

Institutional Review Board (IRB) / Independent Ethics Committee (IEC) Registration Application

Step-by-Step Instructions for (IRB) or (IEC) registration

Note: - Only institutions or organizations that have their own Institutional Review Board(s) (IRB) or Independent Ethics Committee (s) (IEC) should submit an IRB/IEC Registration form. Institutions that do not have their own IRB/IEC but rely on the IRB/IEC of another institution should not submit an IRB Registration.

Indicate by an [X] whether this is a:

"New application" or, "Update or Renewal" of an already existing IRB /IEC The update or renewal includes the "Addition of New IRB(s)".

If the IRB /IEC is already registered with the Ministry of Public Health- Department of Research, please provide your institution's "*IRB Organization (IORG) number*".

ITEM # 1- Organization operation the IRB (s)/ IEC(s)

Type or print the full legal name of the institution or organization that is registering the IRB/IEC and full mailing address. Also, include the street address if it is different than the mailing address.

ITEM #2- Senior or Head Official of Organization Operating the IRB(s)/IEC(s)

Type or print the full name, degree(s), organization title (e.g., President, Provost, Chief Operating Officer), telephone number, fax number, e-mail, and full mailing address for the senior or head official of the organization operating the IRB/IEC [i.e., the person in your organization who is ultimately responsible for the performance and conduct of the IRB(s) or IEC(s).

ITEM #3- People providing this information

Type or print the name, title, telephone number, fax number, and e-mail for the person providing the information submitted on the IRB/IEC Registration form.

ITEM #4- Information on Each IRB/IEC to be Registered, Updated, or Renewed

a. Indicate how many IRBs/ IECs are to be registered, updated or renewed with your submission.

Type or print the following information [items 4(f) for each IRB/IEC to be registered. If you are registering more than one IRB/IEC.



- b. **IRB Number** If your submission is an update or renewal, type or prints the IRB Registration number of the IRB/IEC. For each new IRB/IEC, provide the sequence number (e.g., IRB#1, IRB#4) of the IRB.
- c. For first time submissions of an IRB/IEC Registration, the department of research will name each IRB/IEC using the name of the IRB/IEC Organization in item #1 followed by a sequential number (e.g., IRB#1, IRB#2) for each IRB/IEC registered. For example, if ABC University registers three IRBs, the Department of Research will name the IRBs: ABC University, IRB#1; ABC University, IRB#3.

If you would like to customize or add descriptive Suffix (e.g., Behavioral, Biomedical) to the name given by the Ministry of Public Health, then provide your entry or additional name in this section of the IRB Registration form.

For an update or renewal of an IRB Registration, the IRB name registered with Ministry of Public Health- Biomedical Research Section (or modification of the name) should be entered in this section of the IRB registration form.

Provide the location, city and country, for each IRB/IEC, if different from the location in item #1.

- d. In this section you are asked to provide optional information related to the IRB/IEC. If you choose to answer these questions, indicate your choice with either an [X] or a check mark.
 - 1. Indicate whether or not the IRB or its parent organization has been accredited by a human subject protection accrediting organization. If yes. Provide the name of the accrediting organization and the date of accreditation.
 - 2. Provide the approximate total number (**none**= 0; **small**=1-25; **medium** = 26-99; or **large** = 100 or more) of currently active protocols.

"An active protocol is defined as any protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year".

- 3. Provide the approximate number of full-time positions devoted to IRB's administrative activities. This number should include the sum of all full-time and part-time positions, to include professional, administrative, and support staff.
- 4. Respond with whether or not the IRB reviews or intends to review (within the 3-year period covered by the IRB Registration) research supported by non-Qatari Government entity.
- 5. Provide the approximate number of currently active protocols supported by the Qatari government (Qatar Foundation).
- 6. Provide the approximate number of currently active protocols supported by non-Qatari entity.
- e. Type or print the full name, degree(s), organizational title, telephone number, fax number, email and full mailing address for the IRB/IEC Chairperson. Please make sure to include an email address to facilitate future correspondence.

T: +974 44070000 P.O. Box: 42, Doha - Qatar



f. IRB Roster Form:

General Information – Completion of the IRB Roster is required if your IRB/IEC is designated on an assurance submitted to the department of Research.

If the IRB/IRC is designated under the department of Research assurance, be sure your IRB/IEC meets the requirements for membership. A proper training in programs related to human subject protection module and IRB members module is obligated via completion of CITI training. As detailed in Qatar Ministry of Public Health's "Guidelines, Regulations and policies for Research involving Human Subjects" the IRB shall:

- 1. Have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, and cultural backgrounds and sensitivity to such issues as cultural, religious and community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- 2. Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
- 3. If an IRB regularly reviews research that <u>involves a vulnerable category of subjects</u>, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- 4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- 5. Include at least one member who is not otherwise affiliated with the institution operating the IRB and who is not a part of the immediate family of a person who is affiliated with it.
- 6. Make every effort to ensure that no IRB consists entirely of men or entirely of women. No IRB may consist entirely of members of one profession.
- 7. Have no member participate in the IRB's initial continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. **These individuals may not vote with the IRB**.

8. Each designated IRB committee must have at least <u>one full time Research Coordinator (RC)</u>. The Research Coordinator is ACRP (Association of Clinical Research Professional) and or CIP (Certified IRB Professional) certified.



The RC is certified or eligible to be certified within 1 year of application.

Instructions - At the top of the IRB Roster form please include the name of the IRB Organization designated in **item#1** and the IRB Registration Number and / or Sequence Number [see instructions for **item 4(b)** on page 2].

For each listed IRB/IEC member:

9. Type or print the list of members on your IRB/IEC. Primary members should be listed in the top section of the form and alternate members in the lower section.

Note: Do not list **non-voting** individuals who attend IRB meetings. Their attendance may be documented in minutes of the meeting.

- 10. Type or print the "Gender" [e.g., male (M) or female (F)] and the highest "Earned Degree(s)" (e.g., Ph.D., MD., MSW, B.A.).
- 11. Type or print the IRB/IEC member's "Primary scientific or nonscientific specialty "(e.g., Sociology, Internal Medicine, and Library Services). Also, either in the "Primary Scientific or Nonscientific" field or in "Comments" indicates if a given member provides special representation for the IRB (e.g., prisoner representative, advocate).
- 12. Type or print the IRB/IEC member's "Affiliation with Institution(s)' (e.g., employees, students, board members, alumni, etc., should be listed as "Y" or "Yes"; members with no affiliation or relationship with the institution operating the IRB other than being an active IRB member should be listed as "N" or "No").
- 13. Type or print any additional relevant information regarding a given IRB/IEC member in the "Comments" section (e.g., prisoner representative, advocate).

When listing the alternate members, designate the corresponding number or name of the regular member(s) which a given alternate member represents. This information may be entered in the comments section.



Submitting an IRB/IEC Registration Form to the Department of Research

Please review and proofread all materials to be submitted and ensure that all parts of the registration form are complete and accurate. **Incomplete or incorrect documents may delay processing and registration of your IRB/IEC.**

Completed IRB/IEC registrations should be mailed, faxed, or e-mailed, single-sided, to Department of Research, Ministry of Public Health of the state of Qatar.

If you would like to e-mail your registration, please contact us on: irb@moph.gov.qa

Once your institution's IRB/IEC registration has been processed, the senior or head official of the organization operating IRB/IEC will be notified with the disposition of the application.

After approval, IRB registration is valid for three years.

Institutional Review Board (IRB) / Independent Ethics Committee (IEC) <u>Registration Form</u>

Please complete the form below and submit it to the Research Division at the Ministry of Public Health via **irb@moph.gov.qa**

Note: Only institutions or organizations that have their own Institutional Review Board(s) (IRB) or Independent Ethics Committee (s) (IEC) should submit an IRB/IEC Registration form. Institutions that do not have their own IRB/IEC but rely on the IRB/IEC of another institution should not submit an IRB Registration.

To avoid any delays, please follow the instructions carefully

Date: ___/___/

[] New application [] Update or Renewal - IRB Number: _____

Includes: [] Addition of New IRB(s)

1. Organization Operation the IRB(s)

Name of Organization:

Mailing Address:

Street Address (if different from Mailing Address above):

City:

Country:



2. <u>Senior or Head Official of Organization Operating the IRB(s)</u>

First Name:	Middle Initial:	Last Name:
Degrees or Suffix:	Organizational Title:	
Telephone:	FAX:	E-Mail:
Mailing Address (if different from	Mailing Address above):	
City:		
Country:		
3. <u>Name, Title, Telephone Numb</u> <u>Information</u>	er, FAX Number, and E-mail o	of Person Providing this
First Name:	Middle Initial:	Last Name:
Degrees or Suffix:	Organizational Title:	
Telephone:	FAX:	E-Mail:
Mailing Address (if different from Mailing Address above):		

City:

Country:

4. Information on Each IRB to be Registered, Updated, or Renewed

a) How many IRB(s) are to be registered, updated, or renewed with this submission?

Please provide the information in 4 (b) through and 4 (f) for each IRB.

- b) IRB Registration Number: ______ (e.g., IRB0000xxxx, for updates and renewals)
 Sequence #: _____ (e.g., IRB#1? IRB#3)
- c) Suffix of IRB Name : [see instructions, item 4(c)]:

Provide City and Country (if different from location in item 1):

City: _____ Country: _____

d) Please provide the following (optional) information about this IRB only.



1. Has the IRB or its parent organization been accredited by a human subject protection accrediting organization?

[] Yes [] No

If yes, provide the name of the accreditation:

And the date of accreditation: _____

2. Approximate total number of currently active protocols:

[] none = 0 [] small = 1-25 [] medium = 26-99 [] large = 100 or more

- 3. Approximate number of full-time positions devoted to this IRB
- 4. Administrative activities: _____
- 5. Does the IRB review or intend to review research supported by the Qatari Government?

[]Yes []No

6. Approximate number of currently active protocols supported by the Qatari Government:

[] none = 0 [] small = 1-25

- [] medium = 26-99 [] large = 100 more
- 7. Approximate number of currently active protocols supported by Non- Qatari Government:
 - [] none = 0 [] small = 1-25
 - [] medium = 26-99 [] large = 100 more