

University of Northern Iowa – Institutional Review Board
**Reporting Form for Unanticipated Problems
Involving Risks to Subjects or Others**

| | |
|-------------------------|--|
| IRB Study Number: | |
| Principal Investigator: | |
| Study Title: | |

Provide the following information for each unanticipated problem/event that is being reported on:

| | |
|-----------------|--|
| Date of Event: | |
| Date of Report: | |

Describe problems/event:

Possibly related Probably related Definitely related

Does this problem/event alter risk to past, present or future subjects?

Yes No Don't Know (Insufficient Information)

In your judgment, should this problem/event be added to the consent form as a potential risk?

Yes Provide revised consent form with changes highlighted.

No Explain why not:

**Based on your analysis of this problem/event,
should currently enrolled subjects be notified?**

Yes No

should subjects who have completed the study be notified?

Yes No

Explain:

Principal Investigator's Signature

Date