

Monroe • Polkton • Wadesboro

IRB Unexpected Event Report Form

Principal Investigator:
Address:
Phone Number:
E-mail:
Department, school, or program you represent:
Title of Project:
Unexpected Event Report Submission Date:
1. Describe the unexpected event(s) not outlined in the initial IRB application. Include the dates of occurrences, number of participants, and impact on participants.
2. Describe the actions taken by the research team, if any, in response to the event.

3.	Does the unanticipated event indicate that the research participants are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?
4.	Do you plan to submit an amendment to the current project to the IRB for review? Briefly explain the amendment or why an amendment is not needed.
5.	Will you inform current participants of the unexpected event? If you have or plan to notify participants, describe how and when the notification will occur (provide a copy of the notification to the IRB). If not, explain why not.