TITLE: Principal Investigator Responsibilities		POLICY/PROCEDURE NUMBER: IRB 5	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	8/2010	DATE EFFECTIVE:	2/2020
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STATEMENT/PURPOSE

1. Human Subjects Protection
   a) It is the Principal Investigator's responsibility to be knowledgeable regarding his or her role and responsibilities. The Principal Investigator must sign the application for human subject's research thereby affirming that they agree to uphold the protection of the rights and safety of participants through adherence to federal, state and local laws, CHS CIRB and institutional Clinical Research policies and procedures.
   b) Each Investigator involved in the research is obligated to be personally certain that each participant is adequately informed and freely consents to participate in the research.
   c) The Principal Investigator must personally ensure that every reasonable precaution is taken to reduce risks to the participants.
   d) The Principal Investigator may not initiate any research involving humans without prior CHS CIRB review and approval. In addition, the Principal Investigator may not amend or change an approved protocol without prior CHS IRB review and approval, except where necessary to eliminate immediate harm to the participant.
   e) The Principal Investigator must determine that the resources necessary to protect participants are available prior to conducting the research. In the event the resources necessary to protect participants become unavailable during the course of the study, the Principal Investigator should stop the study until those resources are once again available.

2. Investigator Training
   a) It is the responsibility of each Principal Investigator to ensure that all investigators and study personnel are adequately trained in human subject's research protections as required by CHS CIRB policy and to remain up-to-date with Federal regulations, state and local laws, institutional and CHS CIRB policies and procedures.

3. Supervision and Auditing of Research Process
   It is the responsibility of the Principal Investigator to:
   a) Ensure that all procedures associated with the research are performed with the appropriate level of supervision only by individuals who are licensed or otherwise qualified to perform them.
   b) Ensure adherence to the study protocol and monitor the informed consent process.
   c) Ensure there are appropriate staff, facilities and resources to conduct the research.
   d) Regularly review his or her research processes and address any deficiencies.
   e) Conduct and document auditing of research activities on a regular basis.
   f) Audit the performance of the clinical research site (s) ensuring proper storage and dispensing of drugs, biologics or devices.

g) Report any deviations or violations encountered during supervision and auditing of research processes to the CHS CIRB and/or sponsor as required.

4. Confidentiality
   a) The conditions for maintaining confidentiality of the participant's research records are required for the life of the data.
   b) Each Investigator must also ensure participant privacy and confidentiality according to HIPAA guidelines, institutional and CHS CIRB policies.

5. Recruitment of Participants
   a) Investigators should use fair and equitable recruitment practices in research and avoid practices that place participants at risk for coercion or undue influences.

6. Informed Consent
   a) The Principal Investigator must ensure that the performance of the informed consent process is congruent with CHS CIRB policy and Federal regulations and that it is obtained in a legally effective manner. Informed consent is a continual process.
   b) The Principal Investigator may delegate obtaining informed consent to a member of his or her study team as approved by the CHS CIRB. However, the Investigator is responsible for monitoring the informed consent process and ensuring signed copies of the consent documents have been provided to participants while keeping the original on file.

7. Unanticipated Problems Involving Risk to Participants or Others
   a) The Principal Investigator must report any Internal Adverse Event or Deviation to the protocol that requires prompt reporting according to the CHS CIRB Policy 11, Internal Adverse Event, Protocol Deviation/Violation, Unanticipated Events: Reporting and Review.

8. Participant Complaints or Requests for Information
   a) The Investigators and research staff should be receptive to participant's complaints or requests for information. Investigators and research staff should develop and follow a process to respond appropriately to such complaints or questions.

9. Amendments and Requests for Changes in IRB Application
   a) It is the responsibility of each Investigator not to deviate from the CHS CIRB approved research activities until the Investigator has received written approval from the CHS CIRB.

10. Continuing Review
    a) All approved research proposals, with the exception of those which qualify for exemption in accordance with 45 CFR 46.101 and 21 CFR 56.104(d) must receive continuing review at intervals appropriate to the degree of risk as determined by the CHS CIRB.
    b) Continuing review must be conducted not less than once per year. The Principal Investigator must ensure that continuing review applications are submitted in a timely manner so that their review occurs prior to their expiration date. The Principal Investigator acknowledges that the Federal regulations do not allow a grace period.
    c) Continuing review must be substantive and meaningful. Therefore the Principal Investigator must submit a comprehensive summary of the research activities and progress since the previous continuing review. Each Investigator is responsible for being aware of the current literature in his/her field of study to ensure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven.
    d) The Principal Investigator conducts a comprehensive review of the current literature to assess the continued relevance of the research design.

11. Sound Study Design
    a) The Principal Investigator is responsible for employing a sound study design in accordance with the standards of the discipline. The study design should include reporting mechanisms that provide information to monitor the rights and welfare of participants enrolled in the research. When designing a study or employing a study design developed by an outside entity or sponsor, the Investigator must

determine that the proposed study minimizes risk. Investigators should choose to participate in studies that will likely develop or contribute to generalizable knowledge.

12. Federalwide Assurances (FWA), Other IRB Approvals and Letters of Cooperation
    a) It is the Principal Investigator's responsibility to ensure the proper approvals and agreements are in place at all research sites prior to the commencement of research.

13. Research Records
    a) At a minimum, Investigators are required to maintain research records for at least three (3) years from the date the research is closed by the CHS CIRB and as required by the sponsor.
    b) All research records must be accessible for inspection and copying by authorized representatives of the CHS CIRB, Federal regulatory agency representatives, and the Research Department or Sponsor supporting the research.
    c) In the event the Principal Investigator moves to another location and leaves The Community Health Care System, the CHS CIRB must be notified in advance. The Principal Investigator may either have another Investigator assume Principal Investigator responsibilities or close each of his or her research studies with the CHS CIRB. The Principal Investigator must also notify the CHS CIRB in writing of the plan for the disposition of participants and either destroying the data or transferring the data to another PI.
    d) The investigator is required to maintain adequate records of the disposition of the investigational article, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the investigational article to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21.CFR 312.59.
    e) The investigator is required to prepare and maintain adequate source documents that record all observations and other data pertinent to the investigation on each participant. At a minimum, the source documents should Include:
        - The case report forms;
        - Supporting data including, signed and dated consent forms;
        - Medical records including the participants' hospital chart(s), and
        - The nurses' notes.
        - The source document for each participant shall document that informed consent was obtained prior to participation in the study.
    f) The principal investigator is required to maintain a file of human subjects' research project documents. The file must include, at a minimum, the following items:
        - A copy of the original CHS CIRB submission form
        - A copy of the consent form stamped "Approved" by the CHS CIRB
        - The original of each consent form signed by each participant enrolled in the research. For studies involving in-patients, the investigator is responsible for ensuring that a copy of the consent form is in the patient's medical record.
        - A copy of all correspondence with the IRB, sponsor, funding source, FDA, or others.
        - A copy of the data derived from the study (case report forms, computer data, adverse event reports, drug/device accountability records etc.)
        - A copy of the protocol
        - A copy of the federal grant application (if applicable)
        - A copy of an investigator-initiated IND or IDE application (if applicable)
        - A copy of the Investigational device exemption information (if applicable)

14. Financial Disclosure
    a) The Principal Investigator is required to disclose to the CHS CIRB and potential research participants any significant financial interest in the study or the commercial sponsor of the study to include, but not limited to;
        - Compensation affected by the outcome of the study;
        - Significant equity interest in the sponsor of the study;
        - Proprietary interest in the investigational article;

- Significant payments of other sorts which may include payments made by the sponsor to the investigator or the institution to support activities of the investigator exclusive of the costs of conducting the study (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria during the time the clinical investigator is carrying out the study or for 1 year following completion of the study.

References:
The Belmont Report
Good Clinical Practice Regulations and Guidelines for Clinical Research
45 CFR §46
21 CFR §312
21 CFR §56

Cross References:
CHS CIRB Policies and Procedures
CHS Clinical Research Policies and Procedures

ACCEPTED BY:

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DATE(S) REVIEWED: 11/2017, 2/11/2020

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REVIEWED BY: CHS CIRB 10/12/2010, 8/2013, 6/2016, 2/11/2020

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3/2013	JL
6/2016	JL
11/2017	JL
2/2020	JL