UW ICTR

CLINICAL RESEARCH UNIT (CRU) Guidance Document for Study Implementation

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CRU is a core area of the UW-Madison Institute for Clinical and Translational Research (ICTR), funded by an NIH grant.

While every effort has been taken to include as much detail as possible, processes change and adapt both inside and outside the CRU and as such, this document must be used as direction only.

A. BUDGET DEVELOPMENT/GUIDANCE		
Purpose	**Study Team Responsibilities**	**CRU Responsibilities**
To clarify and identify services/procedures provided by the CRU for budget development.	• Submit CRU Online Consult at https://ictr.wisc.edu/cru_consult prior to contacting the CRU for budget guidance. • Develop study budget based on protocol and lab manual. For CRU charges, refer to CRU Charge Guidance document • When calculating CRU hours for subjects, realistic hours include time for resulting labs and drug preparation/delivery. (For example, standard turnaround time for routine medication orders by UWHC Pharmacy is ~2 hours.) • Submit budget in OnCore. Ancillary Services Report (ASR) will subsequently be distributed for review by CRU Protocol Manager and other UWHC areas. • Provide sufficient information and/or documentation in the ASR for an accurate review. • Revise budget in OnCore as changes occur, and inform CRU of changes. • Notify CRU Protocol Manager when approved budget is available in WISDM (if an industry study). • Complete Study Registration/SMPH Review Process. The study's IRB number will then be available in Health Link, which enables CRU to schedule a visit/admission.	• Provide clarification regarding CRU procedures that may impact budgets. • Answer questions related to CRU charges. Note: Actual specimen processing charges cannot be determined without accurate lab manual and lab kits. • CRU Protocol Manager will review CRU charges provided in the Ancillary Services Report (received by email from OCT). • The Protocol Manager will email the study coordinator that no changes are necessary or ask for clarification of remaining changes/questions. • Prepare billing slip for internal use by CRU.

Step/Purpose	Study Team Responsibilities	CRU Responsibilities
1. CRU Consult Request • To initiate CRU feasibility review. • To facilitate formal review by Protocol Implementation Review Committee (PIR).	• https://ictr.wisc.edu/cru_consult • Complete the online CRU Consult and attach protocol. • If an UWCCC project, submit at time of Collaborator Signoff request.	• Upon receipt of the consult request, the CRU will contact the study team to arrange consult meeting. • Review protocol for feasibility and identify potential issues prior to formal CRU application.
2. Consult Meeting • To review proposed CRU protocol activities. • To facilitate formal CRU PIR approval process.	• Review protocol prior to meeting • In advance of the consult meeting, provide outline of individual visits and associated procedures to be conducted on the CRU (or bring to meeting if unavailable prior to meeting). • Identify anticipated responsibilities of CRU staff, room usage and required equipment use. • Inquire about CRU procedures that may affect feasibility or budget development**.**	• Review Consult Meeting Agenda with study team. • Answer study team questions related to CRU activities that may impact the budget. • Obtain additional information and clarification from study team regarding protocol activities. • Provide study team with CRU requirements. • Answer questions on applicable hospital policies.
3. CRU Application Submission, Review and Approval • To request and receive formal approval for CRU support, to be determined by the CRU Protocol Implementation Review (PIR) Committee.	• https://ictr.wisc.edu/ProtocolReviewProcess • Submit a CRU application (uploaded to ARROW when using HS-IRB or submit directly to CRU if using WIRB). • See above website for application document and detailed instructions on how to submit an application (ARROW or WIRB), and to obtain meeting dates/deadlines. • To prevent delay in the award, submit written response to any CRU PIR Committee concerns as soon as possible. • When CRU Notice of Approval (NOA) is received, review the award for information on the number of subjects, inpatient days/outpatient visits, specific study visits that are approved.	• Convene PIR Committee to determine if study can be supported by CRU. • Provide communication to the study team identifying items needing attention and questions from the committee. • Once committee concerns have been satisfied, send CRU Notice of Approval (NOA) memo to study team (uploaded in ARROW, or sent by email if a WIRB application).
4. Protocol Initiation Meeting • To discuss details regarding study protocol and develop CRU implementation plan. • To initiate development of CRU documents (see list on Page 5).	• Contact CRU to set up meeting as directed in CRU Notice of Approval. • Provide CRU most recent or pending versions of the protocol and guidance documents (e.g. lab/procedure manuals, sponsor equipment, kits) prior to the meeting. • Discuss any questions or concerns regarding implementation of the study on CRU.	• Review most recent version of protocol and associated documents provided. • Prepare meeting agenda and request additional information to conduct or support protocol activities and subject safety. • Discuss questions or concerns regarding implementation of the study on CRU. • Begin development of CRU documents.

B. CRU PROTOCOL IMPLEMENTATION PROCESS (Continued)

Step/Purpose	Study Team Responsibilities	CRU Responsibilities
5. Ongoing Collaboration • To continue exchange of information and facilitate execution of the protocol.	• Exchange information as it becomes available to implement the protocol on CRU. • Provide CRU with most recent or pending versions of protocol and guidance documents (e.g. lab/procedure manuals, sponsor equipment, kits) as soon as they become available. • Periodically update the CRU on study status. • Develop physician orders. • Review CRU documents and compare flowsheets, orders and protocol to ensure they are consistent and meet study requirements.	• Develop CRU documents and forms from information provided from the study team. • Review and approve orders provided by study team. • Provide information for orders development as necessary.
6. Pre-Study Activation Meeting • To finalize preparations for implementation of study.	• Schedule meeting with adequate lead time to discuss changes and implement last minute details. • Ensure meeting is attended by appropriate study personnel.	• Review CRU procedures with study team (e.g. how to make, change, or cancel reservations; check out lab samples; document delivery of physician orders, consents and lab supplies). • Answer remaining question prior to study start date. • Ensure all staff training is completed prior to study activation.
7. Release of Reservation Form(s) • To provide process for study team to communicate reservations request.	• Use the Reservation Form to request visits and admissions listed on the form (additional visits/admissions cannot be added without PIR approval. • Modifications to the reservation form may not be made by the study team. • See Section C. CRU Documents.	• Release form(s) to study team when all implementation and administrative requirements have been met (including, but not limited to, physician orders and CRU flowsheets approved, IRB/WIRB approval, CRU staff training, specimen processing instructions finalized, UWHC study registration, etc.).

C. CRU DOCUMENTS: The following documents are essential to provide both quality study data for your protocol AND a safe environment for your research participants. Accurate documents are necessary to assure that CRU nurses have the information necessary to conduct your study and maintain fidelity to the research protocol.

Document/Purpose	Study Team Responsibilities	CRU Responsibilities
1. Flowsheets • To guide multiple CRU staff in precise documentation, data collection and activities scheduled for CRU inpatient days/outpatient visits. • To serve as a source document for Case Report Forms.	• Provide CRU with protocol, amendments, lab manuals and other guidance material for accurate development of CRU documents (e.g. flowsheets, HFFY, lab set up sheet). • As needed, contact sponsor and/or other sources to obtain/verify additional information for accurate implementation of the study. • Provide timely information to the CRU that may prompt a change in workflow, process, procedures, and/or documentation.	• Develop documents to guide CRU staff activities according to the research protocol and UW hospital requirements.
2. Monograph • To provide overview of the protocol for use by CRU staff and Research Subject Advocates (RSA).	• Same as Flowsheets (see above).	• Develop study overview document.
3. Health Facts for You (HFFY) • To fulfill UWHC policy requiring consistent discharge teaching information for the research participant.	• Provide information for the research participant on study team/PI/on-call MD's contact telephone numbers and paging information for both daytime and after-hours calls. • Same as Flowsheets (see above).	• Develop hospital-required form for subject discharge teaching to include study specific information regarding side effects, diet/activity restrictions, medications and who to call regarding research study questions.
4. Lab Set Up • To assist CRU staff in preparing for specimen collection and processing.	• Submit CRF (Case Report Form) if available, lab manual, and samples of each lab kit and sample collection/ processing supply, including packing slip to CRU. • Same as Flowsheets (see above).	• Develop instructions lab kits and specimen collection/processing / supplies for each visit and/or admission.
5. Study Readiness Sign Off Memo • To document approval of CRU documents for completeness and accuracy.	• Carefully review CRU Flowsheet(s), Health Facts for You (HFFY), Lab Set Up instructions and other CRU documents for accuracy, completeness and agreement with physician orders and protocol. • After reviewing, confirm agreement in writing (an email is sufficient) or provide edits.	• Upon completion of CRU document development, send copy of each document to the study team, along with the Study Readiness Sign-off Form. • If appropriate, send copies of documents to 3P and/or PRC.
6. Reservation Form • To communicate reservation request from the study team to the CRU. • Release of the reservation form is the final step in the CRU Implementation process.	• See Reservation Form section under Section B. CRU Protocol Implementation Process.	• Develop forms for CRU *approved* study visits/admissions. • See Release of Reservation Form(s) section under CRU Process.

D. PHYSICIAN ORDERS		
Purpose	**Study Team Responsibilities**	**CRU Responsibilities**
Physician orders are required to: • Legally delegate activities, within the scope of nursing practice, to the CRU nursing staff. • Ensure a safe process for communicating directives for patient care and research activities. • Support fidelity to the research protocol. Orders must meet requirements of UWHC Administrative Policy #8.16, Patient Care Orders.	• Develop orders that adhere to UWHC policies. • Ensure orders include collection and documentation of data required for study analysis. • Coordinate the review process with all departments (e.g. CRU protocol initiation staff, PRC, 3P, OPOC, radiology, dietitian). • Obtain PI review and approval. • Maintain and update orders when changes occur, including updating footers to correspond with the updated versions. (See Section E. Amendment Process). • Notify CRU and other departments of changes in sufficient time (preferably 2 weeks) to review and prepare for implementation of a change prior to “next” subject visit/admission. • Ensure all personnel have necessary electronic access (e.g. OnCore, Health Link and other security permissions.). Allow time for training required to obtain access.	• Review draft orders. • Approve draft orders and/or provide edits. • Educate PIs/teams on CRU requirements. • Implement orders provided.

E. NOTIFICATION OF CHANGES

Applies to Amendment/Change to the protocol and/or Informed Consent Form; change in laboratory or other protocol manuals; note-to file from sponsor; new document or change in existing documents; change in process; and/or any new information or changes.

Purpose	Study Team Responsibilities	CRU Responsibilities
• To communicate amendment detail that change how the study is conducted on the CRU. • To assure accurate directions are communicated to CRU staff. • To support safe patient care and fidelity to the research protocol.	• Notify CRU of anticipated changes. Please refer to CRU Notice of Approval (NOA) memo for process. • Prior to submission to IRB/WIRB, provide changes and/or amendments to the CRU by email (including expedited reviews). • Complete the CRU Change of Protocol Intake Form (received with CRU Notice of Approval) and email to the CRU Protocol Team at: cruprotocolteam@uwhealth.org. • If change affects the CRU award, submit a revised CRU Application to the CRU Protocol Manager. Please note: this includes change to study population, CRU procedures, number of subjects, days/visits, etc. • Changes may require a review by the CRU Protocol Implementation Review (PIR) Committee. • Allow two weeks for implementation to occur on the CRU. • Revise the budget in OnCore as necessary. • Notify the CRU when the changes are approved by UW IRBs, WIRB and/or sponsor. • Notify all service providers of the changes. Physician Orders: • If the Physician Orders (Health Link or Paper) require change, submit a draft of the changed orders to the CRU for review. • Following review and endorsement by CRU, obtain approval from the PI. • Provide a final “clean” copy of the approved orders to CRU or notify Health Link builders, as appropriate.	• Amend CRU documents and forms to reflect change(s) and obtain approval from the study team. (See Section C. CRU Documents). • After approval is received, provide final “clean” copy of CRU document(s) to the study team. • Educate CRU staff as required. • Notify study team when CRU is prepared to implement change(s). • Implement new procedures according to protocol and orders.

F. DEFINITIONS

- CRU – Clinical Research Unit.
- Notice of Approval (NOA) – A memo that provides detail of CRU support approved, conditions of this approval (if applicable); outlines the CRU patient award [total number of CRU subjects, inpatient days, outpatient visits, and specific study days/visits].
- PIR – Protocol Implementation Review. Members are the CRU Medical Director; staff from ICTR administration; CRU nursing, nutrition, administration and Research Subject Advocate (RSA); UWHC PRC manager and UWHC laboratory manager. Committee reviews all applications requesting CRU support and determines feasibility. If approved, an NOA is issued.
- OCT – Office of Clinical Trials.
- PRC– UWHC Pharmaceutical Research Center. The PRC reviews study feasibility, prepares budget estimates, and manages clinical research drug distribution. All clinical drug research protocols within UW Hospital and Clinics must be coordinated through the PRC.
- RSA – Research Subject Advocate. The CRU Research Subject Advocates (RSAs) review all protocol applications submitted to the CRU Protocol Implementation Review Committee to ensure that the study complies with the Health Sciences Institutional Review Board approval. The RSAs review all adverse event reports, unanticipated events, and protocol violations reported on CRU studies. Along with the CRU Nurse Manager, they also participate in daily "rounds" with CRU participants.