**PHCC Research Submission Checklist**

**Research proposal (Institutional IRB Reliance Application)**

*To be submitted by PI from either of the 3 institutions (UDST, MOPH or UCQ)*

*(All institutions involved in the study 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** |
| F001 | Research Proposal Submission Form | Mandatory |  |
| F005 | Investigator Declaration Form | Mandatory | To be submitted for all key personnel\* |
| N/A | Principal Investigator short CV signed and dated (not more than 5 pages) | Mandatory | To be submitted for the Principal Investigator (PI) |
| N/A | CITI certificate**\*\*** | Mandatory | To be submitted for all key personnel |
| F024 | Principal Investigator/ Site Investigator Support Form | Mandatory | To be submitted for the PI only |
| 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. | 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 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.  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 |
| 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 | 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 other organizations, IRB approvals from engaged\*\* organisations must be obtained before the research is initiated.  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\* |
| N/A | Principal Investigator short CV signed and dated (not more than 5 pages) | Mandatory |  |
| N/A | CITI certificate\*\* | Mandatory | To be submitted for all key personnel\* |
| F024 | Principal Investigator/ Site Investigator Support Form | Mandatory | To be submitted for the PI only |
| 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 |  |
| F019 | Informed Consent Form-PHCC | Mandatory if -individuals over 18 years will be included  -children below 18 years will be included (needs to be completed by Parents) |  |
| F029 | Verbal Assent Script | Mandatory if study aims to include individuals 7-10 years |  |
| 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 | External approvals | Optional | If a research project is proposed to be conducted in collaboration with other organizations, IRB approvals from engaged\*\* organisations must be obtained before the research is initiated.  Research projects proposed to be conducted in schools must include an approval from the Ministry of Education and Higher Education Qatar. |
| **Post Decision** | | | **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 Amendments | 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 | Unanticipated 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 deviation |  |

**\*\*Note:**

**\*** 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 research involving only minimal risk obtaining a certificate in 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)

**For all UDST submissions**

* The Principal Investigator/Site Investigator support form is signed by the Applied Research Department, Innovation and Economic Development
* [irb@udst.edu.qa](mailto:irb@udst.edu.qa) needs to be added as an author and the UDST Applied Research Department, Innovation and Economic Development
* will be notified about submission and decisions through the system.