TITLE: Institutional Authorization Agreement (IAA): Collaborations with Non-Local Institutions and Investigators		POLICY/PROCEDURE NUMBER: IRB 24	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	Facilitated Review IRB 4.1	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	6/8/2007	DATE EFFECTIVE:	7/11/2017
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X	CFNI Munster, Indiana	X	Community Hospital Munster, Indiana	X	St. Catherine Hospital East Chicago, Indiana	X	St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:

CHS CIRB Oversight Jurisdiction: The CHS CIRB defines its scope of oversight jurisdiction to include:

- Human subject research activities conducted at Community Hospital, St. Catherine's Hospital, and St. Mary Medical Center
- Human subject research activities conducted or initiated by CHS employees or agents at any other site
- Human subject research activities that make use of any CHS resources other than faculty or employee time commitment

All research studies meeting these criteria must be submitted to the CHS CIRB for initial review. The CHS CIRB may enter into an IAA to rely on another institution's IRB review or to allow another institution to rely on the CHS CIRB review. The CHS CIRB office will evaluate the research studies to determine if an IAA is applicable and should be entered into. The CHS Institutional Official retains final authority to determine whether the CHS CIRB may enter into an IAA. The PI is encouraged to contact the CHS CIRB office if they are unsure if an IAA is applicable.

The CHS CIRB will assign an independent reviewer to perform a facilitated review of research studies that have been previously reviewed by another IRB and where a request has been made to cede oversight to that IRB. The CHS CIRB will decide on a study–by-study basis whether to accept the review of another IRB or to conduct its own full Board review.

Each IAA will be considered situation and context-dependent. Considerations of whether to enter into an IAA may include:

- Minimization of duplicate effort;
- Engagement of the institutions;
- Lack of local expertise or involvement of certain types of research such as xenotransplantation, embryonic stem cell, phase I clinical trials;
- The location of the research interaction, intervention or subject recruitment;
- Whether there is a prime award for a contract, grant, or cooperative agreement,
- Whether there is a subcontract;
- Whether the Non-Local IRB has an equivalent human research protections program in place;
- Discussions between IRB administrators from each institution to assure an efficient communication process;
- Consultation with Institutional Officials.

The CHS CIRB will enter into an Authorization Agreement (Addendum II) with the Non-Local IRB. Both IRBs will agree to abide by the Delineation of Responsibilities as presented in the Agreement. All Agreements will be kept on file in the Office of the IRB/Bio-Ethics Department. The Director of the CHS CIRB department will be the local contact for the CHS CIRB.

DEFINITIONS:

Engaged in Research: An institution becomes "engaged" in human subjects' research when its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility):

1. intervene or interact with living individuals for research purposes;
2. obtain individually identifiable private information for research purposes,
3. obtain informed consent from human subjects; or
4. receive HHS funds even when all activities are carried out at another institution or by employees of another institution.

The Director of the IRB or designee will make the final determination regarding engagement in human subject's research.

Federalwide Assurance (FWA): A formal, written, binding attestation in which an institution assures the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects at 45 CFR § 46.

Individual Investigator Agreement (IIA): The CHS CIRB **will not agree** to serve as the IRB of Record for external personnel or collaborators engaged in human subject's research and who are not affiliated with an institution with its own IRB.

Institutional Authorization Agreement (IAA): A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying Institution. The agreement is used to describe the terms of the partnership to rely on each other to provide IRB oversight for research studies. Agreements are generally used to cover a single research study, categories of research studies, or all human subjects research (non-exempt research) under an organization's Federalwide Assurance (FWA). If an Institutional Authorization Agreement is needed, the CHS CIRB facilitates the processing of such agreements.

IRB of Record: An IRB that assumes IRB responsibilities or oversight for another institution. Also referred to as the Reviewing IRB.

Local Research Context: Knowledge of the institution and community environment in which human subjects' research will be conducted. In order for an IRB to agree to serve as IRB of Record for another institution, it must have adequate knowledge of local context (e.g., state laws, understanding of cultural context).

Multisite Research: A multisite project is one that is being conducted at one or more sites. All multisite research raises questions about whether sites are engaged in research and if so, how IRB oversight will be provided.

NCI CIRB (National Cancer Institute Central Institutional Review Board): The NCI CIRB provides centralized IRB oversight for institutions conducting certain cooperative group oncology studies.

Relying IRB: A relying IRB is relying on or has ceded IRB review to another IRB (IRB of record or Reviewing IRB) to provide oversight for a specific study or set of studies.

Research at an External Site: Research activities that involve collaboration with sites and/or personnel outside of the CHS entities. All research involving external sites raise questions about whether sites or personnel are engaged in research and if so, how IRB oversight will be provided.

PROCEDURE:

Investigator Responsibilities

1. Prior to submission:
   - The investigator, the co-investigators and the clinical research staff must complete the Required "Orientation of Investigators and Clinical Research Staff" and submit the signed Affirmation Statement and required documents.
   - Complete the Budget Worksheet
   - Obtain approval from the appropriate research committee
   - Obtain Administrative Approval to conduct the research
2. The Principle Investigator/Clinical Coordinator prepares copies of the documentation to be submitted to the CHS CIRB. Documents to include:
   - Request to change the IRB of Record
   - Protocol Submission Form
   - Most recent version of study protocol with appendices
   - Most recent Non-Local initial or continuing review application, Board response and approval letter with the expiration date
   - One copy of the CHS formatted consent and HIPAA addendum (if applicable)
3. All consents must conform to the CHS CIRB formatted consent template.
4. An investigator must submit a "Financial Interest Disclosure Addendum" if they have identified a financial conflict of interest for the study. Submit all documentation to the CHS CIRB office with the completed *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.
5. Will continue to provide the CHS CIRB with ***local*** Adverse Events for review according to IRB Policy 11: Adverse Event or Protocol Deviation/Violation Reporting and Review.
6. The Principal Investigator will continue to report to the CHS CIRB over the course of the study**:**
   - Substantial changes to the study that may significantly impact the health and safety of the local research subjects, i.e., study suspended, closing an arm of the study, grade 4 or 5 adverse events
   - Any changes to the protocol or the consent that would require re-consent of the subject, i.e., new risk information that may affect their decision to continue participation
   - Those adverse events for local subjects that can be "Probably" or "Definitely" attributed to their participation in the study
   - Protocol deviations from the original design of the study

Department Responsibilities

1. New protocols received by the department will be entered into the database and assigned a new protocol number.
2. All documentation received from the local PI will be retained in the CHS CIRB facilitated review binder,
3. 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.
4. The protocol will be forwarded to an independent reviewer who possesses the necessary expertise to competently assess the merit of the protocol within the local context. 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 one (1) week and return the documents to the CHS CIRB office with their recommendation regarding the protocol.
   Options for recommendation:
   - Accept the Non-Local IRB review of the protocol and approves the protocol for initiation within the local context. The Non-Local IRB then becomes the IRB of record and the Non-Local review date will become the official date for continuing review. The CHS CIRB then becomes the Relying IRB. This information will be added to the agenda of the next convened meeting under "Facilitated Review" for the information of the CHS CIRB.

- Does not accept the Non-Local IRB review of the protocol. The CHS CIRB office will request any further documentation if necessary. The entire protocol submission will then be placed on the agenda for Full Review.

5. The investigator will be notified in writing of the final determination of the CHS CIRB;
6. The CHS CIRB will no longer perform continuing reviews, amendment reviews or Non-local SAE reviews for this protocol.

Ceding Oversight to the NCI CIRB

The Community Healthcare System IRB operating under the FWA00001804, as the Component Institution has acknowledged that the review performed by the NCI CIRB will meet the human subject protection requirements of the CHS CIRB. Therefore, the CHS CIRB will only perform a facilitated review of the proposed research and the investigational consent to assess the scientific validity of the research and feasibility of success within the local context.

Investigator responsibilities:

1. The Investigator, co-investigators and clinical research staff must complete the required "Orientation of Investigators and Clinical Research Staff" and submit the signed Affirmation Statement and required documents.
2. Complete the Budget Worksheet
3. Obtain Administrative Approval to conduct the research
4. The Principle Investigators/Clinical Coordinator prepares copies of the documentation to be submitted to the CHS CIRB.
   - Protocol Submission Form
   - Most recent version of the Protocol with appendices
   - Most recent NCI CIRB initial review or continuing review application, Board response and approval letter with expiration date
   - One copy of the CHS formatted consent and HIPAA addendum (if applicable)

5. The Principal Investigator will continue to report to the CHS CIRB over the course of the study**:**
   - Substantial changes to the study that may significantly impact the health and safety of the local research subjects, i.e., study suspended, closing an arm of the study, grade 4 or 5 adverse events
   - Any changes to the protocol or the consent that would require re-consent of the subject, i.e., new risk information that may affect their decision to continue participation
   - Those adverse events for local subjects that can be "Probably" or "Definitely" attributed to their participation in the study
   - Protocol deviations from the original design of the study

Department Responsibilities

1. The protocol and CHS Formatted Consent will be reviewed by the CHS CIRB Chair and/or designees.
2. The CHS CIRB Chair may request further information from the Principal Investigator.
3. Additional reviewers or consultants may be assigned at the discretion of the CHS CIRB Chair.
4. The CHS CIRB Chair will make a recommendation to the Principal Investigator and Administration, if warranted, to proceed with the proposed research or to reconsider initiating the proposed research
5. The Principal Investigator will be notified in writing of the CHS CIRB recommendations

CROSS REFERENCE(S):

CHS CIRB Policy: Institutional Authorization Agreement (Form)
IRB 1: Purpose, Structure and Responsibilities of the Community Healthcare System Central Institutional Review Board
IRB 4: Submission of a Protocol to the CHS CIRB
Facilitated Protocol Submission Form; Review for Local Context
IRB 11: Adverse Event or Protocol Deviation/Violation Reporting and Review

REFERENCE(S):

45 CFR §46.103, §46.114
FDA Information Sheets – Cooperative Research
FDA Information Sheets – Non-Local IRB Review

ACCEPTED BY:

Elizabeth Yee
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Andrej Zajac, M.D.
Chair, CHS CIRB

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

DATE(S) REVISED:

REVIEWED BY: CHS CIRB

Date	Initials
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