



University of California
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Experimental Subject's Bill of Rights

Experimental Subject's Bill of Rights Form

Which Subjects Should Be Offered the Form?

Documentation

Experimental Subject's Bill of Rights Form

Experimental Subject's Bill of Rights Form: ^[1] You must offer research subjects participating in a "medical experiment" (defined below) a copy of this form in a language in which the subject is fluent.

Translated versions of the form

Review our guidance on consenting non-English speakers ^[2] and contact the IRB ^[3] for additional translations.

Amharic/Ethiopian ^[4]	Greek ^[5]	Portuguese ^[6]
Arabic ^[7]	Gujarati (India) ^[8]	Punjabi ^[9]
Armenian ^[10]	Haitian Creole ^[11]	Romanian ^[12]
Bosnian ^[13]	Hebrew ^[14]	Russian ^[15]
Braille (English and Russian): Call IRB ^[3] for a copy	Hindi ^[16]	Spanish ^[17]
Burmese ^[18]	Hmong ^[19]	Tagalog ^[20]

Cambodian [21]	Indonesian [22]	Telugu [23]
Chinese [24]	Italian [25]	Thai [26]
Croatian [27]	Japanese [28]	Tibetan [29]
English [30]	Korean [31]	Turkish [32]
Farsi [33]	Laotian [34]	Ukrainian [35]
French [36]	Mongolian [37]	Vietnamese [38]
Georgian [39]	Nepali [40]	
German [41]	Polish [42]	

Document that each subject received the form using one of the methods describe below [43].

Which Subjects Should Be Offered the Form?

California law, under Health & Safety Code §24172 [44], requires all investigators doing a "medical experiment" to offer their subjects a copy of the "Experimental Subject's Bill of Rights." Failure to do so may result in civil or criminal penalties.

A "medical experiment" is defined as:

The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject. ...

The IRB has interpreted this definition to include almost all studies involving biomedical procedures, placebo controls, innovative therapy and/or normal volunteer subjects.

For these types of studies, you must give a copy of the UCSF Experimental Subject's Bill of Rights to subjects, along with a copy of the study's consent document and possibly the HIPAA authorization form. Include the following statement at the end of the consent form: "You have been given a copy of this consent form and of the Experimental Subject's Bill of Rights to keep."

For non-biomedical studies, the IRB may recommend use of the Experimental Subject's Bill of Rights, though it is not required by law.

Documentation

Subjects do not sign the Experimental Subject's Bill of Rights, but you should document that each subject received the form by one of the following methods:

1. Keep a copy of the Bill of Rights with the subject's initials in his/her study file.
2. Write a note on the consent form confirming that the subject received the Bill of Rights.
3. Write a note in the subject's research record confirming that the subject received the Bill of Rights. **OR**
4. Keep a copy of the Bill of Rights in the subject's research file with the original signed consent form (and HIPAA authorization form, if applicable).

Do **not** submit the Bill of Rights to the IRB via iRIS.

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Source URL: <https://irb.ucsf.edu/experimental-subjects-bill-rights>

Links

- [1] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/English-bill-of-rights.pdf>
- [2] <https://irb.ucsf.edu/consenting-non-english-speakers>
- [3] <https://irb.ucsf.edu/contact-us>
- [4] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Amharic-Ethiopian-bill-of-rights.pdf>
- [5] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/greek-bill-of-rights.pdf>
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- [23] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Telugu-bill-of-rights.pdf>
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- [25] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Italian-bill-of-rights.pdf>
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- [41] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/German-bill-of-rights.pdf>

[42] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Polish-bill-of-rights.pdf>

[43] <https://irb.ucsf.edu/#documentation>

[44] <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5>