Los Angeles County Public Health, Ambulatory Care Network and
Health Services Administration Institutional Review Board
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REQUEST TO WAIVE OR ALTER INFORMED CONSENT PROCEDURE AND/OR ITS DOCUMENTATION

Project Title:

Principal Investigator:
Telephone:

Please check the appropriate box(es) below and attach an explanation specifying the precise alteration(s) or waiver being requested in the informed consent process and the reason(s) for the request. Check the applicable main heading I, II, III or IV and, if IV, check which criterion applies.

☐ **I.** Research or demonstration project conducted by state or local governmental officials that is designed to study, evaluate or otherwise examine certain aspects of or possible changes to public benefit or service programs, and which research could not practicably be carried out without the waiver or alteration.

☐ **II.** Research which meets all of the following criteria:

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

☐ **III.** Use of a short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. A witness to the oral presentation must be present and a written summary of the oral presentation must be approved by the IRB.

☐ IV. Waiver of signed written consent form because <u>either</u>:

☐ 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; or

☐ B. 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.

Note: Under this form of waiver, explicit verbal consent after full explanation is required.