

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 plug-in).
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 website in Word format.
5. The Principal Investigator and Department Chair must sign where indicated on the last page of the Facesheets.
6. Mail one copy of the **signed Facesheets** to HRPP Office, mail code 0052, unless it can be provided as an uploaded document 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		RCHSD		Non-UCSD/RCHSD	
		Projected number of participants to be enrolled for entire project at			UCSD		RCHSD		Non-UCSD/RCHSD	
		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								
		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, gene transfer, and/or DURC agents (for more information, contact EH&S)								
		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									
		Involves Significant Risk Device									
		Involves FDA Investigational Device Exemption(s), 510(k) or FDA Category B device									
		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				
			Dept. of Health & Human Services	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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If you are filling out this form online:

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