**Study Protocol Noncompliance (Deviation or Violation) Report**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *This form refers to the requirements in ICH-GCP Sections 4.5: COMPLIANCE WITH PROTOCOL and 5.20: NONCOMPLIANCE. Obtain an electronic copy of this form and encode all information required in the space provided. Information submitted in this form is subject to full board review by the FEU-NRMF IERC. Print the report in LETTER size paper; then sign and date this form before submission.***

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| **FEU-NRMF IERC CODE:** |
| **STUDY PROTOCOL TITLE:** |
| **APPROVAL DATE:** |
| **PRINCIPAL INVESTIGATOR:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE:** |
| **STUDY SITE ADDRESS:** |
| **SPONSOR:** |
| **SPONSOR CONTACT PERSON:** |
| **Email:**  | **Telephone:** | **Mobile:** |
| **REPORT SUBMISSION DATE:** (to be filled out by FEU-NRMF IERC) <mm/dd/yyyy> |
| 1. **NATURE OF REPORT**
	1. □ **MINOR** **PROTOCOL DEVIATION** (*nonsystematic* *protocol noncompliance with minor consequences, in terms of its effect on the participant’s/subject’s rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*)
	2. □ **MAJOR** **PROTOCOL DEVIATION OR PROTOCOL VIOLATION** *(persistent* *protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients’ safety at risk)*
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| 1. **DESCRIPTION OF REPORTED DEVIATION/VIOLATION:**
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| 1. **DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:**
 |
| 1. **SPONSOR ASSESSMENT OF SEVERITY:**
	1. □ **MAJOR**
	2. □ **MINOR**
 |
| 1. **DESCRIPTON OF SPONSOR CORRECTIVE ACTION:**
 |
| **DATE OF DEVIATION/VIOLATION:** <mm/dd/yyyy> |
| **REPORTED BY:** |
| **DATE OF REPORT:** <mm/dd/yyyy> |
| **PI SIGNATURE:** |
| **Comments of the Primary Reviewer:** |

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| **RECOMMENDED ACTION: (for FEU-NRMF IERC use only)*** 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> |