

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

- 1) To be told what the study is trying to find out,
- 2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
- 3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
- 4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
- 5) To be told of the other choices I have and how they may be better or worse than being in the study,
- 6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
- 7) To be told what sort of medical treatment is available if any complications arise,
- 8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
- 9) To receive a copy of the signed and dated consent form,
- 10) To be free of pressure when considering whether I wish to agree to be in the study.

My study doctor will tell me if the research study is regulated by the Food and Drug Administration (FDA). I understand that if this study is FDA regulated, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may inspect and copy all records relating to my participation in the study.

If you have other questions you should ask the researcher or the research assistant. In addition, you may contact the Institutional Review Board (IRB), which is concerned with protection of participants in research projects. You may reach the IRB office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the UCSF Human Research Protection Program, Box 1288, 490 Illinois Street, Floor 6, San Francisco, CA 94143, or by email at irb@ucsf.edu. Call (415) 476-1814 or email irb@ucsf.edu for information on translations.

The elements of consent were presented orally.

Participant's Name

Participant's Signature for Consent

Parent or Legally Authorized Representative

Witness Signature

Date