

Site Visit Checklist (Self-Assessment Tool)

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: Complete this form if you are a ManilaMed Principal Investigator applying for ethical clearance from the MMERC for a clinical trial or clinical research that will be conducted outside the ManilaMed premises. This form is mandatory for the aforementioned investigator-site category. All fields should be completely filled out. If necessary, supporting documentation may be required.

| | |
|----------------------------------|--|
| MMERC Code | |
| Study Protocol Title | |
| Principal Investigator | |
| Contact Number | |
| External Site | |
| External Site Address | |
| Medical Director (External Site) | |
| Contact Number | |
| Study Sponsor/CRO | |

A. Safety Requirements for Research Participants

Does the study site provide a **24-hr emergency room** service?
 _____ YES, proceed to A-1 and do not fill out A-2
 _____ NO, proceed to A-2

| A-1 | Yes | No | Remarks |
|---|------------------------------|----|---------|
| 1. Does the study site emergency room have a fully loaded e-cart? | | | |
| 2. Does the study site emergency room have a functioning defibrillator? | | | |
| A-2 | | | |
| 1. If there is no 24-hr emergency room service, where do you intend to refer your research participants in case of adverse events especially after office hours? | [Name of emergency facility] | | |
| 2. Describe nature of your appointment in the hospital where patients will be referred for emergency care in case of an adverse event? (NOTE: Final MMERC approval also depends on the logistical feasibility in cases of adverse events to ensure safety of participants) | [description] | | |
| (NOTE: Final MMERC approval also depends on the logistical feasibility in cases of adverse events to ensure safety of participants) | | | |

B. Administrative Questions

| | Yes | No | Remarks |
|--|----------------|----|---------|
| 1. Do you have an office space in the clinic that is conducive to the conduct of the clinical trial? | | | |
| 2. Does the study site have a telephone line? | | | |
| 3. Does the study site have a fax machine on 24 hrs? | | | |
| 4. Can the sponsor commit to pay for expenses for site visit by the MMERC? (1 visit per one year duration of study by two MMERC members and 1 Staff doing the site visit) | | | |
| 5. Are you and your clinic/hospital administrator willing to have a Memorandum of Agreement (MOA) with MMERC regarding the review of the study protocol and monitoring of the conduct of study by the MMERC? | | | |
| 6. Where do you plan to recruit your research participants? | [name of site] | | |
| 7. How many patients with the condition of interest do you see per month in your clinic or hospital? | [quantity] | | |

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|--------------------------------|--|
| Name of Principal Investigator | |
| Signature | |
| Date | |

| | |
|-----------------------|--|
| Name of Administrator | |
| Signature | |
| Date | |