**Study Protocol Amendment Submission Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the FEU-NRMF IERC prior to the implementation of an amendment. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in LETTER size paper; then date and sign this form before submission.***

|  |
| --- |
| **FEU-NRMF IERC CODE:** |
| **STUDY PROTOCOL TITLE:** |
| **APPROVAL DATE:** <mm/dd/yyyy> |
| **PRINCIPAL INVESTIGATOR:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE:** <Name and address> |
| **STUDY SITE ADDRESS:** |
| **SPONSOR:** |
| **SPONSOR CONTACT PERSON:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **AMENDMENT SUBMISSION DATE:** (to be filled out by FEU-NRMF IERC) <mm/dd/yyyy> |
| 1. **NO. OF AMENDMENT/S**:
 |
| 1. **STATE NATURE OF STUDY PROTOCOL AMENDMENT** (cite study protocol section and page where amendment is found)
 |
| 1. **TYPE OF REVIEW**:
	1. □ **EXPEDITED** **REVIEW** FOR AMENDMENTS THAT:
* Do not involve changes in study populations
* Do not involve the collection of stigmatizing information
* Do not change approved use of anonymized or archived samples
* Do not involve further recruitment of participants
* Involve study protocols previously classified under expedited review
* Are administrative in nature (such as contact details of study personnel)
* Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants
	1. □ **FULL BOARD REVIEW** for any amendments not cited under EXPEDITED REVIEW
 |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR**: |

**RECOMMENDATIONS (for FEU-NRMF IERC use only)**

|  |
| --- |
| **Comments of Primary Reviewer**  |
| **Recommended Action*** APPROVAL
* MINOR MODIFICATION TO THE STUDY PROTOCOL , SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE CHAIR
* MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL BOARD REVIEW
* DISAPPROVAL
 |
| **Specific Recommendations:** |
| **PRIMARY REVIEWER** |  | Signature  |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |
| **SECRETARY** |  | Signature  |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |
| **CHAIR** |  | Signature  |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |