

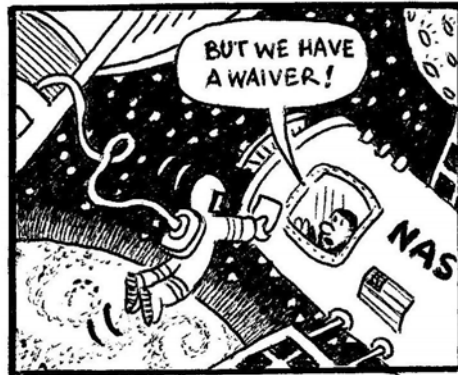
Waiver of Documentation of Consent vs Waiver of Consent

Waiver of Documentation of Consent See MMC's [SOP IC 701](#)

In some situations, the IRB may waive the requirement for obtaining a signed Informed Consent Document ([45 CFR 46.117\(c\)](#)). Investigators may request that the IRB waive the requirement for a signed written informed consent.

The IRB may waive the requirement for a signed consent if it finds:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (the subjects would be placed at risk by documents linking them with an illegal or stigmatizing characteristic or behavior). [Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern]; or
- b. The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.



Waiver of Elements of Consent or Consent Itself See MMC's SOP [IC 702-A](#)

Some research projects would not be possible if informed consent from subjects were required. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or may waive the requirements to obtain informed consent. The IRB may consider waiving the requirement for some or all of the elements of informed consent ([45 CFR 46.116\(d\)](#)).

The regulations state that informed consent may be waived in full or in part if the IRB determines that:

- the research involves no more than minimal risk to the subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.