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### CLINICAL RESEARCH UNIT (CRU) APPLICATION

* **Refer to the *Tools and Resources* section of the main** [**CRU Research Unit webpage**](https://ictr.wisc.edu/program/clinical-research-unit/) **for guidance**

|  |  |
| --- | --- |
| **Full Study Title:**  **(please match IRB title)** |  |
| **Protocol Version/Date:** |  |
| **Principal Investigator(s):** |  |
| **Physician Responsible:** | ***(if PI is not a MD or does not have UW Health admitting privileges)*** |
| **Study Team Name**  **(if applicable):** |  |
| **Primary Contact:** |  |
| **Other Contacts (if applicable):** |  |
| **IRB/Regulatory Contact:** |  |

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| 1. | | **Disease description(s) and *ICD‑10‑CM* Diagnosis Code(s):** | | | | |
|  | |  | | | | |
| 2. | **Expected Study Start Date on CRU** (MM/DD/YY):  *(i.e., best guess of expected date of first visit on CRU)* | | | |  |
|  | Expected Study Duration on CRU (years): | | | |  |
| 3. | **Category**: | | | | |
|  | Not Industry  OR | | For non-industry studies, please check this box if there will be procedure charges billable to insurance as   routine care (e.g., chemotherapy or therapeutic drug infusions or injections)  -------------------------------------------------------------------------------------------------------------------------------------------------- | | |
|  | Industry | | If Industry, please check fee that applies: | | |
|  |  |  | $1,250 | [For studies that do NOT require the option of scheduling OSS Day or Outpatient Visit status within one study visit (example: Study Visit X will always be OSS Days and Study Visit Y will always be Outpatient Visits)] | |
|  |  |  | $1,500 | [For studies that DO require the option of scheduling subjects as OSS Day or Outpatient Visit within one study visit (example: Study Visit X could be either OSS or Outpatient Visit status based on study or subject needs) | |
|  |  |  | If Industry/Category D, please provide a back-up account/project number (e.g., discretionary research fund, PI start-up funds). *This account will be billed only if study budget is not finalized within* ***6 months*** *of CRU PIR review, or if study closes prior to an account number being established.* | | |
|  |  |  | Backup account number (required): | | |
| 4. | **IRB**: | | | | |
|  | UW HS-IRB  UW MRR-IRB  WCG\*  Advarra\*  NCI CIRB\*  Other Ceded\* (identify):  *\*Note: If a Ceded IRB is being used, the study team is responsible for forwarding all change of protocol submissions, approval notifications and approved documents to the CRU.* | | | | |

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| 5. | | **Research Participants and Visits**: | | | | | | | | | | | | | | | | | | | | | | | |
|  | | * Total # of Research Participants expected to be seen on CRU: | | | | | | | | | | | | |  | | | | | | | |
|  | | * Please list the specific Phases/Parts/Arms/Cohorts that you expect to implement on the CRU   (please do not indicate “All”): | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  | | * Overnight Admissions (UH only):  n/a | | | | | | | | | | | | | | | | |
|  | | # of Research Participants: | | | | | | |  | | |  | | | | | | | | | |
|  | | List the specific study days:  *(e.g., Visits 1-2, Days 1-2)*    *------------------------------------------* | | | | | | |  | | | | | | | | | | | | |
|  | | * Outpatient Visits (i.e., not overnight):  n/a | | | | | | | | | | | | | | | | | | | | | | | |
|  | | # of Research Participants: | | | | | | |  | | |  | | | | | | | | | |
|  | | # of visits per participant: | | | | | | |  | | |  | | | | | | | | | |
|  | | For Outpatient Visits, please list the specific study visits by site (UH or EMC) – indicate “n/a” if site is not applicable: *(Note: Request to use EMC should have occurred at time of Consult)* | | | | | | | | | | | | | | | | | | | |
|  | | UH: | |  | | | | | | | | | | | | | | | | | | | |
|  | | EMC: | |  | | | | | | | | | | | | | | | | | | | |
| 6. | | **CRU resources to be used** (check the services below that will be performed by CRU): | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Drug Administration | | | | | | ECGs on sponsor provided equipment | | | | | | | | | | | |
|  | | Blood Drawing | | | | | | Sample Processing *(Note: regulations prohibit CRU from shipping)* | | | | | | | | | | | |
|  | | Other (describe): | | | | |  | | | | | | | | |
|  | | Provide a **detailed description** of your need for our support (i.e., what is checked above) by OSS day/outpatient visit. Please be as specific as possible. (A separate attachment that includes this information is also acceptable. Links to Box cannot be accepted.) | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | |
| 7. | | **Room Usage Only UW Health ECG visits**   check if not applicable | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Please list any additional visits that require UH ECG services but *do not* require CRU nursing support. This includes a single ECG requiring ***> 5 minute*** rest period, or Duplicate/Triplicate ECGs. See [The Pulse link](https://pulse.uwhealth.org/esc?id=kb_article&sysparm_article=KB0052035) for details. | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | |
| 8. | | **Equipment Use on CRU** | | | | | | | | | | | | | | | | | | | | | |
|  | | * CRU Lab Equipment Usage (check all that apply): | | | | | | | | | | | | | | | | | | | | | |
|  | | | None | | | | Centrifuge | | | | -80°C freezer (A) | | | -20°C freezer (A) | | | | Refrigerator | | | |
|  | | | (A) Samples must be picked up at least every 2 weeks; more frequently if study collects a large number of samples; REMINDER: CRU is not involved with the packing and/or shipping of samples | | | | | | | | | | | | | | | | | | | | | |
|  | | | * Other CRU Equipment (check all that apply): | | | | | | | | | | | | | | | | | | | | | |
|  | | | None | | | | Telemetry (UH only) | | | | | Pulse Oximetry | | |  | | | |  | | | | | |
|  | | | * Non-CRU Equipment: Will your study be utilizing equipment on the CRU that you or the sponsor will provide? | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | Yes (if yes, describe):  No | | | | | | | | | | | | | | | | | | | |
|  | |  | | NOTE:   * Electrical equipment that is not UW Health equipment must be checked and approved by UW Health Clinical Engineering. * When not in use for a study visit, equipment must be stored off-unit. | | | | | | | | | | | | | | | | | | | |

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| 9. | | **CRU Research Subject Advocate** (RSA): | | | | | | | | |
|  | | *The CRU RSA reviews all applications submitted to the CRU Protocol Implementation Review group for safety. The CRU Nurse Manager also does check-ins with CRU participants to gauge their understanding of the study.* | | | | | | | | |
|  | | * Who will conduct protocol compliance checks and data accuracy reviews? | | | | | | | | |
|  | | UW-Madison staff member (provide all information requested below)  Staff member from Sponsor/Lead Site  (identify an individual, if possible; otherwise, the Local Contact will be asked to forward any communication)  No one will be performing these functions | | | | | | | | |
|  | | | Name: |  | | | Title: | |  | |
|  | | | Phone: |  | | | Email: | |  | |
|  | | | Affiliation/Department: | | |  | | | | |
|  | | | | | | | | | | |
| **Additional Information Required for ICTR reporting purposes:** | | | | | | | | | | |
| **FDA Applications:** | | | | | not applicable | | | | | |
|  | *Please provide the information you have available at time of CRU application:* | | | | | | | | | |
|  | Type: | | | | IND  BLA  NDA  ANDA  IDE | | | | | |
|  | Number(s): | | | | ( check if pending) | | |  | |  |
|  | Description:  (drug or device name) | | | |  | | | | | |
|  | Holder: | | | | Study PI (as listed above) | | |  | | |
|  |  | | | | Other Investigator (identify): | | |  | | |
|  | | | | Organization (identify): | | |  | | |
| Study is: | | | | | Single Center  Multi Center | | | | | |
| Clinical Trial Phase: | | | | | I  I-II  II  II-III  III  III-IV  IV  pilot  not applicable | | | | | |

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| **Funding:**  In the space below (or on a separate page if more than one funding source), list the funding source(s) that will support the proposed study. | | | | | | | | | |
| * Kind | | |  | | | | | | |
|  | | Non-Industry *(select one or more of the following, if study has multiple funding sources)*: | | | | | | |
|  | | Federal Government  check if subcontract (i.e., main grant is held by PI outside of UW) | | | | | | |
|  | |  | Agency:  PHS (NIH)  DOD  NSF  USDA  Other: | | | | | |
|  | | Foundation  Private or Volunteer Organization  UW-Madison (e.g., dept, start-up) | | | | | | |
|  | | Other: | | | |  | | |
|  | | Industry | | | | | | |
| * Organization Name: | | | | | | |  | | |
| * Funding PI: | | | | | | |  | | |
| *It is preferred (but not required) that the study has initiated budget review (i.e., has at least the “FP” number) before CRU submission. If you do not have complete information at the time of application please check “pending” and provide available information (e.g., “FP” or “AGR” number, Kind, Organization Name, Funding PI). The study team will need to provide complete information [i.e., “AWD” number or Fund-Project # (e.g., ABC1234)] to CRU prior to study initiation.* | | | | | | | | | |
| * If funded by Federal Government, provide Grant #: | | | | | | | | | |
| * If funded by a Federal Subcontract, Foundation/Private/UW/Other or Industry, provide one or more of the following: | | | | | | | | | |
| * FP, AGR or AWD Number (format: “FP”, “AGR” or “AWD” followed by 8 numbers):   N/A, FP number has not been assigned | | | | | | | | | |
| * Account Number (e.g., 133ABC1234): | | | | | | | | | |
| * Period of Support: | | | | | | | to | | |
| * Amount of Support: | | | | | | | $ | | |
| Please submit electronic copies of this CRU Application and other applicable materials described below by email to the CRU Protocol Team group email, [cruprotocolteam@uwhealth.org](mailto:cruprotocolteam@uwhealth.org) and Danielle Gale, [dgale@uwhealth.org](mailto:dgale@uwhealth.org).  *Submitted documents should NOT be password protected*.   Check all documents that are included:  (A) = document is required at time of submission: | | | | | | | | | |
|  | | Protocol (A) | | | | | | | |
|  | | Drafted UW Consent Form(s) (not Sponsor template) | | | | | | | |
|  | | Data Monitoring Committee Charter  N/A  not available at time of application | | | | | | | |
|  | | Data and Safety Monitoring Plan  N/A  not available at time of application | | | | | | | |
|  | | Investigational Drug Brochure(s)  N/A  not available at time of application | | | | | | | |
|  | | Pharmacy Manual (A)  N/A  not available at time of application | | | | | | | |
|  | | Patient drug diaries  N/A  not available at time of application | | | | | | | |
|  | | Lab Manual (A)  no sample processing, or sample processing will not occur on CRU  *(if processing is being done by CRU, a Lab Manual must be attached at time of submission)* | | | | | | | |
|  | | Other materials the applicant feels are pertinent for CRU review:  N/A | | | | | | | |
|  | | List: | | | | | | | |
|  | | If the PI is new to the CRU, please attach a biographical sketch (preferred) or a *Curriculum Vitae*.  N/A  (See <https://grants.nih.gov/grants/forms/biosketch.htm> for biographical sketch forms and instructions.) | | | | | | | |
| ***When submitting applications in ARROW, indicate in the Scientific Review section that the study will use the Clinical Research Unit.*** | | | | | | | | | |

If you have any questions about the CRU Application, please contact Danielle Gale ([dgale@uwhealth.org](mailto:dgale@uwhealth.org)).

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| ***TO BE COMPLETED BY PI* – PLEASE CONFIRM THAT YOU (THE PI) HAVE READ AND ACKNOWLEDGE THE FOLLOWING BY CHECKING THE BOX PRECEDING EACH STATEMENT (1-6 must be checked):**  **As Principal Investigator for this CRU Application, I agree or acknowledge the following:** | | | | |
| **1.** |  | **The PI is a physician** [**credentialed to practice at UW Health**](https://portalclient.echo-cloud.com/37007portal/privportal/msldir.asp?fac=UWHC) **OR** | | |
|  |  | **The PI is not a physician but has a responsible MD co-investigator identified** [**who is credentialed to practice at UW Health**](https://portalclient.echo-cloud.com/37007portal/privportal/msldir.asp?fac=UWHC) | | |
| **2.** |  | **Because the CRU is a UW Health unit, CRU subjects are required to have a Medical Record number** | | |
| **3.** |  | **Because the CRU is a UW Health unit, the use of OnCore is required.** | | |
| **4.** |  | **All UW Health policies will be followed** | | |
| **5.** |  | **The ICTR’s NIH/NCATS grant *UL1TR002373* will be cited on any resultant publications, regardless of the study’s funding source. (Please review** [**ICTR’s Funding Support page**](https://ictr.wisc.edu/about-ictr/our-supporters/) **for details.)** | | |
| **6.** |  | **A PMCID number will be applied for upon any publication acceptance** | | |
|  |  |  | | |
|  |  | **I have reviewed the completed application and take full responsibility for it.** | | |
|  |  |  |  |  |
|  |  | **PI Signature** |  | **Date** |