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 **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 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 ☐ 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**: 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	

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)

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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	

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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					
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:	

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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Click Here to Print **Click Here to Submit Data via Web**