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| --- |
| Initial Application for Clinical Research Form  Medical Research Center, HMC Doha-Qatar |
| Form used to obtain approval to conduct research and if required to submit a complete and comprehensive application for IRB review and approval to initiate research. |

**Application Forms must be submitted electronically. DO NOT PDF OR SCAN FORMS FOR SUBMISSION Save, Rename & Submit**

Rename the file with form name, a reference & version date  *i.e. New\_Protocol\_IQStudy\_07Jul15 i.e. ICF\_IQStudy\_07Jul15*

*The MRC or the IRB, as appropriate, will issue a study # after submission has been received*

**Form Completion Instructions:** Only shaded areas can be edited. These appear on the electronic form as shaded but not when printed. Where indicated: TICK BOXES to indicate an affirmative answer-place curser/pointer over box and click left button of mouse to “x” box to indicate response. TEXT FIELDS are blank and appear shaded; to fill out, type in response. There is a character max limit including, text fields have a 50 character or less limit unless otherwise indicated. DROP DOWN MENUS-use curser to “choose” highlight area, use mouse & click left-side button to open and make selection. Date format is d/mmm/yy. Ensure responses are provided for ALL FIELDS

**Date Form Completed:**

PROVIDE RESPONSE FOR ALL THAT APPLY BELOW *\* Give the best estimate for the following*  MRC USE ONLY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Planned Start Date\*: |  |  | Initial Approval Date: | *Pending* |
| Planned Enrollment End Date\*: |  |  | Date Approval Expires: | *Pending* |
| Planned Study End Date\*: |  |  |  |  |

**Section 1.0 Study Information**

1. Research Summary *Please provide a response for ALL that apply below*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Is the Proposed Study Original Research? *(Generating NEW data or source data that is NOT PRE-EXISTING)* | | | | | | | | | | | | Yes  No | | | |
| Type | |  | | | Phase | |  | | If Other: | |  | | | | |
|  | | | | | | | | | | | | | | | |
| MRC Study # | | | *Pending* | | | | | | | | | | |
| Protocol Title  *500 Character Limit* | | |  | | | | | | | | | | | |
| Principal Investigator\*  *200 Character Limit* | | |  | | | | | | | | | | | |
| Contact Information | | Phone |  | | | | Email | |  | | | |
| Mailing Address  *100 Character Limit* | |  | | | | | | | | | |
| Sponsored? | |  | | | Provide Detail: | | | | | | | | |
| Funded? | |  | | | Provide Detail: | | | | | | | | |
| **\*To Declare Roles & Responsibilities for this Research Study, Refer to the MRC’s ‘Scheme of Delegation List’ and submit with this application** | | | | | | | | | | | | | | | |

1. Research Abstract

|  |  |  |  |
| --- | --- | --- | --- |
| In the shaded area below, give a VERY BRIEF SUMMARY of the proposed research. DO NOT cut & paste aims, literature review, histories or background as to why the research is being conducted. DO NOT provide academic theory from a funding application or PhD dissertation. Leave all this content for the appropriate protocol section, in your attached PROTOCOL (Refer to the Protocol Template).  Describe **WHAT** the research question is, **WHAT** procedures are being done to answer that question & **WHO** it is doing it to, in 10 sentences or less.  Summarize the primary research objective including the planned enrollment, very basic INCLUSION CRITERIA, procedures, anticipated risks and safety concerns, and projected outcome(s) or if it is merely a data review (no enrollment of human beings). *2000 Character Limit* | | | |
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| 1. Anticipated Adverse Events/ Side Effects *(may continue on next page)*   In the shaded area below, provide a summary of the anticipated serious adverse side effects of the proposed research; Also include (and specify) probable risks anticipated with the inclusion criteria of subject enrollment (health status of participant, pre-existing conditions, etc) or anticipated risks/ outcomes related to standard of care procedures & treatments associated with participation in the research. This can be cut and paste from the research protocol, but should be a very clear outline and summary of the anticipated risk to subjects as a result to participation in the research. **NA IS NOT** a sufficient response for interventional studies. *No Character Limit* | | | |
|  |  |

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| 1. Investigator Comments – Statement of Purpose | | | | |
| In the shaded area below, provide a short statement to support why permission to conduct the proposed research should be granted. DO NOT provide academic, literature, or background from a funding application or PhD dissertation or repeat information in Abstract section above.  **NA IS NOT** a sufficient response. *1000 Character Limit* | | | |
|  |  |

**Section 2.0 Starting Point / Baseline**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Protocol | | | | |  |
| A protocol is essential for documenting and reporting the conduct of research. Under ICH GCP, the SCH requires the development of a clear, detailed, scientifically justified and ethically sound protocol that complies with requirements established by national and local laws and regulations, and undergoes scientific and ethical review prior to implementation; Indicate the name and version above. | | | | |
| **Protocol File Name / Title** *100 Character Limit* | | **Version** *30 Character Limit* | |
|  |  | |
| **Provide a COPY of the Protocol with this application.**  **\***Refer to current MRC Protocol Template to assist investigators and study personnel with planning and designing a research protocol. | | |

*ALL Shaded Fields Below have a 300 Character Limit unless otherwise specified*

1. Informed Consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Make selection to indicate **HOW PERMISSION** to participate as a subject in the proposed research will be **DOCUMENTED**. | | |  | |
| *For example, how will an individual’s freely given agreement to participate as a subject in research be obtained and recorded?* | | | |
| 1. If written informed consent **WILL NOT** be requested from the subjects, provide a reason below **WHY** it’s not being documented? | | | | | |
|  | |  | |

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| --- | --- | --- |
| **Primary ICF File Name / Title** *100 Character Limit* | | **Version** *30 Character Limit* |
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| --- | --- | --- | --- | --- | --- |
| 3. Are there additional informed consent forms (ICFs) or other resources used to document consent?  List These Items Below\*-each must be named & version controlled prior to submission for review. | | | | Yes  No  NA | |
| **Document Name / Title** *100 Character Limit Per Entry* | | **Version** *30 Character Limit Per Entry* | |
|  |  | |
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**\*If more space is needed, complete and include the ’Attachment Summary Form’ with this application**

**Section 3.0 Research Participant Population & Subject Recruitment Details**

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| --- | --- | --- | --- | --- | --- |
| 1. Recruitment Details *(may continue on next page)* | | | | | |
| Recruiting is defined for the purposes of this form as the consent and enrollment of living people to participate as a Subject in research in which an intervention or activity is conducted by the researchers for the purpose of research ONLY.  The collection of data from sources other than the Subject’s themselves is NOT the same as the enrollment of subjects in research. | | | | | |
| 1. Is the research enrolling **LIVING PEOPLE** as a **SUBJECT** to participate in the Research? (Participant) | | | | Yes  No |
|  | | | |  |
| NOT RECRUITING people to participate in the proposed research  *For example, the proposed research is collecting Pre-existing DATA ONLY from registries,* | NA | **Planned Data Set #** | 0 | | | |
| *medical records or charts or analyzing previously collected specimens.*  **Tick above if there is NO DIRECT INTERACTION with the Subjects and therefore NO CONSENT or ENROLLMENT of Subjects as part of the research** | | | | | | |

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| 1. If recruiting subjects, provide the quantity of individuals that will be screened in order to identify ELIGIBILITY FOR INCLUSION in the research and the quantity that will need to be ENROLLED AS PARTICIPANTS in the research below. | | | | | | |
|  | | **HMC Planned Screening #** | 0 | **HMC Planned Enrollment #** | 0 | | | |
|  | | | | | | | |
| Tick if subjects will be ENROLLED into the research, BUT the research IS NOT doing anything physical to the subject.  *For example, there are no clinical interventions; no specimens are being collected specifically for research purposes. (This DOES NOT include the use*  *of aliquots of bio-specimens that have been collected as part of clinical diagnosis, treatment or for diagnostic testing)* | | | | | | | | |
| 1. Will Subjects be SCREENED prior to enrollment as participants in the research? *(Checking for Eligibility)* | | | | | | Yes  No | | |
| If YES above, describe below **HOW** participants will be **SCREENED PRIOR TO ENROLLMENT** into the research study? | | | | | | | | |
|  | | | | | | | |

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| --- | --- | --- | --- |
| 1. How long **AFTER APPROVAL** to commence research will subject screening and/or enrollment begin? | |  | |
| 1. Duration of Participation   *For example, How long will a subject remain on the study after giving consent* |  | |
| 1. Intended Study End Date   *For example, 3 years from approval* |  | |

1. External Collaborators & Multi-Site Studies *(may continue on next page)*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Is the research a multi-site study or involve collaboration with an EXTERNAL investigator or institution? | | | | | | | | | | | | Yes  No |
| 1. If subjects are being recruited at sites other than HMC or the research is a multi-center international study, provide the TOTAL quantity of individuals that will be ENROLLED AS PARTICIPANTS in the research below. | | | | | | | | | | | | |
|  | | **Total Planned across ALL SITES**  **Enrollment#** | | | 0 | | **Total Planned at HMC**  **Enrollment #** | | | | 0 | | | |
|  | | | | | | | | | | | | | |
| 1. Does the proposed research ALREADY HAVE approval letter(s) from collaborator institutions?   **\*If YES to Above, include copies of the relevant compliance letters with this application.** | | | | | | | | | Yes  No  NA | | | | | |
| 1. Provide details for EACH external collaborator in the table below | | | | | | | | | | | | | | |
| Site Name | | | Site PI | Email | | Site IRB | | SCH Assurance# | | Project Activities | | | | | |
|  | | |  |  | |  | |  | |  | | | | | |
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| **\*If more space is needed, complete an addendum and include in the ’Attachment Summary Form’ with this application** | | | | | | | | | | | | | |

1. Participant Risk Profile

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Will individuals that can be identified as a member of any of the vulnerable populations listed below be enrolled in the research study? If Yes, Tick All That Apply Below | | | | Yes  No | | |
|  | | Newborns/Infants  Children  Cognitively Impaired  Disabled  Economically Disadvantaged | Pregnant Women/ Fetuses  Prisoners  HMC Employees  Other *30 Character Limit* | |
| 1. Are **NON-ENGLISH**\* resources & informed consent utilized by the site in the conduct of the study? | | | | Yes  No | |
| **\*If YES to Above, Refer to the MRC for Translation Services; List ALL Languages Below** | | | | | |
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| 1. How people will be **NOTIFIED OR APPROACHED** to consider being a research subject in this study?   Tick All That Apply Below If Other is Checked Include Detail in Shaded Fields | | | | | | | **NA** | |
| Doctor Referral(s)  Poster/Roll Ups(s)  Handout(s)  Ads  Direct - In Clinic/Hospital(s)  Researcher’s/PI’s Patient Pool | | | | | | |
| Other *30 Character Limit* | | Other | Other | | | |
|  | | | | |
| 1. Describe the **CONSENT PROCESS** procedures (When, Where, How, by Whom) below. | | | | | | **NA** | |
|  | | | | |
| 1. Describe **HOW LONG** potential participants will have to decide on participation below. | | | | | | **NA** | |
|  | | | |  | |
| 1. Describe how subjects will be **SCREENED FOR ELIGIBILITY** for the study below. | | | | | | **NA** | |
|  | | | | |
| 1. Describe how subjects will be **ENROLLED** into the research study below. | | | | | | **NA** | |
|  | | | | |
| 1. If participants withdraw their consent from study participation indicate what happens to their data?   If OTHER is marked, be sure to specify details below & in the protocol. | | | | |  | | |
|  | | | | |  |
| 1. If participants withdraw their consent from study participation indicate what happens to their specimens?   If OTHER is marked, be sure to specify details below & in the protocol. | | | | |  | | |
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**Section 4.0 Risk Assessments** *(may continue on next page)*

1. Safety - Risk Ratio & Oversight

|  |  |
| --- | --- |
| 1. Do research activities present LITTLE or NO RISK of harm to the research participants? | Yes  No |
| 1. Do anticipated adverse events or risk of harm expected as a result of taking part in the proposed research EXCEED the types of risk that a person NOT participating in the research could reasonably expect or experience in daily life or in the receipt of clinical care? | Yes  No |

|  |  |  |
| --- | --- | --- |
| 1. If the proposed research is reporting to multiple IRBs for this study, does EACH IRB have a valid assurance filed with the Supreme Council of Health (SCH)? If NO, Provide Details Below *500 Character Limit* | | Yes  No |
|  |  |
| 1. Have any of the researchers ever been suspended/removed from any research activities in the past?   **\*If Yes, Refer to the MRC for current policy.** | | Yes  No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. If YES to the use of Medical Procedure(s) *(may continue on next page)*  NA | | | | |
| 1. Indicate below what medical intervention(s) will be performed ON the subject for the sole purpose of the proposed research.   Tick All That Apply Below If Other is Checked, Include Detail in Shaded Fields | | | |
| Clinical Controls/Placebo/Blinding  Clinical/ Surgical Procedures  Emergency Response  Experimental Drug(s)  Experimental Treatment(s) | Biopsy  Bio-specimen Collection  Clinical Interviews/ Assessments  Diagnostic Testing  X-Ray/MRI | Diet or Vitamin Supplements  Environmental Controls  (Temperature, Sleep, Food, etc)  *30 Character Limit Per Entry*  Other  Other |

|  |  |  |
| --- | --- | --- |
| 1. Provide details below for the procedures indicated above, a brief description of **WHAT** specific drug or treatment the subject will be required to take and **WHY** specific medical procedures will be done to them for the proposed research. *500 Character Limit* | | |
|  |

1. If YES to the use of Specimens & the Collection of Bio-specimens  NA

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Indicate below **WHAT** bio-specimens are being collected FROM the subject for the sole purpose of the proposed research.   Tick All That Apply Below If Other is Checked, Include Detail in Shaded Fields *500 Character Limit* | | | | | | | |
| Blood/Plasma  Buccal Swab  Mucosal Swab  Saliva | | Bone Marrow  Tissue/Skin  Tumor  Urine/Stool | Amniotic Fluid/ Fetal Tissue  DNA/RNA-Other  Surgical Biopsy-Other | *30 Character Limit Per Entry*  Other  Other  Other | |  |
|  | | | |  | |
| 1. Provide details below for the specimens indicated above, a very brief description of **WHY** the specimens will be collected and **HOW** they will be used. *For example, to extract DNA or RNA, to identify biomarkers for disease, diagnosis, genetic tests, etc.* | | | | | | |
|  | | | |

*ALL Shaded Fields Below have a 300 Character Limit unless otherwise specified*

1. If YES to the use or collection of Personal Identifiable Information in the Research  NA

|  |  |  |
| --- | --- | --- |
| 1. Describe below **WHAT** identifiable information is being collected, and **WHY** it needs to be used and stored for research. | | |
|  |

1. If YES to the use of Registries, Medical Records/Charts, Patient Files or Hospital Databases  NA

|  |  |  |
| --- | --- | --- |
| 1. Describe below **WHICH** specific resources will be used to collect information for the purpose of the proposed research. | | |
|  |
| 1. Describe below **HOW** you have ACCESS & PERMISSION to use the resources for the purpose of the proposed research. | | |
|  |
| 1. Describe below **WHY** the information is being collected from these resources for the purpose of the proposed research. | | |
|  |
| 1. Describe below **WHAT** information is being collected from these resources for the purpose of the proposed research. | | |
|  |

1. If YES to the use of Questionnaires, Surveys, Interviews or Scripts  NA

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Indicate below **HOW** information is being obtained FROM the subject for the sole purpose of the proposed research.   Tick All That Apply Below If Other is Checked, Include Detail in Shaded Fields | | | | |
| Questionnaire/Survey  Interviews/Scripts  Group Discussions/Scripts  Online Survey  Other | | |
| 1. Provide details in shaded field below details for EACH ticked above, **HOW** these will be administered to the subjects.   **Provide a COPY of the questionnaires, surveys, etc with this submission.** | | | | |
|  |

1. If YES to the use of Coding and/or De-identification of Identifiable Information  NA

|  |  |  |
| --- | --- | --- |
| 1. Describe below specifically **HOW** the data will be coded or de-identified for the sole purpose of the proposed research. | | |
|  |

1. Data Management & Control *All Shaded Fields Below have a 200 Character Limit unless otherwise specified*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Indicate below **HOW** study data will be collected for the proposed research.   Tick All That Apply Below If Other is Checked, Include Detail in Shaded Fields | | | |  | | |
| Study Forms  Study Database  Study Web-Based/App  Other | | | |
|  | | |
| 1. Describe below **WHERE** and **HOW** the study data is physically stored. | | |  | | |
|  | | |  |
| 1. Describe below **WHO** controls access to the study data. | | |  | | |
|  | | |  |
| 1. Describe below **WHO** has access to the study data. | | |  | | |
|  | | |  |
| 1. Describe below **HOW** the study data is accessed. | | |  | | |
|  | | |  |
| 1. Will subject identifiers be shared outside of HMC? If YES describe below **WHOM** the study data is shared. | | | | | Yes  No |
|  | | |  |
| 1. Will the study data is transferred or shared outside of HMC? If YES describe below **HOW** this will happen. | | | | | Yes  No |
|  | | |  |

1. Data Monitoring

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Below provide details of **WHO** and **HOW** subject safety/ risk issues will be reviewed & evaluated   *For example, usually referred to as a safety monitoring plan, includes oversight for the review of subject safety and other outcomes that could require changes to the protocol to ensure the safety of the participants continuing in the research (DOES NOT include IRB oversight)*  *500 Character Limit* | | | |
|  | |
| 1. Indicate how often subject safety will be reviewed. | |  | |
| 1. Indicate if a DSMB (Data Safety Monitoring Board) will be used to review the data. | |  | |

**Section 5.0 Research & Document Summary**

1. Study Snapshot

**Below Check a Box for ALL That Apply to the Proposed Research**

Subjects Receiving Investigational Drug/Treatment  Randomizing  Blinded

Subjects Receiving Treatment/ Intervention as part of Clinical Care

Bio-specimen Collection/Analysis/Storage  Comparative Research (Monitoring Standard of Care/ Outcomes)

Behavioral/ Educational Intervention(s)

Data Coordinating Activities Only (Data Accrual/ Cleaning/ Analysis/ Publication preparation)

Other *(Summarize below 200 character limit)*

B. Research Document Summary

**Below Check a Box for ALL That Apply to THIS Research & provide a COPY of EACH with the Submission**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol  Informed Consent Form - ICF(s)  Case Report Form - CRF(s)  Data Collection Sheet(s) | Focus Group(s)  Interview(s)  Patient Diary  Questionnaire(s)  Survey(s) | Advertisement(s)  Brochure(s)  Handout(s)  Poster/Roll Up(s)  Referral(s)  Script(s) | *30 Character Limit Per Entry*  Other  Other  Other  Other  Other |
| Investigator’s Brochure (IB)  Packet Inserts (Drugs/Devices |

Tick to indicate that an ‘Attachment Summary Form’ is attached to this application.

List must be organized in a manner conducive to review & the electronic files named to support identification of a file without having to open the file.

**Section 6.0 Principal Investigator (PI) Authorization**

Electronic Declaration*By ticking box applicant indicates there is evidence on file of review & approval by PI; The MRC or HMC may request documentation at anytime without notice, failure to provide may result in closure/ suspension of research.*

Tick box if ANYONE involved in the proposed research is a member of RSAC for this research proposal

Tick box if ANYONE involved in the proposed research is a member of the IRB of record for this research proposal

Tick box if the MRC’s ‘Conflict of Interest Form’ has been completed

Tick to Indicate Form Completed by

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Phone: |  | Email: |  |