TITLE: DETERMINATIONS AND MOTIONS BY THE CHS CIRB		POLICY/PROCEDURE NUMBER: IRB 1.3	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	NONE	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	4/06	DATE EFFECTIVE:	2/2023
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X CFNI Munster, Indiana ☒ Community Hospital Munster, Indiana ☒ St. Catherine Hospital East Chicago, Indiana ☒ St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:

The CHS CIRB will take one of the following actions when reviewing information presented at a convened meeting. .

All determinations by the CHS CIRB will either be approved or not approved by a majority of a quorum of the voting members. A quorum will include at least one non-scientific member.

DEFINITIONS

Cause: For research being conducted within the Community Healthcare System cause may be indicated, but not limited to, the following:

- Violation of Federal Regulations, applicable law;
- Violation of requirements, policies or determinations of the CHS CIRB;
- Violation of Community Healthcare System commitments and regulations;
- Violation of standards of professional conduct and practice;
- Evidence associated with increased risk to subjects;
- Study has resulted in unexpected, serious harm to subjects.

Reviewer/Designee: A person that has been identified by the CHS CIRB or CHS CIRB Administrator to possess sufficient expertise to review and offer comment or recommendations regarding a Determination. Reviewer/Designee may include, but is not limited to:

- CHS CIRB Chair
- CHS CIRB Voting Member
- CHS CIRB Administrator
- Consultant, i.e., lawyer, physician, representative of a vulnerable population, etc.

PROCEDURE:

DETERMINATION: *Approved As Submitted*
An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and no changes to the research application are recommended.

To approve a human-subjects research protocol, the CHS CIRB committee/reviewer that is reviewing the protocol must determine that all of the following requirements are satisfied.

1. Risks to subjects are minimized
    a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk

b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

DETERMINATION: *Approved Pending Minor Revisions/Clarifications*

Minor Revisions/Clarifications action is taken if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and the revisions required by the CHS CIRB are such that they only require simple concurrence by the Investigator or the revisions requested are the type that may be approved under an expedited review procedure.

1. To approve a human subjects protocol, pending Minor Revisions/Clarifications, the CHS CIRB/Reviewer must determine that all of the requirements of 45 CFR 46.111 are met, or will be met, after a PI concurs with CHS CIRB requested revisions. The revisions must fall into one of the following two categories.
   a. Revisions are directive in nature
      A protocol or consent may be approved pending Minor Revisions/Clarifications if requested revisions are directive in nature. To qualify under this category, the CHS CIRB does not have to draft the specific language changes that are required. It is sufficient for the CHS CIRB to request revisions with sufficient specificity so that the CHS CIRB Chair or designee can judge whether the revised protocol or consent matches the one that the CHS CIRB was willing to approve.

      Examples of directive comments are:
      - Correction of typographical errors in the consent
      - To add, delete or change language in the consent, may request specific language

      Examples of revisions or clarifications that would not allow a protocol to be approved pending Minor Revisions/Clairfications and that would require the Investigator's responses to be reviewed by the full committee are:
      - To explain why participants under 18 years old may participate
      - To justify the use of placebo
      - To clarify whether participants will be offered counseling
      - To explain how often the DSMB will meet

   b. Revisions requested by the CHS CIRB Reviewer are non-substantive revisions that may be reviewed by the expedited procedure.

      A protocol may be approved pending Minor Revisions/Clarifications if the requested revisions are non-substantive revisions that are not directly relevant to the determinations in 45 CFR 46.111

(See Approved As Submitted section above) that the CHS CIRB needs to make to approve research. These Revisions would be those that could be approved under the expedited review procedure. (See policy on expedited or exempt review.)

2. In accordance with federal regulations, when a protocol is approved pending Minor Revisions/Clarifications, the CHS CIRB Office will record the date of CHS CIRB determination as the date of approval. However, the CHS CIRB Administration will inform the Investigator that the study may not begin until:
    - The Investigator has made the revisions required by the CHS CIRB
    - The CHS CIRB Chair or designee has confirmed the PI's revisions and
    - The CHS CIRB Office issues final approval documents

DETERMINATION: *Deferred: Carried Forward to Next Meeting – Protocol Still Under Discussion*
A study is carried forward if it is still under discussion and no action has been taken, or if it was scheduled for review at a CHS CIRB committee meeting but a quorum was not met.

DETERMINATION: *Deferred: Substantive Revisions Required/Return to Committee*
Approval of a study will be deferred if the study does not meet the criteria for approval as defined in 45 CFR 46.111 or if the CHS CIRB Committee recommends substantial revisions to the CHS CIRB protocol application documents.

1. The Investigator will respond in writing or in person to the recommended revisions to the full Committee for further review and deliberation.

2. The Committee will then make a determination based on the response by the Investigator. The Investigator will be notified, in writing of the Committee's determination.

3. In accordance with federal regulations, when a protocol does not meet the criteria for approval, the CHS CIRB Administration will inform the Investigator that the study may not begin until:
    - The Investigator has made the revisions required by the CHS CIRB
    - The CHS CIRB Committee has confirmed the Investigator's revisions and
    - The CHS CIRB Office issues final approval documents.

4. The CHS CIRB Office will record the date of the CHS CIRB determination "Approved as Submitted" as the date of approval.

DETERMINATION: *Deferred, CHS CIRB Seeking Consulting Opinion*
If the CHS CIRB determines it needs additional expertise to review a study, the CHS CIRB will defer approval of the study and seek a consulting opinion regarding the study from someone who possesses that expertise. The CHS CIRB and CHS CIRB Administrator will identify a consultant and the CHS CIRB Office will then forward the study to the consultant for review. Upon receipt of the consultant's opinion, the CHS CIRB Office will return the study with the consultant's opinion to the CHS CIRB for additional review. The consultant may be asked to attend the next convened meeting to participate in the discussion.

DETERMINATION: *Not Approved*
A study under review prior to initiation or a currently approved study may not be approved when evidence of cause has been determined by the CHS CIRB. Other categories of deferred approval may be attempted before it is determined that the study is not approved. Not Approved determinations are made under full Committee review procedures.

DETERMINATION: *Suspension/Termination of Approval*

1. Suspended by request: Investigators and sponsors may need to temporarily suspend a protocol for reasons not related to noncompliance or risk to subjects. In these cases, the CHS CIRB will suspend the protocol until the investigator requests in writing that the suspension be lifted. Such suspensions may be reported to Administration as deemed necessary by the Chair or CHS CIRB Director.

2. Expiration: When continuing review of a protocol does not occur prior to the end of the approval period specified by the CHS CIRB, the CHS CIRB approval expires automatically and a protocols' approval is terminated. The CHS CIRB Administration will inform the Investigator that:
    - No further subjects may be enrolled in the study.
    - The required documentation may be submitted at the next regularly scheduled meeting of the CHS CIRB for review.
    - The CHS CIRB will notify, in writing, the Investigator, the appropriate Community Healthcare System Administration and the sponsor that the CHS CIRB approval has been terminated.
    - The principal investigator may resubmit the protocol. See Policy IRB 4: Submission of Protocol to CHS CIRB: Initial Review, Continuing Review, Lapse of Approval

3. Termination of Approval for Cause: The CHS CIRB has the authority to suspend or terminate approval of research not being conducted in accordance with Federal Regulations, requirements, policies or determinations of the CHS CIRB, or that has been associated with unexpected serious harm to subjects. The CHS CIRB will notify, in writing, the Investigator, the appropriate Community Healthcare System Administration, the sponsor and the Office of Human Research Protections (for Federally funded studies). See policy: Scientific Misconduct IRB 3

CROSS REFERENCE(S): Policy: Scientific Misconduct IRB 3
Policy: Exempt Review IRB 9
Policy: Expedited Review IRB 8
Policy: Submission of Protocol to CHS CIRB: Initial Review, Continuing Review, Lapse of Approval IRB 4

REFERENCE(S): 45 CFR§46.130 (b)(4)
45 CFR§46.109
45 CFR§46.116(b)(5)
21 CFR§50.25(b)(5)
21 CFR§56.108(a)
21 CFR§56.109

ACCEPTED BY:

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Nancy Moser
Vice President, Corporate Compliance and Risk Management

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Andrej Zajac, M.D.
Chair, CHS CIRB

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Kristin M. Wadkins BSN, RN
Manager, IRB/Regulatory Compliance
Human Protections Administrator, CHS CIRB

ACCEPTED BY: Reviewed by CHS CIRB: 6/13/2006, 7/12/2006, 6/2009, 5/11/2010, 5/2013, 4/2016, 2/11/2020, 2/14/2023

DATE(S) REVISED: 6/2009, 5/2010, 5/2013, 12/2017

REVIEWED BY:

Date	Initials
6/2009	JL
5/2010	JL
3/2013	JL
3/2016	JL
12/2017	JL
2/2020	JL
2/2023	KW