TITLE Purpose, Structure and Responsibilities of the Community Healthcare System Central Institutional Review Board		POLICY NUMBER: IRB 1	
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Supersedes:	Institutional Review Board	Issued By:	CFNI/CHS CIRB
Date Originated:	12/21/04	Date Effective:	12/2023

☒	CFNI Munster, IN	☐	CCNI Munster, IN	☒	Community Hospital Munster, IN

☒	St. Catherine Hospital East Chicago, IN	☒	St. Mary Medical Center Hobart, IN	☐	Hartsfield Village Munster, IN

☐	Community Stroke & Rehab Center Crown Point, IN

POLICY STATEMENT

The Community Healthcare System Central Institutional Review Board (CHS CIRB) is an appropriately constituted administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. It exists in accordance with the Federal Policy regulations (45 CFR § 46) of the Department of Health and Human Services, (HHS) and the regulation (21 CFR §§ 50, 56) of the Food and Drug Administration. The CHS CIRB is registered with the Office of Human Research Protections (OHRP) and operates under one Federalwide Assurance (FWA).

All clinical research activities proposed within the Community Healthcare System must be reviewed and approved by the CHS CIRB prior to initiation by the investigator(s). The involvement of human subjects in clinical research will not be permitted until the CHS CIRB reviews and approves the research protocol, generates the letter of approval for all documents submitted, and until informed consent in a form and manner agreeable to CHS CIRB has been obtained from the subject or the subject's legal representative unless properly waived by the CHS CIRB under Section 45 CFR 46.116 or by any applicable waiver under 21 CFR § 56.105.

The Human Protections Administrator is responsible for establishing and administering institutional policies and procedures through which the CHS CIRB conforms to both the Federal Policy and the FDA regulations that govern the protection of human subjects participating in research.

DEFINITIONS

Federalwide Assurance (FWA) – an assurance of compliance with the federal regulations for the protection of human subjects in research. It is approved by the Office of Human Research Protections (OHRP) for all human subjects research conducted under or supported by the Department of Health and Human Services (HHS). To be eligible for participation in HHS-supported research an institution must submit and maintain compliance with an FWA.

Human Protections Administrator- is the administrative coordinator of the CHS CIRB review process, serves as the OHRP primary contact for issues related to CHS CIRB review, and communicates CHS CIRB policies and procedures to Board members, investigators and their staff. Assures that administrative policies and procedures related to the ethical review of human subjects research in the Community Healthcare System are consistently carried out. Assures compliance with Federal regulations and state laws.

Subjects – Individuals enrolled in a research study.

GENERAL PRINCIPLES

All of the CHS CIRB's human subject activities conducted under its FWA are guided by the basic ethical principles that underlie the conduct of research involving human subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, regardless of funding source. The three basic principles contained in the Belmont Report central to the ethics of research involving human subjects and guiding the CHS CIRB in assuring that the rights and welfare of subjects are protected include: respect for persons, beneficence and justice.

Respect for persons requires that potential subjects be given the opportunity to choose what will or will not happen to them and is the principle upon which obtaining informed consent and the consent process (including information, comprehension and voluntariness) is based. Respect for persons also provides additional protections for potentially vulnerable subjects.

Beneficence is exemplified in the expressions of "do no harm" and "maximize possible benefits and minimize possible harms", both on individual investigator and societal levels, as they extend both to particular research projects and to the research enterprise as a whole.

Justice requires that there be fair procedures and outcomes in the selection of subjects, both individually (by offering potentially beneficial research to all who might benefit) and socially (based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons).

PURPOSE:

The purpose of CHS CIRB review is to assure, both in advance and by periodic monitoring, that appropriate steps are taken to protect the rights and welfare of human research subjects. The focus of the CHS CIRB review process is to ensure that:

1. The risks to human research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk, and whenever appropriate, by using procedures already being performed on subjects for diagnosis or treatment purposes.
2. The risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
    - For the purpose of CHS CIRB consideration, "benefit" is defined as a valued or desired outcome; an advantage.
    - For the purpose of CHS CIRB consideration, "risk" is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. In evaluating risk, the CHS CIRB is to consider the conditions that make the situation dangerous, as opposed to those chances that specific individuals are willing to undertake for some desired goals.
    - In evaluating risks and benefits, the CHS CIRB considers only those risks and benefits that may result from the research (i.e., as distinguished from risks and benefits of treatments or procedures that the patient would undergo if not participating in the research).
    - In evaluating risks and benefits, the CHS CIRB does not consider possible long-range effects of applying knowledge gained from the research.
3. The selection of human subjects for research participation is equitable.
4. Human research subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent is obtained from each prospective human research subject, or his /her legally authorized representative, in accordance with, and to the extent required by federal regulations and CHS CIRB policies.
5. Informed consent of human research subjects is obtained in advance of research participation and appropriately documented in accordance with, and to the extent required by federal regulations and CHS CIRB policies.
6. Information about the study is provided to subjects in a manner that gives them a meaningful opportunity to consider whether or not to participate and avoids the risk of undue influences or coercion.
7. The research plan makes adequate provisions to ensure the safety of human research subjects.

8. There are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.
9. Appropriate additional safeguards have been included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, decisionally impaired persons, or economically or educationally disadvantage persons).

STRUCTURE

The voting membership of the CHS CIRB will be comprised of individuals representing all three hospitals in the system and other members who will be chosen to ensure compliance with the requirements set forth by the Code of Federal Regulations at 45 CFR § 46.107 and 21 CFR § 56.107.

1. The CHS CIRB must have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
2. The CHS CIRB Chair is a non-voting member. In the event there is a tie between board member's votes, then the chair will vote to be the tie-breaker.
3. The CHS CIRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, gender identity or expression and religious or cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
4. In addition to possessing the professional competence necessary to review specific research activities, the CHS CIRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The CHS CIRB shall therefore include persons knowledgeable in these areas.
5. If the CHS CIRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
6. The CHS CIRB may not consist entirely of members of one profession.
7. The CHS CIRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
8. At least one registered professional nurse (RN) shall be a voting member of the CHS CIRB and shall vote on all protocols where the principal investigator or the co-principal investigator is a nurse.
9. The CHS CIRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
10. The CHS CIRB may not have a member participate in the CHS CIRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the CH CIRB.
11. The CHS CIRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the CHS CIRB. These individuals may not vote with the CHS CIRB.
12. Nominations for appointments or requests to serve on the CHS CIRB may be submitted to the Institutional Official, the Human Protections Administrator, or the Chair of the CHS CIRB. Nominations or requests will be reviewed by the Institutional Official and submitted to the CFNI Board of Directors for final approval.
13. The appointment and function of alternate members is the same as that for regular CHS CIRB members, and the alternate's qualifications are comparable to those of the primary member. The CHS CIRB roster identifies the primary member(s) for whom each alternate member may substitute. When alternates substitute for a primary member, the alternate will receive and review the same materials that the primary member received or would have received. The CHS CIRB minutes will reflect any alternate member's attendance at the meetings.
14. The membership of the CHS CIRB shall be reviewed no less than annually and/or upon the resignation of one of its members to assure its continued compliance with the Code of Federal Regulations.

The convened CHS CIRB meetings will comply with the Code of Federal Regulations, 21 CFR § 56.108(c):

1. Except when an expedited review procedure is used, proposed research must be reviewed at convened meetings at which a majority (1/2 membership + 1) of the members of the CHS CIRB are present,

including at least one member whose primary concerns are in nonscientific areas, i.e., a quorum. In order for the research to be approved, it shall receive the approval of a majority of the voting members, including at least one member whose primary concerns are in nonscientific areas, present at the meeting.

2. Whenever possible, it is strongly recommended that all convened meetings take place with all participating members physically present. However, a convened meeting may be conducted via video conferencing and/or telephone conference call if the following conditions have been met;
   a. Each participating CHS CIRB member has received all pertinent material prior to the meeting;
   b. Each participating member can actively and equally participate (can hear and converse) in the discussion of all protocols;
   c. Minutes of such meeting will clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements.
3. Principal Investigators may present new protocols or information at a convened meeting via video conferencing and/or telephone conference.
   a. The PI must have notified the CHS CIRB office one week prior to the meeting;
   b. The PI will remain on the call to sufficiently present and answer questions to the members satisfaction;
   c. The PI will not participate in the deliberations or voting by the members;
   d. The minutes will clearly document the proceedings of the meeting.
4. The CHS CIRB will not allow absentee voting by its members.
5. Research that has been approved by the CHS CIRB may be subject to further appropriate review and approval or disapproval by officials of the institution, but those officials may not approve the research if it has not been approved by the CHS CIRB.

SCOPE OF RESPONSIBILITIES

The CHS CIRB has the responsibility and the authority to ensure that research is conducted in a manner that protects the rights, safety and welfare of human subjects.

The CHS CIRB specifically has the responsibility to:

1. Review and approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research.
2. Require that information given to subjects as part of informed consent is in accordance with 45 CFR §46.116 and documentation of informed consent is in accordance with 45 CFR §46.117, unless a waiver is issued.
3. Review the preliminary determinations of exemption by investigators and supervisors and make the final determination based on the federal regulations. Notice of concurrence for exempt research will be conveyed to the Investigator in writing.
4. Make the determination of eligibility for expedited review procedures under 45 CFR § 46.110 and 21 CFR § 56.16. Expedited review of research activities will not be permitted where full board review is required.
5. Require progress reports from investigators, including continuing review at intervals appropriate to the degree of risk, but not less than once per year.
6. Observe or have a third party observe the informed consent process and the research in response to a deficiency identified by the CHS CIRB.
7. Suspend or terminate approval of research not being conducted in accordance with applicable federal regulations and/or CHS CIRB requirements, or that has been associated with unexpected serious harm to subjects.
8. Place restrictions on a study to ensure the safety of the subjects.
9. Request documentation that investigators are qualified to conduct the research.
10. Ensure constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and Institutional Officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
11. Promptly report to the appropriate Institutional Officials, the Office for Human Research Protections (OHRP), 45 CFR § 46.108, and any other sponsoring federal department or agency head:
    - Any unanticipated problems involving risks to subjects or others
    - Any serious or continuing noncompliance with the regulations or requirements or determination of the CHS CIRB
    - Any suspension or termination of the CHS CIRB approval of research

12. For clinical research being conducted under an Investigational New Drug Application, promptly report to the Food and Drug Administration
    - Any unanticipated problems involving risks to subjects or others
    - Any serious or continuing noncompliance with the regulations or requirements as determined by the CHS CIRB
    - Any suspension or termination of the CHS CIRB approval of research
13. That procedural and record-keeping audits will be conducted not less than once every year for the purpose of detecting, correcting and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by the system.

CROSS REFERENCE:
Policy Number IRB 10: "Human Protections Administrator"
Code of Federal Regulations: 45 CFR § 46, 21 CFR §§ 50, 56
ICH Guideline for Good Clinical Practice as published in the Federal Register May 9, 1997, Section 3, *Institutional Review Board/Independent Ethics Committee (IRB/IEC)*
Letter dated March 28, 2000: IRB Meetings Convened via Telephone Conference Call

ACCEPTED BY:

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Andrej Zajac, M.D.
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DATE REVISED: 8/11/2006, 12/28/2007, 9/2010, 1/2015, 11/2017, 12/2024

REVIEWED BY: CHS CIRB: January 2005, 9/13/06, 2/12/08, 2/2010, 4/2011, 2/2014, 1/2015, 1/2017, 2/11/2020, 2/14/2023, 1/2024
Institutional Legal Counsel Review: February 2005
CFNI Board of Directors: July 20, 2005, 4/2011
MRF Board of Directors: August 23, 2005

Date	Initials
9/2010	JL
4/2011	JL
1/2014	JL
1/2015	JL
1/2017	JL
11/2017	JL
2/2020	JL
2/2023	KW
12/2024	KW