

- INSTRUCTIONS -

New Safety Information Form

This form should be used to submit new information that may impact human subject safety. Such information may present as: 1) Revised Investigator Drug/Device Brochures (IDB); 2) IND Safety reports; 3) Toxicity Reports/NCI Action Letters; 4) data and safety monitoring reports/progress reports; 5) literature reviews; or 6) other safety information that may impact human subject welfare.

Section I: Header Information

- **CHRMS# or CHRBS#:** Indicate the appropriate committee and the unique IRB-assigned number for the study.
- **Principal Investigator:** The name of the local Principal Investigator.
- **Protocol Title:** The protocol title should be the same as the original application title.

Section II: Check What is Being Submitted

- **Investigator Drug/Device Brochure (IDB) Revision**
Attach a double-sided copy of the IDB. ***Include a summary of the specific IDB changes*** from the previously approved edition including revised sections, page numbers, and a description of the changes made to each section.
- **IND Safety Reports**
IND Safety Reports no longer require submission.
- **Toxicity Reports/NCI Action Letters**
Attach a copy of the letter.
- **Data and Safety Monitoring Report or Progress Report**
Attach a copy of the report.
- **Literature Review**
Attach a summary of the new information and include reference(s).
- **Other, specify**
Provide details of the “other” type of safety information that is being submitted and attach any supporting documentation.

Section III: Does the new information impose greater risk of harm to the subjects than previously estimated?

The information being submitted needs to be reviewed by the PI to determine if the new safety information indicates a greater risk than originally estimated. If **yes**, an explanation is required.

Section IV: How does this event affect human subjects, the protocol, and the consent form?

A. Do you have subjects receiving interventions or treatments now?

- We need to establish at the time of the submission, if this new safety information could potentially affect any local subjects.
- Check “Yes” if there are local subjects currently receiving treatment/interventions and “No” if none or not applicable.

B. Is the study open to accrual?

- We need to establish at the time of the submission, if this new safety information could potentially affect subjects that are being screened/enrolled into the study and if the informed consent and/or the protocol would need to be amended.
- Check “Yes” if the study remains open to accrual (i.e. you are still enrolling subjects into the study)
- Check “No” if the study is closed to accrual

C. Should the consent form or any portion of the protocol be revised as a result of this new information?

- If **yes**, submit with this report a REQUEST FOR MODIFICATION/ AMENDMENT TO APPROVED PROTOCOL form and include a copy of the summary of protocol changes and/or consent with changes highlighted and a consent without the highlighting for IRB approval stamp.
- If **no**, provide rationale in the space provided.

D. Will the currently enrolled subjects be informed about the new information?

Check “Yes” if, in the opinion of the PI, it is necessary for currently enrolled subjects (either those in active treatment, follow-up, off-treatment, etc.) to be notified of the new safety information.

- **If yes, describe the proposed method of notification** Describe the method of notification, expected timeframe, and which subjects

(those in active treatment, follow-up, off-treatment, or all enrolled subjects) will be notified.

- **All written material requires IRB review and approval prior to being utilized.** We strongly recommend use of consent form addendum when sharing new information with those subjects that have already been fully consented. *See our forms page for a consent addendum template.*
- **If no, why not?**
Explain why you do not think it necessary to notify subjects.

Section V: Signature

The principal investigator (PI) must review, sign, and date the form. By signing the form, the PI agrees to the following statement, “***By signing below, the Principal Investigator assures the information contained on this form is true and accurate***”.

Safety Report Summary Table

- Summarize IND safety report data in this table.
- **DO NOT ATTACH SAFETY REPORTS**
- **Initial or Follow-up Report:** Indicate if the safety report is the initial or a follow-up (fu) report. If it is a follow-up report, specify the number (i.e. fu# 6)
- **MedWatch/Manufacturer #:** Provide the unique ID associated with the adverse event.
- **Date of Event:** Indicate the onset date of the adverse event.
- **Describe Adverse Event:** Provide the final diagnosis.
- **A. Did the event occur on this study?** Report “yes” if the event occurred on the same protocol or “no” if the event occurred on a different protocol.
- **B. Is the event serious?**

A serious adverse event is either:
 - a fatality

- life-threatening (places the subject at immediate risk of death from the event as it occurred)
 - an inpatient hospitalization
 - a prolongation of an existing hospitalization
 - a persistent or significant disability/incapacity
 - a congenital anomaly/birth defect; or
 - based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
- **C. Was the event unexpected?**

An event **does not meet the criteria of UNEXPECTED** if it is 1) included in the current protocol, drug/device brochure or the informed consent, or 2) due to subject's underlying disease or predisposing risk factors.

- **D. Was the event possibly, probably or definitely related to the study?**

An adverse event is considered to be **RELATED** if there is a reasonable possibility that the event may have been caused by the research intervention.