
Consent Form Requirements for Multicenter studies when CHOP Relies on an external IRB

When the CHOP relies on an external IRB, that IRB (Reviewing IRB) is responsible for the review and approval the overall protocol, as well as the consent form. The CHOP IRB will not provide oversight for the research.

The investigator must ensure that the Reviewing IRB approves a consent document that complies with CHOP's requirements.

Note: Even though CHOP's IRB will not provide oversight, the investigator must submit the study in eIRB to endorse the use of the Reviewing IRB.

1. The consent form must identify CHOP as a site of the research

Use of the CHOP logo is optional and not required. However, CHOP must be identified on the site where the research is taking place.



Informed Consent Form and HIPAA Authorization

2. The emergency contact information (when applicable) must list a CHOP investigator

Principal Investigator: Name Telephone: (xxx)-xxx-xxxx

Emergency Contact: Name Telephone: (xxx)-xxx-xxxx
(only required for studies that [must be a phone number
are greater than minimal risk) accessible 24 hours (i.e. pager,
cell) and answered by
someone knowledgeable about
the study]

After hours please call the CHOP Operator at 215-590-1000
and ask them to page the XXXXX resident/fellow on call.

3. HIPAA language must identify CHOP as one of the organizations/institutions that will have access to the subject's PHI

1. The Reviewing IRB's standard HIPAA language may be used provided that CHOP is listed as one of the organizations that will have access to the subject's PHI.
2. Alternatively, CHOP's standard HIPAA language may be substituted (below).

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from (include all that apply) medical records, procedures, interviews and tests, etc.. Laboratory test results will appear in your medical record with the exception of (list any exceptions, e.g. genetic tests, non-CLIA approved test results, confidential data which must be protected) which are performed only for this research study. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

Include the following ONLY if applicable

- Representatives of XXXX who is the study sponsor funding this research.
- XXXX, who is testing your blood/urine/tissue sample(s). List lab names who receive identifiable specimens.
- The Data Coordinating Center at XXXX (multi-center research studies)
- Groups monitoring the safety of this study (e.g. DSMB)
- The National Institutes of Health (or other funding agencies) who is sponsoring this research;
- The Food and Drug Administration (if applicable)
- Your samples/data will be shared with outside laboratories including XXXX, YYYY and ZZZZ, who will analyze (and store, if applicable) your samples. Your samples/data will be labeled with a XXXX (include whatever is appropriate e.g. study number, date when they were obtained, your initials).

The outside laboratories will not know who you are. Private information such as your name, birth date or medical record number will not be shared with them. (if applicable)

- Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. (if applicable: sexually transmitted diseases, HIV, AIDS, child abuse, etc.)

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

CHOOSE one of the first 2 sentences, whichever applies. There is no set time for destroying the information that will be collected for this study. **OR** The identifiable information from this study will be destroyed XXXX years after the study is completed. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

4. The name and address of the CHOP investigator for withdrawal of permission for HIPAA authorization in writing

Dr. XXXXXX
The Children's Hospital of Philadelphia
Division/Department
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

5. The Contact Information for Questions must include the number for the Office of Research Compliance and Regulatory Affairs at CHOP (not the IRB).

If you are a CHOP patient/subject and have questions about your rights or if you have a complaint, you can call the **CHOP Office of Research Compliance at 215-590-2830.**

6. Injury Compensation Language must comply with CHOP standards

CHOP Standard injury compensation language is included below. It is the investigators' responsibility to ensure that the injury compensation language adheres to the terms of the contract.

Wording for non-industry-funded studies

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

Wording for industry-funded studies

Do not modify the language below without first obtaining permission from the Contracts group in the CRSO.

<https://intranet.research.chop.edu/display/deptcrso/Industry+Clinical+Trial+Agreements>

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency care. Treatment may be billed to you or your insurer. If your injury is caused by a research procedure or the experimental drug/device/intervention, SPONSOR may pay for treating the injury. This does not mean that a mistake happened.

The Hospital does not offer financial compensation or payment if you are injured as a result of participating in this research.

If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

7. The signature page must make clear that the subject is agreeing to allow CHOP use and share health information (and not just the Reviewing IRB's institution.)

The consent form language used by the Reviewing IRB may be substituted for the sample language below as long as CHOP is explicitly listed. CHOP sample language:

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. **You are also agreeing to let CHOP use and share your child's health information as explained above.** If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE: A foster parent is not legally authorized to consent for a foster child's participation.**

8. Assent must be documented as required by the Reviewing IRB.