THE UNIVERSITY OF IOWA

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NOTICE TO NCI CIRB RESEARCHERS

External IRB Coordinator: Nicholas Montgomery, uirb-external@uiowa.edu, (319) 467-0747
Dated January 24, 2020

Dear University of Iowa NCI CIRB Researchers;

The NCI CIRB has updated its policy and procedures in response to the new 2018 Common Rule requirements. These updates include major changes to permissible Informed Consent template language and several process changes. It is important to review the Annual Institutional Worksheet (AIW) to be informed of the processes and procedures set up with the NCI CIRB. The AIW can be accessed by logging into IRB Manager. The changes include:

- Changes to the NCI CIRB allowable consent language
- Requirement of a separate institutional information sheet
- Update on Consent Summary requirements
- Update to Short form and Assent process

Implementation Date for Annual Institutional Worksheet Updates

This new policy will take effect **1/27/20** and will apply to **all** NCI studies that are currently enrolling subjects, or will enroll subjects, regardless of initial approval date. Reconsent of any enrolled subject(s) is not required however any newly enrolled subjects must be consented with the updated consent forms once they are approved by the NCI CIRB.

In order to make these changes, teams will be required to submit modifications in HawkIRB for the applicable studies to update all consent forms and add the stand-alone Information. Sheet. The modifications must include an updated Study-Specific Worksheet that will also be submitted to NCI CIRB for re-approval, accounting for these new requirements. All current NCI CIRB studies will have **sixty days from 1/27/20** to convert to these new requirements.

Informed Consent Document and Use of Institutional Information Sheet

The updated policy states that no language in the NCI CIRB approved consent template may be removed, deleted, or altered in any way. Adding any additional institutional required language to the document is restricted to the following:

- Local contact information.
- State and local laws pertaining to informed consent.

- Institutional policy related to research on NCI-funded studies

The following University of Iowa (UI) template language, when applicable, will be required on a separate UI information sheet. Those sections include the following:

- All MRPC (Medical Radiation Protection Committee) required language
- Pregnancy Testing in Minors
- Collection, Use, or Retention of Social Security number
- HIPAA Privacy Language

The updated NCI CIRB policy now requires HIPAA Privacy Language be provided in a separate HIPAA Authorization form. As such, you will now be required to generate this HIPAA Authorization Form during the HawkIRB submission process ***separately*** from the Consent Form you are accustomed to completing.

When NCI CIRB has been designated as the Reviewing IRB in section I.1, a new selection will populate in the attachments page for the HIPAA Authorization Form template to be used in NCI-reviewed studies. The UI Information Sheet\HIPAA Authorization can be found in the informed consent attachment category in the dropdown list of informed consent documents.

Use of Consent Summary

The requirement to use the UI Consent Summary template for all NCI CIRB studies has been changed. The University of Iowa will accept the NCI CIRB summary of key information (if included in the NCI CIRB consent document) in lieu of a UI consent summary template. If a consent summary is not included as part of the NCI CIRB template consent for any CIRB submission, the UI Consent Summary template will be required.

Use of Short Form Consent and Assent Document(s)

The University of Iowa will defer to the NCI CIRB on the use of Short Form Consents. Their IRB determinations will identify how this process will be defined for the study. The NCI CIRB short forms will also be used in these instances.

The University of Iowa will not require the use of assent forms outside of what is approved by the NCI CIRB. The NCI CIRB's determination on the appropriateness of information summary sheets will be sufficient for use with minors. The University of Iowa policy regarding the assent process is also outlined in the AIW, which are consistent practices regardless of the IRB of record.

More information can be found on the NCI-CIRB page of the HSO website.

If you have any questions or concerns, please contact the External IRB Coordinator at uirb-external@uiowa.edu or (319) 335-6564.