



Unanticipated Problem Form

Site# _____ Participant # _____ Subject's Initials _____ Date of awareness _____

Unanticipated Problems are incidents, experiences, or outcomes that meet all of the following criteria:

1. Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the research protocol and informed consent document approved by the Ethics Committee (EC; includes Institutional Review Boards [IRBs], Independent Ethics Committees [IECs], and Research Ethics Boards [REBs]) and (b) the characteristics of the participant population being studied,
2. Related or possibly related to participation in the research, and
3. Suggest 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.

An unanticipated problem may not necessarily have an accompanied AE associated with it. However, if associated with an SAE, please report via EDC or SAE report form if the EDC is unavailable and **within 24 hours** of awareness.

* Unanticipated Problems need to be reported to the IRB, appropriate institutional officials, the supporting agency head and OHRP in accordance with HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5). <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#AB>

For questions regarding whether an event may be considered an unanticipated problem, please contact the Study Medical Monitor.

Please describe the unanticipated problem below (include problem, how relationship is determined, and time frame):

Please sign below and send copy of the form to connectsafety.sm@thermofisher.com for processing.

Name of reporter _____ Signature _____ Date _____