# iStar User Reference Guide

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# **Questions and Issues**

For policies related questions and issues including how to fill out the application, please contact the respective committee for the application:

#### CHLA

Institutional Review Board, (323) 361-2265 Biosafety Office, (323) 361-6629

USC

Institutional Review Board, (323) 442-0114 Institutional Animal Care and Use Committee, (323) 442-1689 Environmental Health & Safety Office, (323) 442-2200

For technical related questions and issues, please contact: **iStar Technical Support**, (323) 276-2238 Email: <u>istar@usc.edu</u>

# **Getting Started**

#### Dashboard

After logging into the iStar system, you will be redirected to your **Dashboard**. If you have used iStar prior to 2018, this page replaces what used to be **My Home**. Often times, this page is also referred to as your **Inbox**.

Southern California		iSt	ar Develoj	pment			He	ello, <b>John</b>	Doe 🕶
» Da	shboard IR	В	IACUC	IBC	RSC	:	Home		
Pl and Staff My User Roles IACUC Pl & Staff Pl & Staff New IRB Study New Study	application for considerat Use the New Stud Remember that al Use the Continue	nal Folder, the cen on by the IRB/CCI. y button on the left questions marked	trai resource for managing your S Use the following guidelines to su to open the smart form application with a red asterisk are required, and move to the next screen in the	ubmit your Study: n for a new study proposal.	sonal Folder provides all the to	ools you need in Reports	order to complete and submit a Stu	dy	
Does my projec require IRB review? (USC	ID	dy Applications, Ar Name	nendments, Continuing Reports, a	and Reportable Events white	wner	State	ick on the item name for more info	rmation.	
Only)	APPL-16-00167	test 2			dministrator, System	Pre Submissi			
Obtain a Determina	APPL-16-00165	test			dministrator, System	Pre Submissie Pre Submissie			
	3 items	Need Conta € (32) Sista		Quick Links:     CHLA Institution USC Health Sci USC University	of 1 → hal Review Board   ᢏ (323) 9 ences Institutional Review Bo Park Institutional Review Bo Park Institutional Review Bo al Animal Care and Use Comm	61-2265 ard   ᢏ (323) 22 rd   ᢏ (213) 821	10 23-2340 1-5272	/ page	

Dashboard for PI & Staff role

The left hand side contains all the **User Roles** you have been assigned. By default, everyone is assigned the **PI & Staff** role to submit Human Subjects studies, BioSafety applications and Radiation Safety applications. If you indicated during the initial account registration that you also submit Animal protocols, you should also see the **IACUC PI & Staff** role. The tabs available to you under the red banner is also based on the user roles that you have for your account.

USCUniversity Southern Califo	of Children's for the children's contract of the	iS <sup>°</sup>	tar Develop	oment		н	ello, John	Doe 🔻
»	Dashboard	IRB	IACUC	IBC	RSC	Home		
My User F	loles	Page for Jo						
IACUC PI & Staff PI & Staff IACUC New Anima IBC		Welcome to your Personal Folder. Your Personal Folder provides all the tools you need in order to complete and submit an animal protocol to the IACUC, a biohazardous use application to the RSC. Use the following guidelines to submit your protocol/application: <ul> <li>Remember that all questions marked with a red asterisk are required.</li> <li>Use the Continue &gt;&gt; button to save and move to the rext screen in the application.</li> </ul> IACUCC PI Reference Guide   Submission Deadlines   FAQs IBC Reference Guide   Submission Deadlines   FAQs						
New Biohaz	ardous Use Application		ns related to IACUC, please contact			0.		
RSC			e contact the iStar Technical Support					
New Radioa	active Use Application	My Inbox Pre	Submission IACUC Pro	tocols IBC BUAs	RSC RUAs			

Dashboard for IACUC PI & Staff role

Applications for the various committees are referred to differently.

- IRB applications are Studies
- IACUC applications are Protocols
- BioSafety applications are Biohazardous Use Applications (BUAs)
- Radiation Safety applications are Radioactive Use Applications (RUAs)

By default, **My Inbox** displays all the applications in which you are a part of and requires action. New applications can be created via the respective button the on the left hand side under **My User Roles**.

**IMPORTANT NOTE:** If you need to submit Animal protocols and do not see the **IACUC PI & Staff** role in your Dashboard or the **IACUC** tab under the red banner, please contact the iStar Help Desk so we can add that user role for you.

#### **New Applications**

To create a new application, you can either go to the corresponding committee tab under the red banner or in your Inbox. From there, click on the button on the left hand navigation for a new application.

New IRB Study	
New Study	

Button to create a New Study

After you click the "New Study" button, you will be automatically redirected to the first page of the form. From there, you can navigate the different sections of the application using the controls found on the left-hand navigation. Clicking on the respective section name would take you directly to that section.

**IMPORTANT NOTE:** When you first go to this page, only the first page would appear. After you save the application, required sections would automatically appear on the left-hand navigation menu. It is advised that you complete the application in order since the application show questions/sections based on what was answered in earlier questions/sections.

USC University of Children's Southern California	∞ £ iStar	Hello, Johnson Kw	rong <del>v</del>
≡ «	Creating New Study	Go to forms menu	@ Help
01. Project Identification and Abstract	1. Project Identification and Abstract 1.1. "Type of Submission:		
	O Research Protocol or Study on Human Subjects		
	O Grant/Contract Only		
	O Use of Humanitarian Use Device (Not Research)		
	Rety on another IRB (Ceded)     Clean		
	1.2. * Full Title of Research Protocol		
	1.3. * Short Title		
	14. Abstract Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectipurpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; folloplans for analysis.	ves or w-up; statistics and	
	1.5. Select which IRB you are requesting review from:		
	O USC - Health Sciences IRB (HSIRB)		
	O USC - University Park IRB (UPIRB)		
	O CHLA - Institutional Review Board (CHLA)		
	Clear  1.4. To be investigator's knowledge, does the institution have financial and/or intellectual property interests in the sponsor or the products used in this pro An institutional conflict may occur when a financial interest of the institution has the potential to bias the outcome of research conducted by its employees or student unacceptable risk to human subjects.  Yes No Clear		
	😒 Exit 🛛 🖬 Save	Continue	€

Page 1 of the Formset for Study

#### Main Committee Page

When you click on the committee page under the red banner, all the applications that you are a part of in the personnel section would be displayed.

USCU South	University of Children's ern California Hospitol		IRB De	velopn	nent			Hello, <b>Joh</b> r	n Doe 🔻
	Dashboard	IRB	IACUC		IBC	RSC	Home		
	Amendments	Continuing Reviews	Reportable Events	NHSR					
An	D Pages				portable Events, and Em	rgency Use, please use the left hand	navisation menu.		
Re	portable Events	For Policy-Related questions, p				,			
NH	ISR	<ul> <li>USC University Park IRB (2</li> <li>USC Health Sciences IRB (</li> <li>CHLA IRB (323) 361-2265</li> </ul>							
Cre	ate Study	For Technical issues, please co	ntact the iStar Technical Sup	port at (323) 276-223	3.				
Doe	lew Study	Active Studies In	Progress Approv		t Archived	Suspended All Studie	5		
	uire IRB iew? (USC	ID Name	- Last State Change	IRBA	State	Review Type App	roval Date Expiration Date	PI	
onl		APP-17-06326 Test	12/6/2017 10:19 AM	Administrator	Pre Submission	Full Committee Review		Doe	
[ c	Obtain a Determination	1 items			e page 1 of 1	>	10	/ page	
		Filters can	be added to lo	ok for spec	ific applicatio	ns			
			Need Help? Contact the IStar Tech (323) 276-2238 Sistar@usc.edu Copyright © 2017 University of		USC Health Science USC University Parl	eview Board   \ (323) 361-2265 es Institutional Review Board   \ (323) imal Care and Use Committee   \ (32 imal Care and Use Committee   \ (32	821-5272		

IRB tab for Protocols

To search for a specific application, you use **Filters**. Additional filters can be added by using the **Add Filter** link to make the search more specific. Filters can be deleted by clicking on the "x" next to the search box of the respective filter.

Active Studies	In P	Progress	Approved	Exempt	Archived	Suspended	All Studies		
Filter 😨 ID		Enter tex	t to search for	Go	+ Add Filter X CI	ear All			
10	Humo	- Lust otate o	mange	INPA	otate	neview Type	Approval Dat	te Expiration Date	PI
APP-17-06326	Test	12/6/2017 10:1	9 AM	Administrator	Pre Submission	Full Committee Revie	w		Doe
1 items					øpage 1	of 1 🕨		10	/ page

Filter Bar for Studies

#### Main Workspace page

After you created an application, you can view the main workspace of the application when you click on the application name or ID.

<mark>USC</mark> Un Souther	niversity of n California		IACU	JC Development			Не	llo, <b>Johnson Kw</b>
	» Da	ishboard	IRB	IACUC	IBC	RSC	Committees	•••
	Amendments	Renewals	Monitoring Reports	Non Compliance Reports				
-Le	eft-Hand-Navi			Main	Sontent			
Curr	rent State Pre Submission	Johnson	Protocol Testing 1				Protocol APPL-12-0	0001
	Edit Protocol Printer Friendly Version	Principal In Submissio	n Type:	Johnson Kwong New Protocol	Study Contact:			
Acti	ivities	Project Ty Species:	06:	Research Mouse				
Su lacuc	Forward ubmit Protocol c and IACUC Message	Not Review	ved by IBC Not Reviewed b	y RSC				
Manag Ø <sup>©</sup> Ad		History		inge Log Researchers Site Admir	-			
<u>പ്ര</u> Co	opy IACUC Protocol	Filter by			d Filter X Clear All			
Generation Co	ral onflict of Interest Review	o;	Activity Admin	Author Koning-Bastiaan, Ma	rtin	<ul> <li>Activity Date</li> <li>7/24/2013 8:43 AM</li> </ul>		
⊠ Se	and Message to Investiga	tors OS	Admin	Kwong, Johnson		4/5/2013 12:27 PM		
⊠ Se	and Message to IACUC	O <sup>0</sup>	Admin	Kwong, Johnson		2/26/2013 9:33 AM		
	ithdraw	0 0	Protocol Submitted Protocol Created	Kwong, Johnson Kwong, Johnson		12/18/2012 11:21 A 12/17/2012 9:58 A		

Main Workspace for IACUC Protocol

Within the main workspace, you can view the **Current State** of the application on the upper left hand side. The left hand side also contains all the buttons and activities that are available to you based on the state of the application.

If the application is still in a state where you can edit the application, you can edit the application by clicking on the Edit button under the Current State. Otherwise, the button will enable you to view the application in a read-only format. **Printer Friendly Version** will print the entire application into one page.

The right side contains the **Main Content**. The application title appears towards the middle of the page and the application ID is contained in the yellow box to right of the application title. A summary box is displayed right below. Depending on the application, there are different tabs that are displayed under the summary box. However, the **History** and **Documents** tabs always appear for all applications.

# **Edit/View Application Formset**

To navigate between the different sections of the application can be done by selecting their respective names on the left-hand navigation.

USCUniversity of Southern California	iStar Development Has	o, Johnson Kwong <del>-</del>
U4lidate	Editing: APP-19-00028 4Go to forms menu	🖶 Print 🔻 🕜 Help
Identification and Abstract	1. Project Identification and Abstract	
02. Study Personnel	1.1. Type of Submission:      Research Protocol or Study on Human Subjects	
04. Funding Information	O Use of Humanitarian Use Device (Not Research)	
05. Type of Study	Rely on another IRB (Ceded)     Clear	
Review	1.2. * Full Title of Research Protocol	
06. Study Location(s)	test2	
09. Methods and Procedures -	1.3. Short Title	
Selected Descriptors	tesi2	
10. Characteristics of the Study Subject Population	1.4. Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention: objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; plans for analysis.	statistics and
11. Research Objectives and Background	test	
12. Methods and Procedures - Prospective Studies		
13. Methods and Procedures -	1.5. * Select which IRB you are requesting review from:	
Retrospective Studies/Existing	USC - Health Sciences IRB (HSIRB)	
Data	O USC - University Park IRB (UPIRB)	
22. Special Subject Populations	CHLA - Institutional Review Board (CHLA)     Clear	
22b. Special Subject Populations - Employees/Students	1.6. *To the investigator's knowledge, does the institution have financial and/or intellectual property interests in the sponsor or the products used in this project? An institutional conflict may occur when a financial interest of the institution has the potential to bias the outcome of research conducted by its employees or students or to unacceptable risk to human subjects.	
23. Study Resources	_	
24. Subject Recruitment and	Save	Continue 🔿

Page 1 of Edit Study

The lower right corner contains the "Exit", "Save" and "Continue" button. Anytime "Continue" is clicked, it also saves the application.

#### Validate

To view whether or not any required fields are not filled out, there is the **Validate** tab under the red banner on the upper left corner.

Southern California Children's Ch	Star Development
Error/Warning Messages (35)	Editing: APP-19-00028 1. Project Identification and Abstract
01. Project 🔷	1.1. * Type of Submission:
22. Study Personnel     MISSING RECUIRED FIELD - 2.4. Does this study require Cancer Center Committee (Ci) approval?     MISSING RECUIRED FIELD - 2.2. Is the Principal Investigator a student, resident, or withing scholar?     MISSING RECUIRED FIELD - 2.1. Principal Investigator (PI), You must designate on person as the Principal Investigator (PI). You must service with its udy for locatific Internet.	Clear
	· · · · ·

Validate tab

If there are any validation errors, there is shortcut to just go to the question by clicking on the section header in which the error message(s) appears directly beneath.

An application can only be submitted when all the validation issues are fixed.

Southern California Children's Lac-tuse	Star Development Hello, Johnson Kwong -
Error/Warning Messages (35)	Editing: APP-19-00028 (Go to forms menu 🖨 Print 👻 🕑 Help
01. Project 🖌 🗸	I. Project identification and Abstract  I.1. *Type of Submission:  Research Protocol or Study on Human Subjects
O2. Study Personnel     MiSSING REQUIRED FIELD - 2.4. Does this study require Cancer Center Committee (CIC) approval?     MiSSING REQUIRED FIELD - 2.2. Is the Principal Investigator a student, resident, or visiting scholar?     MiSSING REQUIRED FIELD - 2.1. Principal Investigator (PI). You must designate one person as the Principal Investigator.     MiSSING REQUIRED FIELD - 2.5. Specify the grouplorganization who has reviewed this study for scientific ment	Use of Humanitarian Use Device (Not Research) Rely on another IRB (Ceded) Clear  1.2. * Full Title of Research Protocol test2
04. Funding Information 05. Type of Study Review	1.3. * Short Title      test2        A. Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale;     intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if     appropriate); study endpoints or outcome; followus; ratiatistics and plane for analysis.
06. Study Location(s) • MISSING REQUIRED FIELD - 6.1 Indicate the locations where this study will be conducted by the USC/CHLA Investigator(s) (check all that apply): • MISSING REQUIRED FIELD - 6.3. Which site is the coordinating site? 09. Methods and	tost
Procedures - Selected Descriptors 10. Characteristics of the Study Subject Population MISSING REQUIRED FIELD - 10.3. Indicate the exclusion criteria for enrollment. MISSING REQUIRED FIELD - 10.2. Indicate the inclusion criteria for enrollment. MISSING REQUIRED FIELD - 10.1. What is the maximum number of subject you plan to recruit for this site? 11. Research Objectives and	Select which IRB you are requesting review from:     USC - Health Sciences IRB (HSIRB)     USC - University Park IRB (UPIRB)     USC - University Park IRB (UPIRB)     CHLA - Institutional Review Board (CHLA)     Clear      Select in this project?     An institutional conflict may occur when a financial interest of the institution has the potential to bias the outcome of research conducted by its     employees or students to for cerete an unacceptable risk to human subjects.     Yes ● No Clear
Background     MISSING REQUIRED FIELD - 11.2. Provide a summary of the background     of the study, and explain how this research will contribute to existing	Save Continue

Error/Warning Messages Section when validating a Study

### **The History Log**

The **History** tab contains all the activities that were executed in the application and includes the person responsible and the time of execution. Reviews that were submitted are displayed, as well as attachments uploaded. A filter bar is available for searching.

History	Documents	Change Log	Researchers	
Filter 🕜	Activity	Enter text to search f	or Go	► Add Filter 🗰 Clear All
	Activity		Author	→ Activity Date
0	Protocol Created		Doe, John	2/24/2016 11:39 AM

History Log of an IACUC Protocol