Local / Foreign Institutional Review Board (IRB) / Independent Ethics Committee (IEC) Assurance Application for the Protection of Human Subjects Involved in Research

Requirements

Each institution that is engaged in human subjects' research must submit an Assurance to Department of Research of the Ministry of Public Health*. In general, an institution is engaged in human subject's research whenever: (**a**) the institution's employees or agents intervene or interact with human subjects for research purposes; (**b**) the institution's employees or agents obtain individually identifiable private information about human subjects for research purposes; or (**c**) the institution receives Qatari funds to conduct human subject's research, even where all activities involving human subjects are carried out by subcontractor or collaborator.*

The Assurance Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

Follow the instructions below for each item on the Assurance form. If you have further questions after reading these instructions, please contact Research Division, Qatar Ministry of Public Health via email: **irb@moph.gov.qa**

If there are any changes to an Assurance after its approval, the institution should submit an update to that information to Department of Research.

Step-by-Step Instructions for institutional (IRB) or (IEC) Assurance
Top Right-Hand Corner - "New filling" versus 'update or Renewal"

Indicate by an [X] whether it is either:
"New application" or,
"Update or Renewal" of an already existing Assurance

If your institution already has an approved Assurance, the form should be appropriately marked with [**X**] as an ***"Update or Renewal"***, and make sure to include the "***institution's Assurance (IA) number***".

ITEM # 1- Institution Filing Assurance

a. Type or print the legal name of the institution (or the name the institution uses in doing business) that is providing the Assurance. **Please do not provide both names in this section.** Any alternate name(s) or components of the institution filing the Assurance or separate legal entities that will be covered by the Assurance should be listed under Item #2 of the Assurance form.

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Any component that does business in its own name (e.g., applies for research funding) may file its own Assurance form if the organization's administrative structure permits the component to make legally binding commitments to the Terms of Assurance independent of the "parent" institution. Such a decision may be appropriate if the component has its own human subjects' protection program that is separate or distinct from the "parent" institution. Each institution engaged in human subjects' research must submit its own Assurance form, except in the situation where there is a request for an extension of the Assurance to cover individuals at another institution.

b. Type or print the city and state/country where the institution is located.

***ITEM #2*- Institutional Components**

Type or print the names of all components of the institution identified in item #1 that will be covered by the Assurance, including any alternate names used by your institution or its components. Components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution.

For example, ABC University can list its XYZ University Hospital, KLM School of Public Health, etc. as components. In order to keep the listing of components manageable, only list the major components of your institution that is likely to be represented as a research performance site. Please do not list all departments of your institution, as their participation in a study is likely to be represented by the name of the institution or one of the major components.

***ITEM #3*- Statements of Principles**

Indicate by an [x] the statement of ethical principles that govern your institution in fulfilling its responsibilities for the protection of the right and welfare of human subjects in research. The Ministry of Public Health recognizes the US National Institutes of Health, The Belmont Report as acceptable statements of ethical principles for the protection of human subjects in research. If "Other Statement of Principles" is selected, a copy of those principles must be submitted to Department of Research at the time the Assurance form is submitted.

***ITEM #4*-Applicability**

a. Review the Terms of Assurance for Institutions within the State of Qatar to better understand of the regulatory requirements that will be applied to human subjects' research.
b. **Completion of this section is optional**. This section provides the institution with the option of voluntarily applying Guidelines, Regulations and Policies for Research Involving Human Subjects to all research. Indicate with an [x] whether your institution elects to apply these guidelines to all human subjects' research unless the department conducted or supporting the research determines that the research shall be conducted under a separate assurance.

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***ITEM #5*- Designations of institutional Review Boards (IRBs)**

Designate your institution's Institutional Review Boards (IRBs) of record for this Assurance. **You must indicate at least one collaborative Qatari IRB in this section.** ***Please ensure that the Qatari IRBs are registered or are in the process of registering, with the Department of Research at the Qatar Ministry of Public Health prior to submitting an Assurance form to the Department. The Department of Research does not take action on an Assurance form until at least one of the designated IRBs is registered and assigned an IRB Registration number***. If the registration of the IRB is in process when you submit your Assurance, the Department of Research will insert the IRB Registration number. Any IRB relied upon the institution for review of human subjects research to which the Assurance applies must be registered and must be designated under the institution's Assurance. An Assurance may be updated at any time to designate additional IRBs.

If your institution relies on the IRB of another institution or organization, this arrangement must be documented in writing between the two institutions/ organizations. The agreement must be kept on file at the institutions and available for review by Department of Research upon request, but it should not be submitted with the Assurance form.

***ITEM #6*- Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)**

Designate the individual who will serve as the Human Protections Administrator (HPA) (i.e., the primary contact person for human subject's protection issues) for your institution. The HPA would exercise operational responsibility for your institution program for protection human subjects in research. The HPA should have comprehensive knowledge of all aspects of your institution's system for protection human subjects, as well as be familiar with the institution's commitments under the Assurance, and play a key role in ensuring that the institution fulfills its responsibilities under the Assurance. Please note the HPA should be prepared to fulfill the responsibilities noted for all research covered under the Assurance.

Type or print the full name, degree(s) or suffix, institutional title (e.g., administrative title such as manager or director of a given office), institution name, telephone and fax numbers, e-mail address, and full mailing address for the HPA. The e-mail address is very important, as this will provide the means for effective communication.

***ITEM #7*- Signatory Officials (i.e., Official Legally Authorized to Represent the Institution)**

The Signatory Official must be a senior institutional official who has the authority to commit the entire institution named in the Assurance form, as well as all of the institutional components listed under Item#2, to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the Assurance. This individual must also have the authority to assure compliance of the institution represent may not be covered under the Assurance. **This individual must also have the authority to assure compliance of institution and all of its components to the Terms of the Assurance.** Generally, this is someone at the level of President, Chief

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Executive Officer (CEO), or Vice President of a company, or at the level of President, Provost, Chancellor, Vice President, or Dean of an academic institution, unless another
Official has been specifically delegated with this authority. **Typically, the Signatory Official is not a department chair, division director, or another official who only has authority over a portion of the institution**. The Department of Research recommends that an IRB member not serve as the Signatory Official.

The signature of the Signatory Official and the date of the signature must be provided on the Assurance form. The Assurance form with the original signature must be submitted to Department of Research at the Qatar Ministry of Public Health.

Type or print the full name, degree(s) or suffix, institutional title (e.g., administrative title such as President, (CEO), or Vice President, Dean of Research, etc.), institution name, telephone and fax numbers, e-mail address, and full mailing address for the Signatory Official. The e-mail address is very important, as this will provide the means for effective communication. If any these fields are not available, please indicate accordingly rather than leaving the field blank.

ITEM #8- **Assurance Approvals**

Leave this item blank. This section is for use by Department of Research for approval of the Assurance.

Submitting an Assurance Form

Please review and proofread all materials to be submitted and ensure that all parts of the Assurance form are complete and accurate. Submitting **Assurance Forms that are complete will expedite review and approval by the Research Division.**

Please Submit the Assurance Form on the single-sided pages and with the signature of the Signatory Official by scanned PDF copy to: **irb@moph.gov.qa**, regular mail, express mail, or hand delivery to:

Research Division
Ministry of Public Health - 3rd floor
P.O. Box 42
Doha, Qatar

Notification of Approval

When an institution submits the Assurance Form, the person submitting the electronic file, the Human Protections Administrator, and the Signatory Official will receive notification of the approval of the Assurance and providing them with the Assurance number assigned to the institution.
If you have any questions, please do not hesitate to contact:
Biomedical Research at: **irb@moph.gov.qa**

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Local / Foreign Institutional Review Board (IRB) / Independent Ethics Committee (IEC) Assurance Application for the Protection of Human subjects Involved in Research

This assurance is a binding agreement between the Ministry of Public Health (MOPH) and local institutions. It is a documentation of an institutional commitment to comply with the MOPH regulations for protection of human subjects involved in research. The MOPH regulations are based on the US federal regulations (45 CRF 46) and have been acknowledged by the US National Institute of Health

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

Date: ____/____/_____

[ ] New application
[ ] Update or Renewal; Previous Assurance Number: _____

1. Institution Filling Assurance

Legal Name:

City: Country:

2. Institutional Components

List below all Components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Department of Research upon request a brief's description and line diagram explaining Review Board(s) (IRB), IRB support staff, and investigators in these various Components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all Components Listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of the Department of Research.

[ ] Please check here if there are no such components or alternate names.

Name of Component or Alternate Names Used	City	Country if outside Qatar

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3. Statement of principles

This Institution assures that all of its activities related to human subjects' research' regardless of the source of support, will be guided by the ethical principles in the following document(s): (indicate below).

[ ] **The Belmont Report, US NIH, or Qatar's Ministry of Public Health Rules**

[ ] **Others as indicated in item 5:** (*Please submit copy to Research Department with this Assurance*).

4. Applicability

(a) This Institution assures that whenever this institution becomes engaged in human subjects research conducted or supported by Qatari funds, the Institution will comply with the **MOPH policy for protection of human subjects. The MOPH policy is based around the US Federal Policy (also known as the Belmont Report),** unless the research is otherwise exempt from these requirements, or it has been determined that the research shall be covered by a separate assurance.

(b) *Optional***:** This Institution elects to apply the following to all of its human subjects' research except for research that is covered by a separate assurance:

[ ] ***The Belmont Report, US NIH, or Qatar's Ministry of Public Health Rules***

[ ] ***Other*****:** (*Please submit copy to Research Department with this Assurance*)

Assurance of Compliance with the Terms of the Foreign Assurance

Non-Qatari institutions only: This institution assures that whenever it engages in research to which this assurance applies it will comply with the following procedural standards (*please check one or more of the following*):

[ ] The US Federal policy (common Rule)

[ ] The US Food and Drug administration regulations

[ ] The current International Conference on Harmonization E-6 guidelines for Good Clinical Practice (ICH-GCP-E6)

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[ ] The current council for International organization of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects

[ ] The current Canadian Tri-Council Policy statement: Ethical Conduct for Research Involving Humans

[ ] Other standard(s) for the protection of human subjects (*please submit copy to MOPH with this assurance)*

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance *(If the local IRB has not previously registered with MOPH/Research Department or has not provided a membership roster. Please submit to the Department of Research the appropriate IRB registration materials).*

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by the department of Research upon request. Future designation of other IRBs requires an update of the Assurance.

Local and/or foreign IRB Registration Number	IRB Affiliation

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-mail:

Address:

City: Country:

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7. Signatory Officials (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of this assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this assurance, I assure protections for human subjects as specified above. The IRB(s) upon which this institution relies will comply with the terms of this Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. *I am aware that false statements could be cause for invalidation this Assurance and may lead to other administrative or legal action.*

Signature: _____ Date: _____

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

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Address:

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THE DESIGNATED IRB TERMS OF ASSURANCE

1. Human Subjects Research must be Guided by Ethical Principles

All of the Institution's Human Subjects' Research activities will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) Appropriate ethical standard approved by Qatar Ministry of Public Health that have adopted the Guidelines, Regulations and Policies For Research Involving Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in Human Subjects' Research conducted or supported by any research department that has adopted the Guidelines, Regulations and Policies for Research Involving Human Subjects, unless the research is otherwise exempt from these requirements or the research shall be conducted under a separate assurance. In general, the Institution becomes so engaged whenever (a) the Institution's employees intervene or interact with Human Subjects for purposes of research; (b) Institution's employees obtain individually identifiable private information about human subjects for purposes of research; or (c) the Institution receives a direct grant award, from Qatar, to conduct human Subjects research, even where all activities involving human Subjects are carried out by a subcontractor.

3. Compliance with Qatar Policy for the Protection Human Subjects

When the Institution becomes engaged in Human Subjects' Research, the Institution and the institutional review boards (IRBs) designated under the Institution's Assurance will comply with the Guidelines, Regulations and Policies for Research Involving Human Subjects issued by the Qatar Ministry of Public Health. The MOPH regulations are based on the US federal regulations (45 CRF 46) and have been acknowledged by the US National Institute of Health. The Institution also will comply with any additional Human Subjects' regulation and Policies of the institution which conducts or supports the research and any other applicable institutional laws, regulations and policies. The head of the institution retains final judgment as to whether a particular activity is covered by the Guidelines, Regulations and Policies for Research Involving Human Subjects. The institution that conducts or supports the research retains final authority for determining whether the Institution complies with the Terms of Assurance.

4. Written Procedures

a) The Institution submitting the Assurance must ensure prompt reporting to the IRB, appropriate Institutional Officials, the head of the institution conducting or supporting the research (or designee), the funding body, and Qatar's Department of Research at the Ministry of Public Health of any:

1. Unanticipated problems involving risks to subjects or others;
2. Serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB(s); and suspension or termination of IRB approval.

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Upon request, the Institution will provide a copy of these written procedures to the funding agency and the Ministry of Public Health.

b) The Institution must ensure that the IRB(s) designated under the Assurance has established written procedures for:

3. Conducting IRB initial and continuing review (not less than once per year) of research, and reporting IRB findings to the investigator and the Institution.
4. Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to Department of Research at the Ministry of Public Health and the funding body.

5. Scope of IRB(s)'s Responsibilities

All human subjects' research, except for research exempted or waived in accordance with Guidelines, Regulations and Policies for Research Involving Human Subjects established by the Qatar Ministry of Public Health, will be reviewed, prospectively approved, and subject to continuing review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subjects' research. For research approved by the IRB(s), further appropriate review and approval, may be required by the entity conducting or supporting the research or by officials of the institution holding the Assurance.

6. Informal Consent Requirements

Except for research exempted or waived in accordance with Guidelines, Regulations and Policies for Research Involving Human Subjects established by the Qatar Ministry of Public Health informed consent for research to which the Assurance applies will be:

a) Sought from each prospective subject or the subjects' legally authorized representative, in accordance with, and to the extent required by, the Guidelines, Regulations and Policies for Research Involving Human Subjects established by the Qatar Ministry of Public Health.
b) Appropriately documented in accordance with, and to the extent required by, the Guidelines, Regulations and Policies for Research Involving Human Subjects.

7. Requirement for Assurance for Collaborating Institutions

When the Institution holding the Assurance is either: a) the primary cooperative awardees to which the Assurance applies, or b) the coordinating center for research to which the Assurance applies, the institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriately- approved assurance for the protection of human subjects.

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An institution holding an Assurance may collaborate with another institution that does not have an Assurance. In such circumstance, a collaborating institution may operate under the Assurance with the approval of the entity conducting or supporting the research and the institution holding the Assurance.
For research covered by the Assurance, the entity that conducts or supports the research retains final authority for determining which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

8. Written Agreements with Independent Investigators who are not Otherwise Affiliated with the Institution

When the Institution holding the Assurance is either a) the primary awardees to which the Assurance applies, or b) the coordinating center to which the Assurance applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriately- approved assurance for the protection of human subjects.
The engagement in human subjects research activities to which the Assurance applies by each independent investigator who is not otherwise an employee or agent of the Institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject's protection policies and IRB review. The Institution may develop its own commitment agreement in coordination with the entity conducting or supporting the research.
For research covered by the Assurance, the entity that conducts or supports the research retains final authority for determining which independent investigators engaged institutions are engaged in the research and need to cover by written commitment agreement with the institution holding the Assurance.

9. Institutional Support for the IRB(s)

The Institution will ensure that each IRB designated the Assurance has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possess appropriate knowledge of the local research context for all research to which the Assurance applies.

Any designation under the Assurance of the IRB of another institution or organization must be documented by written agreement between the Institutions holding the Assurance and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of the Assurance. The parties involved may develop their own Assurance Authorization Agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to Ministry of Public Health and any entity conducting or supporting research covered by the Assurance.

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11. Educational Training

Department of Research at the Ministry of Public Health strongly recommends that the Institution and the designated IRB(s) established educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles and regulations; written IRB procedures; and institution policies for the protection of human subjects. Furthermore, Ministry of Public Health recommends that IRB members and staff compete relevant educational training before reviewing of human subject's research.

12. Renewal of Assurance

All information provided under the Assurance must be renewed or updated at least annually even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's Assurance for the protection of human subjects.

INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

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