

## 8.2. Terms of Assurance



### TERMS OF ASSURANCE INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

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#### Introduction

The purpose of the *Institutional Biosafety Committee (IBC) Assurance* is to assure the safe acquisition, use, and disposal of all biological agents at any research/academic institution in Qatar. **No activity involving bio-hazardous agents (as listed below in term 1) may be conducted by an institution until the Assurance application, submitted by the institution conducting such activities, is approved by the Ministry of Public Health (MOPH) Qatar, setting forth compliance with the MOPH research policies and regulations.**

#### 1. Applicability

The terms in this policy apply in general, whenever the institutions (employees, hosted visitors, students, participating guests, volunteers, others) intervene or interact with research activities involving the use of potentially **bio-hazardous agents** including but not limited to

- Recombinant or synthetic nucleic acid molecules as definable by NIH guidelines (this includes human gene transfer studies)
  - (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids
  - (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
  - (iii) molecules that result from the replication of those described in (i) or (ii) above
- Infectious agents
- Biological toxins
- Human-derived tissues, fluids, cells, cell lines
- Certain animal-derived tissues, fluids, cells, cell lines

#### 2. Compliance with National Policies and Regulations

The institution and the IBC designated under the institution's Assurance will comply with the MOPH Research Policies and Regulations.

Institutions will also comply with any additional institutional regulations, policies, and procedures which conduct or support the research involving bio-hazardous agents.

Compliance with the MOPH guidelines/policies is important and mandatory because it promotes the safe conduct of research involving recombinant or synthetic nucleic acid molecules. Failure to comply with the MOPH guidelines/policies risks suspension, limitation, or termination of non-compliant research projects.



### 3. Required IBC Documents

- (a) Assurance application
- (b) Reliance agreement (if applicable): When an institution does not have its own IBC, the institution may rely on registered IBC of another institution supported by a reliance agreement. A reliance agreement is a document signed between institutions engaged in research involving biohazardous agents that permit an institution to rely on another registered IBC. The reliance agreements may cover single studies, categories of studies, and collaborative studies. The parties involved may develop their own "reliance agreement" outlining their relationship and commitment that the designated IBC will adhere to the requirements of the Assurance Terms. This agreement permits an institution to cede responsibility and authority for IBC review and approval, to another institution with a duly authorized and constituted IBC. This agreement must be kept on file at both institutions/organizations and must be submitted to the MOPH while filing the assurance application.

Please note that all institutions conducting research involving biohazardous agents participating **MUST** have a valid assurance before initiation of any research activity.

### 4. Educational Training

The institution and the designated IBC(s) must establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IBC members and staff, and other appropriate personnel maintain continuing knowledge and comply with the relevant ethical principles and regulations, written IBC procedures, and institutional policies of research that involves bio-hazardous agents. Furthermore, MOPH recommends that IBC members and staff must complete relevant educational training before reviewing research involving infectious agents, animal use, recombinant or synthetic nucleic acid, and genetically modified materials.

### 5. Written Procedures and Reporting

- a) The institution submitting the Assurance application must ensure prompt reporting to the IBC, appropriate institutional officials, the head of the institution conducting or supporting the research (or designee), the funding body, and HRGD at MOPH of:
- Any serious or continuing non-compliance with the regulations or the requirements or any other determinations that may lead to suspension or termination of IBC approved research project.
  - Unanticipated problems involving risks/harmful procedures.
  - Any proposed changes in research activities.
  - Any adverse events or any significant accident or illness leading to, harm or that is dangerous to humans, animals, and/or environment as indicated in the policy.



- b) The institution must ensure that the IBC(s) designated under the Assurance has established written procedures for:
- Conducting IBC review (not less than once per year) of research and informing IBC findings to the investigator and the institution.
  - Determining which projects require review more often than annually or which projects need verification from sources other than the investigator and no material changes have occurred since the previous IBC review.

Upon request, the institution will provide a copy of these written procedures to HRGD-MOPH.

#### **6. Recordkeeping Requirements**

The institution will maintain the following record for at least three years after the completion of a project.

- A copy of the Assurance and any modifications thereto are approved by the HRGD-MOPH.
- Reliance agreement, if applicable.
- Training and educational documents.
- Elements that are covered under written procedures and reporting (term 5).

Upon request, the institution will provide a copy of these documents to HRGD-MOPH.

#### **7. Compliance with the Terms of Assurance**

The institution accepts and will follow terms 1-6 stated above and is responsible for ensuring that (a) the IBC(s) designated under the Assurance agree to comply with these terms, and (b) the IBC(s) possess appropriate knowledge of the national research context for all research to which the Assurance applies.

#### **8. Renewal of Assurance**

All information provided in the Assurance application must be renewed or updated **ANNUALLY** even if no changes have occurred, to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the IBC institution's Assurance.

**INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE IBC ASSURANCE FILING PROCESS**



## INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) ASSURANCE APPLICATION AND FILLING INSTRUCTIONS

This application form is used to file the **new** Institutional Biosafety Committee (IBC) Assurance application or **renew/update** the existing IBC Assurance application with the Health Research Governance Department (HRGD) at Ministry of Public Health, Qatar (MOPH-Q).

### **How to fill and submit the application**

Please follow the step-by-step instructions below for each item on the IBC Assurance application form. Please review and proofread all materials to ensure that all parts of the application form are complete and accurate. Submitting forms that are complete in all aspects will expedite review and approval by the MOPH. The Signatory Official must be authorized to represent the entire institution and all its components and commit to a legally binding agreement.

Please submit your application via email at [ibc@moph.gov.qa](mailto:ibc@moph.gov.qa). If there is any amendment in the application after its approval, the institution should apply to update that information to HRGD-MOPH via e-mail at [ibc@moph.gov.qa](mailto:ibc@moph.gov.qa).

### **Notification of Approval**

When an institution submits the Assurance form, the focal person will receive notification of the approval with the Assurance number assigned to the institution. If you have any questions, please do not hesitate to contact at [ibc@moph.gov.qa](mailto:ibc@moph.gov.qa).

## **Step-By-Step Instructions to Fill the Application Form**

The HRGD-MOPH guidelines/policies on the use of potentially bio-hazardous agents require that institutions within the State of Qatar carrying out any research activities involving **Bio-hazardous agents** (as defined by the Terms of IBC Assurance) **MUST** have a **MOPH-approved Institutional Biosafety Committee (IBC) Assurance**.

### **ITEM # 1&2 Has your institution previously filed an IBC Assurance application with HRGD-MOPH?**

Indicate by an [X] whether this is a:

“*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 # 3 Institution Filing Assurance Application**

Type or print the legal name and complete address of the institution that is filing the Assurance. Any components of the institution that will be covered by this Assurance application should be listed under **Item #4** of the Assurance form.

### **ITEM # 4 Institutional Components**

Type or print the name of all components of the institution as mentioned in item # 3 that will be covered by this Assurance. Components are generally defined as parts of an institution that may be viewed as separate organizations but legally remain part of the institution. For example, ABC University can list its XYZ University Hospital, KLM School of Public Health, etc. as its components. Please do not list all the 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 # 5 Statements of Principles**

Indicate by a [X] the statement of ethical principles that govern your institution in fulfilling its responsibilities for the use of biohazard agents in research. Apart from MOPH guidelines/policies available on the [HRGD website](#), the MOPH also recognizes the [NIH guidelines](#) for research involving recombinant or synthetic nucleic acid molecules as acceptable statements of ethical principles. If “Other Statement of Principles” is selected, a copy of those principles must be submitted to the HRGD along with the Assurance application.

### **ITEM # 6 Designations of Institutional Biosafety Committee (IBC)**

Designate your IBC(s) of record for this Assurance application. You must indicate at least one IBC in this section. Please ensure the IBC is registered with the HRGD at the MOPH **prior** to submitting an Assurance application to the MOPH.

If your institution relies on the IBC(s) of another institution, this arrangement **MUST** be documented as a reliance agreement between the two institutions. The reliance agreement should define each institution's responsibility. This agreement must be submitted with this Assurance application. Only the registered IBC(s) mentioned in the institution's Assurance application can review research involving biohazard agents at that institution.



**ITEM # 7 IBC Focal point**

IBC focal point must be affiliated with the institution and recommended to be a permanent focal point of the IBC. The focal point is responsible for submitting the Assurance application for approval and will receive notifications by MOPH-HRGD, on behalf of the institution.

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, fax numbers, e-mail address, and full mailing address.

**ITEM # 8 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 as mentioned in item 3 and all the institutional components listed in item# 4 to a legally binding agreement. This individual must also have the authority to assure compliance of the institution and all its components to the Terms of Assurance.

The signature of the Signatory Official and the date of the signature must be provided on the Assurance form submitted to HRGD-MOPH.

Type or print the full name, degree(s) or suffix, institutional title (e.g., an administrative title such as President, (CEO), or Vice President, Dean of Research, etc.), institution name, telephone, fax numbers, e-mail address, and a full mailing address for the Signatory Official.

**ITEM # 9 MOPH Assurance Approvals**

Please leave this section blank. This section is for use by HRGD at the MOPH for approval of the Assurance application.

-End of instructions-

## Institutional Biosafety Committee (IBC) Assurance Application Form

Please complete this form and submit it to the HRGD-MOPH via email at [ibc@moph.gov.qa](mailto:ibc@moph.gov.qa).

### ITEM # 1 Has your institution previously filled IBC Assurance with MOPH?

Indicate by a [x] whether this is a

- “**Update or Renewal**” of an already existing Assurance application (Go to item# 2)
- “**New application**” (Go to item # 3)

### ITEM # 2 Institution IBC name and Assurance number

Name:

Number:

### ITEM # 3 Institution Filling the IBC Assurance Application

Name:

Full Mailing Address:

### ITEM # 4 Institutional Components (if applicable)

Please list below all the components over which the institution has legal authority and will be covered by this Assurance.

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

Name of the components	Address

**NOTE:** The Signatory Official signing this Assurance must be legally authorized to represent the institution and all components listed in the table.



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#### ITEM # 5 Statement of Principles

This institution assures that all its activities related to research involving any biohazard agents listed in Terms of Assurance regardless of the source of funding, will be guided by the ethical principles in the following guidelines and policies: (please select all that applies).

- MOPH Guidelines and Policies related to research involving any biohazard agent.  
 NIH Guidelines and Policies related to research involving any biohazard agent.  
 Other Policies and Guidelines: (Please submit a copy to the MOPH with this Assurance application)

#### ITEM # 6 Designation of Institutional Biosafety Committee

This institution designates the following IBC(s) under this Assurance for review of research at the institute or its component mentioned in item 3 and item 4, respectively. Future designation of other IBCs under this Assurance requires an update of the Assurance application.

- In case of reliance on IBC of another institute please provide reliance agreement(s) with this Assurance application.

IBC Registration Number	Name of IBC as Registered	Type of IBC (Institutional IBC or IBC on which the institution relies)

#### ITEM # 7 IBC Focal Point

Name: \_\_\_\_\_ Title/position: \_\_\_\_\_

Full mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_





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**ITEM # 8 Signatory Officials (i.e., Official Legally Authorized to Represent the Institution)**

I understand the Assurance Terms, which describe the responsibilities of the institution and its related officials. Additionally, I recognize that providing research investigators, IBC members and staff, and other relevant personnel with appropriate initial and continuing education and training about the use of biohazard agents will help to ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on the behalf of this institution and with an understanding of the institutional responsibilities under this Assurance, I assure the proper use and disposal of biohazardous research agents, as specified in the MOPH guidelines/policies. The IBC designated above will review all research to which this Assurance applies. The designated IBC will comply with the **Terms of the Assurance for Institutions within the State of Qatar** and possess appropriate knowledge of the local context in which this institution's research will be conducted.

All information provided in Assurance application is up-to-date and accurate. I am aware that any false statements may cause for invalidation of this Assurance and may lead to other administrative or legal action.

Authorized Official:

Name:

Title/position:

Full mailing address:

Phone:

E-mail:

Signature:

Date:

**ITEM # 9 MOPH Approvals**

*Please leave this item blank. This section is for use by MOPH for approval of the Assurance application*

*Comments:*

Name:

Title/position:

Full mailing address:

Phone:

E-mail:

Signature:

Date: