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**LEGACY HEALTH IRB**

**FORM I: ADVERSE EVENT/SERIOUS ADVERSE EVENT REPORT**

**Use this form for submitting all reportable adverse events (AE) or serious adverse events (SAE). See “Instructions Form I” for completing this form.**

**study information**

Study Title: Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

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

Date of **Submission** of this form: Click or tap to enter a date.

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

**definitions**

**Adverse Event:** Any untoward medical occurrence in a patient or clinical investigation subject

administered an investigational product or having undergone a research procedure which does not

necessarily have a causal relationship with the treatment. An adverse event can be therefore any

unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease

temporally associated with the use of an investigational product or research procedure.

**SERIOUS ADVERSE EVENT:** Any experience encountered during a clinical trial that suggests a significant hazard, contraindication, side effect or precaution. With respect to human clinical experience, a serious adverse event includes any experience that is fatal or life threatening, is permanently disabling, requires in-patient hospitalization or is a congenital anomaly, cancer or overdose, whether or not it is related to investigational drug or device therapy. **ALL subject deaths must be reported promptly, regardless of the cause of death.**

**ON-SITE SAE:** A Serious Adverse Event reported concerning a research subject enrolled in a clinical trial whose Principal Investigator is conducting that study either in their clinic in Portland or at a Legacy facility. On-site reports involve Legacy patients. All on-site reports will receive review by the IRB and a formal response from the IRB e.g., acknowledgement, request for additional information, approval etc.

**OFF-SITE SAE:** A Serious Adverse Event reported concerning a research subject who was enrolled at a site outside the Legacy Health System but pertaining to the same study. Off-site reports are those from other centers. For off-site SAEs attach formal reports filed with the sponsor. Off-site reports may or may not be formally reviewed by the IRB but will reviewed via expedited review first and a decision made regarding it should be reviewed by the full board for fomal action. Off-site SAE’s that trigger a change in research will be reviewed and approved by the IRB.

**IND SAFETY REPORT:** An off-site SAE report generated by the sponsor and forwarded to the principal investigator.

**DSMB:** Data Safety and Monitoring Board is an organization that is responsible for analyzing adverse events in multi-site studies. AEs and SAEs are often reported as a result of a DSMB looking closely at the data.

**AE/SAE report information**

PATIENT INITIALS OR STUDY #: Click or tap here to enter text.

OFF-SITE:  Yes  No

ON-SITE:  Yes  No

DATE OF AE/SAE OCCURRENCE:Click or tap here to enter text.

DATE AE/SAE REPORTED TO PI:Click or tap here to enter text.

DATE OF THIS AE/SAE REPORT: Click or tap here to enter text.

DESCRIBE THE AE/SAE IN DETAIL: Click or tap here to enter text.

DESCRIBE THE ACTION TAKEN BY THE SITE IN REGARD TO THE AE/SAE:

Click or tap here to enter text.

**AE/SAE report ANALYSIS**

Was the AE/SAE related to the investigational drug or device?  Yes  No  Unknown

If the relationship is unknown, is there is a new potential risk?  Yes  No  Unknown

Has the AE/SAE been reported to the sponsor and/or FDA?  Yes  No

Is this AE/SAE mentioned as a risk in the consent form?  Yes  No

Copy current relevant risk language from the consent form:

Click or tap here to enter text.

Does this AE/SAE require a change in the protocol and/or consent form?  Yes  No

Indicate when changes will be made to update protocol or consent form? 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**

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| **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](mailto:reyoung@lhs.org) |  |

**HOW TO SUBMIT THE FORM**

Sign and return or confirm via email the accuracy of this form and send the form with all new or revised documents attachments via email to [irbsubmissions@lhs.org](mailto:irbsubmissions@lhs.org).