UB IRB Protocol Continuing Review and Study Closure Checklist

The following is a brief description of the items required for Continuing Review and Study Closure for Investigator Initiated Protocols and Sponsor/Industry Initiated Protocols to the IRB:

*As of 11/3/2014, all existing documents that are not on the new Toolkit Forms and Templates must be converted to the new Toolkit Forms and Templates to avoid delays in approval. They will NOT be accepted on the old forms.

For studies **closed to enrollment**, the Consent Form is not required for continuing review. The Protocol is required to be converted to the new Toolkit Protocol Template (for non-industry sponsored research) and Site Supplement to Sponsor Protocol Template is required (for industry sponsored research).

For studies open for **data analysis only**, the Consent Form and Protocol are not required for continuing review. However, all other relevant Toolkit Forms must be used (e.g. Continuing Review Form).

- ☐ HRP-212-Form-Continuing Review

For **Continuing Review** only:

- ☐ *Consent (for studies with open enrollment only) (choose appropriate consent document)
  - HRP-502-Template Consent Document (with HIPAA attached)
  - HRP-502A-Template Assent Of Child 7-13 yrs old
  - HRP-502B-Template Consent Script Examples-Oral (Verbal) Consent
  - HRP-506-Template Consent Document-Emergency Use
  - HRP-507-Template Consent Document-Short Form
- ☐ *Protocol (only include if protocol not on new Toolkit Template) (choose appropriate protocol document)
  - HRP-503-Template Protocol (required for all non-industry sponsored research including NIH, Federal, IIP, etc.)
  - HRP-508-Template Site Supplement to Sponsor Protocol (required for all industry sponsored research)
- ☐ Core Data Form
- ☐ New Advertising, Recruitment, or Data Collection Materials
- ☐ Coverage Analysis Billing Grid (required for all studies with clinical procedures, include if not submitted with initial IRB submission or if changes are required)
- ☐ Authorization of Fee Collection for IRB Review Form (industry sponsored research only)

If modifications are requested, submit a separate request for modifications using HRP-213-Form-Modification and include all documents that require modification.

Note: Prior to submission please be sure that all study personnel have completed the appropriate required university training and have updated their Conflict of Interest (COI) disclosures on the university website.

Information about researcher training, the IRB Toolkit, COI requirements, etc. can be found on the following website: http://www.research.buffalo.edu/rsp/IRB/

The Coverage Analysis Billing Grid and Checklist are located on the Clinical Research Office (CRO) website under forms: http://www.research.buffalo.edu/cro/forms.cfm. Instructions on how to complete the Billing Grid are located on the first tab of the Billing Grid spreadsheet.