Harvard Pilgrim Health Care

HARVARD PILGRIM HEALTH CARE IRB
REPORTING REQUIREMENTS: UNANTICIPATED PROBLEMS/ADVERSE EVENTS

REPORTING: Unanticipated Problems/Adverse Events are reported through IRBNet. Forms are available in the 'Forms and Templates' section in IRBNet. Contact the Director, Research Integrity and Compliance Officer (DRICO) at (617) 867-4587 with questions.

An unauthorized use or disclosure of research data by the Institute, or report that a third party had an unauthorized use or disclosure of data provided by the Institute, must be reported to Legal immediately. Institutional and agency reporting (e.g., study sponsor, FDA, etc.) should be done as required according to sponsor requirements, for all other reporting seek guidance first from Legal and the DRICO.

UNANTICIPATED PROBLEMS

- **Report immediately, but not later than two (2) weeks** after the Investigator learns about the problem.
- Unanticipated problems involving risks to subjects or others is any incident, experience or outcome, including an adverse event that meets all of the following criteria:
  (1) unexpected (in terms of nature, severity, or frequency) given (1) the research procedures that are described in the protocol related documents, such as the IRB approved research protocol and informed consent documents, and (2) the characteristics of the subject population being studied;
  (2) related or possibly related to a subject's participation in the research; and
  (3) suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized
- Examples of Unanticipated problems may include:
  - Any adverse event (whether occurring on site or at another site), regardless of whether there is an accidental or unintentional change to the HSC approved protocol that involves risks or has the potential to recur
  - Deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant
  - Publication in the literature, safety monitoring report, including a Data and Safety Monitoring Report, interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research
  - Unauthorized use or disclosure of research data, including from lost or stolen data or equipment, that may involve risk to that individual or others** *(an unauthorized use or disclosure must be reported immediately)*
  - Complaint of a participant or family member that indicates an unanticipated risk
  - Laboratory or medication errors that may involve risk to that individual or others
  - Change in FDA labeling because of adverse consequences or withdrawal from marketing of a drug, device, or biologic used in a research protocol
  - Disqualification or suspension of investigators
  - Sponsor imposed suspension for risk
  - Any event that requires prompt reporting to the sponsor

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ADVERSE EVENTS: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

- **Serious Adverse Events that are Unanticipated Problems must be reported as soon as possible, but no later than one (1) week** of the Investigator becoming aware of the event
- Serious Adverse Events:
    - result in death
    - are life threatening
    - require hospitalization
    - result in persistent or significant disability/incapacity, or any other
    - adverse event that may jeopardize the subjects health
- Investigators shall submit all internal adverse events for all <u>unanticipated</u> (i.e. not consistent with the current Investigator's brochure or with other current risk information) adverse events or problems (both serious and non-serious).
- Investigators shall promptly report any unanticipated study related death to the HSC within two business days of becoming aware of the event.
- Investigators do not need to submit *External Adverse Events that do not* meet the following criteria:
    - Unexpected;
    - Related or possibly related; AND
    - serious or otherwise one that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized

  Note: If a sponsor requires IRB submission, the Investigator may submit them, and the submission will be acknowledged by the IRB. The External Adverse Event will not be deliberated by the IRB. However, if the External Adverse Event changes the risk status or any other element of the consent, an amendment must be filed with the IRB.
- **Unexpected adverse events** are adverse events not consistent with either:
    - The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol related documents of labeling and package inserts; or
    - The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event
- **Related or possibly related:** there is a reasonable possibility that the adverse event may have been caused by the procedures involved in the research.