**PHCC Research Submission Checklist**

**Research Proposal (PHCC Application)**

*PHCC IRB applications must be submitted by a* ***PHCC PI****. Where the PI is not affiliated to PHCC, the* ***PHCC site PI*** *must submit the IRB application.*

*(Any institutions involved in the study with PHCC must include their institutional logo on the header of all the documents shared with subjects)*

| **Document reference #** | **Document Title** | **Requirement** | **Notes** |
| --- | --- | --- | --- |
| **Initial Submission** | | | **to be submitted via** [**Buhooth**](https://www.editorialmanager.com/buhooth/default2.aspx) |
| F001 | Research Proposal Submission Form | Mandatory |  |
| F005 | Investigator Declaration Form | Mandatory | To be submitted for all key personnel\* |
| F024 | Principal Investigator / Site Investigator Support Form | Mandatory | To be submitted for PHCC affiliated Principal Investigator (PI). Where the PI is not affiliated to PHCC, to be submitted for PHCC affiliated site investigator (SI). |
| N/A | Short CV signed and dated (not more than 5 pages) | Mandatory | To be submitted for PI and site PI if the PI is not affiliated to PHCC |
| N/A | CITI certificate\*\*\* | Mandatory | To be submitted for all key personnel\* |
| F010 | Waiver of Authorization | Mandatory if the PI is seeking a waiver of authorization to allow the use/disclosure of PHI for the initial contact or identification of participants who may be eligible to participate in the research described in the IRB application. |  |
| F017 | Informed Assent Form (Children-Minors-Adolescents) | Mandatory if study aims to include individuals 11-17 years and where participants themselves will provide consent. |  |
| F029 | Verbal Assent Script | Mandatory if study aims to include individuals 7-10 years |  |
| F019 | Informed Consent Form-PHCC | Mandatory if the study involves:   * Individuals ≥ 18 years, where informed consent will be signed by the individuals/ their legally authorized representatives (LARs) * Individuals< 18 years, where the informed consent will be signed by their parents / LARs | Note:   1. Avoid technical terms. All information provided in this form must be in lay, simple language easy to understand by the research participant. 2. The text in blue is provided as a guidance for the researcher. Please delete all the text in blue when preparing the final version. 3. Where not applicable, please state so. |
| F021 | PHCC Research Budget Submission Sheet | Mandatory if a budget is required | Only budget applicable to PHCC and its staff will be considered. Please align the contents of this form with that of sections 4.5 to 4.7 for "F001-Research proposal Application Form". These sections contain the necessary details of human resources required to conduct the study and justifications for reimbursement of each task. In addition to listing materials or equipment and any other requirement for the project.  Kindly refer to ‘Finance Policy for Internally Funded Research Studies’ available on PHCC policy portal for further information. |
| N/A | Study tool | Mandatory if a study tool (e.g., questionnaire) will be used to conduct the study | The study tool must be submitted in a language(s) understood by participants. |
| F026 | Online Questionnaire template | Mandatory if questionnaire form will be administered online (e.g. via Microsoft forms) | The online questionnaire template be submitted in a language(s) understood by lay people. |
| N/A | Strategy Planning and Health Intelligence (SPHI) Department Approval | Mandatory if data from electronic medical records is required | Obtain SPHI department confirmation on data availability by submitting draft proposal (form F001) [here](https://phcqatar.sharepoint.com/teams/PHCCKnowledgeManagement/Lists/Research%20Request%20Form/NewForm.aspx). Include BHI reference number in section 3.9 of form F001 once data availability confirmed by SPHI department. |
| N/A | Supporting Documents | Optional | Submit other relevant documents or media that will be shared with participants. For example, phone transcript, SMS message, E-mail message, interview guide, questionnaire, training/educational material etc. |
| N/A | External approvals | Optional | If a research project is proposed to be conducted in collaboration with PHCC, IRB approvals from engaged\*\* organisations must be obtained before the research is initiated.  For research projects collaborating with institutions outside Qatar, PHCC PI must obtain PHCC MD approval for transfer of data outside Qatar.  Research projects proposed to be conducted in schools must include an approval from the Ministry of Education and Higher Education Qatar. |
| **Provisional Opinion** | | | **Amendments made to any document submitted in the initial submission MUST be made using Microsoft Word track changes and submitted via Buhooth.**  **Previously submitted versions of the revised documents MUST not be included in the submission** |
| F001 | Research Proposal Submission Form | Mandatory |  |
| F005 | Investigator Declaration Form | Mandatory | To be submitted for all key personnel\* |
| F024 | Principal Investigator/Site Investigator Support Form | Mandatory | To be submitted for Principal Investigator (PI). If the PI is not affiliated to PHCC, to be submitted for PHCC affiliated site investigator (SI) |
| N/A | Short CV signed and dated (not more than 5 pages) | Mandatory | To be submitted for all key personnel\* |
| N/A | CITI certificate**\*\*\*** | Mandatory | To be submitted for all key personnel\* |
| F022 | PI response to Provisional Opinion | Mandatory |  |
| F010 | Waiver of Authorization | Mandatory if the Principal Investigator is seeking a waiver of authorization to allow the use/disclosure of PHI for the initial contact or identification of participants who may be eligible to participate in the research described in the IRB application. |  |
| F017 | Informed Assent Form (Children-Minors-Adolescents) | Mandatory if individuals 11-17 years will be included | The original completed and signed assent form must be retained with the PI and a copy of the signed form should be given to the subject |
| F029 | Verbal Assent Script | Mandatory if individuals 7-10 years will be included |  |
| F019 | Informed Consent Form-PHCC | Mandatory if   * individuals over 18 years will be included * children below 18 years will be included (to be completed by Parent/Guardian) | The original completed and signed consent form must be retained with the PI and a copy of the signed form should be given to the subject |
| F021 | PHCC Research Budget Submission Sheet | Mandatory if a budget is required | Only budget applicable to PHCC and its staff will be considered. Please align the contents of this form with that of sections 4.5 to 4.7 for "F001-Research proposal Application Form". These sections contain the necessary details of human resources required to conduct the study and justifications for reimbursement of each task. In addition to listing materials or equipment and any other requirement for the project.  Kindly refer to ‘Finance Policy for Internally Funded Research Studies’ available on PHCC policy portal for further information. |
| N/A | Study tool | Mandatory if a study tool (e.g. questionnaire) will be used | The study tool must be submitted in a language(s) understood by participants. |
| F026 | Online Questionnaire template | Mandatory if an online questionnaire form will be used | The online questionnaire template be submitted in a language(s) understood by lay people. |
| N/A | Supporting Documents | Optional | Submit other relevant documents or media that will be shared with participants. For example, phone transcript, SMS message, E-mail message, interview guide, questionnaire etc |
| N/A | External approvals | Optional | If a research project is proposed to be conducted in collaboration with PHCC, IRB approvals from all engaged\*\* organizations must be obtained before the research is initiated |
| **Post Decision Submissions** | | | **On the Main Menu of your application on Buhooth, select the “Send Email” option under the “Action” link to request the application to be reopened to initiate further submissions.** |
| F011 | Appeal Request Form- Research Application | Mandatory for appeal applications | Should be submitted within 30 days of the IRB decision |
| F012 | Notice of Amendment Form | Mandatory for amendment requests | Previously stamped versions of all documents listed in F012-Notice of Amendment Form, track change version of amended documents needs to be submitted |
| F013 | Serious Adverse Events Reporting Form | Mandatory to report adverse events |  |
| F015 | Closure Report | Mandatory to submit closure requests | Should be submitted only for Non-Exempt studies when:  • Study is permanently closed to enrolment  • Participants have completed all research activities  • Collection and analysis of identifiable information is complete |
| F016 | Continuing Review Form | Mandatory to request for extending research activities beyond the approval period (usually 1 year) | Required one month before the approval expiry date. Can accept up to 3 months prior to expiry.  Collaborative sites IRB approval should be uploaded (if collaborative sites are involved) |
| F028 | Protocol Deviation Form | Mandatory to report protocol deviations |  |
| **Budget Reimbursement (Applicable for PHCC staff only)** | | | **To be submitted on ERP via Iexpense** |
| N/A | RBSC approval letter | Mandatory |  |
| N/A | IRB approval letter | Mandatory |  |
| N/A | Extension letter | Mandatory if initial approval has expired |  |
| N/A | Amendment letter | Mandatory the PI has changed |  |
| BR001 | Completion Certificate | Mandatory for reimbursement of personnel effort |  |
| BR002 | Declaration of Task Assignment | Mandatory for reimbursement of personnel effort |  |
| BR003 | MOA between PI and RBSC | Mandatory for reimbursement |  |
| BR004 | MOA between PI and research team member | Mandatory for reimbursement if applicant is not PI |  |
| BR005 | Personal Reward Form | Mandatory for reimbursement of personnel effort |  |
| BR006 | Project time sheet template | Mandatory for reimbursement of personnel effort |  |
| BR007 | Task assignment | Mandatory for reimbursement of personnel effort |  |
| BR008 | Research Dissemination Reimbursement Form | Mandatory for reimbursement of publication fees |  |
| BR010 | BR010 - Extension for reimbursement purposes Form | Mandatory if initial approval has expired and you need extension for the purpose of reimbursement |  |
| N/A | Invoice | Mandatory for reimbursement for publications, consumables, equipment etc |  |
| N/A | Copy of the publication with PHCC as funding source highlighted | Mandatory for reimbursement for publications | Please read the publication reimbursement criteria in your budget approval letter |

**Notes:**

**\*** Key personnel are defined as persons engaged in the conduct of the research activity such that they directly interact with research participants to obtain consent and/or research data or will have access to participants’ private and identifiable private information during data collection or data analysis.

**\*\*** 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

**\*** **\*\*** CITI certificate

A) For IRB applications involving minimal risk one of the following two CITI courses is required for any type of research submitted for IRB approval on BUHOOTH system:

* Research applications for conduct of biomedical research: Biomedical (Biomed) Comprehensive (14 modules)
* Research applications for conduct of social-behavioural research: Social-Behavioral-Educational (SBE) Comprehensive (9 modules)

B) For biomedical trials and clinical investigations involving greater than minimal risk one of the below listed courses may be requested in addition to the previous ones:

* GCP for Clinical Investigations of Devices (10 modules completed)
* GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) (13 modules)