

Reliance Agreement Guidance: Creating Consent Templates When Penn is the Central IRB / Single IRB / IRB of Record

This document provides step by step guidance on how to convert the Penn IRB approved consent form into a consent form template that can be shared with external sites that will rely on the Penn IRB as the IRB of Record or Central IRB. It is expected that this document will be most helpful to Penn research staff that are coordinating multi-site projects. However, Investigators and other research support staff at relying sites and individuals affiliated with other IRBs may find the information in this guidance document to be helpful.

If you have more general questions about Penn serving as a Central IRB for multi-site protocols, please view the Penn as Central IRB FAQ.

This document will not be helpful to individuals who are asking Penn to rely on another external IRB as the IRB of Record for their study.

Getting Started

You should not create a template consent form that can be shared with other sites until you have obtained initial approval from the Penn IRB. This is because the Penn IRB may require substantive and editorial edits to your consent form. You will want to share a template consent that includes language that has been fully approved by the Penn IRB.

In this guidance document, we will be working section by section through the Penn IRB Biomedical Research Informed Consent Template version 6/18/2019 (which can be downloaded from the forms page of the IRB website) to identify where and how to properly include site specific information after the master consent version has been IRB approved. If you are working on a consent form that was drafted from an industry sponsor or other institution's template, some of the references may not be exact. However, it is likely that the information in this guidance will still be helpful to you in creating your template.

Formatting

Tracking: When submitting for initial approval or modification of a site-specific consent form, tracking/highlighting of ALL administrative and major changes is necessary to facilitate a timely review. If any changes are necessary beyond filling in placeholders with site specific info, it's recommended that you include comment bubbles in the tracked consent form or a cover letter to provide clear rationale for why the Penn IRB approved language in that specific section is being changed for that site.

Header: All site versions should have the same basic header, which should include an abbreviated reference to the protocol title and the type of consent form (main consent and HIPAA, genetics sub-study, etc.). Therefore, site specific placeholders in the Header are not anticipated.

Footer: Consent form footers should be at least .5" from the bottom of the page to accommodate the IRB approval stamp.

Version Tracking: All site versions should have the same content in the footer, which should include the consent form version number and date. If you have a general study wide version number and date, no placeholders will be necessary. If you instead use a site-specific version number and date then this will need to include placeholders.

Examples:

- "Penn Site Version 1.2 dated 2/5/17" should be converted to include placeholders "[Site Name] Version [#] dated [MM/DD/YY]"
- "Version 1.2 dated 2/5/17" does not need placeholders.

Cover Page

Document Title: Your document title should be revised to include a placeholder for the study site name

Example:

- "UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM" should be converted to "[NAME OF STUDY SITE] RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM"

Protocol Title: This should be identical to the study protocol title and no conversion should be required.

Principal Investigator and Emergency Contact: These should be site specific and therefore they should be replaced with placeholders.

Example:

Principal Investigator: [NAME]
[ADDRESS]
[PHONE NUMBER]

Emergency Contact: [Phone Number] and [Information on who to ask for when calling]

Why am I Being Asked to Volunteer

The "You are being invited to participate in a research study..." text does not typically contain any site-specific information. Therefore, template placeholders are not expected.

What is the purpose of this research study?

Most of the language in this section is not site specific and template placeholders are not anticipated.

If there is language that indicates that the investigator or university receives compensation from the sponsor to conduct the study, that language should be replaced with a template placeholder.

Example:

"The University of Pennsylvania receives funds from the sponsor of this study to conduct this research" should be converted to "[SITE NAME] receives funds from the sponsor..."

How long will I be in the study?

Most of the language in this section is not site specific and template placeholders are not anticipated.

This section may include information on the overall target enrollment across all study sites and information on how many

subjects will be enrolled at a study site. That information should be revised to include a placeholder. Example:

“At the University of Pennsylvania, we plan to recruit up to 60 patients in the study” should be changed to “At [SITE NAME], we plan to recruit up to 60 patients in the study.”

What am I being asked to do? (Procedures Section)

This section should be written so that it describes the study procedures in a manner that is applicable to all study sites. Therefore, it is not expected that placeholders will be needed in this section. However, the IRB recommends you read through the language to make sure there is no site-specific information in this section. If there is, you may need to revise the language or include placeholders.

What are the possible risks or discomforts?

This section should be written so that it describes the study risks in a manner that is applicable to all study sites. Therefore it is not expected that placeholders will be needed in this section. However, the IRB recommends you read through the language to make sure there is no site-specific information in this section. If there is, you may need to revise the language or include placeholders.

What if new information becomes available about this study?

It is not expected that placeholders will be needed in this section.

What are the possible benefits of the study?

It is not expected that placeholders will be needed in this section.

What other choices do I have if I do not participate?

This section should be written so that it describes the alternatives in a manner that is applicable to all study sites. Therefore, it is not expected that placeholders will be needed in this section. However, the IRB recommends you read through the language to make sure there is no site-specific information in this section. If there is, you may need to revise the language or include placeholders.

Will I be paid for being in the study

If subjects will receive compensation, it is expected that each site will likely negotiate its own compensation structure. In addition, each site will likely have its own institutional template language that discusses compensation. Therefore, it is recommended that all the Penn approved language be replaced with the following template instructions:

[Please include a description of any monetary compensation that will be provided if subjects are compensated for research participate, time, and/or travel. Please adhere to your site’s local policies and procedures for describing compensation in the informed consent form]

Will I have to pay for anything?

This section should be written so that it is applicable to all study sites. Therefore, it is not expected that placeholders will be needed in this section. However, the IRB recommends you read through the language to make sure there is no site-specific information in this section. If there is, you may need to revise the language or include placeholders.

What happens if I am injured or hurt during the study?

This section can be removed if your study is no greater than minimal risk. If your study is greater than minimal risk, it is expected that each site will have its own institutional template language and requirements that discuss what will occur in the event of a research related injury. Therefore, it is recommended that all the Penn approved language be replaced with the following template instructions:

[Please include a description of what treatment will be provided for research related injuries, how treatment for research related injuries will be paid, the subject's responsibilities related to research related injuries, and contact information in the event of an injury. Please adhere to your site's local policies and procedures when completing this section.]

When is the study over? Can I leave the study before it ends?

This section should be written so that it is applicable to all study sites. Therefore, it is not expected that placeholders will be needed in this section. However, the IRB recommends you read through the language to make sure there is no site-specific information in this section. If there is, you may need to revise the language or include placeholders.

How will my personal information be protected during the study?

This section should include general information about protecting confidentiality that can be written in a manner that is applicable to all study sites. The IRB recommends you read through the language to make sure there is no site specific information in this section. If there is, you may need to revise the language or include placeholders.

In addition, sites may have institutional requirements related to confidentiality language. So it is recommended that the following instructional template language be added to your template

[Please include any confidentiality language required by your local site's policies and procedures. For example, if you study involves testing for infectious diseases, please include language describing any reporting requirements that may be applicable.]

Electronic Medical Records and Research Results

This section is language required by the Penn IRB for Penn sites only. Therefore, it is anticipated that most sites will not need a similar section in their consent form. The IRB recommends that you remove all Penn IRB approval language in this section and replace with the following template instruction:

[If your institution has any required language related to the use of Electronic Medical Records, please include that language here. If no language is required, please delete this section.]

HIPAA Authorization Sections:

- What information about me may be collected, used or shared with others?
- Why is my information being used?
- Who may use and share information about me?
- Who, outside the School of Medicine, might receive my information?
- How long may the School of Medicine use or disclose my personal health information?
- Can I change my mind about giving permission for use of my information?
- What if I decide not to give permission to use and give out my health information?

Please note that the Penn HIPAA Authorization language template is a separate document from the Informed Consent Templates. This template is also available on the Forms page of the IRB website. Relying sites are not required to use the Penn HIPAA authorization template. Therefore, any or all of these sections can be replaced with local site HIPAA language if the local IRB requires it. However, many relying sites are willing to use the Penn template language. Therefore, you should review all the HIPAA sections and replace references to University of Pennsylvania, the University of Pennsylvania Health System, and the Perelman School of Medicine with [SITE NAME] placeholders.

Most of the remaining text in these sections is not site specific and therefore additional placeholders are not anticipated.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

No template placeholders are expected for this section. Since Penn is the IRB of Record for all relying sites, the Penn IRB contact information should be included in the consent form.

In addition, we recommend insertion of the following template instructions to this section:

- [If your local site IRB wants to be listed as an entity that can be contacted with questions or complaints, please add there contact information to this section]

When you sign this form... Text box and signature page

Please replace "University of Pennsylvania" with "[SITE NAME]" placeholders throughout this section.