UNIVERSITY OF MINNESOTA

Route this form to: See instructions below
Revised October 2013

Change In Protocol Request

Instructions:

Use this form when submitting change requests to approved IRB protocols. This form is for use when the changes are initiated by the PI. Do not use this form to respond when changes are requested by the IRB. Please do not use this form when responding to changes requested in a stipulation or deferral letter.

Submit this form to the Human Research Protection Program:

U.S. Mail Address: **or**
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

Electronic Submission:
Submit to: irb@umn.edu
PI must submit request using University of Minnesota e-mail Account.

The UMN IRB reviewed and APPROVED this submission including all attachments listed on this form by expedited review.
By Jeffery Perkey on Jun 06, 2014

IRB Protocol Information

IRB Study Number:	**1101S94592**
Principal Investigator:	Ann S Masten
Primary Study Title:	Assessment of Executive Function for the National Children's Study
Date of this Submission	5/27/14
Study Includes	☐ Drug(s) / Biologic(s) ☐ Device(s)

Indicate the type of change(s)	Additional information/requirements
☐ Change(s) to Study Procedures/Protocol Amendment Protocol Version , Dated	**Does the change affect study design, change the study endpoint(s) or change the statistical method?** ☐ **No** ☐ Yes **Is this protocol under Masonic Cancer Center's Cancer Protocol Review Committee (CPRC) review?** ☐ No ☐ Yes, CPRC # If "Yes" is checked for *both* questions above, this submission (Change in Protocol form and any supporting documentation) must be reviewed by CPRC (CCPRC@umn.edu) prior to review by the IRB. CPRC will forward this submission to the IRB after CPRC approval. Submission to CPRC must meet the IRB signature requirement (signed by the PI or sent from the PI's x.500 UMN email account).
☐ Notice of Closure to Accrual	
☐ Recruitment changes/Advertisements	Attach a copy of the revised material (flyer, script, etc.) with the submission
☐ Revised Investigator Brochure	Version , Dated
☒ Updated consent form	Include both an updated form with changes highlighted and a "clean" version
☐ Other	Briefly Describe:

1. **Briefly summarize the change(s). For protocol amendments, do not say "See summary of changes provided with amendment." Rather, summarize the nature of the significant revisions.**

We propose changing the wording in the consent form about "confidentiality." This section will now refer to "privacy" instead. OMB language required for this project also has been added.

2. **Describe the rationale for the change(s):**

NICHD has requested that we change the language of our consent forms for this project to align with new decisions for the overaching National Childen's Study IRB requirements. For the new consent wording, the word "confidentiality" is changed to "privacy." They want us to make these changes in all of our consent forms. The proposed wording is as follows (changes are also noted in the tracked changed/ highlighted versions of the consent form):

[New Version]
Privacy:
Within the limits permitted by law, the records of this study will be kept private to the extent permitted by law. In any sort of report about the study, there will be no information to identify you or your child. Research records will be stored securely and only researchers will have access to the records.

You should be aware that there are legal limits to our ability to keep certain information about you private. If we were to learn that a child is being harmed or that a parent or child seriously intended to harm themselves or someone else, we would be required to report this situation.

[Currently Approved Version]
Confidentiality:
Within the limits permitted by law, the records of this study will be kept strictly private and confidential. In any sort of report about the study, there will be no information to identify you or your child. Research records will be stored securely and only researchers will have access to the records.

You should be aware that there are legal limits to confidentiality. If we were to learn that a child is being harmed or that a parent or child seriously intended to harm themselves or someone else, we would be required to report this situation.

In regard to OMB language, the required language for headings and footnotes have been added as required.

3. **How will these changes affect the overall risk to subjects in this study?**

No change.

4. **Do the changes to the study prompt changes to the consent form(s)?**

☐ **No.**
☒ **Yes. If yes:**

- **Attach a copy of the revised consent form(s) with changes tracked or highlighted as well as a clean copy.**

4.1 Will currently enrolled subjects will be notified of the changes?

☒ **No**
☐ **Yes, explain below how they will be notified** (i.e. subjects will be re-consented with the updated form once approved, subjects will be provided with an information sheet, subjects will be told of changes at next study visit, etc.).

5. List and attach all documents included with this request, including version dates:

Consent Form Delve with 2nd revised HIGHLIGHTED 5.27.14
Consent Form Delve with 2nd session revised 5.27.14
Consent Form Delve with no 2nd revised HIGHLIGHTED 5.27.14
Consent Form Delve with no 2nd session_REVISED 5.27.14
Consent Form UofM with 2nd session revised HIGHLIGHTED 5.27.14
Consent Form UofM with 2nd session_REVISED 5.27.14
Consent Form UofM with no 2nd session revised HIGHLIGHTED 5.27.14
Consent Form UofM with no 2nd session_REVISED 5.27.14

_____ _____

Principal Investigator's Signature **Date**

Cancer Protocol Review Committee (CPRC) Use Only: