Frequently Asked Questions for NCI CIRB Research Teams:

HIPAA Authorization Form and Reconsent Processes

As of October 2019, according to the revised National Cancer Institute Central Institutional Review Board (NCI CIRB) Guidelines for Boilerplate Language, the HIPAA language must not be embedded in the informed consent document and must be a standalone document. To comply with this revision, the DFHCC IRB has created a standalone HIPAA document that must be signed by the participant or a legally authorized representative.

1. **In September 2020, the OHRS and ODQ revised consent forms and uploaded them to OncPro. Does my research team still need to submit an amendment to remove the HIPAA language?**

   No, the OHRS and ODQ have manually fixed the HIPAA document and consent form(s) for research teams. No additional action is required from the research team.

2. **To revise the consent form to align with the NCI CIRB policy, do I submit an Administrative Amendment?**

   No, the various iRIS forms do not include an Administrative Amendment. To revise the consent form to remove the HIPAA language the research team will submit a sIRB Amendment and in Section 2.2 Proposed Changes, the research team must select, "**Editorial, Administrative Changes**". In Section 2.3 Amendment Summary, the research team must include, "Removing HIPAA language from treatment consent to align with NCI CIRB policy."

3. **Can I request that the Dana-Farber Harvard Cancer Center (DF/HCC) HIPAA and Injury language be removed with a recent Sponsor-initiated amendment?**

   Yes, if the research team has recently received NCI CIRB approval of a Sponsor-initiated amendment then the OHRS will remove the DF/HCC HIPAA and Injury language, replace the DF/HCC signature blocks with the NCI CIRB approved signature lines, and create the HIPAA stand-alone document.

4. **Should I remove the HIPAA and Injury language from the consent form before submitting the sIRB Amendment in iRIS?**

   No, the OHRS will remove he DF/HCC HIPAA and Injury language from the consent form and create the stand-alone HIPAA Authorization agreement. When the language is removed from the consent form this causes additional work on the OHRS to review and previously approved consent form(s) posted to OncPro for HIPAA language that is applicable to the study.

5. **Do research teams have to reconsent participants that are currently enrolled on the study or in follow-up?**

   Yes, participants consented to the research study starting **October 1, 2019**, must be reconsented with the NCI CIRB consent form and the standalone DFHCC HIPAA Authorization form. If the participant does not have any study-related visits, then the DFCI

OHRS and CTO highly recommend that participants are reconsented using e-consent procedures. If you have questions regarding reconsenting processes for your study, please contact OHRS at OHRSCentral_IRB@dfci.harvard.edu.

6. **The HIPAA stand-alone document does not revise any of the language that the participant has already consented to. Is the research team required to reconsent participants?**

   Yes, the research team is required to reconsent participants that were enrolled on the study starting October 1, 2019. The DFCI has required that research team reconsent participants to ensure that there are appropriate signatures on the HIPAA document to meet privacy requirements.

7. **In September 2020, the OHRS and ODQ revised the consent form(s) and HIPAA Authorization form for my study. Is reconsent required for my study?**

   Yes, all NCI CIRB studies that have accrued participants as of October 1, 2019 have to reconsent participants that are receiving active treatment and are in long-term follow-up. Please review the response to question #4 regarding the reconsent plan for these participants.

8. **Do I have to reconsent participants that were enrolled on the study before, October 1, 2019?**

   No, the NCI CIRB provided official guidance to relying sties regarding revisions to the boilerplate language in October 2019. Therefore, participants that were enrolled on the study prior to this date do not need to be reconsented.

9. **Do I have to reconsent participants that were lost to follow-up but were consented after October 1, 2019?**

   No, if there are participants that have been lost to follow-up then the research team does not need to reconsent that participant.

10. **How will non-English speaking participants be consented to DF/HCC HIPAA Authorization Form?**

    The OHRS has translated the HIPAA Authorization form into the following languages:

    - Arabic
    - Cape Verdean
    - Chinese Simplified
    - Haitian Creole
    - Portuguese
    - Spanish

    These documents will be posted to the OHRS website with instructional language regarding its use for research teams. If a research team requires additional languages, please contact

the OHRS at OHRSCentral_IRB@dfci.harvard.edu with the language that is required for your study.

11. The Documentation of Assent has been removed with the NCI CIRB Boilerplate revisions. How should the study team document that a pediatric participant has assented to the study?

The NCI CIRB no longer allows additional language to be included with the signature lines and due to a miscommunication between the OHRS and NCI CIRB, the submitted Annual Signatory Worksheet (ASW) omitted the Documentation of Assent signature block. The OHRS has submitted a revised ASW to include NCI CIRB approved Documentation of Assent signature lines.

If a participant is to enroll on a pediatric study, while the OHRS awaits NCI CIRB approval of the revised ASW, the participant is to sign the Participant Line of the NCI CIRB signature line. The research team may choose to create a note to file to indicate why documentation of assent was not documented in the consent form (e.g. *Documentation of Assent was not documented in the ICF because the NCI CIRB Approved ASW did not contain the signature lines as of September 1, 2020. The OHRS is working with the NCI CIRB to add the Documentation of Assent signature lines to the ASW as of October 14, 2020*).

12. What information do I include in the consent form, when submitting a New Protocol Application?

The DF/HCC financial information and signature lines must be incorporated by the research team into the consent form by the research team. The NCI CIRB approved language can be found on the OHRS Website.

13. I submitted a New Protocol Application in iRIS that relies on NCI CIRB. The DFCI IRB sent the following condition:

Please confirm with whom outside the DF/HCC may the participants protected health information be shared with:

- *The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s):*
- *Other research doctors and medical centers participating in this research, if applicable:*
- *Other,*

Should I include this information in the consent form or provide a response to the condition in iRIS?

To ensure that the participant is aware with whom their protected health information will be shared, during the administrative review of the New Protocol Application, the OHRS will require that the research team provide a response in iRIS to the bullet points described above. These bullet points are from question #4 of the DF/HCC HIPAA Authorization template language, which is unique to each study.

14. Should I convert the PDF consent form posted to the Oncology Protocol System (OncPro) to a word consent form to include the HIPAA Authorization Agreement language with the consent form as one document?

No, OHRS will attach the HIPAA Authorization Form to the submission when a sIRB amendment is submitted that includes revisions to the consent form(s). Research teams should not include a HIPAA form when they create the submission. Research staff should never attempt to convert the PDF consent form on OncPro back into a Word file for submission under any situation. This will lead to formatting errors and a delay the approval and activation of the submission.