Amendment Form

WHEN TO USE THIS FORM:

This form must be used to request approval for changes to an active protocol (including recruitment methods, informed consent procedures, study design, research personnel, etc.). Proposed changes cannot be initiated without written IRB approval, except when necessary to eliminate apparent immediate hazards to a subject's health or safety. If you have questions, contact the Children's Wisconsin (Children's) IRB Office at CWHRPP@childrenswi.org.

If the requested change is a one time, temporary, planned protocol exception, please use the Planned Protocol Exception Request Form and refer to the Guidance – Planned Protocol Exceptions.

IRB SUBMISSION INSTRUCTIONS:

Answer all questions on this form. Upload this form, along with any new and/or revised documents, in IRBNet using the amendment submission package. An IRB staff member will contact you with any questions.
Please note: Procedures for submitting revised documents to the IRB have changed. It is important you follow the instructions listed at the end of this form.

Children's Wisconsin IRB#	
Study Title	
Principal Investigator	

1. At the time this amendment is being submitted, is there a pending continuing review for this study, or have been notified via IRBNet that a continue review is due?
   ☐ No ☐ Yes

   1a. If yes, please provide rationale for submitting this amendment before continuing review approval. If unable to provide a justification, the amendment should wait and be submitted after Continuing Review (CR) approval.

   In general, amendment submissions should wait until any pending continuing reviews are finalized and approved. The exceptions to this, which require explanation and justification, above are:

   - Amendment is necessary to protect subject safety and this cannot wait until CR approval.
   - Amendment is a Principal Investigator or staff change that cannot wait until CR approval.
   - There are other, unavoidable review timeline issues that require the amendment submission while the CR is pending.

2. Amendment requested by: ☐ Principal Investigator (PI) ☐ Sponsor

3. As of October, 2017, the NIH has updated their policy on Certificates of Confidentiality and are automatically issuing these for eligible studies that are NIH funded. They no longer issue a paper certificate, nor only submit on request.

   Does this study qualify for a Certificate of Confidentiality? ☐ No ☐ Yes
   For help in determining this see the IRB guidance document or visit the NIH website for information at: https://humansubjects.nih.gov/coc/index.

Updated NIH policy can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html.

If you answered yes, and language regarding this is not included in the consent form(s) you will need to update the consent form to include this language (see the National Institutes of Health [NIH] suggested consent language at https://humansubjects.nih.gov/coc/suggested-consent-language).

4. Amendment Information
   a. Provide a precise **description** of proposed changes and **rationale** for each change.

5. Informing Subjects of New Information
   a. Do consent or assent documents need to be updated as a result of this amendment?
   ☐ Yes ☐ No ☐ N/A – informed consent has been waived for this study (skip to question 6)

   b. Will currently enrolled subjects need to be notified of the changes?
   ☐ N/A – No subjects enrolled
   ☐ No – Changes will only impact subsequently enrolled subjects
   ☐ No – *Please explain:*
   ☐ Yes – (i) The new information will affect participation of current subjects or may relate to subjects' willingness to continue participation in the study. Our site plans to inform:
      ☐ All active subjects
      ☐ All subjects in follow-up
      ☐ All subjects in follow-up and all active subjects
      (ii) The following method(s) will be used to inform subjects of the new information:
      ☐ A letter will sent to subjects
      ☐ Subjects will be verbally informed of the new information (e.g., telephone call)
      ☐ Subjects will be asked to sign a consent form addendum
      ☐ Subjects will be asked to sign a revised consent document
      Additional information, if applicable:

6. Risk/Benefit Assessment
   a. Are any of these changes the result of something that occurred during human subject interaction or an unexpected event? ☐ No ☐ Yes, describe the event and its impact on subjects:

   b. Will the proposed changes alter the risk/benefit profile of the study? ☐ No ☐ Yes, explain:

7. New or Revised Documents
   - Submit only those documents which have been revised, or are new to the study (do not submit unchanged documents for stamping only.) *Use the track changes tool in Microsoft Word to reflect all revisions – not highlighting or underlining.*
   - Submit only a changes tracked version of **locally** created and controlled documents that have been revised.
   - Submit both a tracked and clean version of documents created and controlled by an **external sponsor** that have been revised. For changes to a Sponsor's Protocol (or other sponsor created documents), the sponsor's summary of changes can be submitted in place of a tracked version **if** this reflects the specific sections changed as well as both the old language and the updated language.

This submission changes the following study documents: *This should be answered with every amendment*

- ☐ Children's Protocol Summary / Investigator-written protocol
- ☐ Sponsor's Protocol – Version:
- ☐ Questionnaire, Survey, Data Collection Form
- ☐ Children's IRB Form (consent/HIPAA waiver, etc.)
- ☐ Recruitment Materials
- ☐ IRBNet Registration page: list the section number and describe change(s) made:

(study personnel, study sites, funding/sponsor, conflict of interest disclosures, etc.).

- ☐ Consent/Assent Document. *Include tracked change version.*
- ☐ Translated Materials. *See IRB Policy Non-English Speaking Subjects.*
- ☐ Other:

Select this option if there are changes to any documents not listed above and indicate what the document(s) is.

- ☐ None

a. For investigators who were directly awarded **federal grant funds** for this research: ☐ N/A

i. The research activities described in the grant on file with the IRB:

- ☐ Remain consistent with the revised IRB application.
- ☐ Have changed as a result of this amendment. Changes to the grant are described in question 2a. The Program Officer is aware of these changes (notice attached).

ii. ☐ New federal funding has been secured for this study. The new grant has been uploaded in IRBNet.
Research activities described in the grant are consistent with the IRB application.
For more information, see HHS guidance: http://www.hhs.gov/ohrp/policy/aplrev.html.

8. Conflict of Interest Disclosures

a. If new research personnel are being added to the study: Do any new research personnel or any of their family members (spouse or dependent child) have an incentive or interest, financial or otherwise, that may appear to affect the protection of the human subjects involved in this project, the scientific objectivity of the research or its integrity? ☐ No ☐ Yes* ☐ N/A

b. Are there any changes in reported Significant Financial Interest information related to this project?

- ☐ No Change
- ☐ New research personnel being added have disclosed a Significant Financial Interest.*****
- ☐ Current research personnel have disclosed new Significant Financial Interest information or a change to a management plan.*

**Attach a description of the situation, including dollar values, if applicable.*
Note: It is the PI's responsibility to review applicable MCW/Children's policies on conflict of interest with every study team member and determine whether any member has a Significant Financial Interest related to this project.

- For MCW faculty or staff: please refer to MCW's Research Financial Conflicts of Interest Policy.
- For employees of Children's: please refer to Children's Research Conflict of Interest Policy.
- For subcontractors or physicians/staff who are employed outside of Children's or MCW: please contact Tom Twinem at (414) 266-2215 for further guidance.

9. HIPAA Considerations

a. Will the proposed changes affect the access or use of Protected Health Information (PHI) that has already been approved by the IRB? ☐ No ☐ Yes, explain whether it will be necessary to disclose the changes to those subjects who have already authorized the use and disclosure of their PHI.

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10. Ancillary Services

a. Pharmacy, Laboratory Services, Pediatric TRU, Imaging Services, and other ancillary services have been or will be notified of applicable changes and provided with updated study documents. ☐ Yes ☐ N/A

Reminders:

- **Minor changes** typically qualify for expedited IRB review. All other changes will require full IRB review.
- If there is a **change in PI**, the new PI must 1) include a letter of acceptance; and 2) sign-off in IRBNet.
- If there is a change in study personnel, confirm that **CITI training** is current.
- Notify the IRB if the change required **safety committee notification** (Radiation Safety, MRI Safety, Biosafety).
- If the amendment changes the **study budget** on file (i.e., additional study procedures paid for by sponsor and/or the department), please notify the Children's Research Compliance Manager at dbauer@childrenswi.org.

HOW TO SUBMIT AN AMENDMENT IN IRBNET

A **new** document should be added **only once** – the first time a particular document (consent, protocol, assent, data collection tool, brochure, IB, etc) is added to a project.

- This could be at the initial submission for a new project; **OR**
- It could be at the time of an amendment if an additional, brand new document was created for the study.

A document should be **revised** within a project in only two circumstances:

- When an **amendment** package is submitted; **OR**
- When a package to respond to a **request for modifications** is submitted.

To submit an amendment package in IRBNet, following the steps below.

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the MY PROJECTS page.
Step 2: Click on the Title of the project. Then click on the PROJECT HISTORY.
Step 3: Click on the CREATE NEW PACKAGE button and then the NEW DOCUMENT PACKAGE.
Step 4: This brings you to the DESIGNER, where you can edit existing documents or add new documents.

- To **revise the Registration Page** (on-line document wizard), click the pencil icon, edit, and save.
- To **revise a document** (.doc, .xls, .pdf, etc.) **uploaded in a previous package**:
  - Locate the document that requires revision from the list of documents in the project.
  - Download the previous version (which should be the most current) from IRBNet to your computer, revise as needed, save a tracked version and a clean version to your computer.
  - Upload the tracked version. Instead of adding this revision as a **new** document, you should locate the document in the list for the project, and click on the **pencil** icon (update icon) next to it (**NOT** the Add New Document button).
  - This will bring up a view similar to adding a document, where you can browse for your revision and attach by clicking the **"update"** button.
- To **add a new study document**, click ADD NEW DOCUMENT. Enter the document information, choose the file from your computer and click ATTACH.

Step 5: Click SIGN THIS PACKAGE. The PI signature is required for the amendment package (if needed, the submission creator will need to share with the PI).
Step 6: Click on SUBMIT THIS PACKAGE. Then click on the "Continue" button. In the Submission Type drop-down menu, select "Amendment" and click "Submit."

To review what has been sent, click PROJECT OVERVIEW. The submission will assigned to the next available meeting agenda of the same Board that originally reviewed this study.

Looking for instructional materials on how to respond? An instructional video clip (7 minutes) and handout with screenshots is available at http://www.irbnetresources.org/tresources/training.html/. Enter user name: *chwi* and password: *training*. See section titled R2: Post-Submission Advanced Topics. Add and Revising documents starts on page 11 of the .pdf document.