

<b>UC San Diego</b> <b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b>	<b>OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process</b>		
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The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves waiver or alteration of the consent process. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure). It does not need to be completed or retained.

<b>IRB Number:</b>	
<b>Investigator:</b>	

<b>1. Applicable Considerations (Check one)</b>	
<input type="checkbox"/>	The request is for a complete waiver of informed consent for <u>research</u> <b>not involving</b> a public benefit or service program. <i>(If yes, complete Section 2)</i>
<input type="checkbox"/>	The request is for a complete waiver of informed consent for <u>research</u> <b>involving</b> a public benefit or service program. <i>(If yes, complete Section 3)</i>
<input type="checkbox"/>	The request is for an alteration of informed consent for <u>research</u> <b>not involving</b> a public benefit or service program. <i>(If yes, complete Sections 2 and 4)</i>
<input type="checkbox"/>	The request is for an alteration of informed consent for <u>research</u> <b>involving</b> a public benefit or service program. <i>(If yes, complete Sections 3 and 4)</i>
<input type="checkbox"/>	The request is for a waiver of consent for emergency <u>research</u> and meets the criteria set out in <i>OIA-419 Checklist: Waiver of the Consent Process for Emergency Research</i> , or equivalent. <i>(If yes, STOP. Complete OIA-419 Checklist: Waiver of the Consent Process for Emergency Research, or equivalent.)</i>
<b>2. General Waiver of the Consent Process<sup>1</sup> (Check if "Yes." All must be checked)</b>	
<input type="checkbox"/>	The <u>research</u> involves no more than <u>minimal risk</u> to the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The waiver or alteration will <b>NOT</b> adversely affect the rights and welfare of the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	One must be checked: <input type="checkbox"/> The <u>research</u> is being reviewed under the Revised Common Rule; <input type="checkbox"/> The <u>research</u> uses only de-identified or anonymous <u>private information</u> or biospecimens; or <input type="checkbox"/> The <u>research</u> cannot practicably be carried out without using <u>identifiable private information</u> or <u>identifiable biospecimens</u> because:
<input type="checkbox"/>	The <u>research</u> could <b>NOT</b> practicably be carried out without the waiver or alteration <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Whenever appropriate, the subject or legally authorized representative (LAR) will be provided with additional pertinent information after participation. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> does <b>NOT</b> meet the State of California's definition of a medical experiment. <sup>2</sup>
<input type="checkbox"/>	The <u>research</u> does <b>NOT</b> involve non-viable neonates.

<sup>1</sup> 45 CFR 46.116(f)(3)

<sup>2</sup> California Health and Safety Code Section 24174:

- (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or
- (b) The investigational use of a drug or device; or
- (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

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3. Waiver of Consent Process for <u>research</u> involving public benefit and service programs <sup>3</sup> (Check if "Yes." All must be checked)	
<input type="checkbox"/>	One of the following is true: (Choose One) <input type="checkbox"/> The <u>research</u> is not FDA-regulated. <input type="checkbox"/> The <u>research</u> presents no greater than <u>minimal risk</u> including for FDA-regulated studies.
<input type="checkbox"/>	The <u>research</u> or demonstration project is to be conducted by or subject to the approval of state or local government officials. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. One must be checked) <input type="checkbox"/> Public benefit or service programs. <input type="checkbox"/> Procedures for obtaining benefits or services under those programs. <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures. <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> could <b>NOT</b> practicably be carried out without the waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> does <b>NOT</b> meet the State of California's definition of a medical experiment. <sup>4</sup>
<input type="checkbox"/>	The <u>research</u> does <b>NOT</b> involve non-viable neonates.
4. General Alteration of the Consent Process <sup>5</sup> (Check if "Yes." All must be checked or "N/A")	
<input type="checkbox"/>	Consent is sought under circumstances that provide the subject or LAR sufficient opportunity to discuss and consider whether or not to participate.
<input type="checkbox"/>	Consent is sought under circumstances that minimize the possibility of coercion or undue influence.
<input type="checkbox"/>	The information is given to the subject or LAR in a language that is understandable to them.
<input type="checkbox"/>	The information provided is information that a reasonable person would want to have in order to make an informed decision about whether to participate.
<input type="checkbox"/>	The informed consent begins with a concise and focused presentation of key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the <u>research</u> and is organized and presented in a way that facilitates comprehension. <input type="checkbox"/> N/A The <u>research</u> is being reviewed under the pre-2018 Common Rule
<input type="checkbox"/>	The informed consent includes sufficient detail and does not merely provide isolated facts.
<input type="checkbox"/>	The informed consent does not include exculpatory language through which the subject or LAR waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

<sup>3</sup> [45 CFR 46.116\(e\)](#)

<sup>4</sup> [California Health and Safety Code Section 24174:](#)

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or

(b) The investigational use of a drug or device; or

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

<sup>5</sup> [45 CFR 46.116\(f\)\(2\) & \(3\)](#)