**Continuing Review Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *Ethical clearance or approval is typically granted for a period of one year. Continuing review is required to be done at least once a year, corresponding to the risk assessment of the study protocol. The frequency of continuing review is indicated in the Study Protocol Approval Letter. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form* ***30*** *days prior to expiry date. Obtain an electronic copy of this form and encode all information required in the space provided. Print the form in LETTER size paper; then date and sign this form before submission.*

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| **FEU-NRMF IERC CODE:** |
| **STUDY PROTOCOL TITLE:** |
| **APPROVAL DATE:** <mm/dd/yyyy> |
| **PRINCIPAL INVESTIGATOR:** |
| **Email:**  | **Telephone:** | **Mobile:** |
| **STUDY SITE:** |
| **STUDY SITE ADDRESS:** |
| **SPONSOR:** |
| **SPONSOR CONTACT PERSON:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **SUBMISSION DATE:** (to be filled out by FEU-NRMF IERC) <mm/dd/yyyy> |
| 1. **START DATE:**
	1. Date of research site initialization: <mm/dd/yyyy>
	2. Explanation, if not yet initialized as of date of this submission: <reason/s>
 |
| 1. **ACTION REQUESTED:**
	1. Renewal: New participant accrual to continue
	2. Renewal: Enrolled participant follow up only
	3. Early Termination: Study protocol discontinued ahead of study indicated duration
	4. Other (specify):
 |
| 1. **HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?**
	1. No
	2. Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **SUMMARY OF STUDY PROTOCOL PARTICIPANTS**:
 |
| <number> | * 1. Accrual ceiling set by the IERC
 |
| <number> | * 1. New participants accrued since last review/approval
 |
| <number> | * 1. Total participants accrued since study protocol began
 |
| 1. **ACCRUAL EXCLUSIONS**
	1. None
	2. Male
	3. Female
	4. Other (specify):
 |
| 1. **IMPAIRED PARTICIPANTS**
	1. None
	2. Physically
	3. Cognitively
	4. Both
 |
| 1. **HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?**
	1. No
	2. Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s )
 |
| 1. **HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document**
	1. No
	2. Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE COMMITTEE’S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?**
	1. No
	2. Yes **(**Describe briefly and provide copy of literature cited, including the Investigator’s Brochure if applicable**)**
 |
| 1. **HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?**
	1. No
	2. Yes (Summarize and indicate date/s of SUSAR report submission/s **)**
 |
| 1. **HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?**
	1. No
	2. Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)
 |
| 1. **HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL?** (Indicate registration information)
 |
| * 1. None
	2. IND
	3. IDE
 | FDA Registration No. Product Name: Sponsor: Holder: |
| 1. **HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL**
	1. No
	2. Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)
 |
| 1. **HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?**
	1. No
	2. Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the FEU-NRMF IERC)
 |
| 1. **HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?**
	1. No
	2. Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?**
	1. No
	2. Yes (Append a statement of disclosure)
 |
| 1. **HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL?**
	1. NONE:
	2. DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
	3. ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis.**
	1. No
	2. Yes **(**Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete)**
	1. <Component 1><Provide description as needed>
	2. <Add components as necessary>
 |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR:**  |
| **DATE SIGNED:** <dd/mm/yyyy> |

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

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| **Comments of Primary Reviewer**  |
| RECOMMENDED ACTION:* Uphold original approval with no further action
* Request information: (indicate information)
* Recommend further action: (indicate action)
 |
| **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> |