Guidance on Waivers of Informed Consent
Chaminade University IRB
November, 2015.

What is a waiver or alteration of informed consent or parental permission?

The HHS regulations allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under 45 CFR 46.116(a) and (b).

Waiving the requirement for obtaining informed consent or parental permission means that the IRB has determined that investigators need not obtain the subjects' informed consent to participate in research. For example, some research about natural behavior may require that subjects be unaware that the research is taking place. Such research can only be approved by the IRB if the research meets the criteria for a waiver of informed consent under HHS regulations and for approving research according to 45 CFR 46.111.

An IRB may approve research for which some or all of the elements of informed consent at 45 CFR 46.116 (a) and (b) have been altered, or for which some elements have been left out. For example, some research designs require that subjects be left unaware of the particular purpose of the research, because the subjects' responses might be biased if they know in advance what the investigators are seeking. Such research designs do not preclude offering potential subjects some information about the research and giving them the opportunity to decide whether to participate. The IRB may approve such research in which investigators will leave out or alter elements of informed consent, so long as the research meets the criteria for approving research in 45 CFR 46.111, and the research meets the criteria specified in the HHS regulations for leaving out or altering those elements.

Applicable Regulations

§46.116 An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for

benefits or services under those programs;
and

2) The research could not practicably be carried out without the waiver or alteration.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
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.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)
[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

CUH IRB Procedure For Requesting Waiver of Informed Consent

On CUH IRB Form I, II or III the Principal Investigator should indicate ‘no’ in response to questions regarding informed consent. The PI should provide a cover letter entitled “Request for Waiver of Informed Consent” in which the PI documents specifically the manner in which the proposed study meets one or more of the standards outlined above. This cover letter should be appended to the PDF version of Form I, II or III and submitted with the PI’s application for review.