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**NONCOMPLAINCE REPORTING FORM**

This form should only be used to report observed or apparent noncompliance. Noncompliance is defined as any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations, requirements of the NEOMED IRB Standard Operating Procedures Manual, institutional policies governing human subjects research or the requirements or determinations of the IRB. Examples include, but are not limited to, failure to obtain IRB approval, inadequate supervision, failure to follow recommendations made by the IRB, failure to report unanticipated problems or protocol changes made without IRB approval. Attach any supporting documentation to this form.

Please type only in the gray boxes. To make a box as checked, double-click the box, select “checked”, and click “ok”.

## Section I: Investigator Information

**Principal Investigator:**

Name *(Last, First, Middle Initial)***:**

Phone:       E-Mail:

**Additional Study Contact**:

Name:       Phone:       E-Mail:

Project Title:

Sponsor/Funding Agency:       Sponsor Number:

## Section II: Study Information

This study is:

Open to enrollment

Closed to enrollment

Number of active subjects:

## Section III: Noncompliance Information

1. Provide an explanation of the facts surrounding the noncompliance, including a timeline of occurrence of noncompliance and discovery.

1. Provide an assessment of the increased risk (if any) to subjects resulting from the noncompliance.

1. Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be taken to prevent the noncompliance from occurring in the future (if possible).

\* Please attach any supporting documentation, such as an audit or monitoring report, etc.

## Section IV: Investigator Action

Please indicate any actions that will be taken as a result of this report:

1. The informed consent process/document will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

The informed consent document will **NOT** be revised. Please explain:

1. The protocol will be revised. Please submit an amendment requesting the revisions.
2. Currently enrolled subjects will be notified. Please attach a copy of the notification.
3. Other corrective and/or preventive action will be taken. Please explain:
4. The event compromised the validity of the data. Please explain:

Recorded in the Minutes of:

## Section VI: Investigator Statement of Compliance

By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that procedures performed under this project will be conducted in strict accordance with federal regulations and NEOMED policies and procedures that govern research involving human subjects. He/she acknowledges that he/she has the resources required to conduct research in a way that will protect the rights and welfare of participants and that he/she will employ sound study design which minimizes risks to subjects. He/she agrees to submit *any* change to the project (e.g. change in principal investigator, research methodology, subject recruitment procedures, etc.) to the IRB in the form of an amendment for approval prior to implementation.

## Section V: IRB Approval

This report and the actions described herein has been accepted by the NEOMED IRB, which has determined that the study continues to meet the criteria for IRB approval as outlined in 45 CFR 46.111(a). The IRB has determined that the information provided in this report represents:

Serious Noncompliance

Continuing Noncompliance

Serious and Continuing Noncompliance

NEITHER Serious nor Continuing Noncompliance

Authorized IRB Signature: Date: