Report of External Unanticipated Problems

POLICY:
External events that qualify as Unanticipated Problems (Ups) MUST be reported to the IRB within 10 calendar days of the study team's knowledge of the event.

NOTE: In general, a report that meets the criteria for reporting in an IND safety report should also be considered an 'unanticipated problem' and reported to the IRB.

External adverse events that do not meet the definition of a UP should not be submitted to the Piedmont Healthcare IRB via IRBNet.

DEFINITION:

Unanticipated Problem (UP): An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

IRBNet ID# and Project Title

KEY STUDY PERSONNEL

Includes all individuals who have contact with participants and/or their research data and identifiers for purposes of conducting research. List names, credentials, and study roles. These individuals are required to complete WCG training requirements prior to participating in the conduct of the research. See PHCIRB policies #6423 and # 6434.

Name, credentials and study role

SUBMISSION REQUIREMENTS

- IND safety reports may be submitted batched if received from the sponsor that way. Upload sponsor cover letters in submission.
- External UPs not submitted in an IND safety report must be accompanied by:
  - Explanation of how the event meets the definition of an UP
  - Statement as to whether or not the UP resulted in a modification to the protocol or consent
  - Statement addressing whether the modified protocol or consent, if applicable, has been yet implemented at the local site.

Person Completing this form | **Date**

Signature by the Principal Investigator is REQUIRED. Please have the PI manually sign, scan, and upload this form into IRBNet OR the PI can electronically sign the form in IRBNet after review. If the PI will electronically sign the document just mark the check box next to the date field below.

Investigator Signature | **Date** | ☐