**IRB 413 - Sidra IRB Clinical Research Protocol Template Guidance**

**Purpose**

The research protocol template is an essential part of a research project. It is a full description of the research study and acts as a ‘manual’ for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study’s progress and evaluate its outcomes.

The protocol is a non-technical step-by-step description of your study and should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study (including study design, recruitment procedure, study procedure, etc.) .

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be little chance that the review body will require clarification from the applicant.

The purpose of the template is to assist investigators and study personnel to:

* Formulate a protocol for proposed research.
* Consider all required elements of a protocol in the design of the research.
* Ensure that all protocols follow a consistent format.

**Directions for completing the protocol template:**

1. Enter information in the shaded areas.
2. Enter protocol IRB and SDR numbers. If one has not been allocated, indicate that it is pending.
3. Enter the title of the proposed research study.
   1. The title should be very descriptive of the hypothesis of the proposed research. Always use the protocol title for all research applications, submissions, and funding requests
   2. The title includes key words that identify the topic being studied.
4. Enter the name of the Principal Investigator (PI), there is only one PI per research protocol. (Applications forms to the IRB will permit the listing of all Co-Investigators (Co-I) and study team members)
5. Refer to the description under each section to complete each part.
6. Update the table of contents (Entire Table and not only page numbers) once you finish writing the protocol.
7. Update the Study protocol version date in the footer to be able to track the latest version of your protocol once you finish writing it.

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| ***IRB 413 - Sidra IRB Clinical Research Protocol Template*** | |
| Protocol Title | Enter Protocol Title |
| Protocol IRB Number | Enter IRB Number |
| Protocol SDR Number(s) | Enter SDR Number |
| Funding Source | Enter Funding Source |
| Principal Investigator (PI) | Enter Principal Investigator Full Name |
| PI Department | Enter PI Department |
| Telephone Number | Enter Telephone Number |

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# Synopsis/ Summary

In this section provide a 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 subjects/participants, interventions, methods, data collection 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.

Click or tap here to enter text.

# Abbreviations and Acronyms

List abbreviations, acronyms and terms of reference used in the protocol; provide definitions for each as needed.

Click or tap here to enter text.

# Introduction / Background

In this section provide an in-depth background and introduction to justify the nature, design, and intent of the research (i.e., what is the importance of the topic?). 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. Please limit this section to 1000 words.

Click or tap here to enter text.

# Objectives

In this section, provide a clear statement of the primary and any secondary objectives of the study (i.e., information about the aims and goals a researcher hopes to accomplish by conducting a research study).

Define the hypothesis and state the key questions being asked in the research study.

Click or tap here to enter text.

# Study Methodology

## Study Design

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 the 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? E.g., Study Design and methods
* 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, how it will be collected 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?

Click or tap here to enter text.

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): Click or tap to enter a date. to Click or tap to enter a date.

## Study Population and Study Setting/ Location

In this section describe the location where the research study will be conducted and the study population that is to be enrolled in the study and planned recruitment number; also Inclusion and Exclusion Criteria to be listed here. Also list the clinics and/or hospitals in which this study will be conducted.

Click or tap here to enter text.

## Study procedures

* Provide an outline and describe in detail the processes and operations of the study, including logistics (location of visits).
* 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 risk minimization.
* 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.
* Any procedure such as biopsies, specimen samples, measurements, etc. that are done for research purposes and the purpose of their use in addition to how the risks from performing them are managed.
* 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 and how it will be collected.
* 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)

Click or tap here to enter text.

## Study Duration and Timelines

Expected duration of the study and 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 the 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 the number of visits and procedures to be completed per visit. Indicate the estimated duration required to complete each visit.

Click or tap here to enter text and or table/chart.

## 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.

Click or tap here to enter text.

Describe how data and specimens will be handled study-wide by answering the below questions:

1. What information will be included in that data or associated with the specimens?

Click or tap here to enter text.

1. Where and how will the specimens be stored?

Click or tap here to enter text.

1. How long will the specimens be stored?

Click or tap here to enter text.

1. Who will have access to the specimens?

Click or tap here to enter text.

1. Who is responsible for receipt or transmission of the specimens?

Click or tap here to enter text.

1. How will the specimens will transported?

Click or tap here to enter text.

Storage conditions:

1. How soon after collection should the samples be put under storage conditions.
2. How long will the samples be stored for, and what will be done with the samples after this time (e.g., destruction)
3. Where will the samples be stored; locally at site(s) or sent to a central storage facility (and shipping arrangements if the latter)
4. 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)

Click or tap here to enter text.

# Informed Consent

How people will be NOTIFIED OR APPROACHED to consider being a research subject in the study; the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. Attach copies of these documents with the application.

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 retaping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

Click or tap here to enter text.

1. Describe the CONSENT PROCESS procedures (When, Where, How, by Whom). If the study involves children less than 18 years of age, describe the assent process (age of the subject, capabilities of the subject to understand the assent, if the permission of one parent is sufficient for the research to be conducted or both parents, etc.).

**Legally Authorized Representative (LAR):** Consider the order of priority of family members for a minor or person with diminished capacity is:

* + 1. Husband
    2. Son (the priority is given to the oldest one available or reachable)
    3. Father
    4. Mother
    5. Paternal (from Father’s side) Grandfather
    6. Brother
    7. Wife
    8. Daughter (the priority is given to the oldest one available or reachable)
    9. Sister
    10. Paternal Uncle (priority to oldest one available or reachable)
    11. Paternal Male Cousin (priority to oldest one available or reachable)
    12. Nearest male relative

Click or tap here to enter text.

1. Describe HOW LONG potential participants will have to decide on participation.

Click or tap here to enter text.

1. Describe how subjects will be SCREENED FOR ELIGIBILITY for the research study.

Click or tap here to enter text.

1. Describe how subjects will be ENROLLED into the research study.

Click or tap here to enter text.

1. Indicate what language(s) other than English/Arabic are understood by prospective subjects or representatives

Click or tap here to enter text.

1. 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 their language and provide a certified translation of the consent in their language.

Click or tap here to enter text.

1. Indicate the language(s) that will be used by those obtaining consent.

Click or tap here to enter text.

1. Indicate that the subjects will be provided with a dated, signed copy of the informed consent.

Click or tap here to enter text.

1. 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)

Click or tap here to enter text.

# 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.).

Click or tap here to enter text.

# 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 to 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, 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.

Click or tap here to enter text.

# 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 require validation what will be the mechanism of the validation, etc.)

Click or tap here to enter text.

# Provisions to Monitor the Data to Ensure the Safety of Subjects

The plan might include establishing a data safety monitoring board (DSMB) and a plan for reporting DSMB findings to the IRB and the sponsor (if applicable). If the study does not require a DSMB, 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.
  + 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.

Click or tap here to enter text.

# Study Outcomes

In this section provide details on the outcome measures and the anticipated primary & secondary outcomes.

Click or tap here to enter text.

# Data Storage, Management & Confidentiality

Confidentiality: Outline all the precautions that will be used to maintain the confidentiality of identifiable information by answering the below questions:

1. Indicate below HOW study data will be collected for the proposed research.

Study Forms  Study Database  Study Web-Based/App  Other      (tape recording, photographs, movies, or videotapes, etc.)

1. Detail how study data will be coded/anonymized/deidentified as applicable per your study.

Where all private health information (PHI) will be kept, under whose custodianship, who will have access to all identifiable information and where Provisions to Protect the Privacy Interests of Subjects.

* **Coded:** Data will be coded by a link that will be created and maintained by a secured system and methods between a unique code (Research Study ID) and the patient’s personal health information identifier PHI.
* **De-identified:** Data will be de-identified which means any direct or indirect identifiers or codes linking the data to the patient/individual subject’s identity are removed or destroyed and they will be no chance for disclosure and no data can be linked back to a patient/individual.
* **Anonymous:** Data are considered anonymous if no one, not even the researcher or any third-party entity, can link the data to the patient/individual that might make it possible to identify a patient/individual from a list of subjects.

Click or tap here to enter text.

1. Describe below WHERE and HOW the study data is physically/electronically stored*.* The procedures for maintenance of confidentiality.

Click or tap here to enter text.

1. Describe below WHO controls access to the study data, WHO has access to it and HOW it is accessed. 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. Who is responsible for receipt or transmission of the data?

Click or tap here to enter text.

1. Will subject identifiers be shared outside of the Institution? If YES describe below WHOM the study data is shared with.

Click or tap here to enter text.

1. How long the data will be stored? Include the retention period of the study records post closure. If it is more than 3 years, indicate the reason.

Click or tap here to enter text.

1. Will data samples be shared with external institutions for analyses for the purpose of this study?

Click or tap here to enter text.

1. State that institutional agreements will be attained prior to transferring any data/samples.

Click or tap here to enter text.

# 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.

* 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.
* If applicable, provide a power analysis.

Click or tap here to enter text.

# Adverse Event Reporting

In this section, provide a specify the anticipated adverse events that are related to the research, including a description of how SAEs will be assessed, tracked, and reported.

* **Unanticipated Problem (UP)**: "Any incident, experience, or outcome that meets the following criteria:
  + unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
  + related or possibly related to a subject’s participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
  + suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

It can be an adverse event or any other incident (e.g., false publication, breach of confidentiality, etc.)"

To be reported within Serious UPs within one (1) week of the investigator becoming aware of the event  
- Any Other UP within two (2) weeks of the investigator becoming aware of the problem

* **Adverse Event (AE):** Any unfavorable medical occurrence, including any abnormal sign, symptom or disease, temporally associated with the subject’s participation in the research, regardless of whether considered related to the subject’s participation in the research. Adverse Events encompass both physical and psychological harms and occur most commonly in the context of biomedical research, although on occasion occur in the context of social and behavioral research. To be reported within two (2) weeks of the investigator becoming aware of the problem
* **Serious Adverse Event (SAE):** An Adverse Event that results in (1) death, (2) is life-threatening, (3) results in inpatient hospitalization or prolongation of existing hospitalization, (4) results in a persistent or significant incapacity or disability, (5) results in a congenital anomaly/birth defect or, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition . to be reported within one (1) week of the investigator becoming aware of the event

Click or tap here to enter text.

# 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. State that institutional agreements are or will be attained as applicable before starting the research.

Click or tap here to enter text.

# 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 a tentative timeline for finalizing manuscript, when and where you plan to submit for publication including the type and the tentative number of publications.

Click or tap here to enter text.

# References

Cite the sources of all reference materials used to support the hypothesis.

Click or tap here to enter text.

# 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.

Click or tap here to enter text.

# Protocol Signature Page

I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key personnel, including myself, sub/co-investigators, research coordinators, trainees, and students have completed the SIDRA required training on human subjects’ protection.

I agree to conduct this research study in accordance with the design and specific provisions of this approved protocol. I agree to conduct this research study in compliance with Sidra Policies and Procedures, in full conformance with principles of the “Declaration of Helsinki”, International Harmonization on Good Clinical Practice (ICH-GCP) guidelines and within the research guidelines and regulations of MoPH in Qatar or any other regulations as applicable.

I agree to a continuing exchange of information with the SIDRA IRB including the requirements to:

* + 1. obtain IRB approval before making non-emergency changes/revisions to the project, except where necessary to eliminate apparent immediate hazards to subjects or others,
    2. provide progress reports to the SIDRA IRB at their request (and at least annually),
    3. report to the IRB all unanticipated problems and serious adverse events involving risk to human subjects as per Sidra related policies and procedures, and
    4. accept responsibility to maintain original data and consent forms and submit them for review, when requested.

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| --- | --- |
| Protocol Title | Click or tap here to enter text. |
| Protocol IRB Number | Click or tap here to enter text. |
| Principal Investigator (PI) | Click or tap here to enter text. |
| PI Signature |  |
| PI Signature Date | Click or tap to enter a date. |