



OREGON HEALTH & SCIENCE UNIVERSITY

Research Informed Consent Form

Editing Guidelines

Purpose:

The attached document provides guidelines that may be used in composing and refining informed consent forms. These guidelines are based on the review of hundreds of consent forms as well as regulatory standards, and reflect the most common problems that occur. Following these guidelines is not required, but is recommended. The OHSU Research Integrity Office hopes that this document will be helpful in demystifying the standards used to review consent forms and will result in documents that are clearer, simpler and easier for research subjects to understand.

Audience:

This document may be used by study coordinators, investigators, Institutional Review Board analysts and members, and others seeking guidance on improving the quality and readability of informed consent forms.

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Consent Form

1. Sometimes presented as “Oregon Health and Sciences . . .” or “Health & Sciences.”
2. If there's an address, the zip code may be the outdated, “97201-3098.” It's “97239” now.
3. “Informed Consent Form” and “Consent Form Sample” are common errors.

TITLE:

1. Make sure the title is spelled correctly.
2. Ask the Chair if a title strikes you as coercive.
3. Check the title in the database.

PRINCIPAL INVESTIGATOR:

1. Does the phone number match the HRA and IRQ?

CO-INVESTIGATOR(S):

1. Strike the parentheses or the whole “(S)” if appropriate.
2. Align degree periods to the P.I.'s. Keep “M.D.s” and “MDs” consistent.

SPONSOR:

1. National Institutes of Health. When in doubt about caps, ask or check letterhead.

PURPOSE:

1. Should be brief.
2. Is the purpose stated? Should be near the beginning of the section.
3. Does this section include the length of time the subject will be in the study? Sometimes erroneously states the investigators' (rather than the subjects') time burden. “The study will last” should be stricken.
4. Number of subjects - the consent and the protocol must match; the IRQ must show the same number or a higher one (if it includes screen failures as well as actual enrollees).

PROCEDURES:

1. No need for an introduction. “If you join the study, here are the procedures,” is redundant.
2. Tables almost always should be simplified. Put them near the top. Make sure the headings match the text and make sense—“Day 0” is not meaningful to a layperson. Tables are very difficult for eighth-grade readers to understand, so these should be very simple.
3. Placebo and randomization language often needs to be clarified/revised.

RISKS AND DISCOMFORTS:

1. Are most serious risks/discomforts listed first?

2. Are any risks/discomforts permanent?
3. Would a child understand them? Are they too vague?
4. Is every experimental drug and procedure addressed?
5. Pregnancy statements are often problematic. Templates don't include nursing infants. Male templates direct subject to tell his doctor if his partner becomes pregnant. Males are not allowed to be abstinent.
6. Risks are sometimes introduced for procedures or drugs not listed in PROCEDURES, such as procedures or drugs that are standard of care rather than experimental.

BENEFITS:

1. Analysts and reviewers are very good at telling "may or may not" studies from "will not" studies, but sometimes the first sentence is incorrectly written "You may or may benefit" and there are still some "which"s out there.
2. If this statement is "You will not benefit" in the consent form, check the child assent form. It's not unusual for the assent to have misinformation in this case. Suggestion: "I understand what kind of information the study doctors are trying to gather."

ALTERNATIVES:

1. Check for completeness. There are always alternatives to being a subject in a study.
2. "Comfort care" is not the only alternative.

CONFIDENTIALITY:

1. Check for inclusion of child/elder abuse boilerplate.
2. Some templates don't have it, but suggest adding, "We will not use your name," etc.
3. Subjects should be informed if data containing initials/identifying codes are sent off the hill and informed of how this data will be safeguarded.

COSTS:

1. Simplify. Subjects only want to know how much it's going to cost to sign this form or how much they'll be paid for signing it.
2. Visits must be pro-rated if a subject decides to withdraw.

LIABILITY:

1. Check sponsorship.

PARTICIPATION:

1. P.I.'s phone number might not match CF's 1st page, HRA, IRQ.
2. Look for words "any benefits." This is essential.
3. Is the researcher likely to be the subject's physician?
4. When will the subject be dropped? What will happen if the subject withdraws?
5. Advertising on campus? Probably going to get students.
6. "Discretion" is a difficult word. "The sponsor (the investigators may decide to stop the study" is clearer.

7. What really happens if the subject drops out or the P.I. terminates? Enquiring subjects want to know.
8. Will the subject be told if a new risk is found?
9. “You will be given a copy of this form.” Not “if you sign it.”

SIGNATURES:

1. Add this heading, even if the template doesn't
2. For minor or DI subjects, I add a “Printed Name” line.
3. One Investigator, One Signature Line. (“Mary Katz, M.D.”)

AFTER EDITING:

1. Are there page numbers?
2. Font size/type.
3. Do the paragraphs lack/all have tabs?
4. Is the text-heading relationship consistent?
5. Widows and orphans.
6. Is there adequate white space so that subjects may make notes if they wish?
7. Check HIPAA Research Authorization table.