QBRI
معهد قطر لبحوث الطب الحيوي
Qatar Biomedical Research Institute
جامعة حمد بن خليفة
HAMAD BIN KHALIFA UNIVERSITY

IRB Application Process Guide

The Institutional Review Board (IRB) is responsible for assuring the ethical protection of the rights and welfare of human subjects from research risks. The IRB assures that all human research conducted under the auspices of QBRI/HBKU are ethically and methodologically sound, as required under public law and most importantly, as expected - by public trust. The IRB is a highly professional committee that reviews and approves human research protocols of various disciplines and all related processes and documents to ensure that the rights and welfare of human subjects are protected above all other considerations. The IRB has the authority to approve, require modifications, or disapprove all research activities that fall within their jurisdiction in conformity with all ethical foundations for the protection of human subjects. The IRB functions independently, to protect its ethical mission without compromise and without any perception of conflict of interest or undue influence of power.

How to Apply?

QBRI-IRB receives all submissions through our online application:
https://hbku.wufoo.com/forms/qbrihbku-institutional-review-board/

What to submit for IRB Approval?

The required documents for a New Study are:

- Cover Memo
- Research Plan Summary
- Institutional approval (approval from institute to conduct the study)
- Co-Investigator form (if applicable)
- Conflict of interest disclosure forms (if study involves more than one investigator)
- Questionnaire/Survey/Interview (English/Arabic)
- CITI certificates for each investigator
- CVs for each investigator

The required documents for a Renewal are:

- Annual Continuation Request form
- Institutional Approval
- Cover Memo (in case of modification to original proposal)
- Research Project summary (in case of modification to original proposal)
- CITIs (in case of expiry)

The required documents for an Amendment are:

- Cover Memo specifying request amendment
- Revised document and/or other documents impacted by the proposed research modification.
- Institutional approval

Additional Documents:

- Research conducted upon premises of any institution requires approval of that site. The signed approval letter must grant permission for the researcher to conduct research at that site.
- Students must provide an advisor letter supporting their application.

Forms:

All the forms and templates can be downloaded on our website. Study-specific materials will need to be provided by the researcher. (https://www.hbku.edu.qa/en/qbri/research-areas/research-compliance)

Review Process:

1. Screening process: to check if applicant has provided all the required documents. If any document is missing or incomplete they will be asked to complete their application before further review.
2. Once complete, the application will be sent for review (Exempt, Expedited or Full board).
3. After the review process, the applicant will be notified with the committee's decision. He/she may either receive an approval letter or asked to fulfill some requirements by the committee.
4. Once the investigator has been provided with an approval letter, he/she may start their research work. Researchers CANNOT start their research study unless they get the approval.
5. If your study is approved pending or deferred, you need to make the requested changes and submit the changes to the IRB for review.
6. Approvals are issued with a validity of one year only.
7. If the applicant wishes to make any changes, he/she must be submit an IRB amendment request prior to implementation.
8. If the investigator plans to continue his/her study further, he/she must apply for an IRB renewal.

Types of Review:

Exempt
Committee review is not required for certain categories of research activities that involve little or no risk to human subjects. Only the IRB can determine if research qualifies for Exempt review **Categories:** 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (3) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified. (4) Research and demonstration projects which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in levels of payment for benefits or services under those programs. (5) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

Expedited

Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research

Categories:

(a) Research that may be reviewed by the IRB through an expedited review procedure may include research activities that present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories:

1. Clinical studies of drugs and medical devices only when cleared/approved for marketing and the medical use;
2. Collection of blood samples by finger stick, heel stick, ear stick, or vein puncture;
3. Prospective collection of biological specimens for research purposes by noninvasive means;
4. Collection of data through noninvasive procedures;
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes;
6. Collection of data from voice, video, digital, or image recordings made for research purposes;
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(b) An IRB may use the expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

(c) For multicenter, multinational research projects which have been approved by the IRBs in their relevant countries, the institutional Qatari IRB may carry an expedited review provided that a copy of relevant research ethics information as approved by the other IRBs is submitted.

Full-Board

A full board review is required for research that is not eligible for exempt or expedited review. Research that is determined to involve more than minimal risk, or involves protected populations such as children, pregnant women, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

Categories:

- Research in which the level of risk is determined to be greater than minimal.
- Research that involves sensitive or protected populations (such as children or cognitively disabled individuals).
- Research that involves the use of procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

Timeline: Processing for Exempt and Expedited Review could take up to 40 days. Full board studies are reviewed upon call for full-board meetings when necessary. Each meeting has a corresponding agenda deadline. A study must be submitted on or before the agenda deadline to be reviewed by the board at scheduled meeting. Incomplete submissions may require additional time.