UW - Clinical Research Unit (CRU) Process

CRU Main Page: https://ictr.wisc.edu/groups/clinical-research-unit-cru/

STEP 1: Submit CRU Consult Request (Online)
- PURPOSE: To formally request CRU staff to review study protocol.
- If UWCCC project, submit at least 1 week prior to any request for UWCCC OnCore sign-off.
- See https://ictr.wisc.edu/consults/cru-consult-request

STEP 2: Schedule a Consult Meeting*
- PURPOSE: To review protocol activities expected to take place on the CRU.
- Assists you in identifying the CRU procedures and other items that may affect the budgeting process.
- Obtain/share information on areas of the protocol that may require additional information or clarification.
- Facilitates CRU approval process.

STEP 3: Obtain CRU Approval. Submit CRU Application (Online and Paper documents required to CRU)
- PURPOSE: To request the CRU Protocol Implementation Review (PIR) Committee evaluate your application for approval of CRU support.
- See https://ictr.wisc.edu/guides/cru-protocol-application NOTE: Physicians Orders are no longer required with application.
- Submitted as part of the IRB application or directly to CRU in advance of formal submission to WIRB.

Meeting of CRU Protocol Implementation Review (PIR) Committee
- Consists of staff from ICTR administration, CRU (administration, clinical staff, dietitian Medical Director, Research Subject Advocate) and UWHC [Pharmaceutical Research Center (PRC), UWHC Lab personnel and Research Subject Advocates.
- Meets to review and approve protocol for CRU feasibility. CRU PIR Committee sends Notice of Action to study PI/Team.

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- CRU Notice of Action either approves the study to take place on the CRU and describes award details OR requests additional information needed for approval.

If the Notice of Action from the PIR Committee requests additional information, follow instructions provided in the notice to submit responses to prevent delay in notice of the award.

STEP 4: Schedule a Protocol Initiation Meeting*
- PURPOSE: To discuss details of how to successfully conduct your study on the CRU and develop a plan for implementation.
- Meet within 2 weeks of CRU approval, as directed in the CRU Notice of Action.
- Additional information to support protocol activities and subject safety will be discussed.

STEP 5: Ongoing Collaboration:
- PURPOSE: To execute the plan developed in the previous meetings and keep processes moving forward to achieve successful study activation that preserves protocol integrity, quality data collection, and subject safety.
- ***It is at this point the CRU staff begins to work on the CRU documentation and preparations for implementation of your study on the unit.***

STEP 6: Schedule a Pre-Study Activation Meeting*
- PURPOSE: To finalize preparations for implementation of your study on the CRU.
- Scheduled in advance of study activation to allow time to discuss any changes or last minute details to assure successful implementation.
- Verification/confirmation of the following:
  - Orders without edits; Health Link Access; Lab kits and processing details; CRU forms including flow sheets, Monograph, HFFY and Lab Set Up; Study Readiness sign off.
- Review CRU procedures for:
  - Making and changing reservations; checking lab samples out; documenting delivery of physician orders, consents and lab supplies.

A study-specific Reservation Form is released when all is in place for implementation of study on CRU, and all required UWHC study registration processes are complete.

*CRU meetings mentioned are to be "stand-alone" meetings, not incorporated with site initiation, multidisciplinary team meetings, etc.