UB IRB Initial Protocol Submission Checklist

The following is a brief description of the items required for Initial Protocol Submissions of 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 IRB Library in “Click”.

As of 4/1/2016, all new, non-industry sponsored studies must be submitted using the new version of the HRP-503 Template Protocol (version Jan 2016). Modifications and continuing reviews of currently approved studies will still be accepted using previous versions of the HRP-503 Protocol Template.

- Protocol (choose appropriate protocol template)
  - HRP-503-Template Protocol (required for all non-industry sponsored projects including NIH, Federal, IIP, etc.)
  - HRP-508-Template Site Supplement to Sponsor Protocol (required for all industry sponsored research)
  - Sponsor’s protocol (required for all industry sponsored research)
- Consent [choose appropriate consent document(s)]
  - HRP-502-Template Consent Document (for Adult Consents, Parental Permission, or Assent of Child 14-17 years old\(^1\))
  - HRP-502A-Template Assent of Child 7-13 years old
  - HRP-502B-Template Consent Script Examples-Oral (Verbal) Consent
  - HRP-506-Template Consent Document-Emergency Use
  - HRP-507-Template Consent Document-Short Form
- HIPAA (if applicable)
  - HRP-614-HIPAA-Authorization Template (contained within the HRP-502-Template Consent Document)
  - HRP-610-HIPAA-Worksheet
  - HRP-611-HIPAA-PartialWaiver (required to access PHI for recruitment purposes)
  - HRP-612-HIPAA-Waiver
  - HRP-613-HIPAA-Certificate of De-identification
- Grant Application (if applicable)
- All Advertising and/or Recruitment Materials
- Data Collection Materials (including case report forms, subject questionnaires and surveys)
- Authorization of Fee Collection for IRB Review (for industry sponsored research only)
- Previous Determinations of other IRBs (if applicable)
- Coverage Analysis Billing Grid\(^2\) (required for all studies with clinical procedures)
For research involving children 14 to 17 years old, create the Parent Permission document first using the HRP-502-Template Consent Document and then make the following changes to the document to create the Assent of Child 14-17 document:

- Change consent title from “Parent Permission for a Child” to “Assent of a 14-17 year old”
- Change all references of “your child” to “you”
- Remove any legal language, reimbursement, or compensation language that is not appropriate for the child
- Remove the HIPAA authorization section along with any references to it (e.g., in “What happens to the information collected for the research?” section)
- Use the Signature Block for Assent of Child on the signature page
- Review the document for appropriateness of the language level (e.g. no higher than 8th grade level when possible) for this age group to ensure the understanding of the potential subject.

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.

**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