UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-410 CHECKLIST:** Waiver or Alteration of the Consent Process		
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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.

IRB Number:	
Investigator:	

	1. Applicable Considerations (Check one)
☐	The request is for a complete waiver of informed consent for research **not involving** a public benefit or service program. ***(If yes, complete Section 2)***
☐	The request is for a complete waiver of informed consent for research **involving** a public benefit or service program. ***(If yes, complete Section 3)***
☐	The request is for an alteration of informed consent for research **not involving** a public benefit or service program. ***(If yes, complete Sections 2 and 4)***
☐	The request is for an alteration of informed consent for research **involving** a public benefit or service program. ***(If yes, complete Sections 3 and 4)***
☐	The request is for a waiver of consent for emergency research and meets the criteria set out in *OIA-419 Checklist: Waiver of the Consent Process for Emergency Research*, or equivalent. ***(If yes, STOP. Complete OIA-419 Checklist: Waiver of the Consent Process for Emergency Research, or equivalent.)***
	2. General Waiver of the Consent Process[1] (Check if "Yes." All must be checked)
☐	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	One must be checked: ☐ The research is being reviewed under the pre-2018 Common Rule **and** is not FDA-regulated; ☐ The research uses only de-identified or anonymous private information or biospecimens; or ☐ The research cannot practicably be carried out without using identifiable private information or identifiable biospecimens because*:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subject or legally authorized representative (LAR) will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*
☐	The research does **NOT** meet the State of California's definition of a medical experiment.[2]
☐	The research does **NOT** involve non-viable neonates.
☐	No individuals were previously asked to provide broad consent for use of identifiable private information and/or identifiable biospecimens and refused to consent.

[1] 45 CFR 46.116(f)(3)

[2] 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.

	3. Waiver of Consent Process for research involving public benefit and service programs[3] (Check if "Yes." All must be checked)
☐	The research is not FDA-regulated.
☐	The research presents no greater than minimal risk. *Provide protocol specific findings justifying this determination:*
☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. *Provide protocol specific findings justifying this determination:*
☐	The research 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)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. *Provide protocol specific findings justifying this determination:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	The research does **NOT** meet the State of California's definition of a medical experiment.[4]
☐	The research does **NOT** involve non-viable neonates.
☐	No individuals were previously asked to provide broad consent for use of identifiable private information and/or identifiable biospecimens and refused to consent.
	4. General Alteration of the Consent Process[5] (Check if "Yes." All must be checked or "N/A")
☐	Consent is sought under circumstances that provide the subject or LAR sufficient opportunity to discuss and consider whether or not to participate.
☐	Consent is sought under circumstances that minimize the possibility of coercion or undue influence.
☐	The information is given to the subject or LAR in a language that is understandable to them.
☐	The information provided is information that a reasonable person would want to have in order to make an informed decision about whether to participate.
☐	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 research and is organized and presented in a way that facilitates comprehension. ☐ N/A The research is being reviewed under the pre-2018 Common Rule
☐	The informed consent includes sufficient detail and does not merely provide isolated facts.
☐	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.

[3] 45 CFR 46.116(e)

[4] 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.

[5] 45 CFR 46.116(f)(2) & (3)