**Site Resources Checklist**

**Clinical Trials outside MMMC by MMMC Personnel**

**SELF-ASSESSMENT TOOL**

|  |  |
| --- | --- |
| **DATE** | **<dd/mm/yyyy>** |

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** Complete this form if you are a MMMC principal investigator applying for ethical clearance from the MMMC-RERC for a clinical trial or clinical research that will be conducted outside the MMMC 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.

**Kindly fill out this form accordingly**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Title |  |
| Principal Investigator | <Title, Given Name, Surname> |
| Contact Number |  |
| Contact Number |  |
| External Site |  |
| External Site Address |  |
| Medical Director (External Site) | <Title, Given Name, Surname> |
| Contact Number |  |
| Study Sponsor/CRO |  |

1. **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? |  |  |  |
| 1. Does the study site emergency room have a functioning defibrillator? |  |  |  |
| **A-2** | | | |
| 1. If there is no 24-hours 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> | | |
| 1. Describe nature of your appointment in the hospital where patients will be referred for emergency care in case of an adverse event?   (NOTE: Final MMMC-RERC approval also depends on the logistical feasibility in cases of adverse events to ensure safety of participants) | <description> | | |

1. **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? | | |  | |  |  |
| 1. Does the study site have a telephone line? | | |  | |  |  |
| 1. Does the study site have a fax machine on 24 hours? | | |  | |  |  |
| 1. Can the sponsor commit to pay for expenses for site visit by the MMMC-RERC (1 visit per one year duration of study by two MMMC-RERC members and 1 Staff doing the site visit)? | | |  | |  |  |
| 1. Are you and your clinic/hospital administrator willing to have a Memorandum of Agreement (MOA) with MMMC regarding the review of the study protocol and monitoring of the conduct of study by the MMMC? | | |  | |  |  |
| 1. Where do you plan to recruit your research participants? | | | <name of site> | | | |
| 1. How many patients with the condition of interest do you see per month in your clinic or hospital? | | | <quantity> | | | |
| **PRINCIPAL INVESTIGATOR** |  | Signature | |  | | |
| Date: <dd/mm/yyyy> |  | Name | | <Title, Name, Surname> | | |
| **RERC ADMINISTRATIVE STAFF** |  | Signature | |  | | |
| Date: <dd/mm/yyyy> |  | Name | | <Title, Name, Surname> | | |