****

**LEGACY HEALTH IRB**

**FORM E: CONTINUING REVIEW REPORT AND**

**REQUEST FOR RE-APPROVAL**

**Use this Continuing Review Form to request continuing IRB approval and to provide important information regarding the current status of the study, the number and status of subjects in the study, reportable information, compliance information, monitoring reports, amendments, and any preliminary results or publications resulting from this work. All questions must be answered. Missing information will delay re-review of the study and may result in a lapse of IRB oversight. Use the section “Study Summary Details” to explain or provide additional information regard the status of the study.**

**STUDY INFORMATION** **for Ongoing Studies**

Current Date of Expiration of IRB Approval: Click or tap here to enter text.

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.

Legacy IRB Study Number: Click or tap here to enter text.

**STUDY SUBJECTS**

1. Number of Legacy Health subjects (includes charts and/or specimens)

**currently involved** in the study: Click or tap here to enter text.

1. Number of subjects that have **enrolled** in the study at Legacy: Click or tap here to enter text.
2. Number of subjects that **failed screening** for enrollment at Legacy: Click or tap here to enter text.
3. Number of subjects that have **withdrawn** (by subject or PI) at Legacy: Click or tap here to enter text.
4. Indicate the **reasons for** **withdrawal** (by subject or PI) of subjects, if known: Click or tap here to enter text.
5. Number of subjects **lost to follow-up** (for any reason): Click or tap here to enter text.
6. Number of subjects who **completed** the research: Click or tap here to enter text.
7. Current Status of Study: [ ]  Still Recruiting [ ]  Patient Follow Up [ ]  Data Analysis only

 [ ]  Other (explain):Click or tap here to enter text.

**STUDY COMPLIANCE**

1. Have you enrolled more subjects that you originally intended or planned to enroll? [ ]  **Yes** [ ]  **No**
*If YES, explain why:*Click or tap here to enter text.
2. Indicate the version or date of the current Protocol you are using: Click or tap here to enter text.
*This should be the same version that has been most recently reviewed and approved by the IRB.*
3. Indicate the version or date of the current consent form(s) you are using: Click or tap here to enter text.
*This should be the same version that has been most recently reviewed and approved by the IRB). If no consent form is used, indicate “N/A”.*
4. Have all amendments to the research in the past year been submitted to and reviewed by the IRB in a timely manner?

[ ]  **Yes** [ ]  **No** [ ]  **N/A**
*If no, give an explanation as to why the amendment(s) have not been timely submitted and when an amendment will be submitted:* Click or tap here to enter text.

1. Have all on-site serious adverse events (AE) or unanticipated problems (UP) in the past year been submitted to and reviewed by the IRB in a timely manner? [ ]  **Yes** [ ]  **No** [ ]  **N/A**
*If no, give an explanation* *as to why the report(s) have not been timely submitted and indicate when a report will be submitted:* Click or tap here to enter text.
2. Have all protocol violations, exceptions or deviations in the past year been submitted to and reviewed by the IRB in a timely manner? [ ]  **Yes** [ ]  **No** [ ]  **N/A***If no, give an explanation as to why these report(s) have not been timely submitted and indicate when a report will be submitted:* Click or tap here to enter text.
3. Are all study staff up-to-date in having human subject research protection training (CITI)? [ ]  **Yes** [ ]  **No***If no, give an explanation and indicate when study staff training will be up-to-date:*
Click or tap here to enter text.
4. Does any of the study staff have any financial conflicts of interests (COI) to disclose since the last report?
 [ ]  **Yes** [ ]  **No**
*If yes, give an explanation and provide full details regarding the nature of conflict, the amount of financial interest (if $5000.00 or more), the name of the study staff with the conflict, and the type of the financial interest (fees, honoraria, stock equity, intellectual property interest, or sponsor relationship):*
Click or tap here to enter text.
5. Has the Principal Investigator (PI) had any of the following problems or concerns in the past year: conviction of a crime, FDA Warning Letter, suspension/termination/limitations of clinical privileges at Legacy, or medical board actions in regard to the PI’s medical license status, such as investigations, reprimands or suspensions, etc.? [ ]  **Yes** [ ]  **No**
*If yes, give an explanation and* *provide full details regarding the nature of the problem or concern and how it was resolved:*  Click or tap here to enter text.
6. Have there been any complaints from subjects or others related to the investigator’s conduct of the research in the past year? [ ]  **Yes** [ ]  **No**
*If yes, give an explanation and provide full details regarding the nature of the complaint or concern and how it was resolved:* Click or tap here to enter text.

**STUDY MONITORING**

1. Has there been any interim data analysis or a data safety monitoring board (DSMB/DMC) reports, or any scientific publications since last review? [ ]  **Yes** [ ]  **No**
*If yes, include any report or DSMB/DMC reports that have not yet been submitted to the IRB:* [ ]  Reports Attached
2. Have any of the adverse events, deviations, unanticipated problems or concerns in the past year been at a rate significantly higher than was anticipated at the time of initial review? [ ]  **Yes** [ ]  **No**
*If yes, provide an explanation:* Click or tap here to enter text.
3. Has there been any audit by the sponsor in the past year that resulted in significant findings or concerns regarding your site? [ ]  **Yes** [ ]  **No**
*If yes, include full details regarding the nature of the problem or concern and how it was resolved:*Click or tap here to enter text.
4. In the opinion of the PI, Has the risk/benefit ratio of the study changed in the past year? [ ]  **Yes** [ ]  **No**
*If yes, provide an explanation**:* Click or tap here to enter text.

**Brief study summary**

1. Use this section to elaborate on any issue above that requires additional explanation:Click or tap here to enter text.

**Principal investigator confirmation of report**

As Principal Investigator, I certify that the information provided in this application is true, complete and accurate. Further, I agree to continue to conduct this study in accordance with applicable regulations and Legacy policy.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator/Project Director signature |  | Date |

**end of continuing review form**

**SUBMIT FORM TO:**

irbsubmissions@lhs.org

**QUESTIONS?**

**Rebecca Young, MA, CCRP**

Research Regulatory Specialist

Research Administration

Legacy Research Institute

1225 NE 2nd Ave

Portland, OR 97232

Phone (503) 413-5355

reyoung@lhs.org