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| IRB Change in Protocols Request | | | |
| when to request A change or protocoL for a study approved by hml irb | | | |
| Any proposed change to the IRB protocol or consent form(s) must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. Please complete this form **and submit any relevant documents** to request a change in protocols. In the event we determine that changes are substantial and require re-review, we will contact you. | | | |
| Research PROJECT INFORMATION | | | |
| Project Title: | | | |
| IRB Project ID Assigned by HML IRB: | | | |
| Principal Investigator (PI): | | | |
| PI Phone #: | | PI Email Address: | |
| IRB Approval Date: | | | |
| Provide a description (and attach documentation) of the current process, procedure, tool or consent that is being changed:  Provide a description of the proposed change(s) and any revised materials showing the proposed changes:  Reason/Justification for request of change in protocols: | | | |
| Please answer yes or no to the questions below. If you answer yes, provide a detailed explanation in a separate document. | | | |
| 1. Is the change in protocols in response to an unanticipated adverse event? | | | |
| 1. Is the change in protocols in response to complaints by subjects about the research? | | | |
| HML IRB INTERNAL USE ONLY: | | | |
| Date Received: | Date Processed: | | Date Change Approved: |
| ANY OTHER Actions Taken: | | | |
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