RESEARCH STUDY SUBMISSION CHECKLIST – Specific to Mercy College

Below is a checklist of the documents typically needed to submit a minimal risk study for expedited review with the IRB. You **must** submit a change in research to the IRB if you make any changes after the initial approval is granted. Any changes must be approved *prior to implementation*. There may be additional documents needed on a per study basis.

Every IRB submission will need:

- ☐ **Access to IRB Manager** (electronic submission of required documents to the IRB for review)
  - Submit the following items, for every member of their research team:
    - Initial Access Form for IRB Manager
    - CITI Training Certificate (Basic Researcher Course is completed/current -see separate CITI instructions for new users)
    - Initial Training in Human Subjects Research Protection Statement
    - Signed PI/CO-I Agreement

    Students: must submit these documents to their Program Director, who will review and enter the information into IRB Manager.

    Mercy College Faculty: planning to conduct research, submit your forms directly to IRB@mercy.com
  - Once submitted, the IRB staff will grant access to IRB manager. All study team members will need to know their unique log in and password for IRB Manager. An email is sent to each member of the research team (from the IRB) containing the information.
  - Your IRB Application **will not move forward** if anyone on your team does not have current IRB manager standing. It is often better to remove a team member and add them later (after IRB approval is granted) when their documentation is in order. Otherwise, this could significantly delay IRB review.
- ☐ **Literature Search**
  - Request an IRB Literature Search from the library staff at library@mercycollege.edu, 419-251-1700.
  - Utilize these articles in the Background/Significance section of the protocol.
  - The Lit Search must be upload to IRB Manager in the literature search section of the application.
  - If the library did not complete a literature search, be prepared to provide this information in IRB Manager. Provide a detailed search strategy including date, topic, methods, sources, databases, years covered, keywords/subject headings, and when you conducted your own lit search.
- ☐ **Research Protocol**
  - Include all elements identified in the resources provided to you:
    - Elements of a Research Protocol
    - Research Protocol Template
    - May include a "not applicable" statement if a section does not apply to your study.
- ☐ **Initial review forms in IRB Manager**
  - Select the appropriate form to complete, for IRB review:
    - Expedited
    - Full board
    - Exempt- use the Exempt Determination Form
  - Principal Investigator (PI) electronic sign off in IRB Manager when the PI submits the form. If anyone submits on behalf of the PI, the application does not move forward until PI signs off.
  - Once the PI signs off, the rest of the research team will receive a financial disclosure to sign off.
  - The IRB application **will not move forward** for review until EVERYONE has signed off.

Original Research Checklist Prior to IRB Manager Submission J. Stausmire MSN, APRN.CNS Revised 12/3/2020

Adapted for use by Mercy College EBP/Research Committee 8/12/2021

Helpful Hints:

- ☐ Data elements must be consistent between the Protocol and Data Collection Tools.
  - If there are elements in one document that are not in the other, it will delay approval.
  - Use the same wording.
  - It is helpful if the list/tables in the protocol are in the same order as the data collection tools.
  - The data collection tools also need to match the database where the data will be recorded. Databases are not requested in IRB Manager.
  - Data elements need to be thought out and COMPLETE. Any changes after initial IRB approval, require a change in research form to be **submitted and approved by the IRB** prior to implementation.

Prospective studies will ALSO need:

- ☐ Informed consent
  - There are several types of informed consent options (depending on your type of research), it is best to consult IRB personnel prior to spending time on the wrong template.
  - If your study requires a written pediatric or adult consent you must use the Mercy template. Survey cover letter consents *may* be the only exception.
  - IRB will place an approval stamp on the bottom of the consent document, once approved. You can only use the approved consent form, that includes this IRB approval stamp.

- ☐ Prospective Data Collection Tool(s)
  - IRB will place an approval stamp on the bottom of the data collection tool, you can only collect data on copies of the tool(s) with the approval stamp.

Institutional Review Board IRB@mercy.com	**Physician Assistant Program** Dawn LaBarbera, PhD, PA-C Program Director, Physician Assistant (PA) Office Phone: (419)- 251-1538 Dawn.labarbera@mercycollege.edu **MSN Program** Deborah Karns, PhD, MSN, RN Program Director, Master of Science in Nursing (MSN) Office Phone: 419-251-1718 Deborah.karns@mercycollege.edu **MHA Program** Kimberly Watson, EdD., MBA, BS, RHIA Program Director, Master of Health Administration (MHA) Office Phone: 419-251-1852 Kim.watson@mercycollege.edu **EBP/Research Committee Chair** Dawn Borgerson, MSN, RN, CCRP Office Phone: (419) 251-1305 Dawn.borgerson@mercycollege.edu

Original Research Checklist Prior to IRB Manager Submission J. Stausmire MSN, APRN.CNS Revised 12/3/2020

Adapted for use by Mercy College EBP/Research Committee 8/12/2021