

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, or for VA projects, the Service Chief, 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*

*For sponsored projects include sponsor's project identifier and version number. For VA merit grants, title must match the grant title

Section 2: KEY PERSONNEL

Principal Investigator	Last name		First Name		Degree	
	Title		Department		Mail code	
	E-mail		Phone		Fax	
	Principal Investigator is salaried UCSD or VASD 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 accrual								
		Number of participants accrued thus far at:	UCSD		VASD		RCHSD		Non-UCSD/VASD/RCHSD	
		Total projected accrual for entire project at:	UCSD		VASD		RCHSD		Non-UCSD/VASD/RCHSD	
Yes	No									
		Will recruit participants under age 18 (Note: if study being done at VA facilities, must have VACO waiver)								
		Will recruit women of child-bearing potential								
		Will recruit pregnant women and/or involve human fetus or fetal tissue								
		Will recruit cognitively impaired individuals								
		Will recruit prisoners/incarcerated individuals								
		Will recruit non-English speaking individuals								
		Will recruit patients with cancer or at high risk of developing cancer during the study								
		Plan to bill under SB37/NCD (cancer studies only)								
		Involves VA resources/services such as medical records, funds, staff, patients	If Yes , provide R&D APP number							
		Involves gene therapy, recombinant DNA and/or gene transfer	If Yes , provide BUA number							
		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 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								
		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)								
Yes	No									
		Involves FDA Investigational New Drug Application(s)								
		PI holds or plans to hold IND(s)								
		If Yes to either question, enter the following:								
		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:			
		Project will use VASD Investigational Drug 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 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)							
		VA San Diego Healthcare System hospital or clinics							
		Rady Children's Hospital - San Diego hospital or clinics							
		Other: Describe facilities here:							

Section 6: FUNDING

Funding Source (check all that apply)	Unfunded	Commercial sponsor	Departmental or ORU funding
	HHS	VMRF administered	Academic Senate
	NSF	VA funded	Not for profit foundation
	DoD	Other funding source – specify:	
Funding Mechanism	Grant	Clinical Trial Agreement (CTA)	Gift
	Contract	OCGA Research Agreement (RA)	
	Internal	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)	
	SOM Clinical Trial agreement number	Investigator-initiated or RA number	
	VA PDS 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					
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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, and that you agree to conduct the study in compliance with applicable UCSD, VASD, and Rady Children’s Hospital – San Diego policies as well as state and federal regulations.

Principal Investigator		Date:	
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By signing below, you provide assurance regarding the PI’s qualifications and adequacy of resources to ensure protection of rights and welfare of study participants.

Department Chair		Date:	
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By signing below, you provide assurance regarding the PI’s qualifications and adequacy of resources to ensure protection of rights and welfare of study participants.

Service Chief (for VA projects)		Date:	
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