EmPOWR Research Oversight Committee

I. Overview & Responsibilities

- The Oversight Committee (OC) will be made up of the two Principal Investigators (PIs) as well as other scientists and clinicians (5-7 members).
    - Members will be invited to join by the PIs and appointed for a 2-year term.
    - Members should reflect the scientific, medical, and ethical expertise necessary to perform a thorough review.
    - The OC will include at least one member outside of the Gynecology & Obstetrics Department.
    - The OC may also include a patient or community member.
- Duties include:
    A. Overseeing the operations of the EmPOWR registry & repository.
    B. Regulating access to health information and biospecimens from the registry & repository by reviewing requests from researchers and either approving it, requesting modifications, or denying it.
    C. Reviewing and approving new recruitment materials, SOPs, and updated versions of the protocol or informed consent documents.
    D. Updating policies concerning the storage of health information in the registry and biospecimens in the repository.
    E. Creating and implementing a plan of action if there is a protocol deviation or incidental finding.
    F. Business and cost planning, including assessment of need for equipment and supplies.
    G. Tracking the status and progress of approved research plans, as well as reviewing all abstracts and papers that use data/samples from the EmPOWR registry & repository before they are published.
- The OC will meet on a monthly basis to review all pending access requests and any new study materials. The OC should also review the current functionality of the registry & repository to determine if any policies should be amended.

II. Submission for access to Registry & Repository

- Researchers who request access to data/samples from the registry & repository must submit to the OC:
    1. Letter of intent (LOI) documenting the objectives of the study and variables to be requested. The goal of this LOI is to ensure that the proposed research is sufficiently independent of other approved research proposals. This document must be reviewed and approved by the OC prior to application for IRB approval and completion of the research application.
    2. Full research application, which includes the EmPOWR application form, requested registry fields, IRB Approval Letter (if requesting PHI), and IRB Approved Study Protocol (if requesting PHI).
- When making a decision about whether to grant access to researchers who apply for data/samples, OC members will consider several things:
    - Is the research important for the field?

- Are the overall strategy, methodology, and analyses appropriate for the research question?
- If applicable, does the repository have enough samples to honor the request?
- Is it necessary to contact participants for additional information or samples?
- Will data be shared with other institutions?
- Do the researchers or OC members have any conflicts of interest?