SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS & GYNECOLOGY

STANDARD OPERATING PROCEDURE- POLICY

DEPARTMENT RESEARCH SUPPORT FOR LEARNERS

SCOPE/APPLICABILITY:
Applies to OB/GYN Residents, Fellows & Mentors

POLICY STATEMENT:
To describe department support for learners and mentors in their research (including submissions to the Institutional Review Board (IRB))

PURPOSE:
The OB-GYN Department is committed to supporting learners and faculty in professional development relative to research. We are fortunate to have a dedicated, knowledgeable support team. This SOP outlines procedures to ensure learners/faculty have support, guidance and appropriately utilize our research resources as well as learn the important processes of research.

PROCEDURES:
Use Department Research Start-Up checklist to ensure all required trainings are complete (CITI, GCP, HSC FCOI, ERA COI disclosures, Huron IRB)

Expectations of Learners (Learners are usually ineligible to be IRB PI)/Research Faculty Mentors (including IRB PI)

- Review project with mentor.
- Complete IRB submission with Mentor and Clinical Research Manager (CRM) support - https://hsc.unm.edu/research/hrpo/ - See link to Huron IRB and Form Library within Huron IRB
    - Contact CRM four weeks prior to planned submission to discuss project type and determine which IRB templates to use
    - Meet with biostatistician prior to IRB submission and as necessary (see OB/GYN Wiki on how to schedule appointments, etc.)
    - Once the Learners have completed the research protocol and participant consent templates, data collection forms & advertisements, these forms should then be sent to the Mentor and CRM for review and feedback.
    - Add study team members (all are required to complete necessary training prior to their addition)
        - Study team members usually include the learner, the Faculty Research Mentor(s) (including the PI of record for the IRB), biostatistician and other investigators as appropriate
        - Study team members may include members of the research staff; please discuss this with the CRM prior to submission
    - Email Department Scientific Review form with protocol to OB/GYN Vice Chair of Research (or their designee) for review and signature. Allow 1-2 weeks turn around prior to IRB submission

    - Upload final documents to Huron IRB (including PI's CV) and submit
    - Ensure all study team members complete their COI
    - Respond to clarifications from IRB. CRM is available for advice for clarifications or other changes requested by the IRB.
- Collect data once approved following Good Clinical Practices with study documentation (ask CRM)
- Coordinate and/or lead research meetings with research team members regularly (at least monthly is recommended during the study design period and then as needed as determined by the research team).
- If participants are given compensation, maintain receipts documenting payment/receipt of merchandise cards as appropriate
- Complete all necessary IRB modifications (amend documents, add/remove study team members)
- NOTIFY the CRM when trainees have done the following (as the CRM needs to approve trainees' work):
    - Complete continuing review (annually) for the IRB. Note that "Exempt" projects do not require a Continuing Review
    - Complete abstract/publication. The usual expectation is that the work will be presented at a regional or national meeting AND/OR be published in a peer-reviewed journal.
    - Continuously prepare for potential IRB audits by keeping documentation in order and accessible (discuss record keeping with CRM)
    - Close study and ensure study documents are archived per protocol
- If study remains open, ensure the Research Mentor(s), including the IRB PI of record, are aware of location of all study documents in case of an audit and for destruction at the end of the retention period

Expectations of Research Mentors, including the IRB PI of record

- Aid with the development of and give meaningful guidance on the design of the research project
- Develop timeline of tasks for the research learner (mentee)
- Follow up by phone, email, digitally or in person at least quarterly with all trainee mentees
- If learners do not respond to requests for information on the research project from research staff and/or the Department leadership, the mentor(s) will be contacted
    - Fellows as mentors have the same responsibilities as noted above; however, Attending Research Mentors should be notified regarding all aspects of the research project as they are the PI of record and should be actively involved in these projects.
- If learner is unable to complete any of their responsibilities as listed above, it is the expectation that the mentor(s) will complete the tasks (with assistance from CRM, see below)
- Help learner respond to clarifications from IRB

- Help with the writing and editing of abstract & presentation and ensure the final product is completed and submitted
- Be aware of study status (open or closed) and complete IRB tasks such as continuing reviews if learner has graduated.
- Know where the study documentation is housed for retention, destruction and audit purposes

Expectations of Department Clinical Research Manager

- Help determine what kind of study submission and which templates need to be used
- Guide researcher through process and answer questions as needed
- Assist with submission in Huron IRB as needed
- Review documents and give feedback before submitting to IRB
- Review Good Clinical Practices with Learners/Research Mentors as appropriate

IF FUNDING IS AVAILABLE: Expectations of Department Clinical Research Supervisor & Research Coordinators
(IF there is NOT funding, these responsibilities fall to the Learners with Mentor(s) Supervision)

- Provide feedback during study set-up
- Meet with learner and mentor on a regular basis
- Facilitate administration of study questionnaires, interviews and focus groups
- Schedule appointments and communicate reminders to participants
- Assist with IRB Continuing Reviews
- Assist with sponsor report requests
- Assist in miscellaneous tasks as required

APPROVALS:

SOP Owner:	Karen Taylor	Date:
Chair Approval:		Date: 2/8/2021
Effective Date:		