**Site Resources Checklist**

**Clinical Trials outside FEU- NRMF MEDICAL CENTER by FEU-NRMF Personnel**

**SELF-ASSESSMENT TOOL**

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

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** Complete this form if you are an **FEU-NRMF principal investigator** applying for ethical clearance from the FEU-NRMF IERC for a **clinical trial or clinical research** that will be conducted **outside the FEU-NRMF MEDICAL CENTER** 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**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code:[[1]](#footnote-1) |  |
| Principal Investigator | <Title, Name, Surname> |
| Contact Number |  |
| Contact Number |  |
| External Site |  |
| External Site Address |  |
| Medical Director (External Site) | <Title, Name, Surname> |
| Contact Number |  |
| Study Sponsor |  |
| Study Protocol Title |  |

1. **Safety Requirements for Research Participants**

Does your Institution 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 your emergency room have a fully loaded e-cart? |  |  |  |
| 1. Does your emergency room have a functioning defibrillator? |  |  |  |
| **A-2** | | | |
| 1. If you do not have a 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> | | |
| 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 FEU-NRMF IERC approval also depends on the feasibility of logistics 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. Do you have a telephone line? |  |  |  |
| 1. Do you have a fax machine on 24 hrs? |  |  |  |
| 1. Will the sponsor be willing to shoulder expenses for monitoring of the study by the FEU-NRMF IERC (1 visit per one year duration of study by two FEU-NRMF IERC 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 FEU-NRMF regarding the review of the study protocol and monitoring of the conduct of study by the FEU-NRMF IERC? |  |  |  |
| 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** |  | Name | <Title, Name, Surname> |
| Date: <mm/dd/yyyy> |  | Signature |  |
| **ADMINISTRATOR[[2]](#footnote-2)** |  | Name | <Title, Name, Surname> |
| Date: <mm/dd/yyyy> |  | Signature |  |

1. To be issued upon initial processing by FEU-NRMF IERC [↑](#footnote-ref-1)
2. Signatory official for clinic or hospital [↑](#footnote-ref-2)