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Reliance Agreement Guidance:

Requirements for External Consent Templates when Penn Relies on Another IRB

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 have 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. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. 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 <add any reportable infectious diseases for which testing will be performed specifically for research>, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type 'Reportable Diseases' into the site search bar.

Does the study involve Electronic Medical Records?

The Electronic Medical Record and Release of Study Related Information section is required for research being conducted within Penn Medicine where research data and results may be placed into the electronic medical record or are otherwise built in the EMR. As a reminder, studies must be built into the EMR/PennChart if the study will be utilizing PennChart EMR ordering, billing or recruitment capabilities.

The language should be tailored to your study. Instructional text is included in the section below in red. Instructional text should not be included in the consent form you submit to the Penn IRB. This section was taken verbatim from the Biomedical Informed Consent Form Template posted on the IRB website and that document may be a more useful resource when revising your consent template.

What is an Electronic Medical Record?

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

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of 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). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR/?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

[Include in this section: Specify whether information about test results, procedures, notes, orders, etc. or any other study information that may be shared in a delayed manner, at the end of the study, or will not be shared with subjects. Template language is included in the paragraph below. If there will be no delays in sharing study information within the

EMR, the paragraph below does not have to be included]

Please utilize this section to discuss only study information that is permitted to be placed in the medical record. *Please note the following about diagnostic test or imaging results:*

- ***Results that may be placed in the medical record:*** *Results from testing conducted in a laboratory or center that is part of the Penn Medicine HIPAA covered entity (i.e., the results would have been placed in the medical record, regardless of research participation). Results placed in the medical record are part of the designated record set and the patient has a right to review these results per HIPAA regulations.*
- ***Results that may <u>not</u> be placed in the medical record:*** *Results from biospecimen testing conducted in a laboratory that is not part of the HIPAA covered entity OR results from testing conducted in a non-CLIA certified laboratory (i.e., the results would not have been placed in the medical record as part of clinical care).]*

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

<Add details about what will be shared with research participants in a delayed manner, shared at the end of the study, and/or not shared at all. For example: "test results will be shared with you in a delayed manner, but other study information (e.g., progress notes and research notes) will be withheld until the end of the study.">

Returning Clinically Relevant Research Results

It is likely that the consent form template approved by the central IRB will include language regarding whether clinically relevant research results will be returned to subjects. The Penn IRB will accept the central IRBs approved template language so long there are no discrepancies with the Penn Electronic Medical Record language added to your consent. The IRB recommends you review both sections to make sure it is consistent.

If the central IRB's approved template language is insufficient or you would prefer to use Penn's template language about returning clinically relevant research results, the language provided below can be tailored to your study. Instructional text is included in the section below in red. Instructional text should not be included in the consent form you submit to the Penn IRB. This section was taken verbatim from the Biomedical Informed Consent Form Template posted on the IRB website and that document may be a more useful resource when revising your consent template.

<u>Will I receive the results of research testing that may be relevant to my health?</u>

*[The revised common rule requires that participants be informed "regarding whether **clinically relevant** research results, including individual research results, will be disclosed to subjects, and if so, **under what conditions.**" This section is applicable to all Penn schools and centers.*

This applies to the any type of testing where individual results may be expected. This may include, but is not limited to, diagnostic psychological or neurological testing, testing of specimens using assays or other in vitro diagnostic tests, diagnostic imaging, results other diagnostic devices, etc.

If clinically relevant results will be returned, specify the conditions.

Please note the following related to compliance with FDA regulations: The plan to return results from investigational

diagnostic devices, without confirmation by a medically established device or procedure may not be exempt from IDE regulations.]

***If the study will NOT generate clinically relevant research results**, include the following language.*

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

***If the study will generate clinically relevant research results**, include the following language.*

Results that may be relevant to your healthcare may be released to you. <Add details about the conditions under which clinically relevant results will be released to participants.

- If inclusion in the Penn Medicine EMR is applicable, note that they will be released in the EMR and refer to the Electronic Medical Record and Release of Research Results section in regard to timing;
- If inclusion in the Penn Medicine EMR is not applicable (e.g., Penn Medicine hospital services are not being used), discuss how the results will be released (e.g., discussed with the participant individually or shared with their primary care or a specialist clinician.>

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. The Penn IRB recommends that you incorporate the elements of HIPAA authorization into the main informed consent form and that you use the Penn Template HIPAA authorization language. This language can be found on the forms page of the Penn IRB website.

However, if you would prefer to use the central IRB's approved HIPAA language, the IRB can accommodate this request so long as all the required elements of HIPAA authorization are present. In addition, the IRB requires that the following language be present in the HIPAA authorization section:

Language regarding the Clinical Trial Management System (CTMS):

[This language is required for Penn Medicine expedited and convened research studies]

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Language regarding organization at Penn that may receive information:

Please note that if you are not using the Penn HIPAA authorization template language, you will likely need to add text to specifically list the following as groups that may receive subject information:

- "Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB".

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 University of Pennsylvania Institutional Review Board with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.