OHRPP Update

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Revised Biomedical Consent Forms

- Biomedical Consent Form Template
  - General Biomedical
  - National Cancer Institute
  - Specimen Collection Planned

- Consent Form Standards and Sample Language
Purpose of Revisions*

- Increased readability and ease of use for both subjects and researchers
  - Language level at ~8th grade
  - Formatting is easier to read
- Non-Required Sections and UCLA-isms removed
- Meets national standards and best practices

*With significant input and feedback from various users.
Biomedical Consent Form Template

- Used for > minimal risk medical studies only.*
- Provides updated look and formatting.
- Distinguishes between required and optional sections.
- Provides required and suggested language.
- Uses question and answer format.
- Is written at ~ 8th grade reading level.
- Is accompanied by the UCLA Consent Form Standards document.
- Sections link directly to standards and suggested language.

*Use Behavioral Consent Form templates for questionnaires and quality of life studies.
UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study]

[Insert a lay or working title of the study – for study participants]

INTRODUCTION

[insert name and degrees of the Principal Investigator], and associates from the [insert department affiliation] at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding:
- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because...

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to...

The following definitions may help you understand how this research study is designed:

This study is being funded by...

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY? (optional section)

XX people will take part in this study at UCLA. About XX people will participate in this study nationwide.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:
Before you begin the study, you will need to...

During the study:
If you take part in this study, the researcher(s) will ask you to...

HOW LONG WILL I BE IN THIS STUDY?

This study will last...

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
The possible risks and/or discomforts associated with the procedures described in this consent form include:

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will tell you if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
The possible benefits you may experience from being in this study include...

Possible benefits to others or society:
There will be no direct benefit to you from participating in this study. However, this study will help the researchers learn more about [procedure/drug/intervention/device]. Hopefully this information will help in the treatment of future patients with [disease/condition] like yours. (Note: Do not use this statement if participants will be billed for research-related procedures.)

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available:

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY? (optional section)

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to...

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in
Consent Form Standards

- Linkable from consent form template
- General formatting instructions—required and recommended
- Section-by-Section Instructions and guidance
- Sample and suggested language, for example
  - Risks associated with withdrawing from current medication
  - HIV testing risks
- Required language, for example
  - Treatment and compensation for injury
  - Use of specimens in research
- Guidance for signature lines
- Separate section for genomic research studies