



Weill Cornell Medical College in Qatar



---

# **INSTITUTIONAL REVIEW BOARD PROCEDURES**

## **VERSION 2009.2**

# TABLE OF CONTENTS

---

<b>TABLE OF CONTENTS</b> .....	<b>2</b>
<b>WCMC-Q IRB REVIEW PROCESS</b> .....	<b>3</b>
SUBMISSION DEADLINES AND MEETING SCHEDULES .....	3
MATERIALS SUBMITTED BY INVESTIGATORS .....	3
<i>Initial Review</i> .....	3
<i>Investigator's Response to IRB's Request for Additional Information</i> .....	3
<i>Continuing Review</i> .....	3
<i>Modifications to Approved Protocol</i> .....	3
<i>Adverse Event or Unanticipated Problem Report</i> .....	3
<i>Final Report Form</i> .....	4
MATERIALS REVIEWED BY IRB .....	4
<i>Expedited Review</i> .....	4
<i>Convened IRB Review</i> .....	4
ADMINISTRATIVE REVIEW .....	4
EXPEDITED REVIEW .....	5
CONVENED IRB REVIEW .....	5
IRB COMMUNICATIONS .....	5
CONTINUING REVIEW .....	7
<i>Duration of Approval</i> .....	7
<i>Expiration Dates</i> .....	7
<i>Expired Protocols</i> .....	7
<i>Material Changes since Previous IRB Review</i> .....	7
<b>EXEMPTION FROM IRB REVIEW</b> .....	<b>9</b>
AMENDMENTS TO EXEMPT RESEARCH .....	9
VALIDITY OF NOTICE OF EXEMPTION .....	9
<b>IRB RECORDS</b> .....	<b>10</b>
PROTOCOL RECORDS .....	10
MEETING MINUTES .....	10
IRB MEMBERS .....	11
<i>Membership Composition</i> .....	11
<i>Consultant Requests</i> .....	11
<i>Member Appointments</i> .....	12
<i>Member Training and Education</i> .....	12
<i>Membership Rosters</i> .....	12

## **WCMC-Q IRB REVIEW PROCESS**

---

### **SUBMISSION DEADLINES AND MEETING SCHEDULES**

WCMC-Q IRB publishes [submission deadlines and meeting schedules](#) on its web page. The submission deadlines do not apply to requests for exemptions, which are accepted on an ongoing basis.

### **MATERIALS SUBMITTED BY INVESTIGATORS**

Investigators are required to submit all materials and communications to the IRB via the on-line IRB application system. The WCMC-Q IRB does not accept any paper applications or attachments.

#### ***Initial Review***

Investigators are required to complete the on-line IRB application. In addition, investigators are required to submit the following materials, when applicable:

1. Recruitment materials
2. Informed consent documents
3. Surveys, questionnaires, other instruments
4. Grant application
5. Sponsor's protocol
6. Investigator's drug brochure
7. Device brochure
8. Dietary supplement / botanical product information brochure

#### ***Investigator's Response to IRB's Request for Additional Information***

Investigators are required to submit an itemized response to each of the IRB's concerns. In addition, investigators are required to update all documents and information submitted at initial review as necessary.

#### ***Continuing Review***

In addition to completing the on-line IRB Continuing Review Application, investigators are required to update all documents and information provided at initial review as necessary.

#### ***Modifications to Approved Protocol***

In addition to completing the on-line IRB Amendment Application, investigators are required to update all documents and information submitted at initial review as necessary.

#### ***Adverse Event or Unanticipated Problem Report***

Investigators are required to complete the on-line IRB Adverse Event or Unanticipated Problem Report Application. In addition, investigators are required to submit an IRB Amendment Application when updates to study documents and

information submitted at initial review are required as a result of an adverse event or an unanticipated problem.

### ***Final Report Form***

Investigators are required to complete the on-line Final Report Form at the conclusion of the study. IRB Chair or his/her designee reviews the final report form. Upon review of the form, the reviewer may make one of the following determinations: a) study may be closed without further action; b) additional information concerning subject protection is required; or c) report requires review by the convened IRB.

## **MATERIALS REVIEWED BY IRB**

### ***Expedited Review***

WCMC-Q IRB utilizes an on-line application submission process. The reviewers have access to, and are expected to review, all of the information submitted by the investigators as part of their on-line application. In addition, the reviewers have access to, and are expected to review, regulatory and administrative guidance provided by the IRB staff for each submission.

### ***Convened IRB Review***

For studies requiring convened IRB review, all Board members have access to, and are expected to review, all of the information submitted by the investigators as part of their on-line application. In addition, the Board members have access to, and are expected to review, regulatory and administrative guidance provided by the IRB staff for each submission.

## **ADMINISTRATIVE REVIEW**

Upon receipt of a submission, the IRB staff conducts an administrative review of the application to ensure that the submission is complete and adheres to all applicable regulations. If additional information is required, the IRB staff sends a request for modifications to the investigator. If no additional information is required, the IRB staff, in consultation with the IRB Chair or his/her designee, makes the following determinations:

1. Whether the described activities constitute human subjects research; and
2. Whether the proposed submission requires convened IRB review, if it may qualify for expedited review, or whether the submission meets the criteria for exemption from IRB review.

The above determinations are made based on the policies outlined in the [WCMC-Q IRB Policy Manual](#).

## EXPEDITED REVIEW

Once it is determined that a submission qualifies for expedited review, the IRB staff forwards the submission to the Chair and/or his/her designee for review of the submission. The reviewer conducts the review in accordance with the policies outlined in the “Expedited Review” section of the [WCMC-Q IRB Policy Manual](#).

## CONVENED IRB REVIEW

Upon completion of the pre-review process, the IRB staff, in consultation with the IRB Chair or his/her designee, assigns a primary and a secondary reviewer to each submission. A tertiary reviewer and/or a consultant reviewer may also be assigned when necessary at the discretion of the IRB Chair or his/her designee. The reviewers and/or the consultants provide their comments to the Board at the beginning of the discussion of each submission. When necessary, the reviewer and/or consultant comments may be presented via conference call or through documented reviewer comments. Following the presentation of the reviewer and/or consultant comments, the convened Board discusses the submission and makes final determinations. The convened IRB reviews all items on the agenda in accordance with the policies outlined in the “Convened IRB Review” section of the [WCMC-Q IRB Policy Manual](#).

Submissions for each meeting are accepted in accordance with the posted [submission deadlines](#). Submissions received after the deadline may only be added to the meeting agenda upon approval of the IRB Chair or his/her designee.

## IRB COMMUNICATIONS

The WCMC-Q IRB issues the following communications, as appropriate, for each submission:

1. ***Acknowledgment:*** Acknowledgment is most commonly issued to acknowledge adverse event submissions that do not require any further action.
2. ***No Further Action Necessary Notification:*** This notification is issued in response to a protocol violation or unanticipated problem submission that requires no further action.
3. ***Request for Modifications:*** Request for modifications may be a result of pre-review or IRB review of a submission. It is a request for minor modifications or clarifications. The investigator’s response to the request for modifications may, however, result in the reviewer’s referral of submission for convened IRB review.
4. ***Deferral Notice:*** Deferral notice is issued when the IRB has raised significant concerns regarding a protocol, and the investigator is requested to address

these concerns. The investigator's response to a deferral notice requires review by a convened IRB.

5. **Referral to Convened IRB:** The investigator is notified when a reviewer refers a response to a request for modifications for convened IRB review.
6. **Request for Amendment:** This is the IRB's request for an investigator to submit an amendment application. This is most commonly requested in response to an adverse event submission, a protocol violation, an unanticipated problem submission or an audit.
7. **Submission Tabled Notice:** The IRB informs the investigator when a submission is tabled during an IRB meeting. A submission may be tabled due to a loss of quorum, lack of expertise at the meeting, or other related causes.
8. **Approval or Disapproval notice:** A formal determination notice is issued for each submission.
9. **Audit Notification:** The IRB informs an investigator prior to a planned audit of one of his/her protocols.
10. **Continuing Review Reminder:** The IRB issues a continuing review reminder approximately 60 days prior to the expiration of approval. The IRB also issues a final notice approximately 30 days prior to the expiration of approval.
11. **Expiration Notification:** The IRB issues a notice of expiration once a study has expired.
12. **Closure Notice:** Confirmation of closure of a study. Closure notice is issued when all research activities, including data analysis, have been completed. This is most commonly issued in response to a Final Report submission.
13. **Withdrawal Notice:** This is the IRB's confirmation of a withdrawal requested by an investigator after submission, but prior to its review by the IRB.
14. **Suspension Notice:** Issued by the IRB when a protocol has been suspended. Investigators are required to suspend all research activities, including subject contact, data collection and data analysis, related to a suspended protocol until the suspension has been lifted.
15. **Notice of Study Termination:** Notice of IRB's termination of a protocol. This is most commonly issued when a study remains expired for three months or longer without any action from the investigator.
16. **Notice of Exemption:** A formal determination notice of exemption from IRB review.

17. ***Non-Human Subjects Research Determination:*** Issued by the IRB in cases where the research activities described by the investigator do not constitute human subjects research, as defined in the “Human Subjects Research” section of the [WCMC-Q IRB Policy Manual](#).

The IRB will notify the investigators of its decision to approve, disapprove or require modifications to the proposed research within two weeks of the IRB meeting during which the research is reviewed.

## CONTINUING REVIEW

### ***Duration of Approval***

IRB approval of a research project will be valid for a maximum of one year from the date of IRB review. The IRB may decide to approve a given protocol for duration of less than one year. Such a decision may be based on a number of factors, including but not limited to, the nature of the study, the degree of risk involved, and the vulnerability of the subject population.

### ***Expiration Dates***

Expiration dates of each approval are documented on the approval notice.

For studies approved by a convened IRB, the expiration date is based on the date of the meeting during which the convened IRB approved the submission. Please note that the convened IRB may request minor modifications during this meeting, which must be addressed to the satisfaction of the Chair and/or his/her designee prior to the issuance of an approval notice.

For studies approved via expedited review process, the expiration date is based on the date that the reviewer(s) grants a final approval.

### ***Expired Protocols***

If the approval of a given study expires, and continuing review approval has not been issued by the IRB, the investigator is required to suspend subject contact, data collection and data analysis until the continuation is approved by the IRB.

In case of therapeutic studies, investigators must act in the best interest of continuing subjects. However, no new subjects may be enrolled. Research procedures conducted in order to prevent harm to continuing subjects after the expiration date must be reported to the IRB within two business days of the activity.

If a study remains expired for three months or longer without any action by the investigator, the WCMC-Q IRB will terminate the study, and take appropriate and necessary steps to protect the rights and welfare of human subjects.

### ***Material Changes since Previous IRB Review***

Investigators are required to inform the IRB of any material changes that have

occurred since previous IRB review at the time of continuing review. The IRB may determine that a project requires verification from sources other than the investigator that no material changes have occurred since previous IRB review on a case-by-case-basis.

The IRB may require such verification based on:

1. The complexity of the research project
2. Level of risk involved
3. Vulnerability of subject population
4. History of non-compliance by research investigator
5. Information disseminated by regulatory authorities or other sources
6. Any other factors that the IRB deems reasonable

## **EXEMPTION FROM IRB REVIEW**

---

The IRB, not the investigator, must determine whether a research study meets the criteria for exemption from IRB review, as outlined in the “Research Exempt from IRB Review” section of the [WCMC-Q IRB Policy Manual](#). The investigator must complete the on-line Exemption Application. The IRB staff, in consultation with the IRB Chair or his/her designee, review the Exemption Application. Investigators may not initiate exempt research until and unless they have received a notice of exemption from the WCMC-Q Office of Research.

### **AMENDMENTS TO EXEMPT RESEARCH**

Amendments to exempt research must be submitted via the on-line application system. The IRB staff, in consultation with the IRB Chair or his/her designee, review the request for modifications to evaluate whether the research continues to qualify for exemption from IRB review. If the research no longer qualifies for exemption from IRB review, the investigator is notified and the submission is forwarded for IRB review. If the research qualifies for exemption from IRB review, a new notice of exemption is issued.

### **VALIDITY OF NOTICE OF EXEMPTION**

A notice of exemption is valid for the life of the proposed research, as long as the research is not modified.

## **IRB RECORDS**

---

### **PROTOCOL RECORDS**

The WCMC-Q IRB maintains electronic records of all protocols submitted for IRB review within its electronic review system. Protocol records include, but are not limited to, the following:

1. All research proposals reviewed by the IRB, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports and reports of injuries to subjects;
2. Continuing review activities;
3. Correspondence between the IRB and the investigators; and
4. Statements of significant new findings provided to the subjects.

### **MEETING MINUTES**

The WCMC-Q IRB maintains electronic records of all IRB meeting minutes. IRB meeting minutes include the following elements:

1. Start time, end time, date and location of the meeting
2. IRB member and non-member attendance at the meeting, including an indication of attendance via conference call
3. Conflicts of interest, and notation of any recusals
4. Actions taken and determinations made by the IRB for each agenda item, and the vote on these actions and determinations, including the number of members voting for, against and abstaining
5. Any changes required by the IRB for each submission and the basis for the requested changes
6. If disapproving a submission, the basis for the disapproval
7. Summary of controverted issues and their resolution
8. Notification of expedited approvals granted since the previous IRB meeting

9. If approving a submission, the approval interval for each submission

## IRB MEMBERS

### ***Membership Composition***

The WCMC-Q IRB shall maintain membership to meet the following criteria:

1. A minimum of five members with varying backgrounds.
2. Sufficient qualifications through the experience and expertise of the members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for IRB's advice and counsel in safeguarding the rights and welfare of human subjects.
3. Sufficient expertise to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
4. When reviewing research involving a vulnerable population, such as children, pregnant women, handicapped or cognitively impaired persons, include at least one member who is knowledgeable about and experienced in working with these subjects.
5. At least one scientist member.
6. At least one non-scientist member.
7. At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

### ***Consultant Requests***

The WCMC-Q IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

Consultants may be requested by:

1. IRB Chair or his/her designee upon completion of the administrative review process.
2. Assigned reviewer(s) during the expedited review process.

3. Assigned reviewer(s) prior to convened IRB review.
4. Convened IRB during discussion of submission.

Although consultants may participate in the IRB's discussion of a submission and advise the IRB, they may not vote with the IRB.

### ***Member Appointments***

The Vice Dean for Research and the Director of Research Compliance appoint members to the IRB in accordance with the above criteria. The Vice Dean and the Director review and adjust the membership periodically, but no less than annually.

### ***Member Training and Education***

WCMC-Q IRB member training comprises of the following:

1. All members undergo an orientation with the Director of Research Compliance and/or the IRB Administrator. The orientation includes a discussion of the IRB process, the *Belmont Report* and WCMC-Q policies and procedures. Members are also provided with the following documents at orientation:
  - a. World Medical Association's Declaration of Helsinki
  - b. The Belmont Report
  - c. WCMC-Q IRB Policy Manual
  - d. WCMC-Q IRB Procedures
2. Members are required to complete on-line training in the protection of human subjects offered by the [Collaborative Institutional Training Initiative \(CITI\)](#) prior to the second meeting of their term.
3. Dissemination of information on selected topics and/or presentation by the IRB staff on select topics during the convened IRB meetings on an as needed basis.
4. The journal, *IRB: Ethics and Human Research*, is available to all members via the WCMC-Q Distributed eLibrary. Members should contact the Librarian for access to the journal.
5. A compilation of articles related to research compliance and ethics are made available to the IRB members via the Research Compliance web page.
6. Members are encouraged to attend conferences and/or workshops related to the protection of human subjects.

### ***Membership Rosters***

The WCMC-Q IRB maintains an [electronic roster](#) of the IRB members, which is available on the WCMC-Q IRB web page. The membership roster includes the following information about each member:

1. Name
2. Earned degrees
3. Representative capacity
4. Indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations
5. Employment or other relationship between member and institution