

## UCSD Human Research Protections Program Exempt Status 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 completed, appropriate Research Plan (Research Plan for Categories 1, 2, and 3 or Research Plan for Category 4).
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\*

\*For sponsored projects include sponsor's project identifier and version 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"/>					
Faculty Advisor (if needed)	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> : Previous IRB project number is	
		Number of participants enrolled/records reviewed thus far at ( <i>should be "0" in not renewal</i> )			UCSD	
					RCHSD	
		Projected number of participants enrolled/records to be reviewed for <b>entire project</b> at			UCSD	
		RCHSD		Non-UCSD/RCHSD		
Yes	No	Requesting <b>Exempt Status Review</b> (If no, not eligible for Exempt Status Review)				
		Involves <b>prisoners</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>pregnant women and/or involve human fetus or fetal tissue</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>in vitro fertilization</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>deception</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>potentially cognitively impaired individuals</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>use of school records of identifiable students or interviewing instructors about specific students</b> ((if yes, not eligible for Exempt Status Review)				
		Involves <b>survey or interview procedures with children participants under age 18</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>observation of public behavior when the investigator(s) participate(s) in the activities being observed</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>data collected that includes protected health information or medical information when there is a direct or indirect line that would identify the participant</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>disclosure of sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol</b> (if yes, not eligible for Exempt Status Review)				
		Involves <b>human embryonic stem cells, iPS cells, and/or other pluripotent cells</b> (If yes, not eligible for Exempt Status Review)				
		Involves <b>DNA genotyping or other form of genetic analysis</b> (If yes, not eligible for Exempt Status Review)				
		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 individual HIPAA authorization</b> (i.e., the research will be done without seeking the authorization of persons whose protected health information are analyzed)				

Section 4: 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 5: FUNDING			
Funding Source (check all that apply)	<input type="checkbox"/>	Unfunded	Commercial sponsor – Sponsor initiated
	<input type="checkbox"/>	Dept. of Health & Human Services	Commercial sponsor – PI initiated
	<input type="checkbox"/>	National Science Foundation	Academic Senate
	<input type="checkbox"/>	Department of Defense	Other funding source – specify:
Funding Mechanism	<input type="checkbox"/>	OCTA contract	Internal
	<input type="checkbox"/>	OCGA contract	Gift
	<input type="checkbox"/>	Other funding mechanism – specify:	
Funding Status	<input type="checkbox"/>	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		

Section 6: OTHER PERSONS ASSOCIATED WITH THIS PROJECT					
Role	Last name	First name	Degree	Department	Institution
Co-Investigator					
Co-Investigator					
Co-Investigator					

**Section 7: 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:**

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