

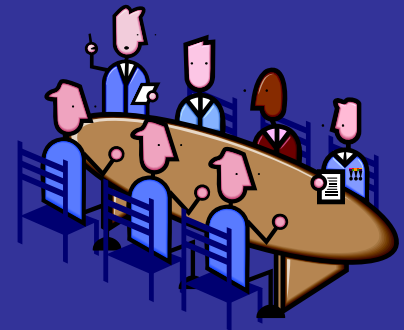
DHHS provides for waiving or altering elements of informed consent under certain conditions [§.116(c)-(f)]. FDA has no such provisions because the types of studies that would qualify for waiver or alteration are either not regulated by FDA or are covered by the Emergency Treatment provision of FDA Regulation 21 CFR 50.23.

- **Waiver of informed consent can not be given when research is subject to FDA regulation.**



Waiver of Informed Consent

- The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided one of the following sets of conditions exists and is documented:

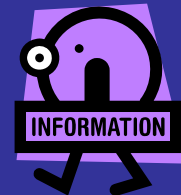


45 CFR 46.116(c) (Must meet one of the following criteria from section 1 as well as criteria number 2) (not applicable to research subject to FDA regulation)

- 1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine at least one of the following (a) public benefit or service programs; (b) procedures for obtaining benefits or services under these programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs**
- 2) AND the research could not practicably be carried out without the waiver or alteration.**

45 CFR 46.116(d) (Must meet all four criteria detailed below) (not applicable to research subject to FDA regulation)

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



Waiver of Documentation of Informed Consent

- Under certain conditions, the IRB can waive the requirement that the participant sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB reviews the written description of the information that will be provided to participants.



The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either (46 CFR 117(c):

- 1) That 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. Each participant will be asked whether the subject wants documentation linking the subject with the research, and the participant's wishes will govern. **(not applicable to research subject to FDA regulation)**

- **OR 2. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.**