**Review Checklist**

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| --- | --- |
| **STUDY PROTOCOL INFORMATION** | |
| **Reference Number:[[1]](#footnote-1)** |  |
| **UPMREB Code:[[2]](#footnote-2)** |  |
| **Study Protocol Title:** |  |
| **Principal Investigator:** | <Title, Name, Surname> |
| **Study Protocol Submission Date:**  *(to be accomplished by UPMREB Staff)* | <dd/mm/yyyy> |
| **Verified Complete by:**  *(to be accomplished by UPMREB Staff)* | <Signature over Printed Name> |
| **Classification of Review:**  *(to be accomplished by UPMREB)* | * **EXPEDITED** * **FULL BOARD** * **EXEMPTED** |
| **Classified by the:**   * **UPMREB CHAIR** * **UPMREB COORDINATOR** | <Signature over Printed Name> |

**UPMREB Form (Type of Submission)**

* **UPMREB FORM 2(B)2012** Printed Registration and Application Form
* **UPMREB FORM 2(C)2012** Study Protocol Assessment Form
* **UPMREB FORM 2(H)2012** Review of Resubmitted Protocol Form
* **UPMREB FORM 3(A)2012** Study Protocol Amendment Submission Form
* **UPMREB FORM 3(B)2012** Continuing Review Application Form
* **UPMREB FORM 3(C)2012** Final Report Form
* **UPMREB FORM 3(D)2012** Study Non-Compliance Report
* **UPMREB FORM 3(E)2012** Early Study Termination Application Form
* **UPMREB FORM 3(G)2016** Suspected Unexpected Serious Adverse Events/Reactions Report
* **UPMREB FORM 3(I)2012** Queries Notification and Complaints

**Basic Documents (must submit for initial review)**

* Research Grants Administration Office (RGAO) Endorsement (refer to UPMREB General Policies and Guidelines for description of RGAO)
* **UPMREB FORM 2(A)2012** Review Checklist
* Study Protocol
* Data collection forms (including CRFs)
* Diagrammatic workflow
* CV of PI and study team members
* Proof of payment of ethics review fee (as applicable)

**Study-specific Documents (submit as needed)**

* Investigator’s Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
* **UPMREB FORM 2(D)2012** Informed Consent Assessment Form (for studies with human participants)
* Informed consent form in English (for studies with human participants)
* Informed consent form in local language (for studies with human participants)
* Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form )
* Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
* Good Clinical Practice (GCP) or Health Research Ethics Training Certificate of PI, Co-I and the rest of the study team (GCP is required for clinical trials) obtained within the last three (3) years.
* Recruitment advertisements (as needed by the study protocol)
* Other information or documents for participants (such as diaries, etc.)
* Material Transfer Agreement or Terms of Reference (for any research involving transfer of biological specimens)
* Memorandum of Agreement (for collaborative studies)
* RGAO-endorsed Clinical Trial Agreement (for sponsor-initiated clinical trials done in UP-PGH; processed separately by the UPM Legal Office and to be submitted to RGAO upon receipt of notification of ethical approval from UPMREB)
* **UPMREB FORM 2(E)2012** Site Resources Checklist for Clinical Trial Outside UP-PGH By UPM Personnel
* Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
* National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while UPMREB review is ongoing)
* Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
* Others (specify):

1. To be issued upon RGAO registration [↑](#footnote-ref-1)
2. To be issued upon initial processing by UPMREB [↑](#footnote-ref-2)