TITLE: Responsibilities of the CHS CIRB Office		POLICY/PROCEDURE NUMBER: IRB 1.4	
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Supersedes:		Issued By:	CHS CIRB
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CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
☐ Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

PURPOSE:

The IRB Office exists to ensure that the functions of the CHS CIRB are managed in accordance with established policies and procedures and conforms to state and federal regulations.

POLICY/PROCEDURE

CHS CIRB Meetings

1. The meetings of the CHS CIRB will be conducted on the second Tuesday of every month
2. The meetings will be conducted at Community Hospital and St. Mary Medical Center by video conference. The attendance at both sites will be reflected in the meeting minutes and by securing separate sign in sheets.
3. Additional meetings may be called by the Chair to complete unfinished business, resolve emergency situations, or at the Chair's discretion.
4. The CHS CIRB office will be responsible for :
    a. Securing date, location and rooms for the meetings.
    b. Reviewing materials submitted to the CHS CIRB to prepare the board agenda and review packet.
    c. Sending agenda and review packet to board members 10 working days prior to the scheduled meeting. The documents will be sent either electronically or in paper format according to the member's preference.
    d. Assuring and accurately documenting that a quorum is met and maintained during the meeting.
    e. Recording and transcribing CHS CIRB minutes.
    f. Preparing and distributing response letters to the investigators within 10 working days following the meeting.
    g. Preparing and distributing reports of suspensions or termination of approval to the appropriate federal and state agencies or organizational departments as required.
    h. Collecting and destroying all agendas from members.
    i. Notifying the institution, in writing, of the CHS CIRB's decisions to approve or disapprove the research activity, or of modifications required to secure approval of the research activity. This will be included in the CHS CIRB Quarterly Summary.
    j. Notifying the Medical Staff Services of any action on a protocol that involves an investigational procedure or requires the approval of additional privileges.
    k. Notifying the appropriate institutional officials and the FDA of any unanticipated problems involving risks to subjects, any instance of serious or continuing noncompliance, any suspension or termination of CHS CIRB approval. Refer to CHS CIRB Policy "Scientific Misconduct in Research"

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.

CHS CIRB Minutes

1. A written summary is recorded for each full Board meeting to include:
    a. Date, time and locations of the meeting.
    b. Attendance including members and non-members present at each site. All sign-in sheets will be kept with the minutes to reflect the presence of members, alternate members, consultants, guests, etc.
    c. The initial and continued presence of a quorum including a non-scientific member.
    d. The use of any expert consultants and their scientific or nonscientific status and specialty.
    e. The number of members voting for, against and abstaining on each action.
    f. Verification that members did not participate in the deliberations or voting on matters in which they had conflicts of interest.
    g. A summary of the proposed research.
    h. The Principal and any Co-Investigators.
    i. The level of risk associated with the research.
    j. The discussion and deliberation of the research.
    k. The basis for requiring changes in or disapproving research.
    l. Summary of discussion of controversial issues, as indicated by a divided vote, and their resolution.
    m. The determination regarding which research requires continuing review more often than annually, as appropriate to the assessed risk.
    n. Summary of actions taken outside of the full Board meeting via an exempt, expedited or limited review process.
2. Meeting minutes are distributed to the Board for review prior to fully convened meetings.
    a. At the meetings, members may accept, request changes, or abstain from voting. This information is noted in the minutes.
    b. Once accepted by the Board as complete and accurate, the CHS CIRB Chair will finalize the minutes with a signature.
3. All signed copies of the minutes and the corresponding agendas and packets will be stored on a disk. All disks will be stored in the locked CHS CIRB Office.

Record Maintenance, Security and Retention

1. Records of active CHS CIRB approved protocols are maintained in a locked, secured area with access limited to the IRB staff. Investigators are asked to submit a request to the IRB Office if any component of the file is needed.
2. Storage and destruction of closed CHS CIRB approved protocols:
    a. Previously approved non-exempt study files will be retained in a secure warehouse for a period of three (3) years following their closure, disapproval, or lapse of approval by the CHS CIRB.
    b. Study files that have a legal hold will be retained in the CHS CIRB office and will be destroyed following their release.
    c. Non –exempt studies, never approved and exempt studies will be retained for three (3) years after the last CHS CIRB action or after withdrawal by the submitter.
    d. All documents will be shredded and disposed of securely after three (3) years.
    e. Notify Information Technology to destroy any electronic documents by either deleting the files or replacing the files with stub files documenting the date of deletion.
3. Records of active CHS CIRB approved protocols are not released unless needed to supplement a review by the CHS CIRB.
4. Only the Human Protections Administrator and the CHS CIRB Office Coordinator will have access to the CHS CIRB Database.
5. All computers within the CHS CIRB Office will comply with System Information Technology policies and procedures regarding securing information.
6. Original copies of the current CHS CIRB signed policies and procedures will be retained in paper copy for a period of two (2) years. Historical policies and procedures will be stored on a disk.

7. Minutes of convened meetings will be retained in paper copy for a period of 2 years. Historical minutes will be stored on a disk.
8. All agendas and meeting informational packets will be stored on a disk.
9. All records will be accessible for inspection and copying by authorized representatives of applicable federal agencies and accrediting organization at reasonable times and in a reasonable manner.

NOTE: IRB records required by the regulations, including meeting minutes, must be retained for at least 3 years after completion of the research that is the subject of the review and must be accessible for inspection and copying by authorized representatives from OHRP and/or FDA at reasonable times and in a reasonable manner (45 CFR 46.115(b); 21 CFR 56.115(b)). Many sets of minutes will have records of review of multiple studies. Relevant portions of the minutes must be retained until the regulatory retention period for each study is satisfied. Institutions and IRBs can expect that representatives of OHRP conducting a compliance oversight assessment, or representatives of FDA conducting a Bioresearch Monitoring inspection, will review minutes and other appropriate IRB records to assess compliance with the regulations.

Protocol Record Content

1. All protocol files will contain copies, including, but not limited to, the following documents:
   a. Original Protocol Submission Form
   b. Grant Applications, if applicable
   c. Most current version of the Research Protocol
   d. All copies of the Hospital Formatted Consent Form and HIPAA Addendum
   e. Subject recruitment or education information
   f. Current Investigator Brochure. Initial paper copy of the IB will be destroyed when a revised IB is received. The revised IB all be sent electronically and downloaded to the electronic study file in the IRB office.
   g. All External Adverse Event Summaries. Sponsor generated External Adverse Event reports will not be submitted to the CHS CIRB unless requested by the sponsor
   h. Questionnaires, survey instruments, or data collection forms
   i. Continuing review and progress reports
   j. Internal Adverse Event reports
   k. Data Safety Monitoring Board (DSMB) reports
   l. All correspondence between the CHS CIRB, the investigator and the Sponsor

2. All protocols will be entered into the CHS CIRB Database following approval. The database will include, but is not limited to, the following information:
   a. Date of initial approval
   b. Date of most recent approval
   c. Date scheduled for continuing review.

CHS CIRB Membership Files

1. The CHS CIRB must keep on file the following information regarding the CHS CIRB
   a. Name
   b. Earned Degrees
   c. Representative capacity
   d. Curriculum Vitae or bio sketch
   e. Indications of experience such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to CHS CIRB deliberations.
   f. A current, signed Conflict of Interest Statement
   g. Indication of required human subjects protection training and continuing education

2. Historical records of CHS CIRB members will be destroyed.

Policies and Procedures

1. The CHS CIRB will keep current policies and procedures on file and available on the CHS CIRB website as a reference for CHS CIRB staff, committees and investigators.

2. These policies and procedures will reflect compliance with the CHS CIRB Federalwide Assurance, the Code of Federal Regulations and the International Conference on Harmonization Good Clinical Practice Guidelines.

3. All policies and procedures will be developed and reviewed according to the Community Healthcare System policies.

CHS CIRB Quarterly Summary and Annual Summary

1. Prepare and distribute a summary of CHS CIRB activities to the boards of Community Foundation Northwest Indiana, Community Hospital, St. Mary Medical Center, and St. Catherine Hospital.

2. Summary will contain:
   a. Decisions regarding protocols that were approved or disapproved or of modifications required to secure approval of the research activity.
   b. Number of open protocols by type.
   c. General activities of the CHS CIRB, i.e., educational offering, correspondence with FDA, etc.

REFERENCE:
Code of Federal Regulations 45 CFR § 46
Code of Federal Regulation 21 CFR § 56
Good Clinical Practice Guidelines
Minutes of Institutional Review Board (IRB) Meetings; Guidance for institutions and IRBs. Issued by the Office for Human Research Protections (OHRP) September 2017

CROSS REFERENCE:
Administration Policy: Policy and Procedure Development and Intranet Access
CC 1.11: Records Management, Retention and Destruction

Further responsibilities of the IRB Office are specifically listed with each procedure.

ACCEPTED BY:

Nancy Moser
Vice President, Corporate Compliance & Risk Management

Andrej Zajac, M.D.
Chair, CHS CIRB

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

DATE REVISED: 8/10/06, 8/24/2007, 1/2009, 7/2011, 12/2014

REVIEWED BY: CHS CIRB 4/06, 9/06, 2/2014, 12/2014, 11/2017, 2/11/2020, 2/14/2023

Date	Initials
1/2009	JL
7/2011	JL
1/2014	JL
11/2017	JL
2/2020	JL
2/2023	KW