CWRH Regulatory Support

UAB MEDICINE
OBSTETRICS & GYNECOLOGY
CENTER FOR WOMEN'S REPRODUCTIVE HEALTH

11/2022

Agenda

1. Overview of CWRH Regulatory Support
   - CWRH Members and ObGyn Department
   - Faculty
   - Fellows and Residents
2. Requesting Support
3. Responsibilities of PI
4. Future Plans for Support
5. Contacts

Support of CWRH Members and ObGyn Department

- **Maintenance of regulatory files of all research submissions**
- **Twice a year reminders (January and July) to faculty/staff to update IRB and GCP training, to ensure that no lapse in training occurs.**
  - cIRB disclosures will be requested on an ongoing basis
- **Provide updated IRB information as related to policy/procedure changes to faculty and staff**

Support of Faculty

- **With active input and review by faculty PI:**
  - Prepare draft IRB and WCG regulatory submissions of initial research applications, amendments and continuing renewals
  - Assist with development of study-related documents such as informed consent
  - Finalize regulatory documents, route for signatures, and submit in Integrated Research Administration Portal (IRAP)
  - Revise Responsible Persons Lists, as necessary, for sponsored research

Support of Faculty continued

- ***With active input and review by faculty PI:***
  - Prepare Fiscal Approval Process (FAP) submissions as applicable, and submit to Clinical Billing Review
  - Upon receipt of IRB reviews, prepare responses for review and input by PI, route finalized documents for signature, and submit in IRAP
  - Assist research staff with initial IMPACT access as well as assisting with regaining access when interrupted due to nearing expiration of IRB approval (staff access often interrupted well before IRB expiration date)
  - Yearly reporting of numbers of each type of IRB submission

Support of Residents and Fellows

- **As preparation of an IRB is considered part of resident/fellow education, it is expected that each be fully involved in preparation of the IRB for their research projects. The following support will be provided:**
  - Once an application is completed in iRAP, request review by CWRH. After review, CWRH will advise the resident/fellow of any edits needed and to obtain signatures on any forms required to accompany submission.
  - Upon receipt of IRB reviews, provide advice and guidance for IRB response.
  - Assist with IRB continuing renewals.

Requesting Support

- **Requests for Regulatory Support should be made via the CWRH webpage (https://redcap.link/dyx5wxlt)**
- **An acknowledgement email will be sent to the submitter within 2 weeks of receipt of the request and including an estimated timeline for review.**
- **Requests will be processed as they are received by CWRH. However, funded projects will be prioritized.**
  - Requests related to grant applications should be submitted when there is evidence that the grant will be funded (e.g., notice of award, official *(not automated)* Just In Time request, or score that is certain to be funded).
  - CWRH leadership will assist with additional prioritization if needed.

Requesting Support (continued)

- Requests for initial full applications must be made well in advance of expected start date, as those submissions can take 8 weeks for approval once submitted. In general, submit request 4-6 months in advance of anticipated start date.
- Amendment approvals can take up to 2-3 weeks, depending on the level of approval needed. Therefore those requests should be planned and submitted to CWRH accordingly. In general, this should be initiated 2-3 months in advance of anticipated amendment.

Responsibilities of the PI

- **To keep submissions moving forward, PI will provide timely response to requests for information from CWRH IRB office regarding their submission**
  - If a response is not received within 2-3 weeks, a second email will be sent. If no response is received after a second request, CWRH leadership will be asked to provide guidance.
- **Ensure research team is up to date on IRB training prior to study initiation**
- **PI or designee will submit the following to the CWRH regulatory office for submission to the IRB as applicable: AEs, SAEs (within 24 hours of knowledge), protocol deviations/violations (within 5 business days), DSMB reports, monitoring visit reports, and FDA reports**

Future Plans for Support

- **Periodic ongoing QC audit of consent documents**
  - IRB office will determine the schedule of studies to receive audits
  - Audits will begin 6 months after study start
  - Study Coordinators will participate in implementing audits

Contacts

- **Contact Lisa Cagle with any questions (ldimperio@uabmc.edu)**
- **Link to IRB guide document:**

  https://www.uab.edu/research/home/irb-guidebook-for-investigators

Questions

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THANKS!!

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