



University of California  
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Home > Recruitment, Consent & HIPAA > EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

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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:** <sup>[1]</sup> 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 <sup>[2]</sup> and contact the IRB <sup>[3]</sup> for additional translations.

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

Cambodian [21]	Indonesian [22]	Telugu [23]
Chinese [24]	Italian [25]	Thai [26]
Croatian [27]	Japanese [28]	Tibetan [29]
English [1]	Korean [30]	Turkish [31]
Farsi [32]	Laotian [33]	Ukrainian [34]
French [35]	Mongolian [36]	Vietnamese [37]
Georgian [38]	Nepali [39]	
German [40]	Polish [41]	

Document that each subject received the form using one of the methods describe below [42].

## Which Subjects Should Be Offered the Form?

California law, under Health & Safety Code §24172 [43], 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 is 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 is 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:** <http://irb.ucsf.edu/experimental-subjects-bill-rights>

### Links

- [1] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/English-bill-of-rights.pdf>
- [2] <http://irb.ucsf.edu/consenting-non-english-speakers>
- [3] <http://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>
- [6] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Portuguese-bill-of-rights.pdf>
- [7] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Arabic-bill-of-rights.pdf>
- [8] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Gujarati-bill-of-rights.pdf>
- [9] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Punjabi-bill-of-rights.pdf>
- [10] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Armenian-bill-of-rights.pdf>
- [11] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Haitian-Creole-bill-of-rights.pdf>
- [12] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Romanian-bill-of-rights.pdf>
- [13] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Bosnian-bill-of-rights.pdf>
- [14] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Hebrew-bill-of-rights.pdf>
- [15] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Russian-bill-of-rights.pdf>
- [16] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Hindi-bill-of-rights.pdf>
- [17] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Spanish-bill-of-rights.pdf>
- [18] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Burmese-bill-of-rights.pdf>
- [19] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Hmong-bill-of-rights.pdf>
- [20] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Tagalog-bill-of-rights.pdf>
- [21] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Cambodian-bill-of-rights.pdf>
- [22] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Indonesian-bill-of-rights.pdf>
- [23] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Telugu-bill-of-rights.pdf>
- [24] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Chinese-bill-of-rights.pdf>
- [25] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Italian-bill-of-rights.pdf>
- [26] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Thai-bill-of-rights.pdf>
- [27] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Croatian-bill-of-rights.pdf>
- [28] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Japanese-bill-of-rights.pdf>
- [29] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Tibetan-bill-of-rights.pdf>
- [30] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Korean-bill-of-rights.pdf>
- [31] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Turkish-bill-of-rights.pdf>
- [32] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Farsi-bill-of-rights.pdf>
- [33] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Laotian-bill-of-rights.pdf>
- [34] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Ukranian-bill-of-rights.pdf>
- [35] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/French-bill-of-rights.pdf>
- [36] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Mongolian-bill-of-rights.pdf>
- [37] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Vietnamese-bill-of-rights.pdf>
- [38] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Georgian-bill-of-rights.pdf>
- [39] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Nepali-bill-of-rights.pdf>
- [40] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/German-bill-of-rights.pdf>
- [41] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/Polish-bill-of-rights.pdf>

[42] <http://irb.ucsf.edu/#documentation>

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