1 PURPOSE

1.1 This guidance describes the information investigators must promptly report to the Sharp HealthCare (SHC) Institutional Review Board (IRB).

1.2 For research overseen by an IRB other than the SHC IRB, investigators should follow the reporting requirements of the IRB of Record as well as the study specific SHC IRB reporting requirements listed in the initial *TEMPLATE LETTER: Non-SHC IRB Reliance Permission to Proceed (HRP-558)*.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in the Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

3.1 Report the following promptly reportable information items to the SHC IRB within five (5) business days of research team becoming aware of the incident, event, or outcome:

- 3.1.1 Protocol deviation that harmed a subject or placed subject at risk of harm
- 3.1.2 Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- 3.1.3 Audit, inspection, or inquiry by a federal agency (e.g., Food and Drug Administration [FDA] Form 483)
- 3.1.4 Written report or action of a government agency, regarding the research, the Principal Investigator (PI) or other research team members, or at the point research team members are added, a history of such report or action, including:
  - 3.1.4.1 Conviction of a crime
  - 3.1.4.2 FDA Warning Letter (an escalation of a notice or issue sent by FDA Officials that requires a written response)
  - 3.1.4.3 Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)
  - 3.1.4.4 Suspension or termination by an IRB
  - 3.1.4.5 Suspension by a federal or governmental agency (such as FDA, Health and Human Services [HHS], or Health Canada)
  - 3.1.4.6 Office of Human Research Protections (OHRP) Determination Letter, Health Canada Inspection Letter with observations, or similar
  - 3.1.4.7 Form FDA 483 in the past 5 years (a notice after an FDA inspection highlighting potential regulatory problems that may require a written response)
  - 3.1.4.8 FDA restrictions placed on investigator(s)
  - 3.1.4.9 Compliance actions taken under non-US authorities related to human research protections
  - 3.1.4.10 Any other negative actions taken by a government oversight office
- 3.1.5 Allegation of Noncompliance or Finding of Noncompliance
- 3.1.6 Unauthorized disclosure of confidential information (breach of confidentiality)
- 3.1.7 Subject complaint that cannot be resolved by the research team
- 3.1.8 Suspension or premature termination by the sponsor, investigator, or institution due to safety or compliance concerns
- 3.1.9 Incarceration of a subject in a research study not approved to involve prisoners
- 3.1.10 Adverse event or Investigational New Drug (IND) safety report that requires a protocol or consent change
- 3.1.11 State medical board or hospital medical staff actions, (denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine, or discipline) regarding any of the following for the PI or research staff, or if research staff are added, a history of such action:
  - 3.1.11.1 Clinical privileges at any site
  - 3.1.11.2 United States Drug Enforcement Administration (DEA) licensure

3.1.11.3 Fellowship/board certification
3.1.11.4 Medical licensure in any state, nation, or province
3.1.11.5 Membership on any hospital staff
3.1.11.6 Prescribing privileges
3.1.11.7 Professional sanctions including fines and public reprimands
3.1.11.8 Professional society membership
3.1.11.9 Research privileges at any site

3.1.12 Unanticipated adverse device effect

3.1.12.1 Unanticipated adverse device effect means any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

3.1.13 Change in financial interest disclosure

3.1.14 Any litigation, arbitration, or settlement initiated related to human research protections

3.1.15 Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the SHC HRPP

3.1.16 Other unanticipated information that is related to the research and indicates that a participant or others might be at an increased risk of harm.

3.2 Information not listed above does not require prompt reporting to the SHC IRB. Modifications and other changes not listed above still require prospective IRB approval before implementation.

4 RESPONSIBILITIES

4.1 Principal Investigators (PIs) or their designee(s) (i.e., other research team members) carry out these procedures.

5 PROCEDURE

5.1 PI or designee submits the following via the identified log in CREDIT/IRBANA or electronically via research@sharp.com:

5.1.1 Protocol deviation that harmed a subject or placed subject at risk of harm.

5.1.1.1 Submit relevant supporting documentation to the “Deviation Log” with a completed *FORM: Promptly Reportable Information (HRP-214)*

5.1.2 Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject.

5.1.2.1 Submit relevant supporting documentation to the “Deviation Log” with a completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.2.2 Per FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (https://www.fda.gov/media/77765/download), site shall report emergency deviations to the sponsor as soon as possible but no later than five (5) working days after the emergency deviation occurs.

5.1.3 Audit, inspection, or inquiry by a federal agency

5.1.3.1 Submit relevant supporting documentation to the “Revision Log” with a completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.3.2 If the site receives a written inspection report and provides a response, the site’s response to the inspection report should be added to the submission at the earliest opportunity, but no later than 15 days following the issuance of the inspection report.

5.1.4 Written report or action of a government agency, regarding the research, the PI, or the research staff, or if research staff are added, a history of such report or action.

5.1.4.1 If report or action is known to the PI or research team at the time of submission of a new study and the information was not previously submitted to the SHC IRB, submit relevant supporting documentation to "Initial, Continuing & Final Reviews" log with completed *FORM: Initial IRB Review Application (HRP-211).*

5.1.4.2 If report or action becomes known to PI or research team after issuance of initial SHC IRB approval, submit relevant information to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.5 <Allegation of Noncompliance> or <Finding of Noncompliance>

5.1.5.1 Submit relevant supporting documentation to "Deviation Log" with completed *FORM: Promptly Reportable Information (HRP-214)* and completed *TEMPLATE: Corrective Action Preventative Action (CAPA) Plan (HRP-585)*.

5.1.5.2 Note: Obtaining prior sponsor and IRB approval for an enrollment (or eligibility) exception avoids a protocol violation. Refer to *FORM: Modification Request (HRP-213)* and *MANUAL: Investigator Guidance (HRP-101).*

5.1.6 Unauthorized disclosure of confidential information (breach of confidentiality)

5.1.6.1 Submit relevant supporting documentation to "Deviation Log" with completed *FORM: Promptly Reportable Information (HRP-214)* and completed *TEMPLATE: Corrective Action Preventative Action (CAPA) Plan (HRP-585).*

5.1.6.2 Report promptly to SHC Compliance Department via www.mycompliancereport.com.

5.1.7 Subject complaint that cannot be resolved by the research team

5.1.7.1 Submit relevant supporting documentation to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214)*. Individually identifiable information should be redacted and replaced with study-specific subject identification number only.

5.1.8 Suspension or premature termination by the sponsor, investigator, or institution due to safety or compliance concerns

5.1.8.1 Suspensions - Submit relevant supporting documentation to "Revision Log" with completed *FORM: Status Change Report (HRP-215)* and *FORM: Promptly Reportable Information (HRP-214)*.

5.1.8.2 Terminations - Submit relevant supporting documentation to "Initial, Continuing & Final Reviews" log with completed *FORM: Continuation Request or Final Closure Report (HRP-212) and FORM: Promptly Reportable Information (HRP-214).*

5.1.9 Incarceration of a subject in a research study not approved to involve prisoners

5.1.9.1 For Federally Funded Research - Submit relevant supporting documentation to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214)* and *FORM: Unexpected Incarceration (HRP-280).*

5.1.10 Adverse event or IND safety report that requires a protocol or consent change

5.1.10.1 Submit relevant supporting documentation (including communications between the sponsor and the FDA) to "Revision Log" with completed *FORM: Modification Request (HRP-213)* and *FORM: Promptly Reportable Information (HRP-214).*

5.1.11 State medical board or hospital medical staff actions (denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine, or discipline) regarding any of the following for the PI or research staff, or if research staff are added, a history of such action.

5.1.11.1 If report or action is known to the PI or research team at the time of initial IRB submission of a new study and the information was not previously

submitted to the SHC IRB, submit relevant supporting documentation to "Initial, Continuing & Final Reviews" log with completed *FORM: Initial IRB Review Application (HRP-211).*

5.1.11.2 If report or action becomes known to PI or research team after issuance of initial SHC IRB approval, submit relevant information to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.12 Unanticipated adverse device effect

5.1.12.1 Submit relevant supporting documentation to "Unanticipated Problems Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.13 Change in financial interest disclosure

5.1.13.1 If the change in financial interest is not significant per *GUDIANCE: Definitions (HRP-001)* and *GUIDANCE: Financial Conflicts of Interest (HRP-055),* submit completed *FORM: Financial Disclosure Statement (HRP-220)* to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214)*.

5.1.13.2 If the change in financial interest is significant per *GUDIANCE: Definitions (HRP-001)* and *GUIDANCE: Financial Conflicts of Interest (HRP-055)*, submit completed *FORM: Financial Disclosure Statement (HRP-220)* and revised informed consent document(s) (see *TEMPLATE: Informed Consent with CA Bill Of Rights and PHI Authorization (HRP-502)* to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214)*. Provided revisions to the informed consent document are limited to those associated with the change in financial interest, *FORM: Modification Request (HRP-213)* is not required.

5.1.14 Any litigation, arbitration, or settlement initiated related to human research protections

5.1.14.1 Submit relevant supporting documentation to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.15 Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the SHC HRPP.

5.1.15.1 Submit relevant supporting documentation to "Revision Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

5.1.16 Other unanticipated information that is related to the research and indicates that participants or others might be at an increased risk of harm.

5.1.16.1 Submit relevant supporting documentation to "Unanticipated Problems Log" with completed *FORM: Promptly Reportable Information (HRP-214).*

6 MATERIALS

6.1 GUIDANCE: Definitions (HRP-001)
6.2 GUIDANCE: Financial Conflicts of Interest (HRP-055)
6.3 MANUAL: Investigator Guidance (HRP-101)
6.4 FORM: Initial IRB Review Application (HRP-211)
6.5 FORM: Continuation Request or Final Closure Report (HRP-212)
6.6 FORM: Modification Request (HRP-213)
6.7 FORM: Promptly Reportable Information (HRP-214)
6.8 FORM: Status Change Report (HRP-215)
6.9 FORM: Financial Disclosure Statement (HRP-220)
6.10 FORM: Unexpected Incarceration (HRP-280)
6.11 TEMPLATE: Informed Consent with CA Bill Of Rights and PHI Authorization (HRP-502)
6.12 TEMPLATE LETTER: Non-SHC IRB Reliance Permission to Proceed (HRP-558)
6.13 TEMPLATE: Corrective Action Preventative Action (CAPA) Plan (HRP-585)

7 REFERENCES

7.1 FDA: 21 CFR 56.108(b); 21 CFR 812.150(a)(4)

7.2 DHHS: 45 CFR 46.103(b)(5); 45 CFR 46.108(a); Guidance - Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (2007)

7.3 ICG-GCP(E6): 3.3.8; 4.12.1; 4.12.2; 5.20.2; 5.21

This document is available on IRBANA or by contacting research@sharp.com.