

**UB IRB Reportable New Information Submission Checklist**  
(SAEs, Safety Monitoring Reports, Protocol Safety Violation, Safety Complaints, etc.)

The following is a brief description of the items required for Reportable New Information Submissions of Investigator Initiated Protocols and Sponsor/Industry Initiated Protocols to the IRB:

Items listed on HRP-214-Form-Reportable New Information require reporting to the IRB within 5 business days.

- HRP-214-Form-Reportable New Information
- Any supporting documents as necessary

Note: If the new information requires modifications to the protocol or consent form, follow the guidelines on the HRP-214-Form-Reportable New Information form.

**Information that does not fall under any of the categories listed on the Reportable New Information Form does NOT require reporting to the IRB. The IRB will withdraw any submission of information that does fall under one of the categories on the form.**