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**Reporting unanticipated problems to a previously approved IRB proposal**

I. Study Information

1. IRB Study number:

2. Title of Project:

3. Principle investigator and title:

II. Unanticipated Problems

1. Description of the incident.

2. Principle investigators assessment of the incident

3. Outline any changes and the significance to the study and changes in the risk/benefit ratio.

4. Any changes that need to be made to the consent statement plus the revised form.

Signature of Principle Investigator:

Date: