

## - INSTRUCTIONS -

### Report of Protocol-Related Problems & Deviations Form

**How to Report:** This form captures all of the required elements for an effective review of protocol-related problems and deviations. The form data fields automatically expand to allow many lines of text. Use the fields for all comments – even if this expands the form to three or more pages, as the Committee prefers to minimize the number of attachments.

The requirements for completing each section of the form are described below.

#### 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.

#### Question 1.

**Date of the Unanticipated Problem.** Indicate the date the problem, event, or deviation occurred.

#### Question 2.

**Was the problem unexpected?** Check yes or no.

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 the subject's underlying disease or predisposing risk factors.

#### Question 3.

**Was the problem related to the research protocol?** Check yes or no.

- An event is considered to be **RELATED** if there is a reasonable possibility that the event may have been caused by the protocol or study interventions.
- If it cannot be determined whether an event is related, it should be reported as “possibly related.”
- If yes, indicate the degree of relation.

#### **Question 4.**

**Did the problem involve a potential risk to subjects or others?**

Even though the event may not have caused direct harm, if there was a **potential** for harm then indicate “Yes”. For instance, a participant may have been given a higher dose of a drug than described in the protocol and no harm was observed nor experienced, **however** there was the potential for harm at that higher dose. Additionally, if a laptop is stolen there may have not been harm to subjects or others; **however** there was a potential breach in confidentiality and thus a potential for harm.

- A. Describe the unanticipated problem.** Include as many details as possible regarding the event.
- B. Explain the potential risk to the subject.** Explain what happened or what could have happened to the subject as a result of this problem?
- C. Provide the outcome for this subject.** Describe, if any, harmful effects that came to the subject.

#### **Question 5.**

**What can this problem be attributed to?** Check appropriate box or explain.

#### **Question 6.**

**Describe steps which have been taken to resolve the problem.** Provide as many details as possible.

#### **Question 7.**

**Describe what procedures have been implemented to avoid future occurrences.** This could range from a simple change in procedure to implementation of a set of standard operating procedures. The Committee may require that additional actions be taken.

#### **Question 8.**

**How Does This Protocol-Related Problem Affect Human Subjects, the Protocol, and the Consent Form?** This section requests specific information for internal assessment of the unanticipated problem being reported.

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

- We need to establish at the time of the submission, if this event/problem could potentially affect subjects that may be receiving study-related treatment and/or interventions.
- 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 event 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) or
- 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 problem? Check yes or no.**

- 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.

**Question 9.**

**Has this unanticipated problem involving risks to subjects or others been reported to someone other than the IRB (i.e., study sponsor, FDA)?**

- Indicate yes or no.
- If yes, please specify to whom this has been reported to, in addition to the IRB.

**Question 10.**

**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***”.