



Shepherd University

Institutional Review Board – Human Participants

Incident Report Unanticipated Problem(s)

The regulatory requirements under 45 CFR 46.103(a) and (b)(5) require those conducting non-exempt research involving human subjects to report any unanticipated problem(s) involving risks to subjects or others; and/or, noncompliance with policy or the requirements or determinations of the IRB to appropriate university officials in a timely manner. Timely manner means as soon as a problem or noncompliance issue is determined. Please forward this form to the President, to the IRB, Chair, or to the SURC Co-Director.

Title of Research Project: _____

Principal Investigator: _____

Funding source: _____

1. Describe the unanticipated problem involving risks to participants or others: (Use additional sheet if necessary.)

2. What action is being taken or what plans made to address the problem?

3. List the parties currently involved who (a) identified the problem, (b) solved or are solving the problem, and (c) are aware of the problem.