**Guidance for Reporting Protocol Violations and Deviations**

**OVERVIEW**
The IRB requires reporting of Protocol Violations and Deviations in order to monitor for *Serious or Continuing Noncompliance*.

*Serious or Continuing Noncompliance* may take the form of a protocol violation or deviations. Some, but not all, protocol violations and deviations are considered serious or continuing noncompliance.

**DEFINITIONS**

**Deviation:** Any change, divergence, or departure from the approved study design or procedures of a research protocol that is under the investigator’s control and that has not been approved by the IRB, and *does not affect* the participant’s safety, rights, or welfare and/or the completeness, accuracy and integrity of the study data. This term, though sometimes used interchangeably with the term “violation,” is (i) most often used when the variance is intended for the safety of one or more research participants or is an unintended change that is not considered as serious as a violation, (ii) is considered *minor* or administrative, and (iii) may involve no more than minimal risk to participants or others.

**Noncompliance:** Failure to comply with federal regulations, state laws, institutional policies, requirements or determinations of the IRB, and/or provisions of the approved research study. It is not considered noncompliance when there is a need to deviate from the approved protocol in order to protect the welfare of research participants.

**Protocol Violation:** Any deviation that *may affect* the subject’s rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data. This term though sometimes used interchangeably with “deviation” is often considered a *major*, more serious, variance from an approved protocol than a deviation.

**Serious Noncompliance:** Failure to comply with federal regulations, state laws, institutional policies, requirements or determinations of the IRB, and/or provisions of the approved research study, where the occurrence involves *substantive* potential or actual increased risk to the safety, rights and welfare of research subjects.

**CONCEPTUALIZING SERIOUS OR CONTINUING NONCOMPLIANCE**

**Non-Compliance**

*Continuing* Noncompliance is repeated occurrences of noncompliance by the same investigator or by the institution. Repetition may be of the same occurrence or different occurrences. This repetition may be in the same or in different protocols by a single investigator. Such repetition if unaddressed may affect the protection of human research subjects. For the institution, repetition may be of the same or different policies, procedures, regulations and/or laws.

**Serious Noncompliance** occurs when instances pose an actual or potential increased risk to the safety, rights and welfare of human research subjects because investigators fail to comply with federal regulations, state laws, SJH policies related to the protection of human subjects, and/or the requirements or determinations of the IRB; or because there is a systemic failure of the...
institution to follow or implement practices described in the SJH policies and/or federal regulations or state laws related to the protection of human subjects in research.

_The diagrams below provide a schematic of how to conceptualize Serious or Continuing Non-Compliance:_

---

**PROCEDURES**

The Principal Investigator (PI) must report Protocol Violations and Deviations to the IRB as outlined below.

**Protocol Violations**

A Protocol Violation is a deviation that *may affect* the subject’s rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data. This term though sometimes used interchangeably with “deviation” is often considered a *major*, more serious, variance from an approved protocol than a deviation.

Protocol Violations may be considered serious noncompliance and are to be reported to the IRB within **5 business days** on the Protocol Violation Report. The investigator must develop a corrective action plan to present to the IRB for review and approval. This corrective action plan will outline what steps the investigator has taken or will take to resolve the event and to prevent such events from occurring in the future.

**Examples of violations** include, but are not limited to the following:

- Intentional deviation from the protocol or regulations in a non-emergency setting
- any unintended or intended deviation from the IRB approved protocol that involves potential risks or has the potential to recur;
• enrollment of subjects not meeting the inclusion/exclusion criteria of an IRB approved protocol;
• failure to withdraw a subject meeting withdrawal criteria;
• inadvertent loss of samples or data;
• failure to obtain informed consent prior to initiation of study-related procedures;
• improper consent procedure;
• failure to follow federal and/or local regulations and policies;
• working under an expired professional license/certification, debarred or disqualified status;
• frequent minor deviations;
• any medication error involving dosing, administration and/or preparation of the study drugs;
• any lapse in study approval where there is a continuation of research activities (i.e. recruitment, enrollment, procedures, data analysis);
• failure to report unanticipated problems to the IRB and/or the sponsor; or
• any event that requires prompt reporting according to the protocol or the study sponsor.

Deviations
A Deviation is considered a minor or administrative divergence from approved design and procedures when the deviation does not affect the subject’s rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data. If a deviation occurs and meets this definition, then the deviation should be reported to the IRB on the Deviation Summary Log and submitted at the time of continuing review. At the time of continuing review, the Deviation Log will be reviewed to determine if continuing noncompliance has occurred.

Examples of deviations include, but are not limited to the following:

• any emergent deviation from the IRB protocol made without prior IRB review to eliminate apparent immediate hazard to a research subject;
• implementation of unapproved recruitment procedures;
• use of an incorrect informed consent version;
• Missing original signed and dated consent form or missing pages from executed consent form;
• Inappropriate documentation of consent, including:
  o Missing signatures
  o Individual obtaining consent not listed on IRB approved application;
• Subject visit/procedure falls outside of the window of time indicated by the protocol, or is not done per protocol, and there is no increased potential for risk to the subject or any damage to the integrity or completeness of the data.

NOTE: Deviations that are not under the investigator’s control (i.e. deviations under patient’s control), are not reportable on the Deviation Summary Log.
The diagram below can be used in order to determine whether an event is reportable:

<table>
<thead>
<tr>
<th>ASK</th>
<th>ANSWER IS YES</th>
<th>ANSWER IS NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the event due to circumstances that are not under the investigator’s control (e.g. patient scheduling conflicts, patient requests, etc.)?</td>
<td>The event is not reportable as a Protocol Violation nor a minor Deviation (on the Deviation Log at Continuing Review). <strong>STOP HERE - DO NOT MOVE ON TO NEXT QUESTION</strong></td>
<td>The event is reportable either as a Protocol Violation or a minor Deviation (on the Deviation Log at Continuing Review). Move to next question below.</td>
</tr>
<tr>
<td>Does the event involve potential risks to the subjects or affect subject rights, safety or welfare?</td>
<td>Reportable as a Protocol Violation within 5 business days.</td>
<td>Reportable as a minor Deviation on the Deviation Log at Continuing Review.</td>
</tr>
</tbody>
</table>

The following tables provide an overview of the reporting requirements to the IRB:

**What, How and When to Report Events that ARE NOT Protocol Violations**

<table>
<thead>
<tr>
<th>WHAT</th>
<th>HOW</th>
<th>WHEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Deviations that are not Protocol Violations</td>
<td>Protocol Deviation Summary Log</td>
<td>At Continuing Review</td>
</tr>
</tbody>
</table>

**What, How and When to Report Events that ARE Protocol Violations**

<table>
<thead>
<tr>
<th>WHAT</th>
<th>HOW</th>
<th>WHEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Violations that may affect the subject’s rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data</td>
<td>On the Protocol Violation Report and submit to the HRPP Office</td>
<td>Within 5 Business Days</td>
</tr>
</tbody>
</table>

**IRB REVIEW PROCESS**

Upon receipt of a Protocol Violation report, HRPP will send the report to the IRB Chair(s) or designated IRB member for review. The IRB Chair(s) or IRB member may request additional information in order to appropriately evaluate the event.

If the IRB Chair(s) or IRB member determines that the event does not meet the criteria for serious or continuing noncompliance that requires reporting, then an acknowledgement of review will be provided and no further action is required. This event will not be placed on an IRB meeting agenda and the information will be filed accordingly in its study folder.

If it is determined that the event appears to be serious or continuing non-compliance, a full IRB should review the information. The report will be reviewed in the next meeting, unless otherwise specified by the Chairs(s).
IRB Actions
After review of an event, the full IRB may take one or more actions. The following are a list of possible actions; however, additional actions may be recommended as applicable:

- No further action is required
- The event does not constitute an unanticipated problem and/or serious or continuing noncompliance
- Accept and approve the investigator’s corrective action plan
- Request additional information
- The event constitutes an unanticipated problem and/or serious or continuing noncompliance
- Require modifications to the informed consent
- Require modifications to the protocol when permissible
- Require the investigator to re-consent enrolled subjects
- Notification of previously enrolled and/or currently enrolled subjects of new information
- Increase monitoring of subjects
- Increase frequency of continuing review
- Observation or monitoring of the research
- Require additional training and education
- Suspension of all or parts of the research
- Termination of the research
- Refer to the appropriate institutional official

After review by the full IRB, the IRB will indicate their determination in writing to the investigator within a reasonable timeframe, but no later than 10 business days of the determination.

When the IRB determines that an unanticipated problem or serious or continuing noncompliance has occurred, or when the IRB suspends or terminates approval of research, a report will be processed according to the SJH guidance Mandated IRB Reporting to Institutional Officials and External Agencies.