SOP 903.003

Title	Non-Compliance
SOP Code	903.003
Effective Date	08-Oct-2019

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
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1.0 PURPOSE

process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of

If intentional, serious or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions.

The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Organizational Official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting (as applicable) to the organization

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Reports of non-compliance may come from any source including the REB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.

5.1 Reports of Non-compliance

5.1.1 Reports of non-compliance in human participant research may come from many sources including, but not limited to, a Researcher (as a self-report), a sponsor representative, a quality assurance or compliance office, a research participant, a member of the research team, or a person not directly involved with the research;

5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance;

5.1.3 Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance inspections, sponsor audits or inspections, or regulatory agency audits or inspections.

5.2 Evaluating Allegations of Non-compliance

5.2.1 When an allegation of non-compliance is referred to the REB, the REB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the REB Chair or designee;

5.2.2 The REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

5.2.3 The REB Chair or designee will conduct an initial review of all allegations tn initial review of all a

5.3.3 If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the REB at a Full Board meeting;

5.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the REB, and will inform the Organizational Official;

5.3.5 The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions;

5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB may consider one or more of the following actions:

Request modification of the protocol,
Request modification of the informed consent document,
Require that additional information be provided to past participants,
Require that current participants be notified,
Require that current participants re-consent to participation,
Modify the continuing review schedule,
Require onsite observation of the consent process,
Suspend the new enrollment of participants,
Suspend REB approval of the research,
Suspend Researcher involvement in the research,
Terminate REB approval of the research,
Require the Researcher and/or staff to complete a training program,
Notify organizational entities (e.g., legal counsel, risk management),
Ensure that all other regulatory reporting requirements are met, as required,
Any other action deemed appropriate by the REB.

5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Chair or designee will notify the Researcher in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The REB Chair or designee will report any serious or continuing non-compliance to the Researcher as well as to the Organizational Official(s), and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the organization;

5.4.3 The REB may submit an allegation of research misconduct to the Organization Official as appropriate;

5.4.4 The REB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

5.4.5
procedure or the review may be referred to the REB, for a decision from the Full Board;

5.4.6 The REB Chair or designee will follow-up to assess any corrective measures implemented by the Researcher.

5.5 Documenting Non-compliance

5.5.1 The REB Chair or designee will document the findings of reports of non-compliance. The report will including the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were
response;

5.5.2 For those incidents of non-compliance referred to the Full Board, the REB Office Personnel will document the following in the REB meeting minutes: a description of the incident and findings, verification of the non-

and actions implemented and plans for further follow-up.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP903.001	15-Sept-2014	Original version
SOP903.002	08-Mar-2016	No revisions needed
SOP903.003	08	