

Guidance for Consent Requirements for Exempt Interview Studies

Aligned with 45 CFR 46.104

1. When Consent Information Is Required

Exempt research does not require formal informed consent, but participants must receive basic information to make an informed decision.

2. Required Elements of an Exempt Consent Script

Introduction

State your name, affiliation, and that this is a research study. Identify funding if applicable.

Purpose of the Study

Provide a brief description of the study.

Why the Participant Was Invited

State the reason they were selected.

What Participation Involves

Describe procedures and duration.

Risks

Primary risk is loss of confidentiality. Explain protections.

Benefits

Describe direct benefits or state that the research benefits general knowledge.

Voluntary Participation

Participation is voluntary; they may stop at any time.

Costs and Compensation

State costs and compensation.

Privacy and Data Use

Explain storage, access, destruction, and future use of data.

Recording

If applicable, describe audio/video recording and retention.

Injury Language

Note that no compensation program exists (institution-specific language).

Contact Information

Provide PI and HRPP contact details.

Explanation of Limited IRB Review

Limited IRB Review is a streamlined form of oversight used when Exempt research involves identifiable information. It applies to certain Exempt categories, including interviews and surveys, when privacy protections must be reviewed. The IRB evaluates how data are collected, stored, protected, and whether risks of disclosure are minimized. Limited IRB Review does not require continuing review or full protocol evaluation, but ensures that confidentiality measures are adequate.

Template Script

INTRODUCTION:

Good morning/afternoon. My name is [Name], and I am affiliated with [Institution]. You are invited to participate in a research study about [topic]. You were selected because [reason].

WHAT WILL HAPPEN:

If you agree, I will ask you questions in an interview lasting about [time]. You may skip any question or stop at any time.

RISKS & BENEFITS:

The main risk is a possible loss of confidentiality. We will protect your information by [describe protections]. There may be no direct benefit to you, but your responses may help improve understanding of [topic].

PRIVACY:

Your information will be stored securely and only the research team will have access. Results will not identify you. [If applicable: The interview will be audio/video recorded and recordings will be kept for X time.]

VOLUNTARY PARTICIPATION:

Your participation is voluntary. You may withdraw at any time without penalty.

COSTS & COMPENSATION:

[Insert applicable language.]

QUESTIONS:

If you have questions about this research, contact [PI]. For questions about your rights as a participant, contact the SDSU Human Research Protection Program at irb@sdsu.edu or 619-594-6622.