TITLE:	**NONCOMPLIANCE**
NUMBER:	514
VERSION:	1.0
EFFECTIVE DATE:	01 JUL 2013
SUPERCEDES/REPLACES:	n/a
FRAMEWORK:	TCPS2
NEXT REVIEW DATE:	01 JUL 2013
SIGNATORIES:	Contained on last page of original document

1 PURPOSE

This Standard Operating Procedure (SOP) provides the process for responding to reports of noncompliance and defines the actions the Research Ethics Board (REB) may take as a result of its review of reports of noncompliance. This procedure ensures quality, completeness, adequate documentation, and compliance with applicable regulatory requirements and guidelines.

2 SCOPE AND APPLICABILITY

This SOP applies to all reports of noncompliance received by the Vancouver Island Health Authority (VIHA) REBs.

3 REFERENCES AND ASSOCIATED DOCUMENTS

3.1 References

- TCPS2
- ICH GCP
- Tri-Agency Framework: Responsible Conduct Of Research
- 45 CFR 46.103 (b)(4)
- 45 CFR 46.103(b)(5)
- 21 CFR 56.108 (b)

3.2 Associated Documents

- 25.3 Research Integrity Policy
- 511 Reporting

4 RESPONSIBILITIES

4.1 **Research Ethics Coordinator (Coordinator)**: Responsible for tracking receipt of reports of noncompliance and coordinating with the Chair to respond, investigate, and report the results of investigation.

4.2 **REB Chair (Chair)**: Responsible for the assessment of reports of noncompliance, including convening investigations, notifications of noncompliance to relevant parties, determining appropriate corrective actions (in consultation with other parties as necessary), and review of responses from investigators.

4.3 **Research Quality Coordinator (RQC):** Responsible for assessing reports of serious and/or ongoing noncompliance for possible risk to VIHA, consulting with Director Research and Capacity Buildilng and Executive Medical Direcotr Research, and recommending corrective actions.

4.4 **Executive Medical Director, Research:** Responsible for approval of any reports provided to government agencies (OHRP, FDA) on behalf of VIHA.

5 PROCEDURE

5.1 VIHA pledges to promote and uphold the highest ethical standards in the conduct of human research. Employees and agents of the organization are required to comply with national and international guidelines and regulations and the requirements and determinations of the REB.

5.2 All VIHA employees share the responsibility for reporting incidences of noncompliance with VIHA policy, national guidelines and the requirements or determinations of the REB.

6 REPORTING CONCERNS

6.1 Reports of noncompliance in human research may come from many sources including but not limited to:

- an investigator (as a self-report);
- a study monitor;
- a sponsor;
- regulatory authority
- a research participant;
- a department head;
- a member of the research team; or
- a person not directly involved in the research.

6.2 Persons raising such concerns are encouraged to express them in writing. However, verbal concerns will be received and should be recorded and retained by the REB office staff.

7 EVALUATION

The Chair, in consultation with the Coordinator, is responsible for the initial review or allegations of noncompliance, review of employee, staff, and faculty reports and complaints and review of audit findings that indicate powerful or serious noncompliance.

8 ALLEGATIONS OF NONCOMPLIANCE

8.1 When an allegation of noncompliance is referred to the REB, the Chair and Coordinator will assess the allegation to determine its veracity. The Chair may then select any of the following methods to gather the required information:

- Conduct an initial review alone;
- Convene a subcommittee of the REB to conduct a review; and/or
- Seek guidance from VIHA legal counsel.

8.2 In most instances, if the legitimacy of the complaint has been confirmed by the Chair, he/she will report the noncompliance in accordance with SOP 511 Reporting.

8.3 If it is determined by the initial review that

(1) the noncompliance was clearly not serious and not continuing,

(2) the research staff recognized the noncompliance, and

(3) the research staff took appropriate corrective actions

then a final report will be forwarded to the PI and the RQC. No further action will be required.

8.4 If it is determined that the noncompliance was clearly not serious and not continuing, but that the research staff did not recognize the noncompliance or the research staff did not take the appropriate corrective actions, the Chair and Coordinator will provide instruction on the appropriate corrective action plan. The final report will be forwarded to the PI and the RQC and the Department Head for the researcher.

8.5 In addition to determining the legitimacy of the complaint, the Chair is responsible for obtaining as much information as possible from the individual who initially reports the incident and for the initial fact finding process to reach a preliminary decision as to whether each incident of noncompliance was serious or continuing.

9 ACTIONS BY THE REB

9.1 The actions the REB may take in response to serious or continuing noncompliance include, but are not limited to, the following:

- Request modifications to the research protocol
- Request modification of the information disclosed during the consent process
- Request that additional information be provide to past participants

- Require the notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research)
- Require that current participants re-consent to participation
- Request modification of the continuing review schedule
- Initiate or increase monitoring of the research
- Request that the consent process be monitored
- Suspend the research
- Terminate the research
- Obtain more information pending a final decision
- Referral to other organizational entities (e.g., legal counsel, risk management, institutional official)

9.2 The Chair will determine appropriate remedial actions in consultation with the Coordinator and RQC. The Coordinator will notify the investigator in writing of the results of the investigation and of any remedial actions required by the REB. A copy of this letter will be forwarded to the investigator's Department Head and the RQC.

9.3 The letter will include a request for the investigator to respond in writing. The REB will review the response to determine its acceptability.

9.4 The REB file will include a description of the nature of the event, the findings, actions taken, and plans for continued investigation or action if required.

10 NOTIFICATION OF FUNDING AGENCIES SUBJECT TO THE TRI-AGENCY FRAMEWORK

10.1 If the noncompliance is related to research funded by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), or the Social Sciences and Humanities Research Council (SSHRC), the REB is required to advise the relevant agency of any allegations related to activities funded by the Agency that may involve signficant financial, health and safety, or other risks.

10.2 The Coordinator and RQC will compose a letter on behalf of VIHA for approval by the Executive Medical Director, Research in accordance with Sections 4.3 and 4.4 of Tri-Agency Framework: Responsible Conduct Of Research.

10.3 Upon approval, the Coordinator will send such notification to the respective Agency and retain a copy in the Research Ethics department.

11 NOTIFICATIONS FOR US FEDERALLY FUNDED STUDIES

11.1 If the noncompliance is determined to be serious and/or continuing, and it is in relation to a study that is funded or supported by the US Federal government or regulated by the US Food

and Drug Administration, the REB will draft notification of the applicable regulatory authorities for approval by the Executive Medical Director, Research.

11.2 Upon approval, the Coordinator will send such notification to the respective regulatory authority and retain a copy in the Research Ethics department.

12 DEFINITIONS & ABBREVIATIONS

12.1 **Serious:** Serious noncompliance is noncompliance that adversely affects the rights and welfare of participants or places participants at increased risk of harm.

12.2 **Continuing:** Continuing noncompliance is a pattern of noncompliance that indicates an unwillingness to comply or a lack of knowledge that may lead to an adverse effect on the rights and welfare of participants or may place participants an increased risk of harm.

12.3 **Noncompliance**:

- Failure on the part of the PI, any member of the study team, or any individual involved in research review or oversight to follow the terms of the REB approval, or
- Failure of the PI, any member of the study team, or any individual involved in research review or oversight to abide by applicable laws or regulations or VIHA policies, including failure to submit research for REB review and approval prior to commencing research

13 APPENDICES

NA

14 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	01 JUL 2013	New procedure