UCD CLINICAL RESEARCH CENTRE (CRC)

APPLICATION FORM

Notes:

* All investigators requesting access to and support from the UCD Clinical Research Centre are required to complete the Application Form for review by the CRC Operations Coordination Group.
* In addition to the completed form, investigators are also asked to submit:
  + Copy of full Study Protocol or Study Design
  + Copy of Ethics Approval for the study (or a letter stating approval is currently being sought)
  + Copy of HPRA Approval (if required)
  + Confirm study funding
  + For Industry Sponsored Studies, defined recharge rates apply. Details are available from the CRC Business Development Manager. These rates have been standardized across all sites and studies.

**Investigator Responsibilities:**

It is the responsibility of the investigator to work with the staff of the CRC to ensure that the research protocol evolves into a functional research study. To facilitate the smooth and proper flow of a research project in the CRC certain procedures must be followed. Time must be allowed for education of nursing, lab and other staff on the unique requirements of the study and will be determined by the CRC Research Coordinator.

**Before a research study begins in the CRC:**

Prior to study initiation and enrolment of study subjects in the CRC, the Study Team and Primary Investigator will meet with the CRC Nursing Staff who have been selected to work up the study. As part of this process, the CRC Nurse will develop a set of protocols ensuring that all CRC Clinical Research Nurses can implement the study in the same manner, ensuring data collection is consistent. The Principal Investigator is responsible for reviewing and approving the flow sheets before the subject visits begin. The CRC Nurse may also assist the study team in developing standards (orders) for study visits to the CRC, and will also help develop sample processing guidelines for the research samples collected during the CRC visits. An added benefit of this process is the review of the protocol by an experienced research nurse will help resolve potential issues affecting implementation. In some cases, the study staff may be invited to participate in in-service training the CRC staff on specific aspects of a study. The success or otherwise of a study may depend on co-operation in this regard and the collaboration of study staff will be required before study can begin.

CRC No. *(Office Use Only)*:

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| 1. **STUDY DETAILS:** | | | |
| **Study to be active at**:  *(tick all that apply)* | Mater Misericordiae University Hospital  St. Vincent’s University Hospital  National Maternity Hospital  National Rehabilation Hospital  Wexford General Hospital  St. Luke’s General Hospital (Kilkenny)  GP Network  Other : | | |
| **Protocol Title:**  *(The full title used in the Ethics Committee submission and the informed consent form title must exactly match the protocol title submitted to the CRC)* |  | | |
| **Principal Investigator:** |  | | |
| Address: |  | | |
| Phone: |  | | |
| Email: |  | | |
| **Co-Investigator(s):** |  | | |
| **Study Coordinator:** |  | | |
| Address: |  | | |
| Phone: |  | | |
| Email: |  | | |
| **Institution/Department:** |  | | |
| **Study Category:**  *(please tick one)* | Interventional Clinical Trial   * + EudraCT Number (if available):   + HPRA Approval Status**:**   Approved  Contingent Approval  Review Pending  Not Yet Submitted  Unknown  Observational Study  Biobank Study  Registry Study  Device Study  Other, specify: | | |
| **Study Origin:**  *(please tick one)* | Investigator-Initiated study  Industry-Initiated research  Name of Sponsor/Company: | | |
| **If this is an Interventional Clinical Trial and Investigator Initiated, please indicate if you are requesting UCD to act as Trial Sponsor:** | Yes  No, provide Name of Sponsor: | | |
| **Anticipated Start Date of Study:** |  | | |
| **Anticipated Stop Date of Study:** |  | | |
| **Total Number of Subjects to be Recruited (at Site):** |  | | |
| **Expected Number of Subjects Recruited per Year (at Site):** |  | | |
| 1. **FUNDING FOR THE STUDY:** | | | |
| **Type of Support:**  *(tick all that apply and provide details below)* | Public Agency  Industry  Charity  Other  None  **\***A copy of your financial contract/grant and a budget should be attached to this application. | | |
| **Name of Funding Agency/Agencies:** |  | | |
| **PI responsible for budget (at Site):** |  | | |
| **Total Amount:**  *(indicate currency)* |  | | |
| **Expected Funding Start Date:** |  | | |
| **Expected Funding Stop Date:** |  | | |
| **Provide short summary of tasks covered by funding:** |  | | |
| 1. **ETHICS COMMITTEE:** | | | |
| **Status:** | Ethics Approval Granted  *(Please attach copy of Ethics approval letter)*  Review Pending  Not Yet Submitted | | |
| **Ethics Committee Location(s):** |  | | |
| 1. **REQUEST FOR CRC RESOURCES:** | | | |
| **CRC Resources requested:**  *(Tick all that apply)* | Facilities for hosting CRC Outpatient Visits  **Research Nurse Support:**  Research Nurse Support (co-ordination of clinical research study including nursing support at study visits, sample collection/management, research data collection & entry)  **Laboratory Services:**  Core Laboratory Services  (Use of Abbott and/or Roche machines for automated biomarker testing or Quanterix platform for automated or manual ELISAs etc.)  Sample Processing Support  Sample Kit Preparation  Sample Storage/Biobanking  Laboratory Bench Space | Desk Space for Research Staff  Study/Protocol Design  Statistics Support/Analysis  Database Creation/Hosting  Support with Ethics Application(s)  **For UCD Sponsored Clinical Trials:**  Pharmacovigilance  Monitoring Services  Support with Regulatory Application(s) | |
| * 1. IF REQUESTING RESEARCH NURSE SUPPORT: | | | |
| Please describe briefly what research services are required for your study. Examples include urine collection, blood drawing, medication administration, special processing of samples, etc. (Also list any potential hazardous materials that may be used in this study, example: reagents for RNA stabilization of tissue samples, dry ice). An estimate of total nursing days should also be included. | | | |
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| * 1. **IF REQUESTING SPECIMEN PROCESSING/STORAGE:** | | | |
| **Specimens to be processed/stored:** | Blood  Serum/Plasma  Saliva  Urine  Spinal Fluid | | Bone Marrow  Temporary Storage  Dry Ice  Other (indicate below)  Pack & Ship |
| **Other Specimens:** |  | | |

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| * 1. IF REQUESTING LABORATORY SERVICES SUPPORT: | |
| Indicate which laboratory resources you are requesting. **Investigators are strongly advised to contact the CRC Scientific Services Manager during the development stage and prior to protocol submission.** | |
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| * 1. IF REQUESTING ANY OTHER CRC RESOURCE/SERVICE, PLEASE PROVIDE GENERAL SUMMARY OF REQUEST: | |
|  | |
| 1. **SIGNATURE:** | |
| **PI Name (printed name):** |  |
| **PI Title:** |  |
| **PI Signature:** |  |
| **Date:** |  |