

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

This form can be used for paper-based submissions to the IRB and also for electronic submissions.  
Please follow the instructions that apply to your submission type:

Instructions for submitting on paper	Instructions for submitting electronically
<ol style="list-style-type: none"> <li>1. Complete all pages of this form. Use Acrobat Reader to fill in this form (preferred) or print or type legibly.</li> <li>2. The Principal Investigator, Department Chair and for VA projects, the Service Chief, must sign where indicated on the last page.</li> <li>3. Attach these facesheets to the completed <b>Research Plan</b>, consents, and other documents associated with the project. Submit <b>2 printed copies</b> of all materials to the UCSD HRPP office, mail code 0052. The template for the Research Plan can be downloaded from <a href="http://irb.ucsd.edu">http://irb.ucsd.edu</a> in MS Word format.</li> <li>4. For sponsored clinical trials, include two copies of the Master Protocol and Investigator's Brochure.</li> </ol>	<ol style="list-style-type: none"> <li>1. Complete all pages of this form. <b>To do this, open the form using your Web Browser</b> to fill in the form (requires Acrobat Reader or plug-in).</li> <li>2. Click the <b>Print button</b> on the last page to make a copy for signatures.</li> <li>3. Click the <b>Submit button</b> on the last page to submit the data from the facesheets to the HRPP office via the Internet.</li> <li>4. The Principal Investigator, Department Chair and for VA projects, the Service Chief, must sign where indicated on the last page.</li> <li>5. Mail one copy of the <b>signed facesheets</b> to UCSD HRPP Office, mail code 0052.</li> <li>6. Upload the accompanying <b>Research Plan</b>, consents and other documents on the <a href="http://irb.ucsd.edu">http://irb.ucsd.edu</a> website. The template for the Research Plan is available on the website in Word format.</li> </ol>

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 <b>renewal of a previous project</b> .
		If <b>Yes</b> : The IRB number for the <b>previous project</b> is _____ and the <b>participant accrual to date</b> at this site is _____
<b>Total projected participant accrual</b> for the entire project: _____		
Yes	No	
		Will recruit participants <b>under age 18</b> (Note: if study being done at VA facilities, must have VACO waiver)
		Will recruit <b>women of child-bearing potential</b>
		Will recruit <b>pregnant women and/or involve human fetus or fetal tissue</b>
		Will recruit <b>cognitively impaired individuals</b>
		Will recruit <b>prisoners</b>
		Will recruit patients with <b>cancer</b>
		Plan to <b>bill under SB37/NCD (cancer studies only)</b>
		Involves <b>VA resources, services including medical records, funds, staff, and/or patients</b>
		Involves <b>gene therapy, recombinant DNA and/or gene transfer</b>
		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>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>
		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>								
Yes	No									
		Involves <b>FDA Investigational New Drug Application(s)</b>								
		<b>PI holds or plans to hold IND(s)</b>								
		<b>If Yes to either question, enter the following:</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>FDA Investigational Device Exemption(s), 510(k)</b> or <b>FDA Category B device</b>								
		<b>If Yes, enter 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 <b>FDA</b> number(s):	1. 2. 3.				
Yes	No									
		Study participants will be exposed to <b>Radiation or Radioactivity that are research-related</b>								
		If <b>Yes</b> , enter the following about the sources of radiation:	<b>Radiographic X-ray</b>	Yes		No				
			<b>Fluoroscopy</b>	Yes		No				
			<b>DEXA (Bone Density)</b>	Yes		No				
			<b>Computed Tomography (CT)</b>	Yes		No				
			<b>Positron Emission Tomography (PET)</b>	Yes		No				
			<b>Nuclear Med. (radionuclide) injections</b>	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 of radiation or radioactivity</b>	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 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									
<b>Funding Source</b> (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:					
<b>Funding Mechanism</b>		Grant		Clinical Trial Agreement (CTA)		Gift			
		Contract		OCGA Research Agreement (RA)					
		Internal		Other funding mechanism – specify:					
<b>Funding Status</b>		Awarded		Pending					
<b>Sponsor Name</b>									
<b>Other project Identifiers</b>		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					
<b>Fiscal Contact</b>		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					
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:					
Other role:					

Section 8: Signatures			
Principal Investigator		Date:	
Department Chair		Date:	
Service Chief (for VA projects)		Date:	

**If you are filling out this form online:**

- **Click the Submit button** to submit the data from the application to the HRPP office via your web browser; you will receive an acknowledgement page back with your assigned Temporary project identifier (your “T-number”). Print the page containing your T-number as a receipt. You will enter that number to upload any accompanying documents, such as the Project Plan, consents, etc. When the HRPP Office accepts your application, you will receive a standard IRB project number to replace the T-number, and can use the IRB project number for all future references and online services related to this project.
  
- **Click the Print button** to make copies for signatures and for your records