent no more than minimal risk to subjects. Also included may be minor updates and changes to ongoing approved research.

It is the policy of the CHS CIRB that all human subjects' research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the expedited categories described in the federal regulations and complies with the Institution's ethical standards.

Investigators do not have the authority to make an independent determination that research involving human subjects may be expedited and must contact the CHS CIRB office concerning the status of proposed research or changes in ongoing research.

Under an expedited review procedure, the review may be carried out by the CHS CIRB Chair or an experienced designated reviewer. The person(s) conducting the expedited review may either approve, require modifications (to secure approval) or refer the research to the convened CHS CIRB for review in accordance with the non-expedited review procedures. In conducting expedited review, the CHS CIRB reviewers may exercise all of the authorities of the CHS CIRB except that they may not disapprove the research.

Expedited Reviews take place independently of the scheduled meetings. Research may be initiated as soon as the Principal Investigator has received written approval. Information pertaining to submissions reviewed via an expedited review process will be communicated at the next scheduled meeting of the CHS CIRB.

Non-research Humanitarian Use Device (HUD): IRBs are responsible for initial as well as continuing review of a HUD. For initial review, 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).

DEFINITIONS

Minor Modifications:
1. Do not affect the design of the research
2. Add no more than minimal risk to subjects

Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

CRITERIA FOR APPROVAL OF RESEARCH USING EXPEDITED REVIEW

Examples of protocols that involve minimal risk and could be considered for expedited review include:

1. Clinical studies of drugs and medical devices only when an investigational new drug application (Title 21, CFR, Part 312) is not required or when an investigational device exemption application (Title 21, CFR, Part 812) 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.
    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 cleared/approved labeling.

2. Collection of blood samples (by finger stick, heel stick, ear stick, or venipuncture), urine samples, or bodily debris (excreta, nail or hair clippings).
    a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml 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.

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 (ECG, EEG, and sonography) that do not apply significant amounts of energy to the body (this specifically excludes x-rays and microwaves).

5. 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 or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes (*Note: does not include audio taping an interview so the researcher does not miss anything).*

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

NOTE: 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 o the specific individuals about whom the information is collected; this is deemed not to be research per 45 CFR §46.102

8. Continuing review of research protocols previously approved by a convened CHS CIRB; a) where the research is permanently closed to the enrollment of new subject, and all subjects have completed all research-related interventions, and the research remains active only for long term follow-up of subjects; or b) where no subjects have been enrolled and no additional risks have been identified; or c) where the remaining research activities are limited to data analysis.

NOTE: For 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 two (2) through eight (8) do not apply but the IRB has

determined and documented at a convened meeting that the research involves not greater than minimal risk and no additional risks have been identified.

In addition to meeting the FDA eligibility criteria indicated above, research qualifying for expedited review must also meet the approval criteria defined by HHS in the Common Rule (CFR 45 §46).

1. The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on subjects should be utilized. For example, obtaining an additional amount of blood at the time of routine venipuncture is preferred rather than doing an additional venipuncture to obtain the research sample.

2. The risks of the research must be reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may be gained.

3. Subject selection must be equitable.

4. Informed consent will be obtained and documented unless a waiver of consent and/or documentation of consent has met the waiver criteria at 45 CFR §46.

5. Where appropriate, there is a plan to collect and monitor data to ensure subject safety.

6. The privacy of subjects and maintenance of confidentiality of data is protected.

7. Where necessary, additional safeguards have been included to protect vulnerable subjects.

Additional CHS CIRB approved Items That May Be Reviewed by Expedited Review unless otherwise specified by the sponsor:

1. 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.

2. Minor amendment changes in previously approved research during the period for which approval has been authorized by the CHS CIRB. Examples may include:
   - 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.

3. Recruitment/advertisements for research
   - Refer to CHS CIRB Policy IRB 7 “Guide to Creating and Submitting Recruitment Materials to the CHS CIRB”

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

Investigator Responsibilities

1. May request an expedited review of materials when submitting a *Protocol Submission Form, Abbreviated Protocol Submission Form, or Protocol Renewal/Closure Form.* All forms must be completed in their entirety even when expedited review is requested.

IRB Department Responsibilities

1. The CHS CIRB Chair or designee will review the Submission Form and supporting documents to make a preliminary determination for an expedited review within one (1) week of receipt.
2. The determination and any supporting statements will be documented on the Expedited Review Checklist and/or the Expedited Review Checklist for Recruitment/Advertisements. The Checklist(s) will be filed in the study binder with the original submission letter.
3. Any questions regarding an expedited status will be referred to the Chair of the CHS CIRB.
4. Any submissions that do not qualify for expedited review will be placed on the agenda of the next scheduled CHS CIRB meeting for Full Board Review.
5. Notification of approval for any submissions that do qualify for expedited review will be sent to the Principle Investigator within ten (10) working days of receipt.
6. The CHS CIRB will be notified of the Expedited Review at its next regularly scheduled meeting.

REFERENCE:
Code of Federal Regulations 45 CFR §46.110
Code of Federal Regulations 21 CFR §56.110
Human Subject Regulations Decision Charts published by the Office for Human Research Protections

ACCEPTED BY:

Elizabeth Yee
Vice President, Clinical Ancillary Services

Andrej Zajac, M.D.
Chair, CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director, IRB/Bio-Ethics

DATE REVISED: 12/28/04, 11/2006, 7/2009, 2/2017, 12/2018

REVIEWED BY: CHS CIRB 4/12/2005, 1/10/2007, 7/2009, 7/2013, 6/14/2016, 3/14/2017, 1/2019, 1/2021

Date	Initials
2/2009	JL
3/2013	JL
6/2016	JL
2/2017	JL
1/2019	JL
1/2021	JL