P&P: IC 702 Version No: 1.2 Effective Date: 1/21/2019	WAIVERS OF INFORMED CONSENT	Supercedes: CPHS Policies and Procedures 10/1/2009

1. POLICY

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, if the IRB finds and documents that the research meets specific regulatory criteria.

Specific Policies

1.1 IRB Waivers of One or More Requirements of Informed Consent

1.1.a In accordance with 45 CFR 46.116 (f), the IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

A. 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

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

1.1.b In accordance with 45 CFR 46.116 (f3), the IRB also may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided the IRB finds and documents that*:

A. The research involves no more than minimal risk to the subjects;

B. The research could not practicably be carried out without the requested waiver or alteration;

C. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

D. The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**

E. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

*If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

1.1.c Waiver of Parental or Guardian Permission (see IC 703, "Assent and Parental/Guardian Permission")

Note: Waiver of some or all elements of informed consent under 45 CFR 46.116 will not apply to any research which falls under the jurisdiction of the FDA, as FDA regulations do not provide for waiver of consent except in specific emergency circumstances (see 1.2 below).

1.2 An Emergency Situation Prior to IRB Review and Approval

For research which falls under the jurisdiction of the FDA, obtaining informed consent shall be deemed feasible except in certain emergency situations described under guidelines 21 CFR 50.23 and 21 CFR 50.24**.** In emergency situations where informed consent cannot be obtained prior to interaction or intervention with a human subject, the Investigator must submit to the IRB, within five (5) working days of the emergency, documentation of the necessary exception.

In review of the documentation, the IRB will ensure that the Investigator and a physician not otherwise participating in the investigation have adequately certified the following in writing prior to interaction or intervention with the subject:

A. the human subject was confronted by a life-threatening situation necessitating the use of the test article;

B. informed consent could not be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject;

C. time was not sufficient to obtain consent from the subject's legal representative;

D. there was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the subject.

1. 3 Screening, Recruiting, or Determining Eligibility

When information or biospecimens are obtained for the sole purpose of screening, recruiting, or determining the eligibility of prospective subjects, informed consent need not be obtained if the following conditions are met and the data will not be stored or used for research purposes:

A. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

B. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimen.

2. SCOPE

These policies and procedures apply to all research submitted to the UC Berkeley IRB.

3. RESPONSIBILITY

The IRB, IRB Chair, and/or IRB member designee is responsible for making a final determination of whether a waiver of informed consent is applicable and appropriate.

4. PROCESS OVERVIEW

The Investigator should include any request for waiver of informed consent or parental permission in the protocol along with justification for the waiver. An OPHS staff member will evaluate this request as part of the pre-review of the application before assigning it for final review, and the IRB members and/or IRB Chair or designee will subsequently evaluate the request, based on relevant regulations and guidance.

If a waiver of informed consent request is not approved, the Investigator will be notified and asked to provide further justification or resubmit a revised protocol that includes an informed consent process.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24

21 CFR 56.109(c), 56.109(d)

45 CFR 46.116

45 CFR 46.408