**PHCC Research Submission Checklist**

**Case Report (PHCC Application)**

*Must be submitted by PHCC PI*

| **Document reference #** | **Document Title** | **Requirement** | **Notes** |
| --- | --- | --- | --- |
| **Initial Submission** | | | **to be submitted via Buhooth** |
| F005 | Investigator Declaration Form | Mandatory | To be submitted for each research team member |
| F006 | Case Report Application Form | Mandatory |  |
| F024 | Principal Investigator/ Site Investigator Support Form | Mandatory | To be submitted for the Principal Investigator (PI). |
| 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 each research team member |
| F008 | Informed Consent for Publication-Case Report | Mandatory | The default requirement is to obtain the informed consent from the study participant |
| F009 | Waiver of Informed Consent-Case Report | Optional (mandatory if F008 is not completed) | To be submitted if the Principal Investigator fails to secure a signed informed consent (F008) from the study participant |
| F021 | PHCC Research Budget Submission Sheet | Mandatory if a budget to cover for publication fees is required | Only budget applicable to PHCC and its staff will be considered. |
| 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** |
| F005 | Investigator Declaration Form | Mandatory | To be submitted for each research team member |
| F006 | Case Report Application Form | Mandatory |  |
| F024 | Principal Investigator/Site Investigator Support Form | Mandatory | To be submitted for the Principal Investigator (PI). |
| N/A | Principal Investigator short CV(not more than 5 pages) | Mandatory | To be submitted for the Principal Investigator (PI). |
| N/A | CITI certificate | Mandatory | To be submitted for each research team member |
| F022 | PI Response to Provisional Opinion | Mandatory |  |
| F008 | Informed Consent for Publication-Case Report | Mandatory | The default requirement is to obtain the informed consent from the study participant |
| F009 | Waiver of Informed Consent-Case Report | Optional (mandatory if F008 is not completed) | To be submitted if the Principal Investigator fails to secure a signed informed consent (F008) from the study participant |
| F021 | PHCC Research Budget Submission Sheet | Mandatory if a budget to cover for publication fees is required | Only budget applicable to PHCC and its staff will be considered. |
| N/A | Supporting Documents | Optional | Submit other relevant documents to support application if available |
| **Post Decision** | | | **Use the ADHOC Email link of the “Action Links” associated with the submission in Buhooth Main Menu to ask the research office to reopen the application** |
| F011 | Appeal Request Form- Research Application | Mandatory for appeal applications | Should be submitted within 30 days of the IRB decision |
| **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 |  |
| N/A | Amendment letter | Mandatory if the PI has changed |  |
| 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 |  |
| 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 |  |
| 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 |

**\*\*Note:**

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:

* Biomedical (Biomed) Comprehensive (14 modules)
* 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)