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| Compliance Checker for Scientific Research Form  Medical Research Center, HMC Doha-Qatar |
| Compliance Checker is a quick form that enables us to improve service by collecting and tracking basic information about research activities and has the added benefit of creating a documented record of oversight requests for individual research.  Completing this form facilitates a check of the compliance requirements of proposed research or expedites review of previously approved research for protocols migrating to the current IRB of record. |

**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. CC\_IQStudy\_08Jul15 i.e. ICF\_IQStudy\_08Jul15*

**Definitions**

1. Research - an activity to learn facts or answer a question; it is described in a written study plan or protocol that is systematically and scientifically designed and intended to socially and/or medically benefit a large population.
2. Risk Profile - measures or metrics that determine if a participant in research will be exposed to greater than minimal risk or harm in excess of those risks associated with normal activities and standard of care medical procedures used for diagnostic tests and treatment. The risk profile for research is determined by the answers to questions in this form.

**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 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:**

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| **Type of Request**  *Make a selection above to indicate why you are filling out this form; For example, what do you want to do? Make quer, get help, check if a research proposal needs review, transfer IRB oversight, etc*  **Research Institution(s)** *Tick ALL that apply*  HMC  WCMC-Q  Other  Indicate above only institutions engaged in the research through a grant or by directly participating in human research activities like obtaining, receiving, keeping PHI, recruiting/consenting people at institutions other than HMC.  **Research Type**  In the dropdown menu above select only one choice that best describes the nature (type) of the research i.e. What are you doing? Refer to *‘Compliance Checker Defining Research – Research Type’* for descriptions of the type of research studies indicated here. If the research can be represented by more than one option, select the type that represents the highest risk.  **Total Anticipated Enrollment** 0  In the shaded area above enter the TOTAL number of participants to be screened and enrolled in the research, both subjects and controls, as indicated in the protocol. | |
| **Research Compliance Tracker** *Tick ALL that apply*  Below tick the box to indicate what will be used for the research. This helps to identify types of oversight needed.  Multi-IRB refers to if subjects are enrolled at other places that have their own IRB approving research for their location/ site, resulting in oversight from multiple IRBs for this research. Proof of oversight by additional IRBs can help to expedite local review of this research. | **Research Procedure Type** *Tick ALL that apply*  Below tick the box to indicate what best describe what will be done to living human subjects enrolled in the research.  *Will subjects be expected to take a drug, have a device implanted, and have medical procedures done to them for tests or for collecting samples specifically for research purposes? Responses below help to calculate risk.* |
| Living Humans/People  DNA/RNA  Multi IRB Oversight  Radioactive Materials/ Radiation Exposure  Animals  Laboratory Work with Chemicals  Biologically Hazardous Materials  None of the Above  Other | Not Applicable – No Procedures  Experimental Drug/Device or Treatment  Invasive Medical Procedures/ Test(s)  Bio-specimen Collection  Surveys  Surveillance  Medical Chart Review/ Use of Registries  Data Review  Other |

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| **PROVIDE A RESPONSE FOR ALL BELOW** | |
| **Research Informed Consent**  Make selection above to indicate how people will be educated in order to make a choice to participate in the research; what resource is used to inform a person’s understanding & freely given agreement to be enrolled as a subject or control in research? | |
| **Use of Medical Procedure**  Select above ‘Yes’ if something is introduced through a body opening, is physically invasive (cutting or puncturing for example with a needle) or requires entry into the body for example to get blood, tissue, cells etc; this does not include saliva/urine. Otherwise select ‘No’.  **Specimen Collection**  Select ‘Yes’ if for the research, if any samples will be taken directly from people to be used or stored; these include all body fluids-saliva, urine, blood, etc & any tissue, cells, DNA, RNA, protein, etc; Otherwise pick ‘No’  **Use of Personal Information**  Select ‘Yes’ if any information collected can link the individual to the data or specimens collected in research or whose access is expected to be kept private & confidential like medical records (commonly called PHI) Otherwise select ‘No’.  **Use of Medical Record**  Select ‘Yes’ if patient medical records or test results will be reviewed for purposes other than to provide medical care/ treatment; like identifying people to recruit for research or collecting information on a disease or condition. Otherwise select ‘No’.  **Use of Questionnaire**  Select ‘Yes’ if a tool is used to gather information from a person, such as a survey, interview, focus group, etc. to learn about attitudes, opinions & practices. This is used in most types of research to learn about people’s behaviors, most commonly used in preparation for research. Otherwise select ‘No’.  **Specimen Storage**  Select ‘Yes’ if samples will be taken directly from people for purposes of storage or sharing after research completion; this is the banking of any bio-specimens: saliva, urine, blood, tissue, cells, DNA/RNA, protein, etc for future use. Otherwise select ‘No’.  **Use of Coding**  Select ‘Yes’ if the only thing that can identify all data/specimens collected for research is a key or list that links a code to the individual enrolled in the research. This means no other information collected can identify people. Otherwise select ‘No’. | |
| **Research Participant Population** *Tick ALL that apply*  Below tick the box to indicate who is physically being recruited as participants in the research (not data points, but people).  *Vulnerable Populations are those people that research may pose extra or unknown risks, due to age, health status, or a disempowered role in society. These are populations that may be reasonably at risk to undue pressure or influence to participate in research or at a higher risk of harm from participation in the research.* | **Research Documents Attached**  *Tick ALL that apply*  Provide any resources with this form that will help to determine oversight, exemption or expedite review of the research. |
| Protocol  Informed Consent Form(s)  Recruitment Materials (Posters/ Roll Ups) |
| Ages 18 – 64  Vulnerable Populations  *Indicate Type* :  HMC Employees  Pre-existing Data/Specimens  None of the above  Other | Research/ Case Report Forms (CRFs)  MRC/IRB Approval Letter(s)  QNRF Award Letter(s)  Application(s)  Other  Other  NA, Nothing Attached |

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| **Research Principal Investigator (PI)** *300 Character Limit* |
| *Indicate in the shaded area below the individual responsible and accountable for the conduct of the research. If the study is conducted by a team, the PI is the leader. There is only one PI. The designation of a PI has no influence on the ability to author publications.* |
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| **Research Protocol Title** *500 Character Limit* |
| *Indicate in the shaded area below the research title. This is a description that concisely states type, purpose and overall objective. Spell out acronyms.*  *i.e. ‘Comparative study of 3 treatments by measuring biomarkers in Middle East & North Africa (MENA) diabetics’* |
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| **Research Abstract** *3000 Character Limit* |
| *Provide in the shaded area below A VERY BRIEF SUMMARY of the proposed or approved/ active research.*  *Describe what the research is doing and who it is doing it to,*  ***DO NOT provide academic, literature, or background from a funding application or PhD dissertation.***  *Summarize the primary research objective including the planned/ approved 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).*  *For ongoing research, also indicate what the current status of the research is, the current number of enrolled subjects , if there have been any modifications to the research as a result of safety concerns or adverse events and when the research or enrollment activities are anticipated to end. If enrollment is closed, indicate research status, level of subject participation, and final enrollment date.* |
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