|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| |  | | --- | | logo copy **UNIVERSITY OF SANTO TOMAS HOSPITAL** RESEARCH ETHICS COMMITTEE 6th Floor St. John Macias O.P. Building  A.H. Lacson St., Sampaloc, Manila 1015 Philippines  Telephone: +63 2 8731-3001 local 2610  Email: [*usth\_irb@yahoo.com.ph*](mailto:usth_irb@yahoo.com.ph)Website: *usthrec.online*  **UNIVERSITY OF SANTO TOMAS HOSPITAL** España Blvd., Manila |   **REQUIREMENTS CHECKLIST FORM** | | | | |
|  | | | | |
| **Instructions to the Researcher:** All submissions must be made online in PDF format (except F08 - MS word) through the **usthrec.online** portal. After receiving acknowledgment from the REC Secretariat, a printed complete set must also be submitted to the REC Office. Submissions are accepted only on Wednesdays and Fridays from 9AM to 3PM. **Incomplete requirements will not be accepted.** The review process follows a first-come, first-served basis, and the cut-off for submissions is the last Wednesday/Friday of the month to be considered for review at the **3rd Thursday full review meeting**. | | | | **Receiving Stamp/**  **Date of Submission:**  **CLICK TO ENTER TEXT.** |
|  | | | | |
| **REC Protocol Ref. No.** | | **CLICK TO ENTER TEXT.** | | |
| **Protocol No./Title:** | | Click to enter text. | | |
| **Name of Investigator:** | | Click to enter text. | | |
| **Department/Section:** | | Click to enter text. | | |
| **Sponsor/CRO:** | | Click to enter text. | | |
| Tick box | BASIC DOCUMENTS: *\*all documents must be arranged in the following order:* | | **Must submit**  *\*in pdf form except REC F08* | |
|  | 1. Request Letter | | A formal letter requesting review, addressed to the REC Head, signed by **ALL** Principal Investigators. | |
|  | 1. Endorsement Letter or certification of technical review and approval. \*For Investigator-Initiated Research Protocols, include/attach a Plagiarism Certificate confirming that the similarity index is 20% or lower. | | A certification stating that the protocol has been technically reviewed, approved, and endorsed. *\*For USTH Trainees, this certification must be signed & issued by their Department Research Committee and noted by DMER.* | |
|  | 1. Requirements Checklist *(REC F06)* | | Ensure all required documents are included. | |
|  | 1. Application Form *(REC F07)* | | Must contain **relevant data and contact information** about the Principal Investigators, study team, and sponsors. | |
|  | 1. Research Protocol & Informed Consent Assessment   Form *(REC F08).* Use *REC F33* for case reports. | | Must be **completely filled out**, including page and paragraph numbers. Submit in MS Word format | |
|  | 1. Certificate of Agreement & Compliance *(REC Form 22)* | | Must be signed by ALL Principal Investigators | |
|  | 1. Clinical Trial Protocol/   Research Protocol | | Provide the following:   * Protocol abstract/project summary * Process flow chart of the protocol (not applicable for case report/series) * Ethical considerations as a separate section in the protocol | |
|  | 1. Informed Consent Forms   In English and Filipino or dialect spoken & understood by research participants. | | For research that poses **no more than minimal risk,** the REC may approve a request to waive some or all elements of informed consent under specific circumstances.  Refer to *NEGRIHP 2022 Edition.* | |
|  | 1. Curriculum Vitae | | An updated short resume of Principal Investigator and research team signed and dated. | |
|  | 1. Basic Research Ethics Training (BRET), Good Research Practice (GRP) or Good Clinical Practice (GCP) Training Certificate (as appropriate) | | Training is mandatory for all staff involved in clinical research to ensure an understanding of ethical research principles. BRET, updated GRP or GCP certificates of the Principal Investigator and research team (valid for 3 years) must be issued by a certified local GCP provider. | |
|  | 1. Photocopy of REC Review Fee payment | | Proof of payment (charge slip & official receipt) | |
|  | 1. Study Budget | | Line-item budget of operational expenses & number of subjects for recruitment including honoraria for investigators, compensation for subjects, other research-related expenses etc. | |
| Tick box | STUDY-SPECIFIC DOCUMENTS: | | **Submit as needed**  *\*in pdf form* | |
|  | 1. Informed Consent Forms:  |  |  | | --- | --- | | **0 to < 7** | Parental Consent | | **7 to < 12** | Parental Consent + Verbal Assent Script | | **12 to < 15** | Parental Consent + Simplified Assent Form | | **15 to < 18** | Co-Sign ICF to be signed by the Participant & Parent | | **18 & above** | Informed Consent Form for Adults | | | Must be provided in English and Filipino or a dialect spoken and understood by research participants.  For research that poses no more than minimal risk, the REC may approve a request to waive some or all elements of informed consent under specific circumstances.  (Refer to the *National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022 Edition.* | |
|  | * Investigator’s Brochure or * Basic Product Information document; * Published literature/ medical device information | | A - For phase I, II, III studies (for pharmaceutically sponsored clinical trial)  B - For phase IV studies | |
|  | 1. Case Report Form & Data Collection Forms | | Only the specified data as required by the objectives of the clinical study should be taken. All personal identifiers are removed or replaced with codes. | |
|  | 1. Questionnaires / Survey Forms | | Study instruments (e.g. surveys, questionnaires, interview guides, etc. & other tools that will be used in the study. | |
|  | 1. Recruitment Materials / Advertisements | | Recruiting documents for participants (e.g. advertisements, posters, flyers, scripts, emails, social media posts, letters, identification cards, videos, etc.) | |
|  | 1. List of other sites (local and international) & assigned Principal Investigators | | For multicenter local and global clinical trials  (with contact numbers and address) | |
|  | 1. Philippine FDA Protocol Approval/   FDA Proof of submission (for clinical trials) | | Certification letter that protocol (including amendments) has been approved by the Philippine Food & Drug Administration (PFDA);  Required prior to the issuance of REC approval | |
|  | 1. Certificate of Medical Device Notification (CMDN) or Certificate of Medical Device Registration (CMDR) | | For protocols using New Device: CMDN for class A devices (low risk) or CMDR for class B, C & D devices (low-moderate, moderate-high & high-risk) | |
|  | 1. **Others:**   Permission Letters, Memorandum of Agreement/ Understanding (MOA/MOU), Material Transfer Agreement (MTA), Insurance Coverage for trial/participants etc. | | Letters to Medical Director, Data Privacy Officer (DPO), Dept Chairs or Unit Head requesting permission to conduct study & to access confidential records, facility use; MOA/MOU on collaboration terms, data ownership, publication rights; MTA for transfer of biological materials or data between institutions; Coverage insurance for trial participants, if applicable. | |
| Tick box  below | **REC PAYMENT FEES** | | All REC payments are fixed fees and are NET of all applicable taxes. | |
|  | **1. Company Sponsored Clinical Trials/**  **Agency/society-funded clinical trial** | | Applicable to studies funded by pharmaceutical companies, funding agencies or approved grants | |
|  | * Initial Review Fee | | **Php 60,000.** Must be paid prior to the initial review. Non-refundable.  Note that Review Fees are separate from Institutional Fees as required by the USTH as site institution. | |
|  | * Continuing Review Fee | | **Php 15,000**. Must be paid upon application for renewal of approval thirty (30) days before expiration date of REC approval; Non-refundable | |
|  | * Amendment Review Fee | | **Php 15,00.** Must be paid upon application of any protocol amendment;  Non-refundable. | |
|  | * Institutional Fee | | 10% of the Study Budget for UST Hospital. Separate payment from the review fee. Must be paid after issuance of REC initial approval; Non-refundable. | |
|  | * Administrative & Research Fee * Procedural fees (if applicable) | | **Php 150,000** p.a. or 10% of the total budget whichever is higher (storage room, rental utilities (excluding additional refrigerators) maintenance of area; See **Amended REC Fees FI-AC-MEMO NO.005-22 dated 01 Aug 2022** | |
|  | **2. Investigator-Initiated Research Protocols:** | | Applicable to locally-developed protocols | |
|  | * USTH Consultants & Employees | | **Php 20,000.** For agency funded protocols;  10% of the administrative cost of the grant or Php 5,000 whichever is higher. | |
|  | * USTH Trainees   (Fellows/Residents, Post Graduate Interns) | | **Php** **2,500** per protocol | |
|  | * UST Undergraduate Students   (currently enrolled under Bachelor’s Degree) | | 10% of administrative cost of the grant or Php 3,500 whichever is higher. | |
|  | * UST Faculty Members (except USTFMS) * UST Post-Graduate Students   (currently enrolled under Medicine, Law, Master’s Degree) | | 10% of the administrative cost of the grant or Php 7,500 whichever is higher | |
|  | * UST Doctorate Degree | | 10% of administrative cost of the grant or Php 15,000 whichever is higher. | |
|  | * Continuing Review Fee * For Consultants & Faculty Members | | **Php 2,000**. Must be paid upon application for renewal of approval thirty (30) days before the REC approval expiration date. | |
|  | **3. Non-UST Research Protocols** | | 15% of the administrative cost of the grant or as follows whichever is higher.   * Students/Trainees – Php 10,000 * Professionals/ Masteral/ Doctorate) – Php 20,000 | |
|  | **REC PAYMENT INSTRUCTIONS** | |  | |
|  | **For ONLINE & CHEQUE payments:**   * See UST Hospital bank details | | **Payee Name/Beneficiary**: UNIVERSITY OF SANTO TOMAS HOSPITAL  **Bank Name:** SECURITY BANK CORPORATION  **Bank Address**: Q. Pavillion UST Espaňa Blvd. Sampaloc Manila 1008 Philippines UST Branch  **Bank Account No**. 0171-008-008-011  **Swift Code**: SETCPHMM | |
|  | **For CASH & CHEQUE payments:** | | * Secure an electronic **Service Invoice** to be issuedby the USTH-REC Secretariat Staff to be presented at the Cashier upon payment. | |
|  | **For Issuance** of **OFFICIAL RECEIPT:** | | * Submit a photocopy or scanned copy of the proof of cheque payment or online payment with the **Service Invoice** to the USTH Cashier for issuance of **Official Receipt.** | |
|  | **For submission of NEW Research Protocol/**  **Clinical Trial:** | | * Include a photocopy or scanned copy of the proof of CHEQUE or ONLINE payment &/or OFFICIAL RECEIPT as proof of payment. * Submit together with the REC Initial Submission Application Requirements through the USTH-REC portal: **usthrec.online** | |
| **GENERAL FORMATTING GUIDELINES:** | | | | |
|  | | | | |
| **Paper size:** A4 size  **Font:** Arial, size 11  **Folder:** 1.5 inch 2-hole black arch file  **Document Requirements: For New Protocols:**   1. Use double-spacing throughout, except for the title page. 2. Include supplementary documents (e.g., Informed Consent Forms (ICFs), Data Collection Form, Questionnaires, CV, GCP certificates, etc.). Ensure each document is **separately paginated** and placed in the appropriate order. 3. Properly accomplish, sign and date all required REC Forms. Submit in REC F08 MS Word format. 4. Number all pages **consecutively**, beginning with the title page. 5. Indicate the type of document with version no. and creation date in the footer, at the lower left corner of each document.  * *Protocol Version No.\_ dated dd\_month\_ yyyy* * *ICF English/Filipino Version No.\_ dated dd\_month\_yyyy*  1. Paginate the documents separately indicating the page number followed by the total number of pages in the lower right corner. | | | **Paper size:** A4 size  **Font:** Arial, size 11  **Folder:** ordinary folder  **Document Requirements: For Resubmissions, Amendments & Final Reports**   1. **Do not resubmit** CV and GCP certificates unless they have been updated. 2. Integrate revisions into the revised/amended research protocol, consent forms and any related documents. Highlight all changes made by **writing modified parts in bold text**. 3. Properly accomplish, sign and date all required **REC Forms** and submit in MS Word format. 4. Attach a copy of the previously issued REC Action Letter for REC Reviewer’s reference. 5. Indicate the type of protocol in the footer at the lower left corner along with the version number and creation date.   **For Resubmissions**:   * *Revised Protocol Version No. 2 dated dd\_month\_yyyy* * *ICF Version No. 2 dated dd\_month\_yyyy*   **For Amendments:**  *Protocol Amendment No. 1 dated dd\_month\_yyyy*  **For Final Reports:**  *Final Report Protocol Version No. 1 dated dd\_month\_yyyy*   1. Paginate the documents separately indicating the page number followed by the total number of pages in the lower right corner. | |