**PHCC Research Submission Checklist**

**Research proposal (National Reliance Application)**

# Application to PHCC as relying institution

**Note:** Please refer to the requirements stated in this document “National Reliance IRB SOP for Investigators.pdf” enclosed in the submission zip file

| **Document reference #** | **Document Title** | | **Requirement** | **Notes** |
| --- | --- | --- | --- | --- |
| **Initial Submission** | | | | **to be submitted via Buhooth** |
| F023 | Request for Reliance Form | | Mandatory | Complete the form excluding section 6 (Signature- Relying IRB) |
| F024 | Principal Investigator/ Site Investigator Support Form | | Mandatory | To be submitted for PHCC site investigator (site PI) only |
| N/A | Principal Investigator short CV signed and dated (not more than 5 pages) | | Mandatory | To be submitted for PHCC site investigator (site PI) only |
| F027 | Research Protocol | | Mandatory |  |
| N/A | | CITI certificate\*\*\* | Mandatory | To be submitted for all key personnel\* from PHCC |
| **Submission post IRB of record (Reviewing IRB) approval** | | | | **to be submitted via Buhooth** |
| F023 | Request for Reliance Form | | Mandatory | Signed by the relying IRB (PHCC) point of contact |
| F027 | Research Protocol | | Mandatory | Approved by the IRB of record |
| F020 | Initial IRB Approval from the IRB of record | | Mandatory |  |
| F005 | Investigator Declaration Form | | Mandatory | To be signed and submitted for each research team member |
| F024 | Principal Investigator/ Site Investigator Support Form | | Mandatory | To be submitted for PHCC site investigator (site PI) only |
| N/A | Approved and stamped study package from IRB of record | | Mandatory |  |
| **Successive Revisions** | | | | **Amendments made to any document submitted during this phase should be highlighted in yellow (to be submitted via Buhooth)** |
| F023 | Request for Reliance Form | | Mandatory | Signed by the relying IRB (PHCC) point of contact |
| F027 | Research Protocol | | Mandatory | Last approved |
| F020 | Initial IRB Approval Letter | | Mandatory |  |
| F005 | Investigator Declaration Form | | Mandatory | To be signed and submitted for each research team member |
| F024 | Principal Investigator/ Site Investigator Support Form | | Mandatory | To be submitted for PHCC site investigator (site PI) only |
| N/A | Principal Investigator short CV signed and dated (not more than 5 pages) | | Mandatory | To be submitted for PHCC site investigator (site PI) only |
| N/A | Approved and stamped study package from IRB of record | | Mandatory |  |

# Application to PHCC as reviewing IRB institution

**Note:** Please refer to the requirements stated in this document “National Reliance IRB SOP for Investigators.pdf” enclosed in the submission zip file

| **Document reference #** | **Document Title** | | **Requirement** | **Notes** |
| --- | --- | --- | --- | --- |
| **Initial Submission** | | | | **to be submitted via Buhooth** |
| F023 | | Request for Reliance Form | Mandatory | Complete and submit one form for each relying institution (signed by the relying IRB point of contact) |
| F005 | | Investigator Declaration Form | Mandatory | To be submitted for each research team member |
| F024 | | Principal Investigator/ Site Investigator Support Form | Mandatory | To be submitted for PHCC affiliated PI and all site investigators (SI) |
| N/A | | Principal Investigator short CV (not more than 5 pages) | Mandatory | To be submitted for PHCC affiliated PI and all site investigators (SI) |
| N/A | | CITI certificate\*\* | Mandatory | To be submitted for each research team member |
| F027 | | Research Protocol Template | Mandatory |  |
| F010 | | Waiver of Authorization | Mandatory if the PI is seeking a waiver of authorization to allow the use 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 |  |
| F018 | | Generic Consent Form-National Reliance Agreement | Mandatory if   * individuals over 18 years will be included * children below 18 years will be included (to be completed by Parent/Guardian) |  |
| F021 | | PHCC Research Budget Submission Sheet | Mandatory if a budget is required | Only budget applicable to PHCC staff will be considered.  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 |  |
| F026 | | Online Questionnaire template | Mandatory if an online questionnaire form will be used |  |
| N/A | | External approvals | Optional | Approvals from other entities should be submitted to support application |
| N/A | | Supporting Documents | Optional | Submit other relevant documents to support application if available |
| **Successive Revisions** | | | | **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** |
| F023 | | Request for Reliance Form | Mandatory | Complete and submit one form for each relying institution (signed by the relying IRB point of contact) |
| F005 | | Investigator Declaration Form | Mandatory | To be submitted for each research team member |
| N/A | | CITI certificate\*\* | Mandatory | To be submitted for each research team member |
| F024 | | Principal Investigator/ Site Investigator Support Form | Mandatory | To be submitted for the Lead institution Principal Investigator (PI). Where the PI is not affiliated to PHCC, to be submitted for PHCC affiliated site investigator (SI) |
| N/A | | Principal Investigator short CV (not more than 5 pages) | Mandatory | To be submitted for the Lead institution Principal Investigator (PI). Where the PI is not affiliated to PHCC, to be submitted for PHCC affiliated site investigator (SI) in addition to the Lead institution PI |
| F027 | | Research Protocol Template | Mandatory |  |
| F022 | | PI response to Provisional Opinion | Mandatory |  |
| F010 | | Waiver of Authorization | Mandatory if the PI is seeking a waiver of authorization to allow the use 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 |  |
| F018 | | Generic Consent Form-National Reliance Agreement | Optional | To be submitted if individuals 18+ years will be included |
| F021 | | PHCC Research Budget Submission Sheet | Mandatory if a budget is required | Only budget applicable to PHCC staff will be considered.  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 |  |
| F026 | | Online Questionnaire template | Mandatory if questionnaire form will be administered online (e.g. via Microsoft forms) |  |
| F030 | | BHI Support Form | Mandatory if extracting data from BHI | The form needs to be signed by BHI team confirming availability of the requested data variables |
| N/A | | External approvals | Optional | Approvals from other entities should be submitted to support application |
| N/A | | Supporting Documents | Optional | Submit other relevant documents to support application if available |
| **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 |  |
| F020 | | Relying Institution Acknowledgement of Initial Approval | Mandatory |  |
| F012 | | Notice of Amendments | Mandatory for amendment requests |  |
| F013 | | Serious Adverse Events Reporting Form | Mandatory to report adverse events |  |
| F015 | | Suspension/Termination/Closure of Research | Mandatory to report suspension, termination amendment requests |  |
| F016 | | Continuing Review Form | Mandatory to request for extending research activities beyond the approval period (usually 1 year) |  |
| F028 | | Protocol Deviation Form | Mandatory to report protocol deviations |  |
| **Budget Reimbursement (Applicable for PHCC staff only)** | | | | **To be submitted on ERP via I-expense** |
| N/A | | RBSC approval letter | Mandatory |  |
| N/A | | IRB approval letter | Mandatory |  |
| N/A | | Extension letter | Mandatory if initial approval has expired |  |
| 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 |  |
| N/A | | Invoice | Mandatory for reimbursement for publications, consumables, equipment etc |  |
| N/A | | Copy of the publication | Mandatory for reimbursement for publications |  |

**\*\*Note:**

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)