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**LEGACY HEALTH IRB**

**FORM F: RESEARCH STUDY MODIFICATION FORM**

**Use this form for submitting all proposed modifications or changes to previously approved research, minor and substantial. See “Instructions Form F” for completing this form.**

**study information**

Name of submitter for this study modification (name and contact information):
Click or tap here to enter text.

Principal Investigator name: Click or tap here to enter text.

Study Title: Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

**modifications or amendments**

Indicate new changes to the study by submitting new study documents **(tracked and clean copies are both required)** showing new versions and dates, documents showing addition of study staff or change in PI, and other changes in research (new sites, miscellaneous sponsor documents, study enrollment halt, etc.).

|  |  |
| --- | --- |
| **Select all changed item(s)** | **Details** |
| [ ]  | Protocol (revision or amendment) | Click or tap here to enter text. |
| [ ]  | Consent Form (revised or new - tracked) | Click or tap here to enter text. |
| [ ]  | Assent Form (revised or new) | Click or tap here to enter text. |
| [ ]  | Advertisements (revised or new) | Click or tap here to enter text. |
| [ ]  | Subject Materials (describe) | Click or tap here to enter text. |
| [ ]  | Investigator’s Brochure (updated) | Click or tap here to enter text. |
| [ ]  | Other study documents (describe and submit) | Click or tap here to enter text. |
| [ ]  | Change in PI (submit new PI’s updated CV) | Click or tap here to enter text. |
| [ ]  | Addition of Study Staff (name and role) | Click or tap here to enter text. |
| [ ]  | Sites (new or added) | Click or tap here to enter text. |
| [ ]  | Other (describe) |  |
|  | Click or tap here to enter text. |
| Provide a brief summary of all proposed changes (or attach sponsor summaries) and provide the reasons for proposed changes |
| Click or tap here to enter text.  |
|  |

**subject notification of changes in research**

Indicate whether the proposed change(s) in research will affect subjects who are actively enrolled and participating in the research regarding study procedures, risks, benefits, costs, compensation, number of visits, duration of study, standard treatment, or any other factor that might affect their willingness to continue to participate.

[ ]  Yes [ ]  No

If yes, indicate your plan regarding how subjects will/should be informed of the changes in the research.

|  |  |
| --- | --- |
| [ ]  Yes [ ]  No | Re-consented with a revised consent form and new signature obtained |
| [ ]  Yes [ ]  No | Advised via Consent form addendum |
| [ ]  Yes [ ]  No | Advised via information sheet or letter |
| [ ]  Yes [ ]  No | Other method (telephone contact, verbally advised at next office visit, other) |
| What is your plan for when subjects will be advised of changes? |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
|  | Click or tap to enter a date. |
| Investigator Signature  | Date:  |

**WHO TO CONTACT FOR FURTHER INFORMATION OR IF YOU HAVE QUESTIONS**

**SUBMIT FORM TO:**

irbsubmissions@lhs.org

**QUESTIONS?**

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