Guidelines

External Adverse Events

The LifeBridge Health (LBH) Institutional Review Board (IRB) only requires submission of an Adverse Event Report form when the external adverse event is serious, unexpected, and related or possibly related to the experimental aspect of the study. In studies involving a drug or biologic, those adverse events which require a change in protocol, consent form, or the risk/benefit ratio for subjects must be submitted to the LBH IRB within 10 days following receipt of the report from the sponsor or cooperative group (see Tables 1 & 2C below). External adverse events that satisfy the above criteria but do not require a change in protocol, consent form, or risk/benefit ratio for subjects should be submitted annually along with the continuing review application (see Tables 1 & 2B below). Adverse events that are not serious, are expected, or are unrelated should not be reported, and will not be reviewed or acknowledged by the LBH IRB (see Tables 1 & 2A below).

The Adverse Event Report for any unexpected adverse event that occurs in a device study requiring a change in protocol, consent form, or the risk/benefit ratio for subjects must be submitted to the LBH IRB within 10 days following receipt of the report from the sponsor (see Tables 1 & 2C below). One original of the Adverse Event Report form and one copy of the IND Safety Report and/or other information received from the outside agency regarding the adverse event must be submitted for LBH IRB review. If revision to the consent form is necessary, also submit one copy of the current LBH IRB approved consent form, one copy of the revised consent form, and one copy of the revised consent form with all revisions clearly high-lighted.

Internal Adverse Events

The LBH IRB only requires submission of internal Adverse Event Reports when the event is serious, unexpected, and related or possibly related to a study drug, biologic, or device. Internal adverse events occurring in a study which satisfy this criteria and require a change in protocol, consent form, or the risk/benefit ratio for subjects must be submitted to the LBH IRB within 10 days following the time it becomes known. All fatal or life-threatening events that occur while the subject is being treated on protocol or occur within 30 days of completing research related interventions must be reported to the Division Chief within 24 hrs and to the LBH IRB within 3 days. One original of the Adverse Event Report form, and one copy of the current LBH IRB approved consent form must be submitted (along with any other relevant information) to the LBH IRB. If revision to the consent form is necessary, also submit one copy of the revised consent form, and one copy of the revised consent form with all revisions clearly high-lighted.
Please carefully review the Adverse Event Reporting Flow Chart (Table 1) and Guideline Summary (Table 2) before filling out the LBH Adverse Event Report form. The form must be filled out on your computer before printing.

After reviewing these Adverse Event Reporting Guidelines and Tables 1 & 2 below, if you still have questions about whether an event constitutes an adverse/unexpected event or questions about completing the Adverse Event Report form, please contact the LBH IRB in the Department of Research at 410-601-9021.

**Serious Adverse Event Reporting in Long-Term Follow–Up Studies**

It is not necessary to report hospitalizations for subjects enrolled in long-term follow-up studies who received their last investigational therapy 30 days prior to the adverse event. Other hospitalizations that are part of the disease process do not have to be reported to the LBH IRB unless they have increased in severity or frequency or if the sponsor requires notification.

**Reporting Deaths in Long-Term Follow–Up Studies**

All deaths must be reported, regardless of the relationship to study drug, biologic, or device or disease progression including those in long-term follow-up studies. The research team should report any death believed to be related to the study protocol as soon as they become aware of the event. Deaths that are unrelated to the study protocol (such as those related to the disease process) should be submitted annually along with the continuing review application.

**Safety Reports**

The LifeBridge Health (LBH) Institutional Review Board (IRB) only requires submission of sponsor safety reports when the adverse events summarized in those reports are serious, unexpected, and related or possibly related to the experimental aspect of the study and require a change in protocol, consent form, or the risk/benefit ratio for subjects. In this case the safety report must be submitted to the LBH IRB within 10 days following receipt of the report from the sponsor (see Tables 1 & 2C below). Safety reports that satisfy the above criteria but do not require a change in protocol, consent form, or risk/benefit ratio for subjects can be submitted annually along with the continuing review application (see Tables 1 & 2B below). Safety reports concerning adverse events that are not serious, are expected, or are unrelated should not be reported, and will not be reviewed or acknowledged by the LBH IRB (see Tables 1 & 2A below).

**What Not to Report**

*Reports of Adverse Events Clearly Not Related to the Research:* Individual reports of adverse events determined to be unrelated to research participation must be retained in the study files for follow-up, documentation and reference. However, these reports should not be submitted to the IRB unless the adverse event is a subject’s death, which should be included in the summary spreadsheet at the time of continuing review.

*Subject Deaths Occurring in Non-Interventional Studies:* Subject deaths occurring in non-interventional studies (i.e., surveys, interviews and observational-only studies) do not need to be reported.
Table 1. Adverse Event Reporting Flow Chart

**Serious Adverse Event**

- **Fatal or life-threatening** event involving a LBH Subject in an interventional study
  - Notify Department Chief within 24 hrs. Report to LBH IRB within 3 days.

- **Persistent or incapacitating event, or hospitalization or prolongation of hospitalization.**
  - Expected
  - Do not report to IRB

**Unexpected / Unanticipated**

- **Minimal Risk Protocol (exempt or expedited IRB review)**
  - Not related to protocol
  - Do not report to IRB

- **Greater than Minimal Risk Protocol (full IRB review)**
  - Related to protocol
    - No change in protocol, consent form, or risk/benefit ratio
    - Report to Sponsor / FDA as required.
    - Report annually to LBH IRB (include type, number, and relationship)
  - Change in protocol, consent form, or risk/benefit ratio
    - Report to LBH IRB within 10 days
    - Report to Sponsor / FDA as required.
Table 2. Adverse Event Reporting Guidelines

<table>
<thead>
<tr>
<th>Research Project</th>
<th>Subject</th>
<th>Event</th>
<th>Result</th>
<th>Reporting Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Observational / Experimental (Single- or Multi-Site)</td>
<td>LBH or non-LBH subject</td>
<td>Anticipated Adverse Event</td>
<td>No change in protocol, consent form, or the risk/benefit ratio for subjects</td>
<td>None</td>
</tr>
<tr>
<td>B. Experimental (Single-or Multi-Site) or Multi-Center Trial with DSMB</td>
<td>LBH or non-LBH subject</td>
<td>Unexpected/Unanticipated and Serious Adverse Event*, or any Protocol Deviation, or Study-wide adverse events, interim findings, and recent literature relevant to a LBH research study.</td>
<td>No change in protocol, consent form, or the risk/benefit ratio for subjects</td>
<td>Annually (including DSMB summaries) via the continuing review process</td>
</tr>
<tr>
<td>C. Observational / Experimental (Single- or Multi-Site) / Multi-Center Trial with DSMB</td>
<td>LBH or non-LBH subject</td>
<td>Unexpected/Unanticipated and Serious Adverse Event*, any Protocol Deviation, or Study-wide adverse events, interim findings, and recent literature relevant to a LBH research study and may be related to study procedure, drug, or device.</td>
<td>Change in protocol, consent form, or the risk/benefit ratio for subjects</td>
<td>Within 10 days. Submit DSMB summary within 10 days of receipt.</td>
</tr>
<tr>
<td>D. Experimental (Single-or Multi-Site)</td>
<td>LBH Subject</td>
<td>Fatal or Life-threatening Adverse Event associated with a LBH research study.</td>
<td>N/A</td>
<td>Notify Department Chief within 24 hrs. Report within 3 days after the PI learns of the event.</td>
</tr>
</tbody>
</table>

* = Death, life-threatening event, persistent or incapacitating event, or hospitalization or prolongation of hospitalization.