SP SP SLCC Office of Sponsored Projects User Guide

Regulatory Compliance

The **Regulatory Compliance** section helps ensure Lead-PIs and their research team have taken the proper steps regarding research on human subjects and the SLCC Institutional Review Board process, and the use of hazardous material in research and SLCC's Environmental Health and Safety Office process.

The Institutional Review Board (IRB) at Salt Lake Community College ensures research conducted at the College remains in compliance with federal guidelines that protect research participants and their personal data and information. The IRB is responsible for human subjects protocol training, the SLCC IRB application process, and IRB determinations.

Lead-PIs and their research team are responsible for following the protocols and processes outlined by the SLCC IRB as well as the instructions outlined in the solicitation regarding human subjects research.

SLCC's Environmental Health and Safety Office provides expertise and advice for compliance with federal, state and local health regulations, as well as current professional practices and guidelines. The office aims to prevent injury, illnesses, and environmental damage through the recognition, evaluation, and control of potential hazards arising from college activities. The office is responsible for compliance with regulations and training in appropriate safety measures.

Lead-PIs and their research team are responsible for contacting SLCC's Environmental Health and Safety Office if their projects will include the use of hazardous materials and following protocols and processes outlined by the office as well as the solicitation.

OSP maintains Regulatory Compliance assurances and determinations regarding sponsored projects in Cayuse SP, providing reasonable infrastructure to ensure the College, its researchers and participants have followed proper protocols, regulations and applicable laws.

This section of Cayuse SP directs the Lead-PI and the project team regarding (1) research on human subjects and the SLCC Institutional Review Board process, and (2) the use of hazardous material research and SLCC's Environmental Health and Safety Office process.

Instructions for Regulatory Compliance Section

Click the **Regulatory Compliance** section from the Proposal Development Menu and begin by reading the instructions at the top of this section.

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N	y Dashboard Report	ing More
lte	m List 20-0067 😤	>> Regulatory Compliance
View	w or Edit completed sections by clicking name next to the check.	Determine if project includes research on Human Subjects. Generally, research activities using and distributing information gathered from human participants require Institutional Review Board (IRB) review.
1	Investigators/Project Team	Does your project involve:
~	Community Benefits/ Strategic Alignment	A. Systematic investigation, testing or evaluation designed to develop or contribute to generalizable knowledge? B. Obtaining data through intervention or interaction with living individuals and/or collecting identifiable private information?
1	Subcontractors/Subawards	If yes to both, indicate in Human Subjects section below, submit request to IRB and update review status. Otherwise, select No.
	Budget	Refer to SLCC's IRB website for additional information and review process
1	Conflict of Interest	If this proposal includes use of hazardous materials indicate below and contact SLCC's Environmental Health & Safety
<	Regulatory Compliance >>	Questions? Please contact the Grant Officer assigned to your area or the Office of Sponsored Projects.
	Intellectual Property	Indiante Deviced Fields
	<u>Activities</u>	Human Subjects
	Proposal Abstract	* Does the prepaged work involve received on WIMAN SUB IECTS as defined above?
	Proposal Attachments	O Yes O No
	Approving Units	
	Submission Notes	Other Research Materials

Human Subjects

Determine if this sponsored project proposal includes research on human subjects. Generally, research activities using and distributing information gathered from human participants requires IRB review.

Federal regulations mandate IRB review of all research involving human subjects. The following are key points to keep in mind about the information and responsibilities prompted by this section:

- SLCC's IRB must review all research involving human subjects.
- If you have any question or doubts, then please contact the Grant Officer assigned to your area or the Office of Sponsored Projects.
- Refer to SLCC's IRB website for additional information: <u>https://i.slcc.edu/ir/irb.aspx</u>
- Request IRB review <u>early</u> in the proposal development process to ensure time to meet submission requirements.
- Follow the solicitation guidelines for required documentation regarding human subjects and SLCC IRB review.

To answer the Human Subjects question(s), first determine if this project involves the following:

- Systematic investigation, testing or evaluation designed to develop or contribute to generalizable knowledge.
- Obtaining data through intervention or interaction with <u>living</u> individuals and/or collecting identifiable private information.

If the work proposed involves the items listed in the bullets above, then answer 'Yes' to the question. Otherwise, select 'No' and move onto the Other Research Materials section.



If you answered 'Yes" to the human subjects question above, the system will prompt you to indicate whether you have submitted an application for IRB review.

* Indicates Required Fields
Human Subjects
* Does the proposed work involve research on HUMAN SUBJECTS as defined above? • Yes • No
* Have you submitted an application for IRB review?

If an application has been submitted for IRB Review, then select 'Yes.' A field box will appear requesting the number on the IRB decision letter. Type the number in the field. If the number is not yet available, type the word "Pending."

* Indicates Required Fields
Human Subjects
 * Does the proposed work involve research on HUMAN SUBJECTS as defined above? Yes No * Have you submitted an application for IRB review? Yes No
* Please provide the human subject information below:
List the number on the IRB decision letter or write "Pending". (Note: Use commas to separate values)

If an application for IRB Review has not been submitted, then select 'No' and acknowledge the only acceptable reason for not submitting an IRB application at this time.

Human Subjects		
 Does the proposed work involve research on HUMAN SUBJECTS as defined above? Yes No Have you submitted an application for IRB review? Yes No 		
* Please indicate your reason for not submitting an IRB application:		
Not required at proposal submission (JIT information to be provided at sponsor request after review of proposal)		

Selecting this option indicates that (1) IRB review is not required by the sponsor prior to or at the time of proposal submission, and (2) confirms that the Lead-PI will request IRB review when

notified by the sponsor. The solicitation will indicate if this is an acceptable option for IRB review.

JIT is an acronym for "Just in Time Information," a term often used by sponsors such as the National Institutes of Health, for grants involving human subjects.

Other Research Materials

Determine if this sponsored project proposal involves the use of hazardous materials.

If the proposal includes the use of hazardous materials, select the applicable item(s) from the list and contact SLCC's Environmental Health and Safety Office for guidance at: <u>https://i.slcc.edu/facilities/departments/ehs.aspx/</u>

If none of the items listed apply to this project, select 'None of the above.'



Save Regulatory Compliance Section in Cayuse SP

Once all appropriate questions have been answered by the Lead-PI in the Regulatory Compliance Section of Cayuse SP, make sure to click Save at the bottom of the page before continuing to the next section.

This section is editable until the project is routed for internal approvals. If the answers need to be erased and re-answered for any reason, then click the reset button at the bottom of the page.

Complete all required fields marked with a red asterisk * before clicking Save.



Next Step

Navigating and completing the **Intellectual Property** section. For more information, see <u>Cayuse SP</u> - <u>User Guide: Intellectual Property</u>.