Unanticipated Problem Report:

Study Number:

Project Title:

Principal Investigator:

PI's Faculty Sponsor:

1. Date of unanticipated problem:

2. Type of unanticipated problem:
   
   • Adverse Event;
   • Deviation;
   • Security Lapse;
   • Other

3. Did the problem occur at a UMD site?
   Yes ___ No ___

4. Did the problem involve a UMD PI?
   Yes ___ No ___

5. Provide a summary of the problem(s):

6. Is the problem related to the study and its procedures, protocols, etc.?
   Yes ___ No ___

7. Is the problem already described in the consent/authorization forms?
   Yes ___ No ___
8. If the problem isn't already described in the consent/authorization forms, should the consent/authorization form be updated?
   Yes ___ No ___

9. Should the research study be changed in a way to reflect this problem?
   Yes ___ No ___

10. Will previously enrolled subjects:
    A. Be given this information?
        Yes ___ No ___

    B. Be asked to re-consent/authorization?
        Yes ___ No ___

11. Has there been a change in the risk/benefit ratio?
    Yes ___ No ___

12. Have any corrective actions or measures been taken to address this unanticipated problem and to prevent future problems?
    Yes ___ No ___

13. Provide a brief summary of corrective measures: