



Institutional Animal Care and Use Committee (IACUC) Assurance for Laboratory Animal Involved in Research Terms of Assurance

1. Researches involving laboratory animal must be Guided by Ethical Principles

All of the Institution's Researches involving laboratory animal will be guided by the ethical principles in:

- (a) **US Department of Agriculture, NIH, or the Ministry of Public Health of the State of Qatar** established "*Guidelines for Laboratory Animal Involved in Research*", or
- (b) **Appropriate ethical standard and guidelines** for research involving laboratory animals **approved** by the Ministry of Public Health.

2. Applicability

These terms apply whenever the Institution becomes engaged in laboratory animal research conducted or supported by any research department that has adopted the "*Guidelines for Laboratory Animal Involved in Research*", to the extent the lab animal research is conducted within Qatar and/or funded by an entity within Qatar subject to the oversight of the Ministry of Public Health., 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 laboratory animal for purposes of research; (b) the Institution receives a direct grant award to conduct researches involving laboratory animal, even where all activities involving laboratory animal are carried out by a subcontractor.

3. Compliance with Qatar Policy for the Protection of laboratory animal

When the Institution becomes engaged in research on laboratory animal, the Institution and the institutional Animal Care & Use Committee (IACUC) designated under the Institution's Assurance will comply with the "*Guidelines for Laboratory Animal Involved in Research*", issued by the Ministry of Public Health. The Institution also will comply with any additional animal welfare 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 for Laboratory Animal Involved in Research*", 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 IACUC, appropriate Institutional Officials, the head of the institution conducting or supporting the research (or designee), the funding body, and MOPH Biomedical Research Section of the State of Qatar:
 1. Unanticipated problems involving risks/harmful procedures to subjects or others;
 2. Serious or continuing noncompliance with the regulations or the requirements or determinations of the IACUC; and suspension or termination of IACUC approval.



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 IACUC designated under the Assurance has established written procedures for:
 3. Conducting IACUC initial and continuing review (not less than once per year) of research, and reporting IACUC 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 IACUC review; and ensuring prompt reporting to the IACUC of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IACUC approval has already been given, may not be initiated without IACUC 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 Biomedical Research Section at the Ministry of Public Health and the funding body.

5. Scope of IACUC(s)'s Responsibilities

The primary responsibility of an IACUC is to ensure, on behalf of institutions, that all care and use of animals is conducted in compliance with the “*Guidelines for Laboratory Animal Involved in Research*”. Each IACUC's operation must be governed by a formal **Terms of Reference (TOR)**, tailored to reflect and refer to the institution's program, including the members of the program and the institution's policies, practices and procedures. All researches involving the use of laboratory animals will be subjected to review, prospective approve, and continuing review at least annually by the designated IACUC. The IACUC will have authority to approve, require modifications in, or disapprove the covered laboratory animal research. For research approved by the IACUC(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. Recordkeeping Requirements

This Institution will maintain for at least three years:

1. A copy of **this Assurance** and any modifications thereto approved by the MOPH Biomedical Research Section.
2. A copy of the IACUC's Term of Reference which has been approved by the MOPH Biomedical Research Section.
3. Minutes of IACUC meetings, including records of attendance, decisions, recommendations.

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



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 laboratory animal.

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 laboratory animal.

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 laboratory animal.

The engagement in researches involving laboratory animal 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 IACUC 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 IACUC

The Institution will ensure that each IACUC designated the Assurance has meeting space and sufficient staff to support the IACUC'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 IACUC designated under the Assurance agrees to comply with these terms; and (b) the IACUC possesses appropriate knowledge of the local research context for all research to which the Assurance applies.

Any designation under the Assurance of the IACUC of another institution or organization must be documented by written agreement between the Institutions holding the Assurance and the IACUC organization outlining their relationship and include a commitment that the designated IACUC 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 the Ministry of Public Health and any entity conducting or supporting research covered by the Assurance.

11. Educational Training

Department of Research at the Ministry of Public Health strongly recommends that the Institution and the designated IACUC established educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IACUC members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles and regulations; written IACUC procedures; and institution policies for the protection of laboratory animal. Furthermore, the Biomedical Research Section at Ministry of Public Health recommends that:

- a) **It is obligate** that IACUC members and staffs complete the e-learning **CITI: Animal Care and Use Course**.
- b) **It is recommended** that IACUC members and staff compete relevant educational training before reviewing of laboratory animal research proposals.

12. Renewal of Assurance

All information provided under the Assurance must be renewed or updated at least every “12 months” (1 year) for institutions inside Qatar and at least every “36 months” (3 years) for institutions outside Qatar, 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 laboratory animal.

INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS



Institutional Animal Care and Use (IACUC) Assurance for Laboratory Animal Involved in Research

Step-by-Step Instructions for Animal Welfare Assurance

The insurance requirement is an assurance of compliance with the “*Guidelines for Laboratory Animal Involved in Research*” established by the state of Qatar Ministry of Public Health (MOPH), aims to provide ethical policy and guidelines for care, use, and humane treatment of animals used in research, testing, and educational activities.

Each institution that is engaged in the care and use of laboratory animal in research must submit an Assurance to the MOPH Biomedical Research Section. In general, an institution is engaged in laboratory animal research whenever:

- (a) The institution’s employees or agents intervene or interact with animal subjects for research purposes’;
- (b) The institution receives funds to conduct animal subject’s research, even where all activities involving animal subjects are carried out by subcontractor or collaborator.

The Assurance Signatory Official must be authorized to represent and commit the enter 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 the Research Division, the Ministry of Public Health of the State of Qatar, 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.

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 # 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.



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 laboratory animal protection program that is separate or distinct from the "parent" institution.

Each institution engaged in researches involving the use of laboratory animal 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.
- c. Indicate whether your Assurance will replace a Multiple Project Assurance (MPA; "M" number) or a Cooperative Project Assurance (CPA; "T" number), by providing the respective number of your current Assurance.

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 laboratory animals in research. The Ministry of Public Health recognizes the US National Institutes of Health as acceptable statements of ethical principles for the care and use of laboratory animals in research. If "Other Statement of Principles" is selected, a copy of those principles must be submitted to the Biomedical Research Section at the time the Assurance form is submitted.

ITEM #4-Applicability

This Animal Welfare Assurance (AW) sample document is provided to assist institutions with the development of an Assurance in accordance with "*Guidelines for Laboratory Animal Involved in Research*".

- 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 the use and care of laboratory animals in 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 laboratory animals to **all research**. Indicate with an [X] whether your institution elects to apply these guidelines to all researches involving laboratory animal, unless the department conducted or supporting the research determines that the research shall be conducted under a separate assurance.



ITEM #5- Designations of institutional Animal Care & Use Committee (IACUC)

Designate your institutional Animal Care & Use Committee (IACUC) of record for this Assurance. You must indicate at least one IACUC in this section. Please ensure the IACUC is registered, or are in the process of registering, with the Biomedical Research Section at the Ministry of Public Health **prior** to submitting an Assurance form to the MOPH. The Biomedical Research Section does not take action on an Assurance form until the designated IACUC is registered and assigned an IACUC Registration number. If the registration of the IACUC is in process when you submit your Assurance, the Biomedical Research Section will insert the IACUC Registration number. Any IACUC relied upon the institution for review of researches involving laboratory animal to which the Assurance applies must be registered and must be designated under the institution's Assurance. An Assurance may be updated/ edited at any time to designate additional housing facilities, and/or IACUC membership modification.

If your institution relies on the IACUC 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 the Biomedical Research Section upon request, but it should not be submitted with the Assurance form.

ITEM #6- Senior Administrators

Designate the individual who will serve as the animal welfare Administrator (i.e., the primary contact person for animal welfare issues) for your institution. The senior administrator would exercise operational responsibility for your institution program for protection of laboratory animal in research. The senior administrator should have comprehensive knowledge of all aspects of your institution's system for protection of laboratory animal, 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 senior administrator 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 Senior Administrator. 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 #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 Assurance, Generally, this is someone at the level of President, Chief 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 Biomedical Research Section recommends that an IACUC 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 Biomedical Research Section at the 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- MOPH Assurance Approvals

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

Submitting Assurance Form

Please review and proofread all materials to be 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 Department of Research.

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



Institutional Animal Care and Use Committee (IACUC) Assurance for Laboratory Animal Involved in Research

Please kindly 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 Animal Care and Use Committee (IACUC) should submit an IACUC Registration form. Institutions that do not have their own IACUC but rely on the IACUC of another institution should not submit an IACUC Registration.

To avoid any delays, please follow the instructions carefully

Date: ____/____/____

New application

Update or Renewal - Previous Assurance Number: _____

1. Institution Filling Assurance

Legal Name:

City:

MPA; "M" number:

Country:

CPA' "T" number

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 Biomedical Research Section upon request a briefs description and line diagram explaining IACUC, IACUC 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 MOPH Biomedical Research Section.

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

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



3. Statement of principles

This Institution assures that all of its activities related to researches involving laboratory animal regardless of the source of support, will be guided by the ethical principles in the following document(s): (indicate below).

US Department of Agriculture, NIH, or Qatar's Ministry of Public Health Guidelines

Other: (Please submit copy to the MOPH Biomed. Research Section with this Assurance)

4. Applicability

(a) This Institution assures that whenever it engages in laboratory animal researches conducted in Qatar, the Institution will comply with the **Terms of the Assurance for Institutions within the State of Qatar**, 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 researches involving laboratory animal except for research that is covered by a separate assurance:

US Department of Agriculture, NIH, or Qatar's Ministry of Public Health Guidelines

Other: (Please submit copy to the MOPH Biomed. Research Section with this Assurance)

5. Designation of Institutional Review Boards (IACUC)

This Institution designates the following IACUC for review of research under this Assurance (If the IACUC has not previously registered with the Biomedical Research Section, nor provided a membership roster. Please submit to the Biomedical Research Section the appropriate IACUC upon request. Future designation of other IACUCs requires an update of the Assurance.

IACUC Registration Number	Name of IACUC as Registered with Department Of Research

6. Senior Administrator (e.g., Animal Welfare Contact Person)

First Name: Middle Initial: Last Name:
Degrees or Suffix: Institutional Title:
Institution:
Telephone: FAX: E-mail:
Address:



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

I understand the Assurance Terms which describe the responsibilities of the Signatory Official, the IACUC Chair, the senior Administrator and the staff in charge, under this Assurance. Additionally, I recognize that providing research investigators, IACUC members and staff, and other relevant personnel with appropriate initial and continuing education about laboratory animal care and use 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 Institutions responsibilities under this Assurance, I assure the welfare of laboratory animal, as specified above. The IACUC designated above is to provide review for all research to which this Assurance applies. The designated IACUC 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 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:

Telephone:

FAX:

E-mail:

Address:

City:

Country: