Application form

For Ethical Approval of Research Involving Humans

Sultan Qaboos Comprehensive Cancer Centre, Sultanate of Oman

**Ethical approval must be obtained by all faculty, staff/students/residents prior to starting research with human subjects or human tissue**.

The ethical application for ethical approval form is divided into two parts:

**Part 1:** Statement of Research Ethics

**Part 2:** Outline of Proposed Research

The signed hardcopies of the Ethical Application Form and application checklist must be forwarded to the Ethics Committee Office and an electronic copy MUST be e-mailed to the email address below:

Email: mrec@cccrc.gov.om

**Failure to submit the electronic copy may result in the delay of the review process.**

|  |
| --- |
| **Part 1: Statements of Research Ethics** |

|  |
| --- |
| **SECTION 1 - PROJECT DETAILS** |
| Project title |  |
| **Principal Investigator:**  |
| (Only current SQCCCRC faculty and staff can be named as the Principal Investigator. This is the person to whom the ultimate responsibility for the project lies. If it is a student project, provide the student’s details under co-investigator) |
| Title and Name: |   |
| Staff ID: |       |
| Department: |        |
| Email: |        |
| Phone: |       |
| Co-principal Investigator |
| Title and Name: |        |
| Staff ID: |       |
| Department: |        |
| Email: |       |
| Phone: |       |
| Co-investigator 1 |
| Title and Name: |        |
| Staff ID: |        |
| Department: |        |
| Email: |        |
| Phone: |       |
| Co-investigator 2 |
| Title and Name: |        |
| Staff ID: |        |
| Department: |   |
| Email: |   |
| Phone: |        |

Additional list(s) of Co-investigators can be given in a separate page.

The research proposal and ethical application form is part for projects for:

 Faculty, staff at the Sultan Qaboos Comprehensive Cancer Centre

 External/Non-CCCRC application

 Students / residents

|  |
| --- |
| **SECTION 2 - PROJECT SUMMARY** |
| A plain English description of the project aims, (research methodology and outcomes) in no more than 100-150 words. |

|  |
| --- |
|  **SECTION 3 – FUNDING AND CONFLICT OF INTEREST**  |
| (i) Please state the sources of all funds to be used for this project, if any. |  |
|  |  |
|  (ii) Is this project part of a multi-centre research project? If YES, please provide copy of the ethical approval from the study centre. |  YES NO  |  |
|  |  |
| (iii) Conflict of Interest: Will you or any of the researchers receive any sort of remuneration or reward from non-University Sources for work done in this research. If YES, please provide necessary information. | YES NO  |  |
|  |  |
| **SECTION 4 – RISKS AND BENEFITS**  |

Provide sufficient information to enable the Committee to judge whether any risks to which the participants may be exposed are warranted by the possible benefits/outcomes of the study. How will the researcher deal with situations in which participants are identified to be at risk?

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 5 - CONSENT (Form should be in English and Arabic)** |

|  |
| --- |
| Describe how participants will consent to participate in the study, and how they will be informed of their rights. If consent form is not required, indicate the reason for why it is not required.  |

|  |
| --- |
| **SECTION 6 – CONFIDENTIALITY**  |

1. Please provide details of the storage and security arrangement(s) for the personal information that will be collected within the study to ensure confidentiality. Storage of the data is the responsibility of the principal investigator and he/she must describe how the patient identifiers (e.g. MRN), if needed, are kept and coded. Statement must also be provided on how data are transferred to external institute/agency.

|  |
| --- |
| **SECTION 7 – PROJECT MANAGEMENT** |

**Research timetable**

Please provide an overview of the research plan which includes specific milestones and deliverables.

**Research management arrangements**

Please explain the practical arrangements for managing the research and its constituent components

**Expected Output of Research/Impact**

Please describe how the outcomes of this research could be translated into the wider healthcare

community to provide improvements in service delivery, patient health and/or wellbeing at SQCCCRC.

**Success criteria and barriers to proposed work**

Please set out the measurements of success you intend to use and also the key risks to delivering this research

and what contingencies you will put in place to deal with them.

|  |
| --- |
| **SECTION 8 – METHODS OF DISSEMINATING THE FINDINGS OF THE RESEARCH** |

Please describe your plans for disseminating the findings of this research.

|  |
| --- |
| **Part 2: OUTLINE OF PROPOSED RESEARCH** |

|  |
| --- |
| OUTLINE OF PROPOSED RESEARCH |
| Proposed research outline must include a literature review, methods to be used; long and short term goals, protocol, and practical significance of outcome, exclusive plan and pertinent references. Maximum of 3 pages of at least 10 font size (Times Roman), single spaced.Introduction (Why is this research important in terms of improving the health of the public and/or patients)Aim of the Study Research Methodology Applicant must provide details on the study design & sampling strategies (cases & control), sample size, inclusion/exclusion criteria, use of invasive methods, and use of hospital diagnostic facility, recruitment of research assistant and payment, patient sample collections.References  |
| **Collaboration:**1. Are there any expected collaborative arrangements in this Research Project?
2. Name and address of the collaborating organization(s)/person(s):

|  |  |  |
| --- | --- | --- |
| **Name of collaborator** | **Name of the Organization** | **Address/email** |
|  |  |  |
|  |  |  |
|  |  |  |

 |
| Please provide details of the resources (including facilities, staff and equipment) that are required for conducting the research, and outline how the resource requirements will be met at the proposed University/hospital site. |
| Provide information to demonstrate that the researchers involved in the project have the necessary training, expertise and experience to carry out their role in the research. Provide necessary publications, if available.  |

|  |  |
| --- | --- |
|  |  **SECTION 9 - SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK** |
|  | Please set out the measurements of success you intend to use and also the key risks to delivering this researchand what contingencies you will put in place to deal with them. |
|  | **SECTION 10- INTELLECTUAL PROPERTY AND INNOVATION** |
|  | What relevant IP (patents, design right, copyright etc.) is held by the applicants and how does it relate to this application? Will any IP be produced or improved during the proposed research? |
|  | **SECTION 11 - SIGNATURES** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator |       | Date |       |
|  |
| Co-Principal Investigator |  | Date |       |
| Co-investigator |  | Date |       |
| Co-investigator |       | Date |       |
|  |
| Add more signatures as required. |

 |
|  |  |

|  |  |
| --- | --- |
|  | **SECTION 12 - CHECKLIST (a soft copy of checklist items must be submitted)**  |
|  | 1. Application form (Part 1 & 2).
2. Signature collected for all investigators.
3. Information sheet for Participants in English & Arabic, if applicable.
4. Consent form in English & Arabic, if applicable.
5. Questionnaires in English & Arabic, if applicable.
6. Good Clinical Practice Certificate for applicant and co-investigators (for interventional studies and clinical trials).
7. Impact analysis form for studies requiring clinical trials unit support (Appendix 1)
8. Electronic copy sent to the Secretary of the Ethics Committee - mrec@cccrc.gov.om
 |
|  | **SECTION 13 - DECISION / APPROVAL** |
|  | For Research Ethics Committee: Date of Meeting: Reviewed/Evaluated by: **Approved****Conditional Approval****Pending Approval** |

Dr. Khadra Ahmed J Galaal

Chairman, IRB & Ethics Committee

Sultan Qaboos Comprehensive Cancer Centre

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Appendix 1**

**CTD/Forms\_001 CTD Impact Analysis Form**

**Purpose:**

The purpose of this form is to determine the extent of utilization of clinical trials department services, resources and collaborative services when applying for a clinical trial starting at SQCCCRC. Information provided in this form will facilitate communication about potential studies. It will help determine any specific accommodation required to conduct the study.

***Name of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Name of person completing the form:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Contact Number:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Department/Disease Site:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Protocol Title:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions:**

* This form **must** be submitted to and approved by the CTD - prior to Institutional Review Board (IRB) application to determine the feasibility of the study in utilizing CTD services.
* An emailed response will be sent to the PI within 2 weeks of submission.
* Please indicate N/A for sections that do not apply to your clinical research study proposal.
* Completed forms are to be returned to Aida Al Kindy a.alkindy@cccrc.gov.om

|  |  |  |  |
| --- | --- | --- | --- |
| **Areas of Impact** |  | **Services needed**  |  |
| **Clinical Research nurse coordinator services**  | 1 | Review of protocol in relation to the various departments impacted at SQCCCRC.  | □ |
| 2 | Provide suggestions on feasibility and flow of clinical trial activities. |  |
| 3 | Support on site feasibility analysis questionnaire.  | □ |
| 4 | Support in Clinical Trials Agreement Review (Contracts) \*(All contracts have to go through Head of Clinical Trials Department (Dr. Munjid Al Harthy) review and legal department review and approval.  | □ |
| 5 | Billing sponsor for invoiceable items and follow up on payments.  | □ |
| 6 | Carrying out randomization and medication kit number dispensing for enrolled patients.  | □ |
| 7 | Data Management including data entry and queries resolution for clinical trials.  | □ |
| 8 | Screening potential patients for eligibility. | □ |
| 9 | Explaining the informed consent to patients in collaboration with PI.  | □ |
| **Area of Impact** |  | **Services Needed** |  |
| **Clinical Research nurse coordinator services (continued)**  | 10 | Filing and maintaining of regulatory documents including Investigator Site Files (ISF) and study participants files. (Including training logs, delegation logs, Investigator Brochures (IBs), newsletters and other regulatory documents required by sponsors)  | □ |
| 11 | Managing clinical trials patients including following up of their visits, booking appointments, seeing patients during their appointments. | □ |
| 12 | Implementing Nursing procedures: Vital signs, ECG, blood collection, patient assessments, administering research study questionnaires, etc.  | □ |
| 13 | Administration of investigational products by Research nurses. Please specify possible units. □ Clinical trial department □ DCU□ IPU/ ICU  | □ |
| 14 | Research Blood Sample Collection- pharmacokinetic samples, please specify frequency/ # of samples/ Cycles: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ |
| 15 | In-service education about the clinical trial for the nursing staff. (Other Staff education about the trial)  | □ |
| 16 | Coordination with radiologist / PI about tumor assessment using RECIST 1.1 or version specified in the protocol.  | □ |
| **Investigational Drug Pharmacy Services**  | 17 | Application for import permit from MOH. The principle investigator will provide the pharmacy director with all required details to communicate with MOH to obtain an import permit which will be followed by study sponsor. | □ |
| 18 | Receiving of Investigational Product | □ |
| 19 | Storage of Investigational Product(Please specify storage conditions and space requirements) | □ |
| 20 | Drug Preparation  | □ |
| 21 | Drug Dispensing frequency | □ |
| 22 | Education about IDP to patients or the staff  | □ |
| 23 | Drug Accountability and compliance  | □ |
| 24 | Assisting team in managing drug restock according to protocol. | □ |
| **Area of Impact** |  | **Services Needed** |  |
| **Correlative studies support from CTD in collaboration with Research lab and radiology (for trial activities after study activation).**   | 25 | Ordering supplies from sponsor  | □ |
| 26 | Development of study specific laboratory kits(Including ordering tubes, designing requisition forms and assembling kits) | □ |
| 27 | Storage of laboratory kits (CTD space utilization)  | □ |
| 28 | Request for archival samples (Internally or externally)  | □ |
| 29 | Arranging for biopsies to collect fresh sample. | □ |
| 30 | Coordinate with research lab for slides preparation.  | □ |
| 31 | Processing samples in the research lab or clinical lab if indicated.  | □ |
| 32 | Coordinate storage and shipment of samples  | □ |
| **Space utilization**  | 33 | Clinical Trials Unit beds needed Duration of stay: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Frequency of visit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Additional description:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ |
| 34 | Storage facility for clinical trial equipment, material or documents.Amount of space needed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Duration of storage required(years)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ |
| **Other services**  | 35 | Statistician support | □ |