

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: