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| Adverse Event Reporting Form | | | |
| What and when to report | | | |
| An adverse event is any injury, problem, or unfavorable occurrence experienced by human participants or others during conduct of research activities. Adverse events may or may not be caused by the research protocol. They are recognized as occurring in the same span of time with the research. An adverse event may be anticipated and thus listed in the risks section of your protocol. If it is not included in the risk section of your protocol, it would be considered unanticipated. Examples of reportable events include complaints received from a research participant, parent, or guardian; incidents involving physical, psychological, or social harm to participants; and breaches of confidentiality. Any unanticipated adverse events should be reported to HML IRB within 3 days of the occurrence. If you are not sure whether an event qualifies as a reportable event, it is recommended that you report it. | | | |
| Date of Reporting to HML IRB:  Date of Event: | | | |
| Research PROJECT INFORMATION | | | |
| Project Title: | | | |
| IRB Project ID Assigned by HML IRB: | | | |
| Principal Investigator (PI): | | | |
| PI Phone #: | | PI Email Address: | |
| IRB Approval Date: | | | |
| Brief description of the event: | | | |
| How did you become aware of the event? | | | |
| Could this event or a similar event to occur again? | | | |
| Has the level of risk changed because of this event? | | | |
| Should affected subjects be notified of the event (if they do not already know)? | | | |
| Do additional subjects need to be notified because of the event? | | | |
| Do protocols need to be revised because of this event or change in risk? | | | |
| **Please attached as a separate sheet any additional details about the event and any follow up to date.** | | | |
| HML IRB INTERNAL USE ONLY: | | | |
| Date Received: | Date Processed: | | Date Resolved: |
| Action Taken: | | | |
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