Institutional Review Board (IRB) Authorization Agreement

Name of Institution Providing IRB Review ("Institution A")

Name: _____

Federal Wide Assurance #: _____

IRB Registration #: _____

Name of Institution Relying on the Designated IRB ("Institution B")

Name: Mercy College of Health Sciences IRB

Federal Wide Assurance #: N/A

IRB Registration #: IRB00012073

The official signing below agrees that Mercy College of Health Sciences IRB may rely on the designated IRB for reviews, approvals, and continuing oversight, as provided under "Division of Responsibilities between Mercy College of Health Sciences and the External Institution or Research Site," as its human subject research described below:

This agreement applies to all human subject research covered by Institution B's FWA.

__ This agreement is limited to the following specific protocol: _____
(*enter name of study and study # here*)

Other (describe): All human subject research conducted by Mercy College of Health Sciences in collaboration with _____ *(name of Institution A).*

The review performed by the designated IRB will meet the human subject protection requirements of Institutions B's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meeting will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Name and Title of Signatory Official (Institution A)

Name: _____

Title and Location: _____

Email Contact: _____

Signature: _____ Date: _____

Name and Title of Signatory Official (Institution B)

Name: Dr. Joan McCleish, PhD, RN

Title and Location: IRB Chair, Mercy College of Health Sciences, Des Moines, Iowa

Email Contact: IRB@mchs.edu

Signature: _____ Date: _____

Division of Responsibilities between the Mercy College of Health Sciences IRB and the External Institution or Research Site

This document supplements the Institutional Review Board (IRB) Authorization Agreement between Mercy College of Health Sciences IRB (Institution B) and external institution named in the aforementioned agreement.

The following division of responsibilities is based on the premise that the primary function of the **Institution Providing IRB Review ("Institution A")** is initial and continuing review of the multi-site human subjects research noted in the IRB Authorization Agreement, and that the primary function of the local **Institution Relying on the Designated IRB ("Institution B")** is consideration of local context and oversight of local performance for the research at Institution B's site(s),

The responsibilities of Institution A's IRB are to:

1. Maintain a human subject protection program compliant with 45 CFR 46 and 21 CFR 56.
2. Perform initial and continuing review of research, including but not limited to requested changes to approved research and report of unanticipated problems or non-compliance, and make determinations regarding final approval or disapproval in compliance with the Belmont Report and applicable federal regulations and guidance.
3. Maintain, and upon request make accessible to appropriate officials from Institution B, records and documentation of IRB review and determinations.
4. Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CRF 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each study.
5. Notify appropriate officials at Institution B immediately if there is ever a suspension or restriction of the IRB's authorization to review studies.
6. Notify the Institution B of any IRB policy decisions or regulatory matters that might affect Institution B's reliance on Institution A's IRB reviews.

The responsibilities of the local Institutional (Institution B) are to:

1. Ensure the safe and appropriate performance of the research at its institution. This includes, but is not limited to, monitoring protocol compliance and managing non-compliance, managing any unanticipated problems or adverse events occurring at the institution, ensuring qualifications of research staff, and providing a mechanism by which complaints about the research can be made by local study participants or others.
2. Provide the names and addresses to the Institution of A's IRB Office of local contact persons who have authority to accept a facilitated review and/or correspond on behalf of Institution B (e.g. the local IRB Manager or Chair).
3. Establish and follow a written procedure for performing facilitated review.
4. Maintain records for each study that Institution B is engaged in and relying on Institution A's IRB approval and oversite for.
5. Maintain a human subjects protection program complaint with 45 CFR 46 and 21 CFR 56 – including an OHRP-approved Assurance for human subjects research and if applicable, an OHRP IRB registration number.
6. Maintain compliance with its own state, local, or institutional requirements related to the protection of human subjects.

Further Delineation by Topic

A. **Assent (for studies involving children)** – Institution A's IRB will make the determination whether assent of the child is required. Whether and how to document assent is the purview of the local institution (Institution B).

B. **HIPAA** – Compliance with HIPAA regulations are considered local context issues and remain the purview of the local institution (Institution B) and its local IRB or Privacy Board.

C. **Incompetent Adults** – Institution A's IRB determines whether 'individuals with impaired decision making capacity' as a category are eligible for a study. The local institution (Institution B) must follow state law and its institutional policy regarding the authority of legal guardians to consent to research, as well as documentation of proxy consents.

D. **Informed Consent Document** – As part of facilitated review, the local institution (Institution B) may:

- Add local boilerplate additions to the informed consent document to comply with its state or local laws, institutional requirements, or IRB policies and
- Make minor word substitutions or additions in the informed consent document to facilitate better comprehension by the local population as long as the proposed changes do not alter the meaning of Institution A's IRB approved contents. The informed consent text may not be otherwise deleted or contradicted.

Revisions/changes to the informed consent document other than those described above require full Board review at the local level (by Institution B's IRB), and facilitated review may not be used.

The translation of the informed consent document into languages other than English is the responsibility of the local institution.

E. **Prisoners** – If Institution A's IRB is not constituted to review studies eligible for prisoners, per 45 CFR 46 Subpart C, then it cannot be the IRB responsible for review if Institution B wants to enroll a prisoner. Institution B will be responsible for obtaining adequate IRB review of the study with the inclusion /enrollment of prisoners as per Federal regulations.

F. **Serious Adverse Events** – Serious adverse events that occur at the local institution (Institution B) must be reported to the Institution B's local IRB as per local institutional policy and should not be reported to Institution A's IRB.

G. **Reporting Unanticipated Problems** – Unanticipated problems that occur at and are limited specifically to the local institution (Institution B) must be managed by the local institution. Institution B is responsible for managing these according to its FWA and institutional procedures. If Institution B's local IRB determines that an unexpected incident, event, or outcome meets the regulatory definition of unanticipated problem, it is Institution B's responsibility to report it to OHRP/FWA.