1. **Synopsis\***

In this section provide a brief summary of the research study (250-300 words).

* 1. 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).
	2. Someone who knows nothing about the research should be able to get a clear snap shot of the proposed research and intend outcome.
1. **Abbreviations and Acronyms**

In this section provide a list of abbreviations, acronyms and terms of reference used in the protocol that may not be part of general knowledge outside of research or researcher specialty.

* 1. Provide definitions for each as needed
1. **Introduction / Background \***

In this section provide an in-depth background and introduction to justifying the nature, design and intent of the research and should include the following:

* 1. Provide an introduction to the topic of research interest, what is known already - literature review of relevant findings (Brief and focused)
	2. Highlight the areas or points where there is missing information in the literature, i.e. justification for the research
	3. Indicate the aims of this study– what the study is going to find out, and in one sentence how this is going to be achieved.
	4. 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.

The background should not be an exhaustive literature review.

* 1. This is NOT where the scientific activities and methods for the proposed research are described, but describes the intended impact of how this research study will substantially add benefit to science, health care provision, etc,

Such as change clinical practice, save money; improve health outcomes or quality of life in the population.

Include an economic or social impact if possible/ relevant.

1. **Objectives \***

In this section provide a clear statement of primary and any secondary objectives of the study, include a clearly defined hypothesis and anticipated outcome.

1. **Study Methodology \* What Type of Study is it?**

In this section outline and describe in detail the intentions and actions of the study.

Although on the template this is one section, the Researcher must consider all aspects of the following and how each is applicable to the proposed research.

Describe the methodology of the proposed research study such as if it is a retrospective review of already existing data, an investigational treatment, a non-therapeutic study such as DNA research, if the research is generating new data, if it is an intervention to change behaviors or improve treatment outcomes, etc.

At minimum the following should be explained

* 1. Type of study (How would the study be classified?)

Is this a clinical trial, retrospective data review, non-therapeutic biomedical research, etc?

What are the comparisons and/or interventions being studied? If the research is a cohort study or survey then what are the exposures or predictors of interest?

* 1. Setting & Location

Where is the research going to be carried out (i.e. hospital in Qatar)

Are there multiple sites?

* 1. Sample size calculation or justification of numbers

How many participants or data sets are needed to conduct the research?

The above should be based on previous data or a statistical hypothesis

i.e. how many people will be enrolled, how many data sets collected to identify an outcome of the research that is a result than that which occurs that is greater than by chance (power of the research or p-value).

* 1. Detail the interventions involved in the research

What are you doing and who are you doing to?

* 1. Describe what data and or samples (bio-specimens/information) will be collected at each time point and why
	2. Specific details are required for treatment interventions and therapeutic treatments that involve drug(s), medical devices and changes to clinical care.

For example are the risks to the subject’s worth the anticipated benefit to the individual, research community, or science?

Are the risks to participants in the proposed research reasonably worth the anticipated benefits to clinical/health outcome?

1. **Study Population \* What is the Study Population Data or People?**

In this section describe the study population that is to be enrolled in the study; is the source of the research participants or data?

* 1. Quantity of participants or data sets needed to conduct the research.
	2. Is it PRE-EXISTING data (registry, databases, biobanks) or will the proposed research be collecting NEW data or enrolling subjects?
	3. If enrolling living human subjects, how and where are they going to be recruited from? For example, patients, registries, recruitment for the general populations, schools, etc.
	4. How has privacy or confidentiality of participants or their data been addressed?
	5. Are they a member of a population that could be considered vulnerable or at risk to pressure to participate in research or at higher risk of harm from the research?

For example, patients, children, pregnant women, economically disadvantaged, disabled, etc

* 1. Explain how potential subjects are identified and recruited?

For example will adverts, posters or other actions be used to recruit subjects; will they be recruited by clinical staff or research staff?

* 1. What is the Inclusion/Exclusion criterion?

Must the participant have a specific health condition or be healthy? For example have a condition such as asthma or diabetes to participate?

1. **Study Procedures \***

This is the most comprehensive part of the protocol, it outlines and describes in detail the processes and operations of the study, including logistics.

Although on the template this is one section, the Researcher must consider all aspects of the following and consider how each is applicable to the proposed research.

This section also determines the oversight and compliance required by the research including SCH, HMC, MRC, IRB, Ethics, etc.

Study Procedures - Type, Timelines, Interventions

In this section describe all the procedures that will be used to conduct the research and how they affect the participants enrolled in the research.

1. Study timelines- Expected duration of the study and start times, stages of the study such as screening, treatment phase, subject visit numbers, etc
2. Is it a multi arm trial?

For randomized studies- How are patients going to be randomized (a simple diagram showing treatment arms is often useful- attach file to protocol)

1. Blinding- Will the subject’s be blinded from knowledge of treatment intervention or use of placebo? Is the study double blinded? Are both clinician and subjects blinded?

Support rational for blinding and randomization.

1. Detail the interventions or treatments used, how they are delivered (if applicable) and who is going to deliver them?

For example, are these patients in a hospital and clinicians are doing the procedures or will subjects go to a trial site and have procedures done by trial staff? (Clinicians vs researcher staff)

1. Clarify what procedures are specific to participation in the research and not clinical standard of care. (Therapeutic vs experimental treatments or placebo)
2. Other details of particular ways the subject will be treated during the study independent to the specific intervention(s)

For example will other drugs not be allowed or will the subject’s diet or environment be controlled or limited in some way, can the subject be enrolled and participating concurrently in another research project?

Study Procedures - Human Subjects

In this section describe the intended enrollment of people in the proposed research.

* 1. Will living human subjects be recruited?
	2. How may?
	3. How long will participants be expected to take part in the research?
	4. Is there follow up? When and for what?

Study Procedures - Informed Consent

In this section describe if the research will be obtaining informed consent from participants prior to enrollment and participation in the proposed research. (when, where and by whom)

1. Elaborate on where and how consent will be requested, and how long subjects will have to decide on participation?
2. Is the consent in languages other than English? If so, how are they translated?
3. Who will be responsible for directly interacting with the participant to get consent
4. Is the language used on the informed consent form (ICF) the same as the spoken language that occurs between the research staff and the participant in order to obtain consent?
5. Is there more than one type of informed consent form (ICF)?
6. How will informed consent be documented? Recorded? Accent ?
7. Can the research request a waiver of informed consent prior to the intervention?

*(In very special cases, such as emergency research in which consent of the participants may affect the patient outcomes or low to no risk research in which consent of the participants may affect the results)*

Study Procedures - Risk

In this section describe the anticipated risks associated with participation in the research

1. What are the anticipated risks to the subject associated with participation in the research (i.e. illness, injury, death) This is specific to the individual participating.
2. Describe the risk to participation in the study that will be included in the ICF (if different from the above)
3. Indicate if these risks are different (higher or lower) than those associated with receiving standard clinical care or choosing not to participate in the research. For example procedures for blood draw, MRIs, etc

Study Procedures - Bio-Specimens & Sample Collection

In this section describe what specimens or samples will be collected specifically for research, if the bio-specimen is from a sample taken from clinical care procedure (i.e. a blood sample taken for care, and the left over being used for research) or if the collection is ONLY for research and if specimens will be stored long-term and/or destroyed.

1. Describe what specimens or samples will be collected specifically for research purposes
2. Specify if the bio-specimen will be taken from a sample that was already collected from a clinical care procedure (i.e. a blood sample taken for clinical testing and an aliquot is taken from the left over amount for research) or
3. Specify if the sample collection is only for research purposes

i.e. a blood draw that would not otherwise occur being performed ONLY for research purposes

1. Will boi-specimens be stored long-term?
2. How will they be destroyed after the research is complete?
3. If a subject withdraws consent, what happens to the samples?

Consider what happens to data/specimens if subject withdraws consent.

Study Procedures - Outcomes

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

1. Outcome measures used
2. What are the primary and secondary outcomes

(Note there should be only one primary outcome)

Study Procedures - Data Collection & Integrity

In this section provide details on how data will be collected, transcribed, transferred and used.

1. What data is going to be collected?

If the data is from a registry or pre-existing data source does the PI need permission to access or use data for research purposes (is documentation needed to prove right of use)?

1. What data is collected at specific time points in the research?
2. How is it collected? (Directly or indirectly)
3. Who has authority to collect it, when & where?
4. Can the data be correlated to the research participant (identifiers)?
5. How is source data transferred from research sites and protected?
6. Will data be entered into a database? By who & how (using CRFs)?

Study Procedures - Subject Withdrawal/ Withdrawal of Consent

In this section describe why a subject may be withdrawn from the study by the PI, what happens to the data or bio-specimens if a subject withdraws consent, and how complaints from participant’s in research are handled.

1. Are there any conditions that will cause a patient to be withdrawn from the study?
2. What happens if a patient wishes to withdraw consent?
3. Have the subjects been provided with a resource to confidentially log concerns or complaints about the researcher or research participation?
4. **Data Management \***

In this section describe how data will be managed after collection, how is it secured, stored and destroyed. Consider who has access, delegated rights and ownership of the generated / used data.

1. Provide drafts as attachments to the Protocol of the Case Record Forms (CRF) used to collect research data, or other materials such as surveys or questionnaires used to collect research data.
2. Is the data reviewed during and throughout the study?

Is there a data monitoring plan (DMP) or data safety monitoring plan/board-(DSMB)?

1. Is the data individually identifiable, coded with a key, de-identified or aggregated?
2. Will a database be used?
3. Will individual subject data or information be used for future research?

If yes, in what format (de-identified)?

1. Will collected and/or stored data be de-identified?
2. Will a code or key be maintained correlating data to subject after the research has completed?

If yes, describe how privacy and confidentiality of the data will be maintained

1. Where, how and for how long is data going to be stored? How is it secured?
2. What happens to the data if the participant withdraws consent?
3. When (at what time point) and how will data be destroyed?
4. **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; also provide a description of the stop rules for participation in the research.

* 1. Provide a definition of an Adverse Event (AEs) and Serious Adverse Event (SAEs) based on the study
	2. How and when do adverse events need to be reported to the PI, oversight bodies, etc?
	3. Detail of how safety data and adverse events will be identified and reported
	4. Safety monitoring, include methods and timings for assessing, recording, and managing adverse events and safety parameters
	5. Also include how will these procedures and stopping rules will be reported for a study participant or if study closure is required (prior to completion of research)
1. **Statistical Analysis\***
	1. Detail the analysis plan
	2. Detail how the primary and secondary outcomes will be analyzed.
	3. Detail statistical methods to be used
	4. Who is going to carry out the analysis?
2. **Quality Assurance, Monitoring & Safety\***

In this section briefly describe any plans or committees responsible for the review and monitoring of research conduct, data quality, safety and performance outcomes.

* 1. Are any external committees overseeing the study such as an IRB, Ethics, Study Steering or Data and Safety Monitoring Board?
	2. Will there be an interim analysis? If so when and how often?
	3. How will research staff be trained on the ICF & protocol (including modifications to the protocol or ICF)?
	4. Are there any specific metrics being collected to measures safety or data quality?
1. **Ethical Issues\***

In this section provide a description of how human subjects’ protections are in effect, if there are inducements for recruitment, what is the risk profile of research, known risks of research procedures (history) and which compliance entities will provide oversight for people enrolled in the proposed research.

* 1. Will subjects be paid or given incentives to participate in the research?
	2. Have interventions been used before?
	3. What goes beyond standard practice or standard of medical care?
	4. Will a placebo be used?
	5. Are there already effective treatments vs the study treatment?

Identify, specify and justify any dual relationships, intended deception or financial inducement to participate in the research

* 1. Identify and justify any non-negligible risk or burden
1. **Sponsor, Funding & Collaborator Information** *(Refer to MRC Policy & Requirements)*

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

As relevant, include information on key collaborators, sub-contractors, etc to support feasibility and anticipated liability of research conduct for multi-center studies.

Do not include budgeting, direct and indirect costs or other financial specifics, as this is handled through a different MRC process.

1. **Dissemination of Results and Publication Policy**
	1. The protocol should specify intended dissemination of results in the scientific media (publication/presentation)
	2. if findings will be released to the community and/ or the participants
	3. if findings will be disseminated to policy makers or public media, where relevant.
	4. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.
	5. To co-author or publish, a researcher is NOT required to be a PI or Co-PI on a research study.
2. **References**

Cite the sources of all reference materials used to support the hypothesis so that a reader or reviewer can find them;

* 1. Provide a list of the literature review, resources, previous studies, etc
	2. The references have several styles and are generally known as end notes, foot notes or bibliographies for making reference to source materials used in the research/ publication.
	3. These “notes” are text placed at the bottom of a page or at the end of document.

They provide an author's reference to the main text or citations of a work quoted or referenced in a paper supporting the content of the text, or both utilized to formulate the work.

* 1. Footnotes are notes at the bottom of the page while endnotes are collected under a separate heading at the end of a chapter, volume, or entire work.
	2. Endnotes have the advantage of not affecting the layout of the main text, but may cause inconvenience to readers who have to move back and forth between the main text and the endnotes.
	3. A bibliography is a complete or selective list of all resources documenting authorship, subject, date and place of publication that are used or consulted in the preparation of the work or that are referred to in the text. It is also the summary or master list of all endnotes and footnotes used in the work.

In English, a footnote is normally flagged by a superscripted number immediately following that portion of the text the note is in reference to, each such footnote being numbered sequentially. Occasionally a number between brackets or parentheses is used instead, typographical devices such as the asterisk (\*) or dagger (†) may also be used to point to footnotes; In Arabic texts, a specific Arabic footnote marker is also used.

Refer to the institutions formatting requirements however the most common formats for citing sources are the

* + 1. APA: American Psychological Association

APA citation style refers to the rules and conventions established by the American Psychological Association for documenting sources used in a research paper. APA style requires both in-text citations and a reference list. For every in-text citation there should be a full citation in the reference list and vice versa.

For examples and more detailed information about APA citation style, refer to the Publication Manual of the American Psychological Association and the APA Style Guide to Electronic References.

Also, for automatic generation of citations in appropriate citation style, use a bibliographic citation management program such as Refworks or EndNote

* + 1. MLA: Modern Language Association

The Modern Language Association (MLA) establishes values for acknowledging sources used in a research paper. MLA citation style uses a simple two-part parenthetical documentation system for citing sources: Citations in the text of a paper point to the alphabetical Works Cited list that appears at the end of the paper. Together, these references identify and credit the sources used in the paper and allow others to access and retrieve this material.

* + 1. Annotated Bibliography

An annotated bibliography is a list of citations to books, articles, and documents. Each citation is followed by a brief (approximately 150-word) descriptive and evaluative paragraph, the annotation. The purpose of the annotation is to inform the reader of the relevance, accuracy, and quality of the sources cited.

1. **Appendices**

An appendix is a list of any attachments or supplements to the protocol or any document that will be used to support research conduct.

Examples are case report forms, data collections sheets, informed consent forms, etc

All intended forms or resources that will be used in the conduct of research to collect data, interview people, recruit participants, etc. need to be provided as an attachment to the protocol and listed in the appendices.