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# Consent Form

**Study Title:** *Insert Full Title of the Protocol*

Version Date: Month, Day, 20XX

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

DELETE these instructions before submission/use

1) Types of Research: This template is intended for exempt studies that involve a simple survey (exempt category 2) but could be adapted for exempt research in educational settings (category 1).

2) HIPAA Authorization: This template does not include HIPAA authorization language. If HIPAA applies to the study, then the mandatory HIPAA language must be included, either as part of this consent or in a stand-alone HIPAA authorization. See the IRB website for combined consent/HIPAA authorization language and for model stand-alone HIPAA authorization.

3) Documentation: This template does not include a signature page (there are no specific requirements for written consent for exempt research). If written consent will be obtained, a signature block to document consent will need to be added.

4) IRB Oversight: The IRB does not approve exempt research. Do not include the IRB footers or state that the IRB has approved this study as part of this consent form/process.

You may be eligible to take part in a research study. The information that will be discussed gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating. The word “we” means the study doctor and other research staff.

## Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have XXXX. *Briefly include the major reasons why the subject is being approached to participate, e.g. “…you are a resident at CHOP.”*

## What is the purpose of this research study?

We are conducting a research study on XXXX. *[Provide a brief description of the overall research.]*

## What is involved in the study?

If you agree to take part in this study, we will ask you to answer a few questions about XXXX. If you agree, the questionnaire will take about XXXX minutes. *[Edit as appropriate to describe the research procedures.]*

## What are the risks and benefits of this study?

As with any study involving collection of data, there is the possibility your confidentiality information will be shared with others. Every precaution will be taken to secure your personal information to ensure confidentiality.

*(If CHOP employees or students are participants, add the following):* Your decision to participate will not be shared with your supervisor and will not have any effect on your performance evaluation or employment status.

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help determine XXXX.

## Do you need to give your consent in order to participate?

By completing the questionnaire, you are indicating that you have had your questions answered, and you agree to take part in this research study.

Participation in this study is voluntary. Your health care provider at CHOP will continue to provide you with health care services even if you refuse to participate.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. You can stop the questionnaire at any time.

## What about privacy and confidentiality?

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. People from oversight agencies and organizations such as the Department of Health and Human Services, Office for Human Research Protections may also look at your study records.

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

By law, CHOP is required to protect your private information. The investigator and staff involved with the study will keep your private information collected for the study strictly confidential.

## Financial Information

*[Include a financial section only when it is relevant. If there is no payment to or costs for subjects, this section could be omitted.]* There are no costs or payments to participate in the study. The study is funded by XXXX.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. XXXX at xxx-xxx-xxxx. You may also talk to your own doctor if you have questions or concerns.