

## UCSD Human Research Protections Program Biomedical Project: Standard Application for Review

### Instructions for submitting

1. Complete all pages of this form. **To do this, open the form using your Web Browser** to fill in the form (requires Acrobat Reader or Acrobat).
2. Click the **Print button** on the last page to make a copy for signatures.
3. Click the **Submit button** on the last page to submit the data from the Facesheets to the HRPP Office via the Internet.
4. When you submit the Facesheets, the HRPP system will give you a Temporary Project ID (a "T-number"). Once your information has been imported into the HRPP database, usually within 1-2 working days, the project will receive a HRPP project number, and you will receive an e-mail noting the HRPP project number. You will then need to log into your "My Protocols at a Glance" through [eIRB services](#). Click on the link for your "new" project and you may begin to upload the Research Plan, consents/assents, and other documents, as appropriate. The template for the Research Plan is available on the HRPP website in Word format.
5. The Principal Investigator and Department Chair must sign where indicated on the last page of the Facesheets.
6. Upload the **signed Facesheets** through [eIRB services](#).

### Section 1: PROJECT TITLE

Sponsor's protocol number	

### Section 2: KEY PERSONNEL

	Last name	First Name	Degree
Principal Investigator	Title	Department	Mail code
	E-mail	Phone	Fax
	Principal Investigator is salaried UCSD employee (check Yes or No): Yes <input type="checkbox"/> No <input type="checkbox"/>		
Contact	Last name	First Name	Degree
	Title	Department	Mail code
	E-mail	Phone	Fax

### Section 3: PROJECT CHARACTERISTICS

Yes	No				
		This is a <b>renewal of a previous project</b>		If <b>Yes</b> : Previous IRB project number is	
		This project is <b>closed to participant enrollment</b>			
		Number of <b>participants enrolled thus far at</b>		UCSD	RCHSD
		Projected number of participants to be <b>enrolled for entire project at</b>		UCSD	RCHSD
		Is a <b>multicenter/multisite study</b>			
		Involves participants <b>under age 18</b>			
		Involves <b>women of child-bearing potential</b>			
		Involves <b>pregnant women and/or involve human fetus or fetal tissue</b> (if yes, see <a href="#">here</a> )			
		Involves <b>potentially cognitively impaired individuals</b>			
		Involves <b>prisoners</b> (if yes, see <a href="#">here</a> )			
		Involves <b>non-English speaking participants</b> (if no, ensure Research Plan provides justification, see item 10 <a href="#">here</a> )			
		Involves patients with <b>cancer or at high risk of developing cancer during the study</b> (If yes, contact <a href="#">PRMC</a> )			
		Involves the use of <b>ResearchMatch</b> (for more information, see <a href="#">here</a> )			
		Involves <b>compensation for participation</b>			
		Involves <b>event(s)/procedure(s) billable to sponsor/insurance/subject</b> (for more information, contact <a href="#">OCAA</a> )			
		Involves <b>infectious agents, gene therapy, recombinant DNA, and/or gene transfer</b> (for more information, contact <a href="#">EH&amp;S</a> )			
		Involves <b>DURC agent(s)</b> such as Botulinum neurotoxin (Botox), Francisella tularensis, etc. (for more information, see <a href="#">here</a> )			
		Involves <b>waiver of consent</b> (i.e., the research will be done without seeking the consent of persons whose records/tissue are analyzed)			
		Involves <b>waiver of documented consent</b> (i.e., consent obtained but there is no signed consent form)			
		Involves <b>partial waiver of individual HIPAA authorization</b> for procedures preparatory to research and/or recruitment			
		Involves <b>banking of tissue or fluids</b>			
		Involves <b>DNA genotyping or other form of genetic analysis</b>			
		Involves <b>human embryonic stem cells, iPS cells, and/or other pluripotent cells</b> (for more information, see <a href="#">here</a> )			
		Has a <b>Data and Safety Monitoring (DSM) Board or DSM Plan</b>			
		Discloses <b>financial interest(s)</b> (if yes, submit Conflict of Interest Disclosure Supplement — for more information, see <a href="#">here</a> )			

Section 4: INVESTIGATIONAL DRUGS, DEVICES AND PROCEDURES											
Yes	No										
		Involves <b>FDA-regulated product(s)</b>									
		Indicate <b>Phase of Trial, if appropriate</b>		Phase I	Phase II	Phase III	Phase IV				
Yes	No										
		Involves <b>FDA Investigational New Drug Application(s)</b>									
		<b>PI holds or plans to hold IND(s)</b>									
		<b>Meets criteria for IND exemption</b> (for more information, see <a href="#">here</a> )									
		<b>If Yes to any question, enter the following, as appropriate:</b>									
		Investigational <b>drug name(s)</b> ; one drug name and associated <b>IND number</b> per line.	Drug name(s):	1. 2. 3.	and IND number(s):	1. 2. 3.					
		Project will use UCSD Medical Center Investigational Drug Service:				Yes:		No:			
		Project will use RCHSD Investigational Pharmacy Service:				Yes:		No:			
		If the Investigational Drug Service <b>will not be used</b> , enter the following:		<b>Location</b> where drugs will be stored:							
				<b>Name of person</b> responsible for dispensing study drug(s):							
				<b>Phone number of person</b> responsible for dispensing study drug(s):							
Yes	No										
		Involves <b>Non-Significant Risk Device</b> (for more information, see <a href="#">here</a> )									
		Involves <b>Significant Risk Device</b> (for more information, see <a href="#">here</a> )									
		Involves <b>FDA Investigational Device Exemption(s), 510(k)</b> or <b>FDA Category B device</b> (for more information, see <a href="#">here</a> )									
		If <b>Yes</b> , enter <b>device name(s)</b> ; one device name and associated <b>FDA-assigned IDE, 510(k)</b> or <b>Category B identifier</b> per line:	Device name(s):	1. 2. 3.	and FDA number(s):	1. 2. 3.					
Yes	No										
		Study participants will be exposed to <b>Radiation or Radioactivity</b>									
		If <b>Yes</b> , enter the following about the sources of radiation:		Radiographic <b>X-ray</b>	Yes		No				
				<b>Fluoroscopy</b>	Yes		No				
				<b>DEXA</b> (Bone Density)	Yes		No				
				Computed Tomography ( <b>CT</b> )	Yes		No				
				Positron Emission Tomography ( <b>PET</b> )	Yes		No				
				Nuclear Med. ( <b>radionuclide</b> ) injections	Yes		No				
				<b>If Yes, Name(s) of Nuclear Medicine Procedure(s)</b>							
				A non-routine radioactive drug			Yes:		No:		
				<b>If Yes, enter Radioisotope Use Authorization (RUA)*</b>							
				<b>Other form</b> of radiation or radioactivity			Yes:		No:		
		<b>If Yes, describe</b>									

\*Projects with this type of Radioisotope use must complete RDRC application available from Radiation Safety Office.

Section 5: FACILITIES WHERE STUDY WILL BE CONDUCTED									
Yes	No								
		UCSD Healthcare hospitals or clinics							
		UCSD Center for Clinical Research Services (CCR)							
		Rady Children's Hospital - San Diego hospital or clinics							
		International site(s) – please describe:							
		Other – please describe:							

Section 6: FUNDING									
Funding Source (check all that apply)			Unfunded	Commercial sponsor – Sponsor initiated	Departmental or ORU funding				
			HHS (NCI, NIMH, NIHLBI, NIA, etc.)	Commercial sponsor – PI initiated	Not for profit foundation				
			National Science Foundation	Academic Senate					
			Department of Defense	Other funding source – specify:					
Funding Mechanism			OCTA contract	Internal					
			OCGA contract	Gift					
			Other funding mechanism – specify:						
Funding Status			Awarded	Pending					
			Name of Sponsor						
Other project Identifiers			UCSD OCGA proposal number	Sponsor's ID (e.g., NIH grant Nr)					
			Clinical Trial Agreement number	Investigator-initiated or RA number					
			Other project identifier						
Fiscal Contact			Last Name	First Name	Department				
			E-mail	Phone	Fax				

Section 7: OTHER PERSONS ASSOCIATED WITH THIS PROJECT					
Role	Last name	First name	Degree	Department	Institution
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Other role:					
Other role:					
Other role:					

**Section 8: SIGNATURES**

By signing below, you certify that the information provided about this study is accurate to the best of your knowledge, that you and the key personnel associated with the study have completed the appropriate CITI training, that you have adequate resources to protect rights and welfare of participants, and that you agree to conduct the study in compliance with applicable UCSD and Rady Children's Hospital – San Diego policies as well as local, state, and federal regulations.

Principal Investigator		Date:	
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By signing below, you provide assurance that the PI's qualifications are appropriate for this study and that adequate resources are available to ensure protection of rights and welfare of study participants.

Department Chair		Date:	
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