

**Instructions for Submission of
Unanticipated Problem, Incident, and New Information Reporting Form
Health Sciences IRB • Health Sciences Minimal Risk IRB**

Protocols submitted without the applicable materials below or accompanied by an incomplete or unsigned form will be returned and NOT scheduled for review. Please submit the following documents to the Health Sciences Institutional Review Board Office, 2500 Overlook Terrace #B3088 Madison, WI 53705. **Do not submit copies of the instruction pages.**

- _____ One (1) original of the completed **Unanticipated Problem, Incident, and New Information Reporting Form** signed by the Principal Investigator
- _____ One (1) copy of any supporting materials, such as a Data Safety Monitoring Board Report, Action Letter, journal article, audit report
- _____ If subjects will be informed of new information related to this research study via letter, submit one (1) copy of the proposed correspondence for review
- _____ If a protocol amendment accompanies the report indicate this on the form and submit a *Change of Protocol* form that describes the changes to this document
- _____ Submit a disk or CD with an electronic version (in a format accessible by MS Word) of your application and any applicable consent documents.