**CSB/SJU IRB Course Approval Application**

Submit your completed application to the IRB Chair at irb@csbsju.edu

Name of Course Instructor:

Department:

Course Name, Number and Section:

Semester/Year:

Provide a description of the research theme(s) of the course including the types of research projects, and typical research tools used (e.g., surveys, interviews, experiments, exercise tests, blood tests, etc.). Include as much information as possible regarding the populations to be studied, recruitment, compensation, and how the data will be kept confidential.

**Research themes:**

**Research tools:**

**Populations:**

**Recruitment:**

**Compensation:**

**Data Confidentiality:**

**Ethics Training:**

All students must complete the CITI online research ethics training course for research involving no more than minimal risk. Students should submit their Completion Reports to the faculty member, who will save them with other documents relevant to the class projects. Students may not begin data collection or recruitment of participants for their project until their Completion Reports have been submitted. Instructions for accessing the ethics training are available on the [IRB website](https://www.csbsju.edu/institutional-review-board) and also from the IRB Chair.

In addition, course time must be allotted to discuss the elements of informed consent, ethical research practices, the role of the IRB, etc.

**Please describe the ethics training students will receive in this course in addition to the online CITI training:**

**Collection of Potentially Biohazardous Samples**

If the research involves collecting potentially biohazardous samples (e.g., biological fluids such as blood), proper training for handling of biohazardous materials must be included in the course or completed via online training and proof of competency obtained for each student working with the samples. Biohazardous materials, or "biohazards", are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals, or the environment.

Students must also have completed the Hepatitis B vaccination series

\_\_\_\_\_\_ Place a check here if research in this course may involve collecting potentially

 biohazardous samples

**Instructor Certification Statement**

By electronically signing below, I certify/agree to the following:

I am aware of and agree to policies and procedures that ensure student research will be conducted according to the IRB & federal guidelines protecting human participants. I further stipulate that both my teaching assistants and I will:

* complete the on-line training course,
* discuss important aspects of human research protection, such as maintaining confidentiality and minimizing risk,
* supervise students on all phases of their research to ensure compliance with CSB/SJU IRB policies and procedures,
* ensure that informed consent is obtained from all participants and that signed informed consent forms (when required) will be kept on file for documentation,
* report any problems occurring during any of the research projects to the IRB Chair immediately, and
* meet with students periodically and discuss their progress to ensure that projects are conducted in accordance with the IRB’s requirements.

I acknowledge that, as the Instructor, I am accountable for the design, conduct, and oversight of all projects undertaken by students in the class. I will submit an end-of-semester report to the IRB Chair within two weeks following the semester and keep copies of all student research project descriptions and informed consent forms on file.

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Course Instructor’s Signature (type your name to sign electronically) Date

**Before research projects can be initiated, approval for each project must be obtained from the Chair of the IRB.**

A project description and the informed consent form for each student research project must be submitted to the IRB Chair before any data collection or subject recruitment can begin.

* The project description should include the following:
* who the participants will be and how they will be recruited
* the procedures to be used
* how risks will be minimized and how confidentiality of the data will be maintained
* an explanation of the debriefing process and how participants may obtain information about the study results
* Each student/team must develop and use an approved informed consent form