

Process for Study Activation on CRU:

1. Submit a CRU Consult Request to formally request CRU staff review study protocol and initiate a feasibility review.

- This should be submitted at least **one month** before you submit your IRB application and for UWCCC, this should be submitted at least 1 week prior to requesting OnCore sign-off.
- Requests for feasibility reviews or Ancillary Service Report reviews will not be accepted until a CRU Consult has been submitted.
- There is no charge for this service. Charges only apply to industry studies upon submission of a CRU Application.

2. CRU will schedule and facilitate a consult meeting.

- At the consult meeting, CRU will review proposed CRU visits and protocol activities.
- The consult meeting will also assist you in identifying other items that may affect the budgeting process.

3. Study team is responsible to develop a study budget based on the study protocol and lab manual.

- Refer to the CRU Budgeting Toolkit to assist you in selecting the correct CRU visit charge(s) and applicable UW Health injection/infusion charges when developing your study budget.
- For new industry-sponsored studies only:
 - Please make sure to include the CRU Proposal Review and Implementation fee in your budget. This fee will be assessed against study accounts upon CRU protocol approval.
 - The CRU also assesses fees for amendments, or for rush implementation of study or amendment initiation.
 - Refer to the CRU Fees for Industry Funded Studies document for additional details.

4. Submit CRU Application.

- Your application will be reviewed by the CRU Protocol Implementation Review (PIR) Committee to confirm feasibility and CRU support. When approved, a Notice of Award is issued.
- The CRU Application should be submitted at least one month after the CRU Consult meeting; preferably prior to obtaining IRB approval.
 - For Applications reviewed by the UW HS- or MRR-IRBs:
 - In the Scientific Review section in ARROW, indicate the study will use the Clinical Research Unit and upload the CRU Application under the Supplemental Information section.
 - Your application will automatically forward to CRU's PIR Committee for review.
 - For Applications submitted to an external/ceded (non-UW Madison) IRB (e.g., Western IRB/WCG, Advarra, NCI CIRB, etc.):
 - Please indicate in the Scientific Review section that the study will use the UW Clinical Research Unit.

- Please submit electronic copies of application materials described below to the CRU Protocol Team group email (cruprotocolteam@uwhealth.org) & Danielle Gale (dgale@uwhealth.org).
- Application materials to include:
 - CRU Application (signed)
 - The most current sponsor protocol/grant application. (If you need to create a protocol document, it should follow the [HS-IRB's Protocol Guidelines](#).)
 - Draft Consent Form(s), Assent(s), Study Summary/Information Sheet(s), and HIPAA authorization form(s) as applicable.
 - Data Monitoring Committee Charter, if applicable
 - Investigational Drug Brochure(s), if applicable
 - Patient drug diaries, if applicable
 - Pharmacy Manual, if applicable
 - Other materials the applicant believes are pertinent for CRU review
 - If this is the Principal Investigator's first CRU application, also include a Biosketch (preferred) or Curriculum Vitae (CV)
- If Notice of Action received from PIR Committee, follow instructions provided in the notice and submit responses promptly to prevent delays.
- Once approved by the CRU PIR Committee, you will receive a Notice of Award.

5. Continue collaborating with the CRU protocol team lead to facilitate operationalization of the protocol on CRU.

6. Once all CRU procedures have been clarified, CRU documents and provider orders approved, staff training (if needed) has been completed, IRB approval and study registration / SMPH sign off is complete, the CRU Reservation form will be released and you can begin scheduling participant visits on the CRU.

7. Please refer to CRU Guidance for Study Implementation for additional details and an outline of study team and CRU responsibilities.