CWRH Regulatory Support

January 10, 2019

Regulatory Support at CWRH for all 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
- Provides updated IRB information as related to policy/procedure changes to faculty and staff

Regulatory Support at CWRH for Faculty

With active input and review by faculty PI:

- Prepare draft IRB and WIRB 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

Regulatory Support at CWRH for Faculty (cont'd)

- 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
- Assists research staff with initial IMPACT access as well assisting with regain of 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

Regulatory Support at CWRH for Fellows and Residents

As preparation of an IRB is considered part of your education, it is expected that fellows and residents should be fully involved in preparation of the IRB for their research projects. The following support will be provided:

- Generic draft forms for retrospective cohort studies, prospective cohort studies, and IRB exempt studies:
  - These forms will contain standard language typically used for these studies (as well as common supplementary forms needed to go along with the HSP). Areas that require completion will be highlighted. Forms will be accessed on the CWRH Web Page for Members Only (insert link here)

Regulatory Support at CWRH for Fellows and Residents (cont'd)

- Draft forms for amendments will also be available.
- Completed forms will be sent to CWRH for review. After review, they will be sent to the resident/fellow with any changes and to obtain signatures.
- The signed forms will be returned to CWRH for IRAP submission.
- Upon receipt of IRB reviews, provide advice and guidance for IRB response.
- Assistance with IRB continuing renewals

How to request Regulatory Support from CWRH

- Requests for Regulatory Support can be made at the CWRH web page (insert web page)
- An acknowledgement email will be sent to the submitter within 2 weeks of request receipt, with an estimated timeline for review.
- Requests for support will be processed as they are received by CWRH. However, funded projects will be prioritized. Requests for projects related to grant applications should be submitted when there is evidence that the grant will be funded (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)

How to request Regulatory Support from CWRH (cont'd)

- 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 a 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.

CWRH contacts

- For additional questions about CWRH resources, please contact Dr. Lorie Harper (lmharper@uabmc.edu)
- For additional IRB questions, please contact Lisa Dimperio (ldimperio@uabmc.edu)