**REQUIREMENT CHECKLIST – INITIAL SUBMISSION**

 **(Form 2.2)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Submission (MMM/DD/YYYY)** |  | **IRB Protocol Number** |  |
|  |
| **Sponsor** |  | **Sponsor’s Protocol Number** |  |
|  |
| **Principal Investigator** |  | **Co-investigator(s) (if any)** |  |
|  |
| **Principal Investigator’s Signature**  |  | **Principal Investigator’s Contact Number** |  |
|  |
| **Protocol Title** |  |

**TO THE IRB SECRETARIAT:** *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (√) MARK ON THE BOXES, IF APPLICABLE*

|  |  |  |
| --- | --- | --- |
| **Put a check mark (***√***)** | **NUMBER OF COPIES** | **DOCUMENT SUBMITTED** |
|  | **1** |  Accomplished forms: -Application Form (Form 2.1) |
|  | **1** | -Protocol Summary Sheet (Form 2.5) |
|  | **1** | -Protocol Information (Form 2.7A) |
|  | **1** | -Protocol Evaluation (Form 2.7B) |
|  | **1** | -Informed Consent Evaluation Form (Form 2.8) |
|  | **1** | Letter of intent with itemized documents submitted. |
|  | **1** | Accomplished Research Protocol Evaluation Forms (REFORM) signed by the Department Chair. (for In-house Residents, Fellows and Interns only)  |
|  | **1** | Detailed protocols and other protocol-related documents |
|  | **1** | Gantt Chart of the Protocol |
|  | **1** | Flow Chart  |
|  | **1** | Curriculum vitae and Good Clinical Practice Certificate (updated every 3 years) of the Principal Investigator and Co-investigator(s). |
|  | **1** | PowerPoint Presentation of the brief summary of the research  |
| ***If applicable, submit the following:*** |
|  | **1** | Informed Consent Forms (English and Tagalog and/or other applicable dialect) |
|  | **1** | Assent Form |
|  | **1** | Case Report Forms or Data Collection Forms |
|  | **1** | Diary Cards and other materials related to the study (e.g., recruitment materials, etc.) |
|  | **1** | Study Budget |
|  | **1** | Certification of FDA approval to conduct the trial in the Philippines (\*parallel review by MMC IRB while awaiting FDA approval is allowed) |
|  | **1** | Investigator’s Brochure |
|  | **1** | Protocol Review Fee (P60, 000.00) for sponsored study protocols conducted by consultants.(\*Please make your check payable to Makati Medical Center – This fee is non-refundable and non-transferable once review is initiated.) |

*\*Note: Handwritten forms will not be accepted.*