**REQUIREMENT CHECKLIST –**

**RESUBMISSION/ AMENDMENT PROTOCOL (Form 2.4)**

**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. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

|  |  |  |  |
| --- | --- | --- | --- |
| **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** |  |
|  |
| **Date of Initial Approval** **(for amendment)** |  | **Type of Submission** | [ ]  Resubmission  |
| [ ]  Amendment |
|  |
| **Protocol Title** |  |
|  |
| **Submitted by** |  | **Signature**  |  |
| ***CHECKLIST OF REQUIREMENT BEFORE SIGNING OF CLINICAL TRIAL AGREEMENT*****TO THE IRB SECRETARIAT:***CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (√) CHECK MARK ON THE TICK* *BOXES, IF APPLICABLE.* |
| **No. of Copies** | **DOCUMENT SUBMITTED** |
|  |  | **Accomplished Forms** |
|   | [ ]  **1** | Application Form 2.1B (for resubmission) or Form 2.1C (for amendments) |
|  | [ ]  **1** | Protocol Evaluation Form 2.7A |
|   | [ ]  **1** | Protocol Evaluation Form for Resubmission 2.7C (for resubmission) |
|   | [ ]  **1** | Protocol Amendment Review Form 3.2 (for amendments) |
|   | [ ]  **1** | Letter of intent including the list of documents submitted |
|   | [ ]  **1** | Letter from the adviser and chairman of the Research Committee of the Department attesting that the document resubmitted has been **reviewed and approved** (for In-house Interns, Residents and Fellows only) |
|   | [ ]  **1** | Resubmitted or amended documents (including a copy of the IRB queries for resubmissions) |

|  |  |
| --- | --- |
| **No. of Copies** | **DOCUMENT SUBMITTED** |
|  |  | **If changes were made on the protocol, informed consent forms, or other documents applicable:** |
|  | [ ]   |  Highlight (or in bold and underlined) the changes made |
|  | [ ]   |  Place flagging on the page where the revisions are located |

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening.

After receiving an e-mail notification that your submission is “complete”, submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph