University at Buffalo The State University of New York

BUFFALO Clinical and Translational RESEARCH CENTER

Clinical Research Office

UB IRB Protocol Amendments and Modifications Checklist

The following is a brief description of the items required for Protocol Amendments and Modifications 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.

- ☐ HRP-213-Form-Modification

If any changes are made to any of the following items, include with submission:

- ☐ *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)
  - 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
- ☐ Investigator's Brochure
- ☐ Coverage Analysis Billing Grid
- ☐ All Advertising, Recruitment, or Subject Materials (including subject questionnaires and surveys)
- ☐ Core Data Form (update as needed)

The following items are considered Amendments and Modifications:

- Amendment to Protocol
- Updated Investigator Brochure
- Amended Consenting Document(s)
- New or Changed Data Collection Forms (Questionnaires, Surveys, etc.)
- New or Changed Advertising or Recruitment Materials
- Changes to Research Staff (this requires a change in IRBNet in the "Share" listing and may involve a change to the staff information in Core Data Form)
- Study Site Changes (this requires a change in IRBNet Core Data Form)

If this amendment/modification is being submitted for changes made to eliminate an **immediate hazard** to subjects or others, you **must also submit HRP-214-Form-Reportable New Information** to inform the IRB.

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.