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| Study Title: |  |
| Lead Principal Investigator and Institution Address: |  |
| Site Investigator and Institution address |  |

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NOTE: After completion, kindly delete the instructions provided beneath each section.

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| Synopsis *In this section provide a brief summary of the research study (250-300 words).*  *The synopsis consists of 1-2 sentences of background, then a concise objective for the research followed by a brief description of research participants, interventions, methods, data collected and proposed analysis ending with the anticipated outcome(s).*  *Someone who knows nothing about the research should be able to get a clear snapshot of the proposed research and intended outcome.* |
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| Abbreviations and Acronyms *List abbreviations, acronyms and terms of reference used in the protocol; provide definitions for each as needed* | |
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| Introduction / Background *In this section provide an in-depth background and introduction to justifying the nature, design and intent of the research. At the end the reader should have a clear idea of the research question, an understanding that it is original and relevant, and how this research will help fill the gap in knowledge.*  *This is NOT where the scientific activities and methods for the proposed research are described.* | |
| Objectives *In this section provide a clear statement of the primary and any secondary objectives of the study*  *Define the hypothesis and state the key questions being asked in the research study.*   Indicate if this is a retrospective data review  * **Retrospective Chart/data Review** *(Retrospective means the data is already in existence when the project is submitted to the IRB for initial review.*   **Provide the date range of the chart review** *(if this is a retrospective chart review, the end date must come before the submission date): mm/dd/yyyy to mm/dd/yyyy* | |  | | |  | | |
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| Study Methodology *In this section outline and describe in detail the intentions and actions of the study. The researcher should consider all aspects of the following and how each is applicable to the proposed research.*  *At minimum the following must be explained*   * *Type and classification of study, comparisons and/or interventions. What is being studied or compared? If the research is a cohort study or survey then what are the exposures or predictors of interest?*    + *Sample size calculation or justification of numbers*   Indicate the total numbers of subjects who will be screened for eligibility vs the maximum number of subjects to be enrolled in the study per each study recruitment site   * *Details of the interventions (not procedures) involved in the research; what are you doing and who are you doing it to?* * *Describe what data/samples (bio-specimens/information) will be collected at each time point and why*   *\*\*Specific details are required for treatment interventions and therapeutic treatments that involve drug(s), medical devices and clinical care. Are the risks to participants in the proposed research reasonably worth the anticipated benefits to clinical/health outcome?* | | |  |
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| Study Population and Study Setting/ Location *In this section describe the study population that is to be enrolled in the study, planned recruitment number and Inclusion and Exclusion Criteria to be listed here. Also list the Hospitals in which this study will be conducted ( e.g. HGH, Rumailah etc)* | |
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| Study procedures  * *Provide an outline and describe in detail the processes and operations of the study, including logistics* * *Describe and explain the study design.* * *Provide a description of all procedures being performed because the subject is taking part in the research, including procedures being performed to monitor subjects for safety or minimize risks.* * *Describe when these procedures are performed [Do not describe procedures that will be performed regardless of whether the subject takes part in the research describe these procedures in the Background section.]* * *Describe*    + - * *Procedures performed to lessen the probability or magnitude of risks.*       * *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*       * *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*       * *What data will be collected including long-term follow-up.*       * *Is there any imaging involving ionizing or non-ionizing (including MRI) radiation in this research project whether as part of standard care or for research purposes? (If yes, please provide more details about the dose and frequency)* | |
| Study Duration and Timelines *Expected duration of the study& start times, stages of the study such as screening, treatment phase, visit numbers, approximately how long it will take to enroll all study participants, and the estimated date for the investigators to complete this study’s primary analyses. etc.*   * *If you need to invite the subjects more than once to complete the study procedure (i.e. interview, focus group, fill out more than one survey, repeat the study procedures etc.) state number of visits and procedures to be completed per visit. Indicate the estimated duration required to complete each visit.* | |
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| Informed Consent  1. *How people will be NOTIFIED OR APPROACHED to consider being a research subject in this study; the methods that will be used to identify potential subjects.* 2. *Describe materials that will be used to recruit subjects. Attach copies of these documents with the application.* 3. *For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.*      1. *Describe the CONSENT PROCESS procedures (When, Where, How, by Whom).*      1. *Describe HOW LONG potential participants will have to decide on participation.*      1. *Describe how subjects will be SCREENED FOR ELIGIBILITY for the study.*      1. *Describe how subjects will be ENROLLED into the research study below.*      1. *Indicate what language(s) other than English/Arabic are understood by prospective subjects or representatives.*   *If subjects who do not speak English will be enrolled, describe the process to ensure that the written information provided to those subjects will be in that language and provide a certified translation of the consent in their language*   1. *Indicate the language(s) that will be used by those obtaining consent.* 2. *Indicate that the subjects will be provided with a dated, signed copy of the informed consent*   *If waiver of contest is required, indicate the reason the Waiver or Alteration of Consent Process is required (consent will not be obtained, required information will not be disclosed, or the research involves deception)* | |
| Risk *In this section describe the anticipated risks associated with participation in the research (i.e. illness, injury, death)* *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.*  *If applicable, describe any costs that subjects may be responsible for because of participation in the research.*  *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*  *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*  *If applicable, describe risks to others who are not subjects.*  *If you are conducting genetic research include the risks below:*  *• Genetic information is unique to each individual but people share some genetic information with blood relatives. Genetic information from them could therefore be used to help identify the participants and vice versa.*  *• Although we will protect the information, yet people may develop ways in the future to link the genetic or medical information in our databases back to subjects.*  *• Since some genetic variations can help to predict future health problems, this information might be of interest to health providers, life insurance companies, and others. Law enforcement agencies can also use genetic variations to identify a person or his/her blood relatives. Therefore, genetic information potentially could be used in ways that could cause subjects or their family distress, such as by revealing carrying a genetic disease.* | |
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| Bio-Specimens & Sample Collection *In this section describe what specimens or samples will be collected specifically for research, if specimens will be stored long-term and/or destroyed. Consider what happens to data/specimens if subject withdraws consent*  *If data or specimens will be banked for future use, describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*  *If the banking is to be included under a separate repository protocol, refer to the repository protocol number and the approved procedure*  *Storage conditions:*  *how soon after collection should the samples be put under storage conditions*  *how long will the samples be stored for, and what will be done with the samples after this time (e.g. destruction)*  *where samples will be stored; locally at site(s) or sent to a central storage facility (and shipping arrangements if the latter)*  *what conditions should the samples be stored under (if samples are to be stored in specialist fridges or freezers e.g. a -80°C freezer, then it is beneficial to specify that samples will be stored at -80°C +/- 10°C (or the tolerance to which you specify), rather than to state -80°C. This will avoid numerous notifications of temperature deviations, when not really required)*    Sharing Results with Participants  *Describe if study results or individual participant results [such as results of investigational diagnostic tests, genetic tests, or incidental findings] will be shared with participants’ physicians or anyone else (e.g., the participant’s primary care physician, referring physician etc.)*  *Describe the mechanism of sharing results (how will they be shared, by whom, if genetic results that require validation what will be the mechanism etc.)*  Provisions to Monitor the Data to Ensure the Safety of Subjects   * The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. If the study does not require a data safety monitoring board/committee, detail the data monitoring plan for the study. * Describe the following in this section:   + - * The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.       * What data are reviewed, including safety data, untoward events, and efficacy data.       * How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).       * The frequency of data collection, including when safety data collection starts.       * Who will review the data.       * The frequency or periodicity of review of cumulative data.       * The statistical tests for analyzing the safety data to determine whether harm is occurring.       * Any conditions that trigger an immediate suspension of the research.   Explain who, how, when and how frequent the collected data will be monitored and the % of data that will be monitored | |
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| Outcomes *In this section provide details on the outcome measures and the anticipated primary & secondary outcomes* | |
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| Data Collection, Management & Confidentiality  1. *Indicate below HOW study data will be collected for the proposed research.*   *Study Forms  Study Database  Study Web-Based/App  Other*  *Please detail how study data will be coded:*     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 Institution? If YES describe below WHOM the study data is shared*      * Describe the procedures for maintenance of confidentiality. * Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. * Detail where all private health information (PHI) will be kept * under whom custodianship * who will have access to all identifiable information and where Provisions to Protect the Privacy Interests of Subjects | |
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| Subject Withdrawal/ Withdrawal of Consent *In this section describe why a subject may be withdrawn from the study by the PI,( describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.) what happens to the data or bio-specimens if a subject withdraws consent*  *If applicable, describe any procedures for orderly termination.*  *If applicable, describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*  *Specify how data/samples collected up to the point of withdrawal will be handled (if they will be used or destroyed, if subjects will be given the option to choose etc.)* Statistical Consideration and Data Analysis *In this section detail the analysis plan, how the primary and secondary outcomes will be analyzed, statistical methods to be used and who is going to carry out the analysis?*   * *When applicable, provide a power analysis.* * *Describe any procedures that will be used for quality control of collected data.* * *Describe how data and specimens will be handled study-wide:*  1. *What information will be included in that data or associated with the specimens?* 2. *Where and how data or specimens will be stored?* 3. *How long the data or specimens will be stored?* 4. *Who will have access to the data or specimens?* 5. *Who is responsible for receipt or transmission of the data or specimens?* 6. *How data and specimens will be transported?* 7. *Will data samples be shared with external institutions for analyses for the purpose of this study?*   *• Include the retention period of the study records post closure.*  *• State that institutional agreements will be attained prior to transferring data/samples* | |
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| Adverse Event Reporting *In this section, provide a definition of anticipated adverse events that are related to the research, including a description of how SAEs will be assessed, tracked and reported* | |
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| Ethical Consideration *A statement that the study will be conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP) and within the laws and regulations of MoPH in Qatar.* | |
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| Sponsor, Funding & Collaborator Information *Provide basic details of the lead sponsor and/or funding bodies, including name, and contact information, allocated number for the research, etc. For example QNRF* | |
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| Dissemination of Results and Publication policy *List any meetings or conferences where you will be presenting the data and the results of your study. Please provide timeline for finalizing manuscript and when and where you plan to submit for publication. Any presentation, abstract, or manuscript must be made available for review by The Medical Research Center prior to submission.* | |
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| References *Cite the sources of all reference materials used to support the hypothesis* | |
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| Appendices *List in this section all intended forms or resources that will be used in the conduct of research to collect data, interview people, recruit participants.* | |
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