

<b>UC San Diego</b> <b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b>	<b>OIA-401 CHECKLIST: Pre-Review</b>		
	NUMBER	DATE	PAGE
	OIA-401	09/06/2023	1 of 1

The purpose of this checklist is to provide support for Office of IRB Administration (OIA) staff conducting pre-review. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

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

**Regulatory Oversight (Check all that apply)**

<input type="checkbox"/>	(DHHS)	<input type="checkbox"/>	(DOD)	<input type="checkbox"/>	(DOJ)	<input type="checkbox"/>	(EPA)	<input type="checkbox"/>	Other Federal Agency:
<input type="checkbox"/>	(FDA)	<input type="checkbox"/>	(DOE)	<input type="checkbox"/>	(ED)	<input type="checkbox"/>	(VA)	<input type="checkbox"/>	ICH-GCP

**Restrictions (Check if applicable)**

<input type="checkbox"/>	Principal investigator is <u>restricted</u> .
--------------------------	---

**Missing Materials**

<b>Missing Materials</b>	
--------------------------	--

**Special Determinations (Check all that apply)**

<input type="checkbox"/>	<u>Children</u>	<input type="checkbox"/>	Not significant risk device	<input type="checkbox"/>	Waiver/alteration of the consent process
<input type="checkbox"/>	<u>Wards</u>	<input type="checkbox"/>	Non-viable neonates	<input type="checkbox"/>	Waiver of <u>HIPAA</u> authorization

<input type="checkbox"/>	<u>Pregnant subjects</u> <sup>1</sup>	<input type="checkbox"/>	Neonates of uncertain viability	<input type="checkbox"/>	Waiver of consent documentation
<input type="checkbox"/>	<u>Prisoners</u>	<input type="checkbox"/>	Cognitively impaired adults	<input type="checkbox"/>	Waiver of consent process for emergency <u>research</u>

**Risk Level (Check one)**

<input type="checkbox"/>	More than <u>minimal risk</u> to subjects	<input type="checkbox"/>	No more than <u>minimal risk</u> to subjects
--------------------------	---	--------------------------	--

**Protocol Tracking (Check all that apply)**

<input type="checkbox"/>	Social/Behavioral/Education	<input type="checkbox"/>	Biomedical/Clinical
--------------------------	-----------------------------	--------------------------	---------------------

**Final Contingencies**

<b>Final Contingencies</b>	
----------------------------	--

**STUDY CLOSURE**

<input type="checkbox"/>	<u>Research</u> can be closed.
--------------------------	--------------------------------

<sup>1</sup> Applicable for research that is funded by Health and Human Services (HHS) or Homeland Security and includes pregnant subjects. Research involving intentional exposure of pregnant subjects and/or children to insecticides is not approvable.