

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 **Save** button on the last page to save the form 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

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

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

*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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