



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 under this form is subject to full board review that issued ethical clearance or approval for the study.*

RIHS ERC CODE:		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	Telephone:	Mobile:
STUDY SITE:		
STUDY SITE ADDRESS:		
REPORT SUBMISSION DATE:		
<i>(To be filled out by the Principal Investigator):</i>		
1. NATURE OF REPORT 1.1. <input type="checkbox"/> MINOR PROTOCOL DEVIATION <i>(non-systematic 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)</i> 1.2. <input type="checkbox"/> MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION <i>(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)</i>		
2. DESCRIPTION OF REPORTED DEVIATION/VIOLATION:		
3. DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:		

ERC Form 4D: Protocol Deviation

4. SPONSOR ASSESSMENT OF SEVERITY:

4.1. ☐ MAJOR

4.2. ☐ MINOR

5. DESCRIPTION OF SPONSOR CORRECTIVE ACTION:

6. DESCRIPTION OF PREVENTIVE ACTION TAKEN:

DATE OF DEVIATION/VIOLATION:

REPORTED BY:

DATE OF REPORT:

PI SIGNATURE:

RECOMMENDED ACTION:

- ☐ Submission of additional information
- ☐ Submission of corrective action
- ☐ Invitation to a clarificatory interview
- ☐ Requirement for an amendment
- ☐ Site visit needed
- ☐ Suspension of recruitment
- ☐ Withdrawal of ethical clearance

PRIMARY REVIEWER

Signature

Date:

Name