TITLE: Continuing Review of a CHS CIRB Approved Protocol; Lapse of Approval		POLICY/PROCEDURE NUMBER: 7.1	
AUTHOR:	Jana L. Lacera, RN, MSA. CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	Submission of a Research Study: Initial Review and Continued Review, Lapse of Approval IRB 4	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	12/09/03	DATE EFFECTIVE:	1/2021
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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:

The CHS CIRB is responsible for conducting continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected and to review the progress of the entire study. Research approved by the CHS CIRB may continue only for the time period set by the IRB. For certain research studies, these periods are controlled, in part, by the DHHS and FDA regulations for human subject research. Where a formal continuing review is required either by regulation or through a determination of the CHS CIRB, the maximum approval period is one year minus one day. In these cases, in order to conduct research for more than one year, a continuing review process is mandatory.

When continuing review is required, the CHS CIRB will conduct continuing review of human participant's research at intervals appropriate to the degree of risk. Common reasons for reviewing research studies more frequently than annually may include:

1. The study team's conduct in prior studies suggest that closer monitoring by the IRB is warranted;
2. The study poses more than minimal risk to participants;
3. The study involves novel interventions;
4. The study poses more than minimal risk to participants and would be expected to be completed in less than a year; or
5. The study involves vulnerable participants.

Studies approved prior to January 21, 2019 will be transitioned to the Revised Common Rule during the Continuing Review process. The transition will be documented in the meeting minutes and the determination letter sent to the investigator.

Under the Revised Common Rule, continuing review is no longer a regulatory requirement for the following types of research [studies initially reviewed on or after 1/21/2019].

1. Research (minimal risk) that was eligible for expedited review at the time of initial approval,
2. Exempt research (minimal risk) conditioned on limited IRB review,
3. Research that has completed all interventions and now only includes analyzing data, even if the analysis involves identifiable biospecimens or information,
4. Research where all study-related interventions are completed and the remaining study activities only include accessing follow-up clinical data from clinical care procedures.

These exceptions to the requirement for continuing review do not apply to FDA-regulated research including research that is subject to both HHS and FDA jurisdiction. .

For studies reviewed under the Revised Common Rule where there is no regulatory requirement for continuing review, the CHS CIRB may determine that continuing review is still required. For studies where continuing review is not required by regulation but the IRB determines that continuing review is required, the IRB must provide the rationale for this determination and document it as part of the IRB review process. If a continuing review will not be required, the CHS CIRB will require an annual update of the status of the research. The investigator will be responsible to inform the CHS CIRB when the research has been completed.

Approval automatically expires if a continuing review application is not submitted for review prior to the expiration date. If a continuing review application is submitted and CHS CIRB review is not scheduled before the approval date expires, all research activity must stop until the review occurs. The IRB has the authority to allow continued participation of subjects in research for which IRB approval has lapsed while the continuing review process occurs if there is an overriding safety concern or ethical issue that indicates it is in the best interest of the participants to continue. In such cases where participants may continue in the research, all other activity must stop until the CHS CIRB completes the review process. If approval lapses, the IRB does not have the authority to allow new enrollment while the continuing review process is conducted.

Investigator Responsibilities for studies that are required to undergo Continuing Review

1. Even though the CHS CIRB office sends notification of continuing review, investigators are responsible to track renewal dates and submit necessary documentation prior to the protocol expiration date.
2. Complete and submit the *Request to Renew a Research Study and the Summary of Clinical Trial Adverse Events Form* for each enrolled subject.
3. An investigator must submit a "Financial Interest Disclosure Addendum" if they have acquired a financial interest in the sponsor since the original approval date or last continuing review date.

   Note: For Registry Studies: Submit the total number of subjects enrolled in the registry since the protocol was approved. It is not necessary to complete a *Summary of Clinical Trial Adverse Events Form.*

4. Complete the Clinical Research Review process if the design of the study or the agreement has changed within the last year that might affect the monetary or clinical resources to the entity.
5. The Principle Investigator is not required to attend the scheduled meeting to present a protocol for continuing review.
6. The Principle Investigator will be required to submit an *Appeal of Closure form* in addition to the *Request to Renew a Research Study* if there has been; (1) no accrual in a two (2) year period, (2) evidence of recent scientific publications that may potentially impact the continued conduct of the research study, or (3) risk/benefit assessment that would affect the consideration of renewal of the research protocol.
7. The Principal Investigator may be required to attend the scheduled meeting to present the Appeal of Closure.

Investigator Responsibilities for studies that are NOT required to undergo Continuing Review

Regardless of the requirement set by the CHS CIRB for reporting study progress (continuing review, progress report or no reoccurring report of progress), investigators still must inform the IRB of:

1. Modifications to the protocol that may affect the minimal risk determination;
2. Closure of the study at the local site.

CHS CIRB approval will remain in effect (no expiration date) until:

1. All research activities are complete:
2. The IRB suspends or terminates approval; or
3. The IRB determines Continuing Review is required.

NOTE: The CHS CIRB will request a status update report annually.

Department Responsibilities

1. As a courtesy, a notice of impending renewal will be sent to the Principle Investigator one month prior to the final date for the submission of documents for the next convened meeting.
   NOTE: In order to comply with the federal regulations regarding a 364 day renewal schedule and to avoid lapses in review, the CHS CIRB automatically sends renewal reminders on an eleven (11) month schedule.
2. 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.
3. The CHS CIRB office will determine if any further Quality Assurance monitoring is necessary on the medical records of the subjects listed on the *Summary of Clinical Trial Adverse Events*.
   a. Further QA monitoring is required if there has not been concurrent submissions of Internal Adverse Events during the course of the approval period.
   b. Further QA monitoring is required if it appeared as a condition of the initial approval.
   c. Further QA monitoring is required if there has not been concurrent monitoring of protocol deviations reported during the course of the approval period, i.e., information received by the Office of irregularities in the consent process, injury to subjects, omitted study interventions, etc.
   d. Further QA is required if the CHS CIRB detects a trend in adverse events or protocol deviations.
4. The protocol may be forwarded to an independent reviewer after it has cleared the preliminary review process at the discretion of the CHS CIRB office or the CHS CIRB Chair. The independent reviewer will possess the necessary expertise to competently assess the continued merit of the protocol. The reviewer(s) will receive all of the documents submitted for review. The reviewer will complete their task within one (1) week and return the documentation to the CHS CIRB office listing their recommendation regarding renewal of the protocol. The reviewer may be asked to attend the meeting to discuss their findings.
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 quorum of the committee including one member whose primary concerns are in nonscientific areas.

LAPSED OR EXPIRED PROTOCOLS

FDA regulations at 21 CFR Part 56 makes no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically.

It is the responsibility of the principal investigator to submit the documentation required by the CHS CIRB for continuing review within the designated review period. If continuing approval is not issued prior to a protocol's expiration date, the protocol will be inactivated by the CHS CIRB. **The PI will be notified to stop all human subjects' research activity, including enrollment and the retrieval and analysis of data.**

Such expiration of CHS CIRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations. However, investigators are required to notify the Sponsor if their IRB approval lapses. Repeated or very lengthy lapses in CHS CIRB approval may be deemed to be continuing non-compliance with the regulations and the requirements of this policy, and result in corrective action in addition to notification of funding agencies and federal oversight agencies.

Investigator Responsibilities

1. Protocols without CHS CIRB approval (lapsed) for less than thirty (30) days may be re-activated by the PI:
   a. Submit a *Request to Renew a Research Study and* a *Summary of Clinical Trial Adverse Events Form;*
   b. Explanation of why the submission of the continuing review application was delayed.
2. Protocols without CHS CIRB approval (lapsed) for greater than thirty (30) days will be terminated by the CHS CIRB. The PI may re-apply for approval by:
   a. Submit a *Protocol Submission Form* as required for the submission of a new protocol
3. In the event that a protocol has lapsed and the withdrawal of research interventions may place subjects of the study at risk, the PI may request that the CHS CIRB grant permission to allow the continuation of activities

required for subject safety prior to reactivation by submitting;
a. Completed *Request to Renew a Research Study;*
b. Explanation of why the submission of the continuing review application was delayed;
c. A discussion of why the suspension of research activities would adversely impact subject safety or not be in the subject's best clinical interest;
d. If research related interventions have been continued with subjects on a lapsed protocol, a discussion of the circumstances that necessitated this action.

NOTE: Research activities, i.e., recruitment, enrollment, data retrieval, etc., may only be resumed after the PI receives approval to resume the research.

Department Responsibilities

1. Review application for renewal and forward for immediate consideration by the CHS CIRB Chair.
2. Send written notification of the CHS CIRB determinations regarding continuation of research interventions with previously enrolled subjects, if appropriate.
3. Send written notification of the CHS CIRB determination regarding continuing approval for the protocol.

REFERENCES
Revised Common Rule: CFR 46 §45

REFERENCE:
Policy: CHS CIRB Fees IRB 5 and CHS CIRB Fee Invoice
Policy: Quality Assurance Activities: Audits and Monitors IRB 14
Policy: Review of QA/QI Projects IRB 4.1
Policy: Expedited Review: IRB 7.4
Policy: Exempt Review: IRB 7.3
Policy: Institutional Authorization Agreement (IAA): Collaborations with Non-Local Institutions and Investigators: IRB 24

ACCEPTED BY:

Elizabeth Yee, Institutional Official

Andrej Zajac, MD
Chair, CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Director, IRB/Bio-Ethics

DATE(S) REVISED: 1/2019

REVIEWED BY CHS CIRB: 9/2018, 1/2019, 1/2021

Date	Initials
9/20/2018	JL
1/2019	JL
1/2021	JL