**Guidance for submitting to the Drexel IRB for local review of NCI CIRB studies**

Consent Form Guidance:

Download the current, approved sample CIRB consent form(s) to develop the Drexel site consent form(s). **Refer to the current, approved boilerplate language for the information to include on the consent form(s)**.

To find the approved boilerplate language, sign into the CIRB IRB Manager website (<https://nci.my.irbmanager.com/Dashboard/PortalHome.aspx>). On the home page, under the xForms section, find the bullet point “Research staff at Drexel University have **[#] unsubmitted** and **[#] total** xForms.” Click on the “**[#] total**” link. Locate the current, approved Annual Signatory Institution Worksheet from the list of xForms. The current, approved version of the Annual Signatory Institution Worksheet will be identified by the following table fields:

Form: ”1- Annual Signatory Institution Worksheet”
Stage: “Complete”
Started: Sort by newest

Locate the section of the Annual Signatory Institution Worksheet xForm that says “Approval Letter for your reference” and open the Approval Letter PDF attached to this section. The current, approved boilerplate language is on the Approval Letter.

**CIRB does not permit any deletions from the consent form**. The only permitted information that may be added to the consent form is the approved boilerplate language. (Reference: <https://ncicirb.org/content/guidelines-permitted-boilerplate-language-additions>)

Below is the list of consent form sections and instructions for each section. Asterisks (\*) indicate sections where boilerplate language should be added:

Overview and Key Information

No changes permitted.

What am I being asked to do?

No changes permitted.

Taking part in this study is your choice

No changes permitted.

Why is this study being done?

No changes permitted.

What is the usual approach to my [insert type of cancer, other]?

No changes permitted.

What are my choices if I decide not to take part in this study?

No changes permitted.

What will happen if I decide not to take part in this study?

No changes permitted.

What are the risks and benefits of taking part in this study?

No changes permitted.

If I decide to take part in this study, can I stop later?

No changes permitted.

Are there other reasons why I might stop being in the study?

No changes permitted.

What is the purpose of the study?

No changes permitted, including number of local participants to be enrolled.

What are the study groups?

No changes permitted.

What exams, tests, and procedures are involved in this study?

Generally, no additions to this section are permitted, including Standard of Care.

What risks can I expect from taking part in this study?

No changes to the risk tables are permitted.

Dosimetry information related to research images or research radiation may be added in the consent document by way of the Study Specific Worksheet if needed. This may not be included if the scans or radiation are all standard of care.

GINA language should not be included as boilerplate language. When applicable, GINA language will be included in the model consent form. Additional language regarding the risks of genetic testing, that is not standard of care, should be submitted by way of the Study Specific Worksheet if required by State law.

What are my responsibilities in this study?

No changes permitted.

\*What are the costs of taking part in this study?

No *deletions* permitted.

Refer to the approved boilerplate language for the information to add to this section.

Any payment to the sites by the NCI should not be included in the consent form.

Do not insert financial conflict of interest (COI) for an institution or investigator in this section. COI should be included in its own section at the end of the document, before the signature block and submitted in a Study Specific Worksheet.

\*What happens if I am injured because I took part in this study?

Refer to the approved boilerplate language for the information to add to this section.

Who will see my medical information?

HIPAA language must not be embedded in the informed consent document and must be a standalone document. Use the HRP-505 FORM Permission to Use Private Identifiable Health Information for Research to obtain HIPAA Authorization.

\*Where can I get more information?

Refer to the approved boilerplate language for the information to add to this section.

Optional Studies and Contact for Future Research

Institutions can change the circling Yes or No to checking Yes or No.

Institutions can add a sentence that an Optional Study is not offered at their institution or is closed to accrual. Text that is in the model consent form must remain.

My signature agreeing to take part in the study

No changes or additions to template text are permitted, including attestations. Institutions can add, not replace, appropriate signature lines with dates and times.

Submission Guidance:

Create a COEUS protocol submission and specify the Type as “NCI CIRB” on the General Info page. Add all Drexel study personnel to the Investigators/Study Personnel tab. Upload the following to COEUS on the Attachments page:

* The following documents should be attached as a .zip file because COEUS cannot open them when they are attached as individual documents:
	+ CIRB’s approval letter with the most recent approval interval. This may be an initial approval letter or a continuing review approval letter. The letter must show that the protocol has an up-to-date approval period.
	+ Approved study-wide protocol
* CIRB Approval of the Study-Specific Worksheet
* Consent form(s) including the approved boilerplate language additions
* HRP-505 FORM Permission to Use Private Identifiable Health Information for Research
* Financial Conflict of Interest Disclosure forms for Drexel personnel
* Facility Research Committee Approval Letter (if applicable)
* Applications from St. Christopher’s Hospital for Children require a completed HRP-200 FORM - Initial Review
* Applications from St. Christopher’s Hospital for Children require an HRP-201 FORM - Contact Information Form for Drexel personnel

Once the required information is included, submit the protocol. To begin the submission process, click the **Submit to IRB** menu item from the column on the left-hand side. Validation will be requested. Select **OK** and **OK** again. Select the submission **Type** from the drop-down box. Be sure to select **Initial Protocol Application** for a new protocol. Select **To Be Determined** from the **Review Type** drop-down box. Click the **Submit** button to submit to the IRB. The user will receive a message asking whether they wish to submit the protocol. Click **OK**.