



## Reliance Agreement Guidance – Requirements for External Consent Templates

This document provides step by step guidance on how to revise the informed consent form templates when the Penn IRB has agreed to rely on an External IRB. It is expected that this document will be most helpful to research staff that will be submitting reliance agreement requests to the Penn IRB. However, Penn Investigators, other research support staff, and individuals affiliated with other IRBs may find the information in this guidance document to be helpful.

If you have more general questions about the Reliance Agreement Process, please view the Reliance Agreement Guidance: External IRB Review FAQ.

This document will not be helpful to individuals who are asking Penn to serve as the IRB of Record for other sites.

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### **Getting Started**

If you have decided to rely on an external IRB as the IRB of Record, the study sponsor or lead site will most likely provide you with a template consent form. You will need to revise this template consent form so that it complies with the policies and requirements of Penn's Human Research Protections Program.

The Penn IRB does not require or even recommend that you thoroughly re-format the consent template to align with the Penn Template Consent Form found on the forms page of the IRB website. Many central IRBs and local sites will not approve your revised consent if you alter the entire document to incorporate the formatting and organizational structure of the Penn template.

This document provides instructions on how to edit the consent form template to incorporate language required per Penn policies. A revised consent form should be included in your HS-ERA



application requesting a reliance agreement with the external IRB. Please note that tracked or highlighted changes are not required.

**Fill in Penn Specific Information**

The template consent form will likely have several placeholder sections where you can input Penn specific information such as contact information for the research team and the name of the institution. Please make sure you complete all those sections. Please make sure the consent form has complete contact information for the PI and a 24 hour number subjects can call in the event of an emergency.

**Are Subjects Being Compensated?**

If subjects will receive compensation for their participation in the study, please make sure that the section of the consent form that discusses compensation includes the following language:

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that total \$600 or more in a calendar year.

**Does the Study Pose Greater than Minimal Risk?**

If the study poses greater than minimal risk, the consent form must describe what will occur in the event of a research related injury.

If the study is not industry sponsored or if the sponsor is not providing any coverage for research related injury, the consent form should include the following language:

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

If the study sponsor will provide coverage for research related injury, please include language describing that coverage in the consent form. The IRB will review that language to compare it with the executed Clinical Trial Agreement. Revisions to the consent form may be required if there are discrepancies between the coverage described in Clinical Trial Agreement and the coverage described in the consent form.



***Will infectious disease testing be performed for research purposes?***

If the study involves testing for infectious diseases, please add the following language to the consent form:

If you test positive for [reportable infectious disease], by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born.

The site will include this additional information if they are reporting a positive HIV result. The site will explain how confidentiality will be maintained. The site will be specific about how records will be secured to protect the identity of the subject, state the IRB at the University of Pennsylvania will have access to the records, explain how subjects will be de-identified; and if code numbers be used. Please note; the content of this section will vary according to the research design. There may be cause for more or less protections depending on the nature of the research. The suggested language will be altered by the site when necessary. Check the submitted consent form.

This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

***Does the study involve Electronic Medical Records?***

If the study involves the collection of data from subjects medical records or if research data could be added to subjects' medical records, please include the following language in the consent:

**What is an Electronic Medical Record and/or a Clinical Trial Management System?**

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study



team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

This language can be tailored to better apply to your study. For example, if all subjects enrolled in your trial are already receiving care within UPHS, you can remove the 3<sup>rd</sup> paragraph. Also, if your study will make use of the sensitive ordering functionality in PennChart, then you should revise this language to clearly describe how some tests will be kept separate from the medical record.

**Does the study involve the use, collection, or disclosure of Protected Health Information?**

If the study involves the use, collection, or disclosure of Protected Health Information, then the consent form should also include a HIPAA authorization section. If the template consent form includes all the required elements of a HIPAA authorization, then no changes may be required. However, if the template consent does not include a HIPAA authorization, you should incorporate HIPAA information using the Penn HIPAA authorization template language. This language can be found on the forms page of the Penn IRB website.

If you receive a template consent form that has a separate HIPAA authorization section with its own signature area, the IRB recommends you incorporate that language into the main consent form. This is not required but it is encouraged because it will prevent potential deviations where subjects sign the consent form but do not sign the HIPAA authorization.

**Who should subjects call with questions?**

Frequently, the IRB of Record will request that its contact information be added to consent forms so that subjects can call with any questions or complaints about the research. This is acceptable. However if you also want to insert the Penn IRB's contact information or if the IRB of Record requests that the Penn IRB's contact information be added, please insert the following language:

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may also contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.