

**Institutional Review Board  
Rush-Presbyterian-St. Luke's Medical Center**

**SAFETY REPORT FORM FOR:**

- Serious Adverse Experiences
- Serious and Unexpected Adverse Experiences
  - Serious Other/Not Related

**Serious Adverse Event reports are a serious component of the IRB oversight process. Failure to provide timely and complete reports may result in an audit, or cessation of project research.**

**SCOPE OF REPORTING**

The Rush IRB requires Investigators to file these Safety Reports for all subjects enrolled in the comprehensive study protocol -- whether the event occurred at the Rush site, off-site under the supervision of the Rush Investigator, or at a totally different site of a large national multi-site study under the supervision of a different PI and a different institution. However, studies that have identified an Independent Data and Safety Monitoring Board (DSMB) will only be required to submit summary reports semi-annually for non-Rush serious adverse events, including deaths. The following are requirements of a DSMB:

A DSMB is defined as an independent panel of experts who have no financial, scientific, or other conflict of interest with the trial. The primary function of the DSMB should be to act in an advisory capacity in order to monitor subject safety and evaluate the efficacy of the intervention.

If submitting a report from the DSMB, the following information must be included in addition to the cover memo:

- A brief narrative section describing the status of the study, progress, or findings to date, and any issues.
- A statement regarding whether the study should continue or be terminated.
- A summary of the number of adverse events that have occurred.

Please note: no identifying subject information should be on the DSMB report.

In regard to submitting serious adverse event (SAE) reports for participants in long-term follow-up studies but no longer receiving study treatment, after either 1 or 5 years (whichever is appropriate to the study in question) the Rush IRB will require reports only on deaths involving participants treated at Rush. Thus, instead of requiring you to submit all fatal event reports for the entire length of the study, we will limit our review to only Rush-related deaths that occur either;

- 12 months after treatment ends\* for advanced disease studies or
- 5 years after treatment ends\* for adjuvant studies

\*Or longer if dictated by the Protocol.

**INSTRUCTIONS FOR COMPLETION AND SUBMISSION OF THIS FORM:**

1. Complete one "Safety Report Form" for **each** adverse event.
2. Submit one copy of the current consent document.
3. Safety Reports may be bundled by ORA project, with a single copy of the current consent document.
4. The Principal Investigator must sign each "Safety Report Form," and the original signed report must be submitted to the IRB Administration Office (Room 544 Armour Academic Center). FAX submissions and e-mail submissions are NOT acceptable.
5. **For death safety reports, include a copy of the last approved consent form, and 13 copies of the submission for review.**
6. No hand written submissions will be accepted (word processor or typewritten only for legibility).
7. Please submit all supplementary or supporting data with each Safety Report Form.
8. Do not submit Data Safety Monitoring Board (DSMB) Reports with this form. Submit all DSMB reports with a cover memo, identifying the project by ORA identification number.

## REQUIREMENTS

The Rush IRB requires Investigators to provide the following information in a timely way during the course of a study:

- Serious Adverse Experiences (SAEs), whether or not considered related to the investigational drug, device or product; AND
- Serious and Unexpected Adverse Experiences; AND
- Serious Other/ Not related

Investigators are required to make timely reports of these events to the study Sponsor and/or the FDA whenever required, in accord with 21 CFR 312, 600, & 812; the Sponsor contract; and the IRB-approved protocol.

## DEFINITIONS

“**Timely**” reporting means the Investigator will notify the Rush IRB in writing (FAX, memo or letter) within **seven days for all Serious Adverse Experiences (SAEs)** and within **fifteen** days for unexpected adverse experiences, unanticipated problems involving risk to subjects, and subject complaints.

**Serious Adverse Experiences (SAEs)** consist of any adverse drug (or device or biological product) experience occurring at any dose that results in any of the following outcomes:

- death
- life-threatening adverse drug/device/product experience
- inpatient hospitalization
- prolongation of existing hospitalization
- persistent or significant disability / incapacity
- congenital anomaly / birth defect

**Serious Unexpected adverse drug (or device or biological product) experiences** encompass any adverse experience not listed in the current labeling for the drug/device/product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. “Unexpected” refers to an experience that has not been previously observed (i.e., included in the labeling), whether or not the experience might be “anticipated” from the pharmacological/functional properties of the product.

**Serious Other/Not Related** consists of events unexplained in the context of the original research proposal and the scientific literature at the time the protocol was first submitted to the IRB.

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SAFETY REPORT FORM FOR (check all that apply):**

Serious Adverse Experience

**Is the experience/problem and severity listed in the risk section of the consent form?**     Yes     No

Serious and Unexpected Adverse Experience

Serious Other/Not related

Did the experience/problem occur in a subject enrolled at:

Rush or enrolled at Rush

At another study site

Study Status:

Indicate the number of subjects enrolled in the study at Rush:

Open to enrollment

Closed to enrollment, with follow-up

Closed to enrollment, no follow-up

ORA #:

Principal Investigator:

Project Title:

1. Date of experience or problem:        /        /

2. Describe experience or problem:

3.  Initial report of this experience/problem – OR --  Follow-up #        for this experience/problem

4. Age of Subject:

5. Sex of Subject:  Male  Female

6. Outcomes attributed to experience/problem:

Death

Life-threatening situation

Hospitalization: Initial, prolonged, or re-hospitalization

Disability

Congenital anomaly

Required intervention to prevent permanent impairment/damage

Other

7. In the opinion of the reporting Investigator or Sponsor, was the experience/problem caused by the therapy or procedures associated with this research protocol?

Not related

- Unlikely
- Possibly
- Probably
- Definitely related
- Insufficient information

8. Do you agree with the reporting Investigator's/sponsor's assessment?  Yes  No

If you do NOT agree, you must explain why:

9. Does the outcome of this problem/experience lead you to **revise the risks listed in the consent form?**  Yes  No

If YES, exactly what changes do you recommend for the Informed Consent Documents?

10. Is this research study monitored by an Independent Data Safety Monitoring Board (DSMB)?  Yes  No

If YES, list the name and location of the DSMB:

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Rush Principal Investigator signature

Date

**For Reviewer Use Only:**

**Administrative stamp, send to file**

Reviewed and signed, send to file, no further action recommended at this time. \_\_\_\_\_

Return to PI for additional information: \_\_\_\_\_

Requires review by full IRB due to the following concerns: \_\_\_\_\_