جامعة
حمد بن خليفة
HAMAD BIN KHALIFA
UNIVERSITY
عضو في مؤسسة قطر
Member of Qatar Foundation

Hamad Bin Khalifa University
Institutional Review Board

Application Guidelines and FAQs

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1. Introduction

The Institutional Review Board (IRB) is responsible for ensuring 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 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.

If you have any questions about the Institutional Review Board (IRB), please feel free to contact the HBKU-IRB Office directly: hbkuirb@hbku.edu.qa.

2. How do I apply for IRB?

HBKU-IRB receives all submissions through the online application portal: qbri.cayuse.com

To log-in you will require a Cayuse user account, which the HBKU-IRB Office creates on your behalf.

If you do not have a user account, please send an email, "Cayuse User Account Creation Request" with the below information to hbkuirb@hbku.edu.qa:

- Name:
- Surname:
- Name of HBKU college/institute:
- Email address:
- Contact number:
- Professional title: [M/PhD Student/Professor/Scientist etc.]

Once an account has been created, you will receive a system generated email containing a username and temporary password. Follow the instructions in the email to activate your account.

After your account is active, please see the video on the HBKU research compliance website on how to successfully create and submit an application via Cayuse.

3. What documents do I need to complete my application?

Please remember that all templates can be found on the HBKU Research Compliance webpage (https://research.hbku.edu.qa/research/compliance/irb)

3.1. I am submitting a new application:

Initial/New Study	
*	Valid **CITI certificates** for each investigator. • You will need to do either a "Biomedical Research Ethics Course" or "Social & Behavioural Research Course" depending on the scope of your research. Please see section 4, for more details.
*	Up-to-date **CVs** for each investigator listed.
*	**Research Plan**. • Remember to include the aim, methodology and data confidentiality.
*	**Approval** to conduct the study: • Supervisor approval (for students) • Dean/Institutional approval (for all applicants)
*	**Consent Forms** (Eng/Ar). • Depending on your study scope you will either use the Biomedical informed consent template or the Social Studies informed consent.
*	Participant **recruitment documents** (flyer/email/poster). • This is the text that will be used to inform the public of your study. It should provide enough information to allow a person to decide if they are eligible and willing to participate in your study.
*	**List of questions** for the questionnaire/survey/interview (Eng/Ar).
*	If the research activity will be conducted on a site within Qatar but outside HBKU **a letter of authorization to access that site** needs to be provided.
*	If the research activity will include participants that are employees of an organization/entity outside of HBKU, **a letter of support** from that organization needs to be provided.
*	If conducting research outside of Qatar: **Foreign IRB approval** from the country's IRB or the equivalent competent authority is required.
*	In the case of secondary use of samples: **IRB approval** and a **copy of the approved consent** form used to collect primary clinical data and biospecimens is required.
*	Research that involves lab work: A valid approval or evidence of submission to the **Institutional Biosafety Committee (IBC)** for the proposed research.
*	Applications that fall under the category of "**health research**" are required to submit a **scientific evaluation** along with the proposal.

3.2. I am submitting a renewal application:

Renewal	
	Annual Continuation Request form Please include: • A summary of the progress made in the past year. • The number of participants recruited at the time of application.
	Study documents for new approval stamp.
	Institutional approval to continue the study.
	Updated **CITI certificates** (if expired).
*	If any **AMENDMENTS** are being requested at the time of renewal submission, please follow the instructions in **3.2 and 3.3.**

3.3. I am submitting an amendment request:

Please be reminded that you may request for an amendment at any time during the approval period. Research must be conducted according to the submitted research protocol outlined in the approved proposal. Please consider that any modifications to any aspect of the approved research plan may render your IRB approval invalid. Any amendments must be submitted to the IRB Office and it cannot be implemented until IRB approval has been given.

It is the responsibility of the PI to ensure that modifications are only implemented once approved by the IRB.

Amendment	
	Cover Memo • specifying a request for amendment • including details and justification of the amendment.
	ALL revised documents and/or other documents impacted by the proposed amendment. • Please ensure that you outline/specify your amendments in the documents and make sure all revised changes in the documents are highlighted. • Final copies, without highlights will also be submitted for administrative purposes.
	Institutional approval • This will be required for certain amendments (e.g. Change in PI) and will be confirmed by the HBKU-IRB.

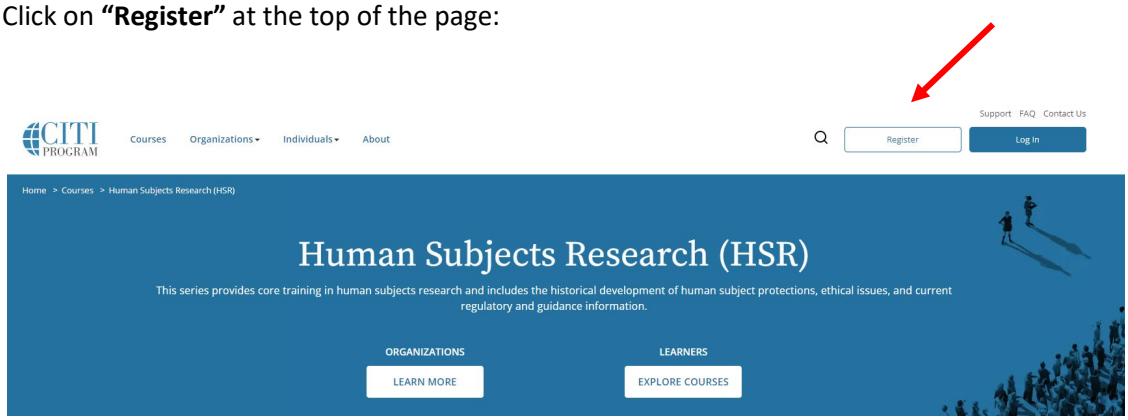
4. How do I obtain my CITI certificate?

The online CITI Ethical Training examination should take around 2-3 hours to complete. The study materials are part of the examination. No formal coursework is involved. This should be undertaken anytime during your first year of study as the CITI is valid for 3 years.

The course can be found at the following link: **CITI Human Subjects Research**

Please follow the instructions below to successfully enroll for the CITI course.

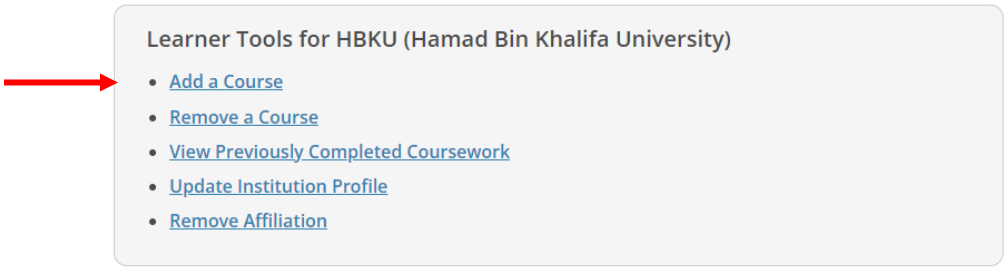
Step 1: Click on **"Register"** at the top of the page:



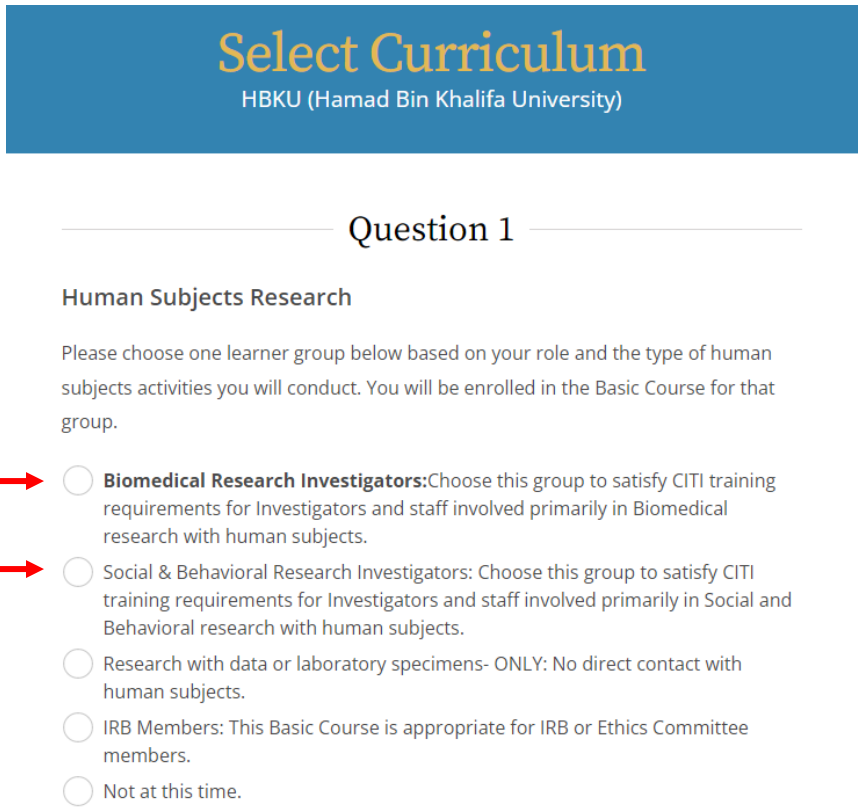
Step 2: Follow the instructions to complete the registration process.

Step 3: Once you have registered, click on "**Main Menu/My Courses**" and under this, you will see the drop down menu for "**HBKU (Hamad Bin Khalifa University)**" course, click on "**View Courses**":

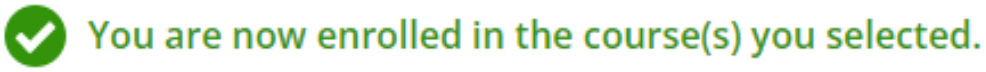
Step 4: Under "My Learner Tools for HBKU (Hamad Bin Khalifa University), click on "**Add a Course**":



Step 5: Next select the course you need to take, either "**Biomedical Research Ethics Course**" or "**Social & Behavioral Research Course**" and click "submit":



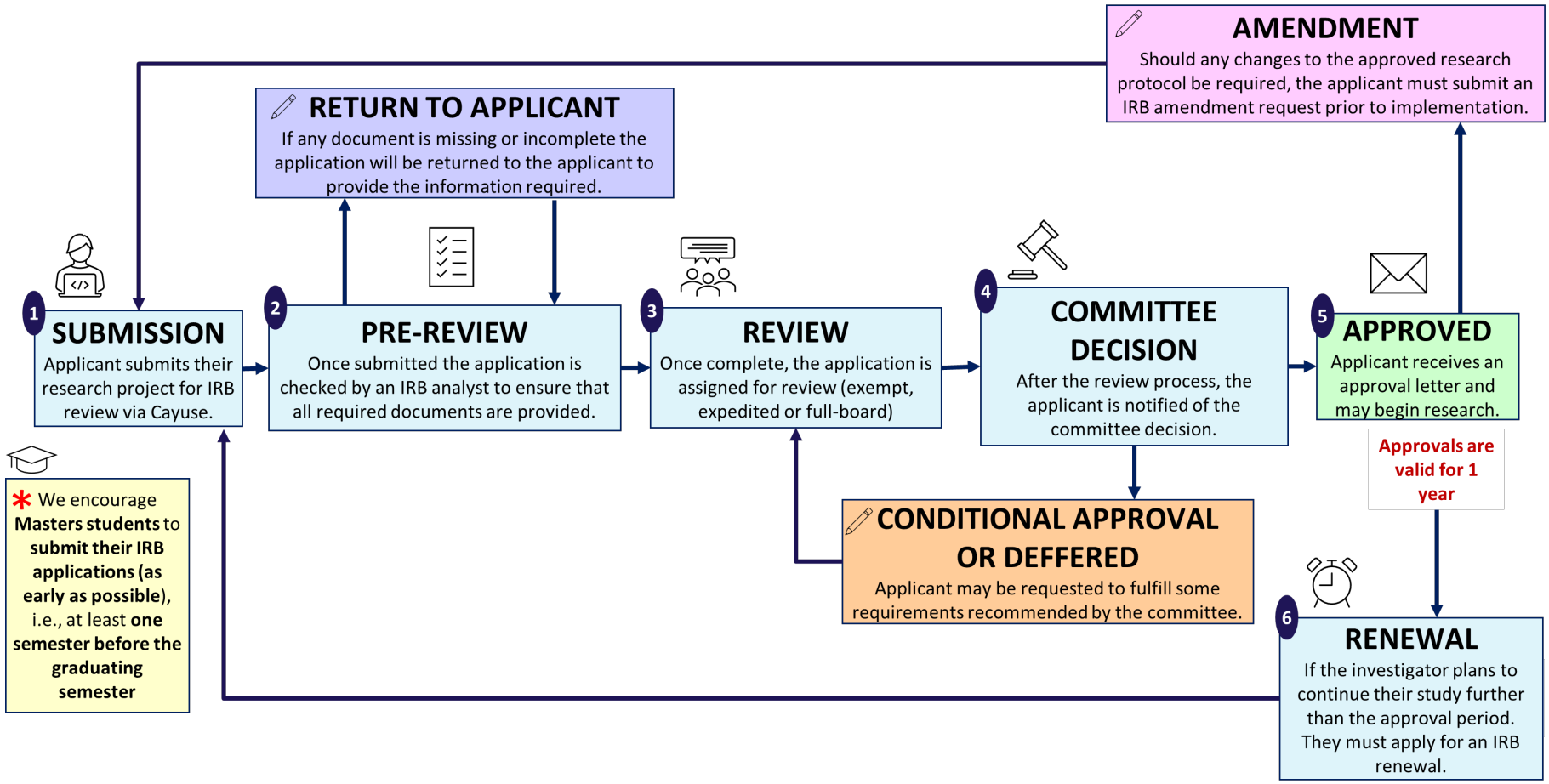
Step 6: Once selected the appropriate course(s) you should see the following message appear at the top of the screen:



Step 7: Click on the course that you have enrolled for and begin the modules.

5. What is the review process?

The HBKU-IRB review process follows the below steps:



6. Types of reviews

6.1. 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	Exempt Review
(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. iv. Possible changes in levels of payment for benefits or services v. 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.

6.2. Expedited

Research that may be reviewed by the IRB through an expedited review procedure may include research activities that:

1. present no more than minimal risk* to human subjects, and
2. involve only procedures listed in one or more of the following categories:

Categories	Expedited Review
(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 purpose
(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

- 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

- 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.

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

7. 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 at the scheduled meeting.

Incomplete submissions may require additional time.

8. Frequently Asked Questions (FAQs): Application Considerations

The below questions are commonly asked by students during their IRB application submission.

8.1. What should be included in my research proposal?

The research plan should include a discussion of methodology (how you plan to treat your topic), sample size (where relevant), a brief bibliography, a list of interview questions (where relevant), a sample survey(s)(where relevant) and data confidentiality. This may be submitted by the end of your first year of study, ideally by the first week in April.

This is separate from the formal M.A. or Ph.D. thesis/dissertation proposal which you will submit during the Fall term of your second year.

8.2. How do I prepare the informed consent forms?

The templates for the forms can be found on the HBKU research compliance web page. They are available in both English and Arabic. Depending on whether your study is related to the social or biomedical field, please select the template accordingly.

Please ensure that you follow the instructions in the template and complete all the necessary sections of the form as they relate to your research. Keep in mind that when your study is approved, your participants will be required to sign the form – therefore ensure that all information related to your study is accurately captured.

NB: For the submission process, do NOT submit signed copies.

8.3. I plan to conduct interviews for my research, is there anything I should consider?

Yes, as the researcher you need to address the following questions in the proposal: What is the nature of the interview sample and the interviews? Is it a randomized sample? Will the interviews be semi-structured? Will the interviews be transcribed, audio or video recorded? How will you maintain the confidentiality of the personal information of participants? Will you de-identify or use codes for the study?

8.4. My interviews, survey, questionnaire will be specific to individuals involved in a certain organization/entity with Qatar, is there anything I should consider?

Yes. If you plan to recruit participants for your study who are employed or part of a certain organization or entity outside of HBKU, a support letter will be required from that organization/entity.

8.5. My research will include the recruitment of participants outside of Qatar. Is there anything I should consider?

Yes. If you plan to recruit participants for your study who are outside of Qatar, IRB approval will need to be obtain from the appropriate foreign ethics authorities. IRB approval provided from HBKU-IRB only covers studies undertaken within Qatar.

Please email the HBKU-IRB Office should you need further information regarding international studies.

8.6. How will the data be handled and stored during the research?

As the researcher you need to ensure that the data and confidentiality of your participants are protected throughout the duration of the study and beyond. In your application please be as explicit as possible when describing your plan for data handeling, storage and destruction.

For example:

- I will store the data on an encrypted flash drive/hard disk to which only I have access.
- I will scan the consent forms and upload them to my password-protected computer and shred the originals. I will destroy the data after X years. (Typically, the duration is three years.)
- Interview data will be retained on my password-protected/-encrypted hard disk/USB flash drive for X years after which I will destroy the data. (Typically, the duration is three years.)
- Any audio and video recordings will be destroyed after X years. (Typically, the duration is three years.)

8.7. I have already undertaken interviews for my thesis; can I still get IRB approval?

Unfortunately, retroactive approval is not possible. Legally you are not allowed to conduct interviews without permission and the University cannot approve a thesis that includes interview data without IRB approval.

8.8. I am planning to do a survey/questionnaire, do I still need to apply to the IRB?

Yes. Your survey may be exempt. But only the IRB can make that determination.

8.9. I believe my study is exempt; do I still need to apply to the IRB?

Even if you believe your thesis is exempt, you still need to apply to the IRB. Only the IRB can make this determination.

8.10. What if my application is sent back to me by the IRB?

If the IRB has returned an application before the IRB review, this usually means that certain basic information is missing. For instance, you have not submitted the required documents, or provided enough background in your application.

Typically, applicants neglect to answer the following questions:

- What is the sample size?
- How will the participants be recruited for the study? Have I attached the emailer/flyer/poster that I will use to recruit my participants?
- What method(s) is employed in data collection?
- What kind of study is it: Qualitative? Quantitative? Both?
- How will the applicant ensure the confidentiality of the data?
- For how long will the data be retained after the study? Why?
- When and where will the study take place? Have I obtained the necessary approvals if participants are outside of HBKU? Do I have a letter of support from the specific organization within Qatar? Do I have a foreign IRB approval if my study includes participants outside of Qatar?
- If conducting interviews remotely, what means will be used? More than one method or platform (e.g. SKYPE, Zoom, Webex, Microsoft Teams, Google Duo, etc.) can be employed but this needs to be specified.
- What platform will you use for your online survey?
- Do the consent forms include all relevant information to ensure that my participants are aware of all aspects of the study and their participation?
- How will the consent forms be signed?

8.11. I am planning to audio or video record my interviews, what considerations should I take into account?

If video or audio recordings of interviews are included in your research activity, this should be clearly stated in the IRB application. The applicant must obtain written permission from the interviewee to do so (this can be included as a section in the consent form).