

# Standard Operating Procedures



<b>TITLE: National Reliance Agreement-IRB Submission Process for Investigators</b>		
<b>SOP No: IRB SOP 1</b>	<b>Version No. 1</b>	<b>Effective Date: 27 Sep 2022</b>
<b>Section: IRB</b>		<b>Last Revision Date: NA</b>

## 1. PURPOSE/ INTRODUCTION/BACKGROUND

- 1.1. This procedure establishes the IRB submission process for research proposals when Hamad Medical Corporation (HMC), Weill Cornell Medicine in Qatar (WCM-Q), Sidra Medicine (SM), Qatar Biobank (QBB), and Primary Health Care Corporation (PHCC) are collaborating in human subjects' research under the reliance agreement executed by all parties.
- 1.2. Any participating institutional IRB may serve as the Reviewing IRB for all/any relying institutions, when reviewing institution faculty employee is the lead Principal Investigator and reviewing IRB is the lead institution on the project. All other parties if involved will be the Relying Institution in this case.
- 1.3. This procedure begins when the Principal Investigator has a study to be submitted under the reliance agreement for IRB review.
- 1.4. This procedure ends when the Relying Institution(s) completes institutional review and releases acknowledgement for the submission.
- 1.5. All institutions reserve the right to require joint IRB review or to change the decision to cede review to one another for a given project

## 2. SCOPE

This SOP applies to non-exempt human subjects' research proposed to be conducted between collaborating institutions who have signed the multi-institutional IRB reliance agreement. This Agreement is to avoid duplication of IRB reviews and shorten the period of the approval process among the parties to this Agreement.

## 3. ABBREVIATIONS & DEFINITIONS

- 3.1. **Reviewing IRB:** The "IRB of record" to which authority for IRB review and oversight has been ceded by any other Participating Institution for research under this agreement.
- 3.2. **Reviewing IRB Institution(s):** The Institution whose IRB is the Reviewing IRB for any other Participating Institution for research under this agreement.
- 3.3. **Relying Institution(s):** A Participating Institution that cedes IRB review to a Reviewing IRB for research under this agreement.
- 3.4. **Reviewing Institution's PI:** The lead Principal Investigator (the Lead PI) with ultimate responsibility for the conduct and integrity of Research (generally, the initiating Principal Investigator or funding Principal Investigator, as applicable).
- 3.5. **Relying Institution's PI:** Principal Investigator at the Relying Institution(s) (the site PI).
- 3.6. **Point of Contact:** Individual who serves as the contact person responsible to communicate on behalf of the institution with respect to this agreement.

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3.7. Collaborating Institutions: The collaborators here refer to the following Institutions: Hamad Medical Corporation (HMC), Weill Cornell Medicine in Qatar (WCM-Q), Sidra Medicine, Qatar Biobank (QBB), and Primary Health Care Corporation (PHCC)

## 4. PROCEDURE

4.1. For submission of studies where IRB of any institute will serve as the IRB of Record and either institutions will be the Relying IRB.

4.1.1. The Reviewing Institution PI or research team member has to submit the study package for review and approval according to the requirements of IRB of Record.

4.1.2. The Reviewing Institution PI or the research team must ensure the reliance request form is completed and submitted to Reviewing Institution along with the submission package.

4.1.3. Complete the required steps with IRB of Record to receive IRB approval and stamped study package.

4.1.4. Relying site PI or research team has to submit the approved study package secured from IRB of record and IRB determination letters to relying institution(s) for institutional review & acknowledgement. Scientific Review will be waived as this has been completed at the reviewing institutions (This will be at the discretion of the relying institution(s)).

4.1.5. In case of any institutional review comments (e.g., at the site level) from the Relying Institution that would affect the IRB approved study package, Reviewing Institution PI needs to submit the changes to IRB of Record for review and approval prior to implementation.

4.1.6. Once the institutional review process is complete at the relying institution(s), an acknowledgement letter will be issued.

4.1.7. The reviewing institution's PI has to submit the acknowledgement letter to IRB of record for notification.

4.2. Reviewing institution PI or research team member will submit study package for review and approval according to the requirements along with the Request for Reliance form .

4.2.1. Reviewing Institution PI will complete the required steps to receive IRB approval and stamped package.

4.2.2. Relying site PI or research team has to submit the IRB approved study package and IRB determination letters to relying IRB(s) for institutional review & acknowledgement prior to engaging in the research. Relying IRB(s) will perform institutional review and verify eligibility, training, and complete COI reviews for all their researchers

4.2.3. If there are any aspects of the project that differ from what was submitted at the request stage, relying IRB will review the updated information to ensure the details meet the requirements for review under the reliance agreement.

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4.2.4. In case of any institutional review comments from the relying institution(s) that would affect the IRB approved protocol & information, reviewing institution PI needs to submit the changes to IRB of record for review and approval prior to implementation.

#### 4.3. Submission requirements for Relying Institution(s)

##### 4.3.1. Initial:

- IRB approval letter on the approved reliance template
- Approved application from IRB of record including list and roles of entire study team including the delegates from the relying institutions engaged in human subject activity.
- CV and training for research personnel in accordance with their respective collaborators' policies
- Approved study documents including but not limited to protocol describing the role of collaborators, consent form, data collection sheets and any advertisement or recruitment materials that have been approved and stamped by the IRB of record

##### 4.3.2. Amendments:

- Amendments including personnel changes approved by the IRB of record must be submitted to relying IRB for notification within 2 weeks of receiving the approval notice
- Any changes to the initial approval of the study must be submitted to the IRB of record before implementing it in the relying institution.

##### 4.3.3. Continuing review/progress report:

- Continuing review approval letter, progress report & stamped versions of the study documents. Valid training for research personnel in accordance with collaborators policies
- Continuing reviews must be submitted to relying IRB within 2 weeks of receiving the renewal from IRB of record.

##### 4.3.4. Reportable events:

- Reportable events as defined by the MoPH Guidelines are to be reported to respective IRB through the site PI, it is the Lead PI responsibility to ensure the IRB of record is notified and other relying institutions.

##### 4.3.5. Project closures:

- Investigators are required to submit the following for closure of sites
- Final reports submitted and reviewed by the IRB of records with supporting documents must be submitted to relying IRB within 2 weeks of receiving the closure notice from IRB of record.

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- 4.3.6. Once the institutional review process is complete at relying institutions, an acknowledgement letter will be issued.
- 4.3.7. Reviewing Institution PI has to submit the acknowledgement letter to IRB of record for notification.
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**Note: The process flow is the same for initial reviews, all amendment including personnel updates, continuing review, and reportable events.**

- 4.4. For eligibility and training, each research personnel should abide by their respective institutions' policy requirements.

## **5. RESPONSIBILITIES OF REVIEWING INSTITUTION PI**

- 5.1. Collect information from the Relying Institution(s) PI required for the protocol application, including but not limited to the information listed below and any information that must be considered by the Reviewing IRB and provide such information to the Reviewing IRB.
- 5.2. Collect the following information for the IRB application:
  - a. List of all research personnel involved in the study at Relying Institution(s).
  - b. CVs and evidence of training for the PI and research personnel at the Relying Institution(s).
  - c. Financial interest disclosure for PI and each research personnel involved in the study at the Relying Institution(s).
- 5.3. Promptly provide the Relying Institution PI with:
  - a. All IRB determinations and IRB approved versions of all study documents.
  - b. Approved modifications, amendments, or changes to the protocol.
  - c. Approval of continuing reviews, reviews of unanticipated problems.
  - d. Any other information required by the Reviewing IRB to be provided to the Relying Institution.
- 5.4. Collect the Relying Institutions' acknowledgement and study package and submit to the Reviewing IRB for notification.
- 5.5. Notify the Relying Institution(s) of any post-approval events.
- 5.6. Ensure institutional approvals from the Relying Institution(s) are obtained prior to activation of the study at the Relying Institution(s).
- 5.7. Conduct the protocol and obtain informed consent as approved by the Reviewing IRB.
- 5.8. If at any time study approval lapses, cease all human subject research work related to the protocol at the Relying Institution(s). If the Relying Institution(s) determines that subjects who

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are already enrolled on the trial may be harmed if research ceases, notify the Reviewing Institution's PI about the individual subject(s) and the justification for remaining on the trial.

- 5.9. Collect required information from the Relying Institution(s) PI in order to complete the continuing review submission form.
- 5.10. Collect reports from the Relying Institution(s) PI of any unanticipated problems deviations, suspensions and terminations, noncompliance, subject complaints, and submit such reports to the Reviewing IRB.
- 5.11. Notify the Relying Institution(s) PI about any lapses of approval. Forward to the Reviewing IRB, any request from the Relying Institution PI for continuation of a specific patient on a research protocol during a lapsed period of approval.
- 5.12. Promptly cooperate with any Reviewing or Relying Institutions' investigation regarding serious or continuing noncompliance or an unanticipated problem upon request.
- 5.13. Promptly cooperate with any Reviewing or Relying Institutions' quality assurance/quality improvement or monitoring of the study protocol upon request.

## **6. RESPONSIBILITIES OF RELYING INSTITUTION PI**

- 6.1. Provide the Reviewing Institution PI any information that must be considered by the Reviewing IRB for the Relying Institution(s).
- 6.2. Provide the Reviewing Institution's PI:
  - a. List of all research personnel involved in the study at the Relying Institution(s).
  - b. CVs and evidence of training for the PI and all research personnel involved in the study at the Relying Institution in accordance with the relying institution's policies.
  - c. Any other information required by the Reviewing IRB regarding the PI and/or research personnel involved in the study at the Relying Institution.
  - d. Any other institutional specific requirements. Eg: Reliance Request form.
- 6.3. Ensure to abide by the eligibility requirements as per institutional policies for the researchers from the Relying Institution(s).
- 6.4. Submit the approved study to the relying institution's IRB and provide CV, training and COI forms as per institutional policies and procedures.
- 6.5. Assure that any additional ancillary reviews for human research protection reviews (hospital committees, pharmacy, nursing, radiation safety, etc.) are obtained and followed at the Relying Institution(s).
- 6.6. Provide to the Reviewing Institution's PI any comments from the Relying Institution(s) that may affect the IRB approved study documents.
- 6.7. Provide the acknowledgement letter (as applicable to the relying institution's process) to the Reviewing Institution's PI.

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- 6.8. Assure that research activities at the Relying Institution(s) are not initiated until all Reviewing and Relying Institution(s) requirements for the study regarding funding and clinical trial agreements are finalized.
- 6.9. Conduct the protocol and obtain informed consent as approved by the Reviewing IRB.
- 6.10. As requested on a continuing basis, provide the Reviewing Institution's PI with any information necessary for the continuing review process. This may include information regarding subject recruitment, summary of all enrolled subjects, screen failures, minor violations and all other information needed for continuing review.
- 6.11. If at any time study approval lapses, cease all human subject research work related to the protocol at the Relying Institution. If the Relying Institution(s) determines that subjects who are already enrolled on the trial may be harmed if research ceases, notify the Reviewing Institution's PI about the individual subject(s) and the justification for remaining on the trial.
- 6.12. Consistent with the Reviewing IRB's policies, report all post-approval events such as proposed amendments, deviations, subject injuries, unanticipated problems involving risks to subjects or protocol violations to the Reviewing site PI.
- 6.13. Promptly cooperate with any Reviewing or Relying Institutions' investigation regarding serious or continuing noncompliance or an unanticipated problem upon request.
- 6.14. Promptly cooperate with any Reviewing or Relying Institutions' quality assurance/quality improvement or monitoring of the Study protocol upon request.
- 6.15. In the event of an audit, allow the Reviewing Institution's PI and Institutional Officials access to research related records.
- 6.16. Maintain records of all research and related activities conducted under the Reliance Agreement for at least 5 years, and longer if required by sponsors or other applicable regulatory bodies, after completion of any study.
- 6.17. Promptly respond to all requests for information from the Reviewing Institution PI or Reviewing IRB, including but not limited to the information set forth in this SOP.
- 6.18. Cooperate with the Reviewing Institution in reporting and resolving any conflicts of interest reported by the Relying Institution(s) PI(s) and/or research personnel at the Relying Site(s), including but not limited to entering into management plans, as required by the Reviewing IRB.

Version	Description of update	Effective Date
V1	First version	27 Sep 2022