**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> |