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:

Note: As of 11/1/2015, IRBNet can no longer be used for IRB submissions. Please use the new software “Click” that can be found on the IRB website. Templates and documents can be found in the Library in “Click”.

For studies closed to enrollment, the Consent Form is not required for continuing review.

For studies open for data analysis only, the Consent Form and Protocol are not required for 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 (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)

- Coverage Analysis Billing Grid (required for all studies with clinical procedures, upload most recent version of the CA)

- New Advertising, Recruitment, or Data Collection Materials

- Authorization of Fee Collection for IRB Review Form (industry sponsored research only)

If modifications are requested, chose “Modification and Continuing Review” in “Click” and include all documents that require modification with a summary of the modifications.

Note: Prior to submission, please be sure that all study personnel have completed the appropriate required university training and have updated their UB 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: https://www.buffalo.edu/research/research-services/compliance/irb.html

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.