



Informed Consent Waiver Request

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Instructions: This form must be submitted if you are either not intending to consent the subjects of your research project or you are only requesting DSHS data. The justification for your reason(s) must be included.

Title of Protocol:

Principal Investigator:

I am requesting Waiver of Informed Consent (*Check the box next to the criteria that give reason for your request for a waiver of informed consent and provide a detailed justification based on your choice*)

- 1. The research or demonstration project is to be conducted by or is 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 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.

Justification (be specific to this regulation):

OR

- 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.

Justification (be specific to this regulation):

I am requesting Waiver of Documentation of Informed Consent (*Check the box next to the criteria that give reason for your request for a waiver of documentation of informed consent and provide a detailed justification*)

- The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality

Justification (be specific to this regulation):

OR

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

Justification (be specific to this regulation):

I am requesting Waiver of the following Elements of Informed Consent

- 1. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

Justification (be specific to this regulation):

- 2. A description of any reasonably foreseeable risks or discomforts to the subjects

Justification (be specific to this regulation):

- 3. A description of any benefits to the subject or to others, which may reasonably be expected from the research

Justification (be specific to this regulation):



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4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
Justification (be specific to this regulation):

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
Justification (be specific to this regulation):

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
Justification (be specific to this regulation):

7. An explanation of whom to contact for answers to pertinent questions about the research subjects' rights, and whom to contact in the event of a research-related injury to the subject
Justification (be specific to this regulation):

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
Justification (be specific to this regulation):