|  |
| --- |
| Progress Report for Continuing Review or Final Report for ResearchMedical Research Center, HMC Doha-Qatar |
| Form used to report on the current progress of previously approved research in order to obtain approval to renew IRB oversight of ongoing non-exempt research involving human subjects. Same form can be used to close out research activities.Reports should include a summary of serious adverse events, protocol deviations & modifications that occurred during the period under review. The submission should provide a clear snap shot of research progress, performance and outcome of the research (final report), including if findings will be or have been published or shared publically. |

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

Rename form with Study Reference Number, PR or FR & date. *i.e. 12345\_PR\_05Jul15 or 12345\_FR\_05Jul15*

Study# needs to be included on any attachments

**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:**

TICK **ALL** THAT APPLY BELOW *\* Give the best estimate for the following*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [ ]  Progress Report |  | [ ]  Final Report |  | [ ]  Oversight Lapse |  | [ ]  Never Initiated |
| Initial Approval Date:  |       | Closure Date: |       | Last Review Date\*: |       | Approval Date: |       |
| Date Approval Expires: |       |  |  | *\*Any type of IRB review, i.e. amendments, etc* |  |  |
| Last Review Date\*: *\*Any type of IRB review,* *i.e. amendments, etc* |       |

**Section 1.0 Study Information**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type |  | Phase |  | If Other: |  |
|  |
| MRC Study # |  |
| 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 following field below provide a brief purpose for the conduct of the study, including a summary of study protocol & anticipated outcome(s). Include intention to publish, patent, license or present findings. *2000 Character Limit* |
|  |  |

|  |
| --- |
| 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* |
|  |  |

|  |
| --- |
| 1. Investigator Comments - Status Update
 |
| In the following field below provide comments to support submission; If submitting a Progress Report, provide a brief summary of status. If CLOSING the study provide the reason for the closure (planned, completed, etc) including if it was completed or if there are intended publications, patents, licensure or presentations. For final reports, a statement must be included as to how data/ identifiers/ bio-specimens, etc will be maintained, stored or destroyed.**NA IS NOT** a sufficient response. *4000 Character Limit* |
|  |  |

**Section 2.0 Revision History**

Has ANYTHING CHANGED since Initial Approval or Previous Renewal?

**[ ]  Yes** MUST Complete ALL Below: Don’t forget to provide update in the Investigator Comments below for research status.

**[ ]  No\*** If No, Applicant may tick NA for relevant sections \*By ticking **NO** the PI is declaring that there have been no changes to the approved protocol during the period under review & there are no documents or materials requiring approval or acknowledgement.

 \*Must still provide a brief summary in Investigator Comments below indicating the status of the research.

1. Protocol & Informed Consent Amendments [ ]  NA– ONLY IF No Changes

|  |  |
| --- | --- |
| **Protocol**  Title & Version |  |
| **Primary ICF** Title & Version |  |

|  |  |
| --- | --- |
| 1. Has the Protocol or Approved Study Design been **MODIFIED** in any way during the period under review?
 | [ ]  Yes [ ]  No  |
| 1. Has the Informed Consent been **MODIFIED** in any way during the period under review?
 | [ ]  Yes [ ]  No [ ]  NA |
| 1. If YES to either of the above: Were subjects **RE-CONSENTED** or informed of the modifications?
 | [ ]  Yes [ ]  No [ ]  NA |
| 1. If NO to the above, EXPLAIN **WHY** subjects were not re-consented or informed of the modifications below. *No Character Limit*
 |
|  |
| 1. Are there additional informed consent forms (ICFs) other than the one listed above?

*List These ICFs Below-each must be named & version controlled*  | [ ]  Yes [ ]  No [ ]  NA |
| **Document Name / Title** *100 Character Limit Per Entry* | **Version** *30 Character Limit Per Entry* |
|       |  |
|       |  |

 If more space is needed, complete and include the ’Attachment Summary Form’ to this application

1. Other Approved Changes [ ]  NA– ONLY IF No Changes

Below provide a list of approved changes to the study during the past approval period (i.e. amendments, safety changes, ICF, PI changes, etc). The PI is required to maintain a revision history of changes to protocol: Minor administrative changes need not be listed below; if there were none for the period under review indicate NA above.

|  |  |
| --- | --- |
| **Date Approved**  | **Description of Change** *100 Character Limit Per Entry* |
|       |       |
|       |       |
|       |       |
|       |       |

[ ]  Tick to indicate that an ‘Attachment Summary Form’ is included with this application.

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

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

1. Recruitment Status

|  |
| --- |
| **[ ]** Tick if the Study is in Data Review/Analysis or Follow Up ONLY i.e. Research is NOT doing anything to the subject  |
| 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 research enrolling **LIVING PEOPLE** as a **SUBJECT** to participate in the Research? (Participant)
 | [ ]  Yes [ ]  No  |
| **[ ]** NOT RECRUITING people to participate in research *For example, the 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** |

|  |
| --- |
| **[ ]** Tick if Enrollment Has EXCEEDED\* Approved MRC/IRB Sample Size **\*PI must suspend recruitment. Contact MRC immediately**  |
| 2. | **HMC Approved Enrollment #**Only for this site if this is multi-site study | 0 | **HMC** **Current/ or Final** **Enrollment #**This matches response to Section B 4) below | 0 |
| 3. | If the enrollment at the site is not as expected or **ZERO**, provide an explanation as to why enrollment is delayed.  | 250 character limit |
| 4. | Are Subjects being SCREENED prior to enrollment as participants in the research? | [ ]  Yes [ ]  No  |
| 5. | Duration of subject participation after screening & documentation of informed consent |       |
| 6. | Planned Study End Date |       |
| 7. | Final Reporting OnlyIf Multi-Site Study-are **ALL** Sites Closing? | [ ]  Yes [ ]  No [ ]  NA |
|  | Site Closure Date (Date all activities & analysis are complete) |       |

|  |  |  |
| --- | --- | --- |
| 1. Local Enrollment Numbers
 | **[ ]** NA - Tick ONLY IF NO Subject Enrolment Ever | **NOTE FORM DOES NOT DO CALCULATIONS** |
| Description | Value | Calculation |
| 1. **Past:** Total participants reported as enrolled at **LAST** Progress Report (or 0 if 1st Renewal)
 |      | a |
| 1. **New:** Total participants **NEWLY** enrolled since last approved Progress Report
 |      | b |
| 1. **Total:** The **TOTAL** number of Subjects Enrolled at **THIS SITE** at the time of this report
 |      | a + b = c |
| 4) **Withdrawn/Lost:** Total # of subjects withdrawn/lost **FROM PARTICIPATION** at this site ever |      | [ ]  NA |
|  Have any subjects been withdrawn by the Investigator ever?  *1000 character limit*  | [ ]  Yes | No [ ]  |
| Provide a brief explanation below explaining WHY each subject was withdrawn or lost from the study for the period under review. |
|  |

1. Participant Risk Profile Changes  *ALL Shaded Fields Below have a 300 Character Limit unless otherwise specified*

|  |  |
| --- | --- |
| 1. Have there been **CHANGES** to the types of people **ENROLLED**? Can subjects be identified as any of the following?

If YES, Tick ALL That Apply & Provide Details in Shaded Field Below as to WHY |  |
|  | [ ]  Newborns/Infants[ ]  Children [ ]  Cognitively Impaired[ ]  Disabled[ ]  Economically Disadvantaged | [ ]  Pregnant Women/ Fetuses[ ]  Prisoners[ ]  HMC Employees[ ]  Other *30 Character Limit* | [ ]  Yes [ ]  No  |
|  |
| 1. Have there been **CHANGES** to the **NON-ENGLISH**\* resources & consent used at the site? If YES, Explain Below
 | [ ]  Yes [ ]  No |
|  |
| \*Refer to the MRC for Translation Services |
| 1. Have there been changes to how people are **APPROACHED** to consider being a research subject?

If YES, Tick ALL That Apply & Provide Details for EACH in Shaded Fields Below | [ ]  Yes [ ]  No [ ]  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*  |  | **[ ]  NO CHANGES TO RECRUITING MATERIALS OR SOURCES** |
|  |
| 1. Have there been changes to the **CONSENT PROCESS** procedures (When, Where, How, by Whom)
 | [ ]  Yes [ ]  No [ ]  NA |
|  |
| 1. Have there been changes to **HOW LONG** potential subjects will have to decide on participation?
 | [ ]  Yes [ ]  No [ ]  NA |
|  |  |
| 1. Have there been changes to how subjects will be **SCREENED FOR ELIGIBILITY** for the study?
 | [ ]  Yes [ ]  No [ ]  NA |
|  |
| 1. Have there been changes to how subjects will be **ENROLLED** into the research study?
 | [ ]  Yes [ ]  No [ ]  NA |
|  |
| 1. Have there been changes to what happens to the data of subjects that withdraw their consent?
 | [ ]  Yes [ ]  No [ ]  NA |
|  |
| 1. Have there been changes to what happens to specimens when subjects withdraw consent?
 | [ ]  Yes [ ]  No [ ]  NA |
|  |

**Section 4.0 Risk Assessments** *(may continue on next page)*

1. Safety - Risk Ratio & Oversight Changes

|  |  |
| --- | --- |
| Have There Been ANY Significant New Findings that Resulted in Modifications to the Safety Profile & Conduct of the Study During the Period Under Review? | [ ]  Yes No **[ ]**  |
| i.e. from data review & analysis, DSM, SCH, etc; If NO, Applicant may tick NA for all relevant sections below, but must confirmALL RESPONSES BELOW ARE UNCHANGED ORNO |
| For Example: 1. Changing the risk-benefit assessment of the study or modification to inclusion/ exclusion criteria
2. Indicating a need to change the protocol or the informed consent (Amendments, Enrollment Closures, etc)
3. Resulting in a cause to suspend or close the study
 |  |

|  |  |
| --- | --- |
| 1. Has the risk profile for participation as a subject in research changed?
 | [ ]  Yes [ ]  No [ ]  NA |
| 1. Have the use/ sharing of subject identifiers changed during the period under review?
 | [ ]  Yes [ ]  No [ ]  NA |
| 1. Has another IRB approved continuing review or extended IRB oversight for this study?
 | [ ]  Yes [ ]  No [ ]  NA |
| 1. Have any of the researchers been suspended from research in the past 12 months?
 | [ ]  Yes [ ]  No |
|  |
| 1. Since the last review, have there been any deviations\* from the approved study design?

If YES, a summary describing the deviations, severity, outcomes, corrective and preventative action must be provided either below or as an attachment to this report; **\*Refer to current MRC Policies for deviations** | [ ]  Yes [ ]  No [ ]  NA |
| *unlimited* |
| 1. Has the profile of adverse events changed from previous experience or those expected?

i.e. frequency, severity or specificity | [ ]  Yes [ ]  No [ ]  NA |
| 1. Since the last review, have there been any serious adverse events\* (SAEs)?

If YES, a summary for each event describing the SAE, severity, outcome, corrective and preventative action must be provided either below or as an attachment to this report; **\*Refer to current MRC Policies for AEs.** | [ ]  Yes [ ]  No [ ]  NA |
| *unlimited* |

|  |
| --- |
| 1. Changes to the Use of Medical Procedure(s)? *(may continue on next page)* [ ]  Yes [ ]  No [ ]  NA
 |
| 1. Have there been changes to the medical intervention(s) performed ON the subject for the sole purpose of the research?

If YES, Tick ALL That Apply & Provide Details for EACH 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)[ ]  Other *30 Character Limit***[ ]  NO CHANGES TO APPROVED PROCEDURES** |

|  |
| --- |
| 1. Provide details below describing **WHY** specific medical procedures have been changed from those approved for the research.

Provide Details in Shaded Field Below *500 Character Limit*  |
|  |

|  |  |
| --- | --- |
| 1. Changes to the Use of Specimens & the Collection of Bio-specimens?
 | [ ]  Yes [ ]  No  |
| 1. Have there been changes to WHAT bio-specimens are being collected FROM the subject for the purpose of the research?

If YES, Tick ALL That Apply & Provide Detail in Shaded Fields |
| [ ]  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 **[ ]  NO CHANGES TO APPROVED COLLECTION** |  |
| 1. Provide details below for the specimens indicated above, a very brief description of **WHY** the specimens collected have changed and **HOW** they will be used. *For example, to extract DNA or RNA, to identify biomarkers for disease, diagnosis, genetic tests, etc.* Provide Details in Shaded Field Below *500 Character Limit*
 |
|  |

 *(may continue on next page) ALL Shaded Fields Below have a 300 Character Limit unless otherwise specified*

|  |  |
| --- | --- |
| 1. Changes to the Use or Collection of Personal Identifiable Information in the Research?
 |  [ ]  Yes [ ]  No |
| 1. Have there been changes to **WHAT** identifiable information is being collected, and **WHY**? If **YES**, Provide Details in Shaded Field Below
 |
|  |

|  |  |
| --- | --- |
| 1. Changes to the Use of Registries, Records/Charts, Patient Files or Hospital Databases?

If YES, Tick ALL That Apply & Provide Details for EACH in Shaded Fields Below | [ ]  Yes [ ]  No |
| 1. Have there been changes to **WHICH** specific resources are being used to collect information for the purpose of the research?
 |
|  | [ ]  Yes [ ]  No  |
| 1. Have there been changes to **HOW** you have ACCESS & PERMISSION to use the resources for the purpose of the research?
 |
|  | [ ]  Yes [ ]  No  |
| 1. Have there been changes to **WHY** the information is being collected from these resources for the purpose of the research?
 |
|  | [ ]  Yes [ ]  No  |
| 1. Have there been changes to **WHAT** information is being collected from these resources for the purpose of the research?
 |
|  | [ ]  Yes [ ]  No  |

|  |  |
| --- | --- |
| 1. Changes to the Use of Questionnaires, Surveys, Interviews or Scripts?

If YES, Tick ALL That Apply & Provide Details for EACH in Shaded Field Below | [ ]  Yes [ ]  No  |
| 1. Have there been changes to the information **COLLECTED** from the subject in the approved materials listed below?
 |
|  [ ]  Questionnaires/Surveys [ ]  Interviews/Scripts [ ]  Group Discussions [ ]  Other **[ ]  NO CHANGES TO APPROVED MATERIALS** |
| 1. Provide details in shaded field below for a description of **HOW** the changes apply for EACH indicated above.

**Provide a COPY of the questionnaires, surveys, etc with TRACKED CHANGES showing the modifications made with this submission.** |
|  |

1. Changes to the Use of Coding or De-identification of Information? [ ]  Yes [ ]  No

|  |
| --- |
| 1. Explain below **WHAT** changes have been made to **HOW** the data will be coded or de-identified for the research and **WHY**?
 |
|  |

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

|  |  |
| --- | --- |
| 1. Have there been changes to **HOW** study data will be collected for the research?

If YES, Tick ALL That Apply & Provide Details for EACH in Shaded Fields Below | [ ]  Yes [ ]  No |
|  [ ]  Study Forms [ ]  Study Database [ ]  Study Web-Based/App [ ]  Other **[ ]  NO CHANGES TO DATA COLLECTION & CONTROL** |
|  |
| 1. Have there been changes to **WHERE** and **HOW** the study data is physically stored?
 | [ ]  Yes [ ]  No  |
|  |  |
| 1. Have there been changes to **WHO** controls access to the study data?
 | [ ]  Yes [ ]  No  |
|  |  |
| 1. Have there been changes to **WHO** has access to the study data?
 | [ ]  Yes [ ]  No  |
|  |  |
| 1. Have there been changes to **HOW** the study data is accessed?
 | [ ]  Yes [ ]  No  |
|  |  |
| 1. Have there been changes to if identifiers will be shared outside of HMC, and to **WHOM** the data is shared with?
 | [ ]  Yes [ ]  No  |
|  |  |
| 1. Have there been changes to if the study data is transferred or shared outside of HMC, and **HOW** this happens?
 | [ ]  Yes [ ]  No  |
|  |  |

I. Data Monitoring

|  |  |
| --- | --- |
| 1. Is there DSMB oversight?
 | [ ]  Yes [ ]  No |
| * 1. If YES above, provide the date of the last DSMB review
 |  Yes No [ ]  NA |
| * 1. Was the outcome of the DSMB review to recommend that the research continue?

**Must Provide a copy of the letter received by the DSMB documenting outcome of the review.** | [ ]  Yes [ ]  No [ ]  NA |
| 1. If the response to question 1 above is **NO**, and the research does not have a DSMB providing oversight, provide an explanation describing how safety is being monitoring , how the data has been reviewed, how risk issues have been evaluated & how often this review takes place and by whom in the space below

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) *2000 Character Limit* |  |
|  |  |

**Section 5.0 Research & Document Summary** *(may continue on next page)*

1. Study Snapshot

 **Below Check a Box for ALL That Apply to the Current State of the Research**

[ ]  Subjects Receiving Investigational Drug/Treatment [ ]  Randomizing [ ]  Blinded

[ ]  Subjects Receiving Treatment/ Intervention as part of Clinical Care [ ]  Treatment Phase Finished

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

[ ]  Behavioral/ Educational Intervention(s) Not Completed

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

[ ]  Study is CLOSED to Enrollment of NEW subjects.

[ ]  Recruitment Finished: Date last participant was consented:

[ ]  Date of last visit or contact with subject for the purpose of the research:

[ ]  Study Activities are SUSPENDED, provide date of suspension/halt:

[ ]  Date Subject Enrollment was OPENED:      [ ]  Date Subject Enrollment was CLOSED:

[ ]  Other *(Summarize below 200 character limit)*

**Must provide a copy of last signed consent (after hiding subject’s details)**

**Must provide Conflict of Interest forms for all research team members along with this progress report. COI should be sent to MRC on yearly basis**

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 Below*[ ]  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 to indicate if there was a delay in reporting & provide explanation BELOW

[ ]  Tick to Indicate Form Completed by

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