

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 11/3/2014, all documents must be submitted on the new Toolkit Forms and Templates. The IRB will NOT accept new submissions on the old Forms and Templates.

- HRP-211-Form-Initial Review*
- Protocol (choose appropriate protocol document)
 - 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)
- Consent [choose appropriate consent document(s)]
 - HRP-502-Template Consent Document (for Adult Consents, Parental Permission, or Assent of Child 14-17 years old**)
 - 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-Partial Waiver
 - 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 subject questionnaires and surveys)
- Core Data Form
- Authorization of Fee Collection for IRB Review (for industry sponsored research only)
- Previous Determinations of other IRBs (if applicable)
- Coverage Analysis Billing Grid (required for all studies with clinical procedures)

*Remember to include the following requested documents in Appendix B or Appendix C of the HRP-211-Form-Initial Review (if applicable):

- Investigator's Brochure/ Package Insert
- IND FDA Letter
- or
- IDE Device Description/ Product Labeling
- IDE FDA Letter

**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
- 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.

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.