TITLE: Submission of a Research Study: Initial Review of Protocols		POLICY/PROCEDURE NUMBER: IRB 7	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:	Submission of Protocol Submission of Protocols for Annual Review/Renewal Submission of a Research Study: Initial Review and Continued Review, Lapse of Approval	Issued By:	CHS CIRB
Date Originated:	12/09/03	Date Effective:	1/2021
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	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 Principle Investigator/Clinical Coordinator is responsible for the timely and complete submission of all documents requiring review by the CHS CIRB to the CHS CIRB office.

The Calendar for Submission of Documents will be published on January 1 for that calendar year. The calendar will list the CHS CIRB meeting dates, location of the meetings, and the final date for documents to be submitted for the next scheduled CHS CIRB meeting. Documents may be submitted at any time but must meet the published deadline to be placed on the agenda of a particular meeting. Any documents submitted for review after the scheduled deadline will be placed on the agenda of the meeting following the next scheduled meeting.

All documents must be submitted with the appropriate form and completed in full. Those documents that are lacking any elements required for review will be returned to Principle Investigator. They may be re-submitted when the documentation is complete. The Principle Investigator may be required to submit additional information as determined by the CHS CIRB office.

A new protocol will not be accepted for review when the investigator (s) or clinical research staff have not completed the Required “Orientation of Investigators and Clinical Research Staff” and submitted the required documentation and a signed Affirmation Statement to the CHS CIRB office. (Effective September 1, 2006)

A new protocol will not be accepted for review without the accompanying CHS CIRB Fee.

Any documents requiring Full Board Review will be distributed to the CHS CIRB membership two (2) weeks prior to the scheduled meeting for review.

Any submission of a new protocol that meets the requirements for Not Human Subjects Research, Exempt or Expedited Review be reviewed within 2 weeks of receiving the documents and the appropriate correspondence will be issued. The communication will be reported for the information of the Full Board at the next convened meeting.

No more than three (3) new protocols will be accepted for review at each convened meeting to allow for adequate preparation prior to the meeting and substantive, thorough review during the meeting.

The Principle Investigator will be notified of the CHS CIRB’s decision of approval, request for additional information or disapproval of the submission within ten (10) working days following a convened meeting.

INITIAL SUBMISSION OF NEW PROTOCOL

New protocols submitted for Full Board review include those that are first time submissions or those that have been closed and that the investigator wishes to re-activate.

Initial review of research must be conducted at a convened meeting except where expedited review is allowable under the Federal Regulations. During initial review of research, the CHS CIRB assesses the proposed protections of the rights and welfare of human subjects participating in research. In order for a protocol to be approved, it must receive the approval of a majority of the quorum, including at least one member whose primary concerns are in nonscientific areas, present at the meeting.

NOTE: 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.

At the time of initial approval and then with subsequent continuing review, the CHS CIRB determines the frequency and extent of continuing review for each study appropriate to the degree of risk, but not less than once per year. The CHS CIRB, at its discretion, may require protocols to undergo continuing review more frequently as warranted by such factors as the nature of the study; the degree of risk involved; and the vulnerability of the study subject population. Factors that may determine the frequency of review include:

- Risks to subjects – participants have a high probability of experiencing life-threatening or disabling events;
- Involvement of vulnerable populations;
- Research for which participants would be exposed to additional risks (e.g., phase I studies), breach of confidentiality, disproportionate number or severity of adverse events;
- Research conducted internationally;
- Involvement of recombinant DNA or other types of gene transfer studies;
- Use of waiver of informed consent;
- Recommendations from other ancillary committees;
- Previous suspensions of the research due to non-compliance, record-keeping, or other concerns;
- Any other reason for which a CHS CIRB member believes that review more often than annually is appropriate.

Investigator Responsibilities

1. Prior to submission:
   - The investigator, the co-investigators and the clinical research staff must complete the “Orientation of Investigators and Clinical Staff” and submit the required documentation and a signed Affirmation Statement to the CHS CIRB office.
   - Complete the Budget Worksheet
   - Complete the Clinical Research Agreement Review
   - Complete the Agreement to Participate as a Clinical Investigator
   - Initiate the process for Credentialing for Investigational Procedures through Medical Staff Services, if the protocol requires additional privileges.
2. Complete and submit the *Protocol Submission Form*
3. Submit the documentation required on the *Protocol Submission Form*
   - NOTE: The investigators must present evidence of having obtained or are in the process of obtaining the necessary privileges to perform all of the procedures outlined in the study from the Credential’s Committee.
4. An investigator must submit a “Financial Interest Disclosure Addendum” if they have answered “Yes” to any portion of Part C, “Education/Conflict of Interest Requirements” on the Submission Form.
5. For investigators using a Short Form consent for oral presentation or a consent form in another language; refer to IRB 15.1; Barriers to Informed Consent
6. The Principle Investigator or one of the Co-Investigators is required to attend and present the protocol to the CHS CIRB when scheduled.

- NOTE: The Principal Investigator must notify the CHS CIRB office when they are delegating the presentation to a co-investigator. The protocol will not be automatically be placed on the next agenda if the investigator or the co-investigator has failed to appear at the scheduled meeting without proper notification.

. 7. Principal Investigators may present new protocols or information at a convened meeting via telephone or video conferencing:
   - The PI must have notified the CHS CIRB office one week prior to the meeting;
   - The PI will remain on the call to sufficiently present and answer questions to the members satisfaction;
   - The PI will not participate in the deliberations or voting by the members;
   - The minutes will clearly document the proceedings of the meeting.

Department Responsibilities

1. New protocols received by the department will be entered into the database and assigned a new protocol number.
2. An initial review of the protocol will be completed using the *Checklist for Initial Review of Protocols* by the administrative staff. Investigators will be contacted to provide clarification and/or additional documentation if necessary.
3. The Investigator Brochure will be forwarded to a registered pharmacist for review and comments.
4. The protocol will be forwarded to an independent reviewer if the administrative staff determines that the protocol requires further review prior to placing it on the CHS CIRB agenda. The independent reviewer will possess the necessary expertise to competently assess the merit of the protocol. Additional reviewers may be assigned at the discretion of the CHS CIRB Chair. The reviewer(s) will receive all of the documents submitted for review with a copy of the *Checklist for Initial Review of Protocols*. The reviewer(s) will complete their task within 1 week and return the documents to the CHS CIRB office with their recommendation regarding the approval of the protocol.
5. The CHS CIRB Chair or the CHS CIRB office may elect to table the protocol if the formal review process is not completed by the date of the CHS CIRB meeting or may proceed with the presentation of the protocol before a convened meeting.
6. The CHS CIRB office will notify Medical Staff Services of any action on a protocol that involves an investigational procedure or requires the approval of additional privileges. The CHS CIRB, at its discretion, may impose additional criteria and/or training to those required by the sponsor.

SUBMISSION OF PROTOCOL RELATED DOCUMENTS DURING THE COURSE OF THE STUDY

The CHS CIRB is responsible for conducting a review of all protocol related documents for ongoing research when there has been a modification to the approved protocol or as requested by the sponsor. This is to ensure that new or modified risk information is reviewed promptly and conveyed to the subjects when deemed appropriate.

NOTE: According to the Office of Human Research Protections (OHRP), when a protocol amendment involving any new or modified risk information is issued, new subjects cannot be enrolled in studies until the designated IRB has reviewed and approved the changes to the informed consent and protocol documents.

Investigator Responsibilities

1. Complete and submit an *Abbreviated Protocol Submission Form*.
2. Submit all supporting documentation of the modification from the sponsor and those documents requested on the *Abbreviated Protocol Submission* form.
3. Provide an explanation of the significance of the modification.
4. Provide an explanation of the actions taken to implement the modification.

5. Make note of any change to the risk/benefit ratio that result in changes to the informed consent.

NOTE: The investigator must notify the CHS CIRB of his intent to suspend enrollment until approval of the modification is received.

Department Responsibilities

1. An initial review of the documents will be completed by the administrative staff. Investigators will be contacted to provide clarification and/or additional documentation if necessary.
2. The CHS CIRB office will use the Expedited Checklist to determine if the modification may be expedited or requires full board review.
3. The administrative staff will forward the documentation to the CHS CIRB Chair or designee if necessary for further review/clarification prior to making any determination of exempt or expedited review. A determination of full board review will not require prior review by the CHS CIRB Chair.
4. The administrative staff will note any significant information that would change the risk/benefit ratio and require a change to the informed consent and therefore;
    a. Re-consent the enrolled subjects with the revised consent form, or
    b. Advise the investigator of the need to suspend enrollment until final approval of the informed consent is obtained.
5. Send written notification to the investigator within 1-5 business days for all submissions that qualify for expedited review.
6. Submissions that require full board review will be placed on the agenda of the next convened meeting.
7. Send written notification of CHS CIRB determination following convened meeting.

INITIAL REVIEW OF PROTOCOLS THAT HAVE RECEIVED PRIOR REVIEW BY A NON-LOCAL IRB

Refer to IRB 10: Institutional Authorization Agreement (IAA): Collaborations with Non-Local Institutions and Investigators

REFERENCE:

Policy: Barriers to Informed Consent IRB 12.1
Policy: Education and Training Of CHS CIRB Members, Investigators and Clinical Research Staff IRB 18
Policy: CHS CIRB Fees IRB 19 and CHS CIRB Fee Invoice
Policy: Review of QA/QI Projects IRB7.2
Policy: Expedited Review: IRB 7.4
Policy: Exempt Review: IRB 7.3
Policy: Budgeting Format: Explanation and Justification CLR 8
Policy: Clinical Research Agreement Review for Research Conducted within a CHS Entity CLR 9
Policy: Institutional Authorization Agreement (IAA): Collaborations with Non-Local Institutions and Investigators: IRB 10

ACCEPTED BY:

Elizabeth Yee, Institutional Official
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: 12/9/04, 2/28/06, 4/07/06, 8/11/2006, 12/05/2006, 9/12/2007, 2/12/2008, 6/2008, 7/2009, 6/2012, 6/2018

REVIEWED BY: CHS CIRB 12/14/2004, 9/13/06, 1/10/2007, 10/10/2007, 2/12/2008, 6/10/2008, 6/9/2009, 9/2009, 3/2012, 8/2012, 4/14/2015, 9/11/2018, 1/12/2021

Date	Initials
9/2007	JL
6/2009	JL
3/2012	JL
3/1/201	JL
6/2018	JL
1/12/2021	JL