UCSD Human Research Protections Program
SCRO / 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. Ensure the title matches the title used on the ESCRO Project Standard Application for Review previously submitted. 3. Click the **Print button** on the last page to make a copy for signatures. 4. You will then need to log into your "My Protocols at a Glance" through eIRB services. Click on the link for the appropriate project number 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.

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 ☐ No ☐					
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**, the 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**		
☐	☐	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)		

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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 General Clinical Research Center (GCRC)
☐	☐	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	

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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					
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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, 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:	

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:	

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:	

If you are filling out this form online:

- **Click the Print button** to make copies for signatures and for your records.

Click Here to Print