Human Research Protection Program

Institutional Review Board (IRB)
Quality Improvement Unit (QIU)
Gamete, Embryo and Stem Cell Research Committee (GESCR)

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RE: IRB Required Language on Informed Consent Forms

Dear Principal Investigator,

This letter may be shared with research sponsors to describe required, unalterable language that must be included as written on all relevant UCSF informed consent documents (**CONSENT TO PARTICIPATE IN A RESEARCH STUDY).** We have written these sections in plain language to make them understandable to all potential research participants. The language has been subjected to extensive stakeholder, risk management, and legal review and addresses many federal, state, and University policies governing research on human participants. Consequently, the language is not subject to any alteration. Nothing may be removed or added to the language. Any attempts at modifying this language are not permitted, including expanding on or contradicting this required language in other sections of the informed consent form. The language and associated rationale are available **here** and cover the following components of consent:

All Informed Consent Forms

Why have I been given this document?

Do I need to take part in this study?

Are there benefits to taking part in the study?

What are my other options if I don't want to take part in this study?

What are the risks of this study? (Introductory statement)

How will my information be used?[1]

How will information about me be kept confidential?

What happens if I am injured or feel harmed because I took part in this study?

Are there any costs to me for taking part in this study?

Can I stop being in the study if I want to?

Can I be removed from the study by the Principal Investigator?

What are my rights if I take part in this study?

Who can answer my questions about this study?

Consent -- PARTICIPATION IN RESEARCH IS VOLUNTARY

[1] Includes required language when study includes NIH Data Management and Sharing Plan

When Study Design Dictates

If my condition improves while taking the study drug, can I continue taking it after the study?

What are the research procedures? (Standardized language for placebos, radiation, MRIs, *etc.*)

What are the risks of this study? (Standardized language for randomization risk, placebos, phlebotomy, radiation, MRIs, using your tissue for research, reproductive risks,[2] *etc.*)

Will I be paid if I take part in this study? (Standardized language if there is no payment)

Will I share in any profits from this study?

Will I be reimbursed for expenses if I take part in this study? (Standardized language if there is no reimbursement or no expenses)

Genetic Testing Statement

How will my genetic information be shared?

Genetic testing confidentiality statements

Illegal activity confidentiality statement

Certificate of Confidentiality

Does this study involve testing of reportable diseases and conditions that must be reported to the public health department? (*e.g.*, HIV+, hepatitis B & C, COVID-19 test results)

Treatment and Compensation for Injury

Where can I get more information about this study? (For clinical trials)

Donation of Human Fetal Tissue for Research Purposes

We thank you for your partnership in our efforts to ensure improved research participant comprehension and streamlined IRB review of your consent documents.

Sincerely,

Edward Kuczynski
Director, Human Research Protection Program

[2] including acceptable methods of contraception