**IRB Initial Routing Form for New Projects**

**Applicant Information**

**Date Submitted:** Enter date

**Title:** Enter title of research project

**Applicant Name:** Enter name

**Applicant Phone:** Enter phone number

**Applicant Email:** Enter email address

**Applicant Address:** Enter mailing address

**Organization:** Enter university or organization affiliation

**Existing IRB:** Yes/No

If yes, please attach with submission.

For doctoral candidates, date dissertation committee approved project proposal: Enter date

**Study Background**

**Anticipated Start Date for Research:** Enter date

**Anticipated Duration of Research (not to exceed 12 months):** Enter number of months

**Anticipated Total Number of Human Subjects:** Enter number of human subjects

|  |
| --- |
| Check below if the majority of the human subjects will be from any of the following populations: |
| Minors (under 18)  Cognitively Impaired  Human Fetuses or Neonates  Pregnant Women  Prisoners  Students  Economically/Educationally Disadvantaged  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Data Collection**  Surveys  Interviews  Focus Groups  Observations  Document Analysis  Statistical Analysis  Other, please specify: **Specify the methodology** |

**Other organizations involved in project, if applicable:** Enter other organizations

**FSCJ Resources Requested**

|  |  |
| --- | --- |
| *Check below the college resources you are requesting for your study. The IRB Chair will notify you in advance should there be a cost associated with obtaining the resource(s).* | |
| Resource | Explain |
| Student-, Faculty-, and/or Staff-Level Data |  |
| Institutional-Level Data |  |
| Access to labs |  |
| Access to facilities/meeting space |  |
| Access to documents/public records |  |
| Other, please specify: Specify the FSCJ resources requested |  |

**Description of Research Activities**

**I. ABSTRACT:**Include a brief summary of the project.

Enter information

**III. RECRUITMENT PROCEDURES:**Describe the selection of subjects and method of recruitment including any inclusion and exclusion criteria. Attach recruitment letters, advertisements, etc.

Enter information

**VI. RISKS:**Describe the potential risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes psychological and social risk.

Enter information

**VII. CONFIDENTIALITY OF DATA:**Describe the methods to be used to ensure the confidentiality of data obtained, including plans for dissemination and publication, disposition or destruction, etc.

Enter information

**Complete the following statement by checking one box below. My research methodology is anticipated to involve**

* Quantitative methods (either mostly or completely)
* Qualitative methods (either mostly or completely)
* Mixed (quantitative and qualitative) methods

## Research Questions

List your research questions.

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Hypotheses

If your study will involve one or more statistically testable hypotheses, state each null hypothesis (H0).

Example: *For the course <specify course>, daily study hours are equal for 100% online and 100% classroom students.*

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Human Subjects

If your study will involve human subjects, provide a brief description of each distinct group.

Example: *Group 1 – FSCJ students enrolled in <specify course> in the <specify term> semester.*

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Attachments

Please attach any additional documentation (e.g., surveys, questionnaires, other data collection documents) that describes your anticipated study methodology. Briefly describe each attachment.

|  |  |
| --- | --- |
| **Filename** | **Brief Description** |
|  |  |
|  |  |
|  |  |

**Submission**

*Applicants should submit completed IRB Initial Routing Form along with necessary attachments via email to* [*IRB@fscj.edu*](mailto:IRB@fscj.edu)*. Questions about the IRB process can be addressed to* [*IRB@fscj.edu*](mailto:IRB@fscj.edu)*.*

**IRB Decision *(to be completed by IRB Chair and HSA)***

**Project Review Category**

**IRB Educational Training**

Principal Investigators (PI) of expedited or full review projects are required to complete IRB educational training before the project begins. Options for IRB educational training may be obtained from the IRB Human Subjects Administrator.

|  |
| --- |
| **PI is not required to complete IRB education training because the project is exempt.**  **PI is required to complete IRB training and has completed it on Enter date.**  **PI is required to complete IRB training and has not yet completed it.** |

**Select the project’s review category from the list below:**

**Project is “Exempt” from 45 CFR 46 Regulations[[1]](#footnote-1) because it falls into one or more of the categories below:**

1) Research conducted in educational settings involving normal educational practices.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless subjects can be identified, disclosure of subjects’ responses could place them at risk for criminal or civil liability, research involves sensitive or personal topics, or it involves survey/interview research on minors.

3) Category 2 research that is conducted on elected or appointed public officials or candidates.

4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if sources are publicly available or subjects cannot be identified.

5) Reserved for Federal Government Research. Not available for local IRB exemptions.

6) Taste and food quality evaluation and consumer acceptance studies.

**Project qualifies for “Expedited IRB Review” because it is not “exempt,” involves no more than minimal risk and falls into one or more of the categories below.**

1) Clinical studies of drugs and/or medical devices that are not investigational and are approved for marketing.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3) Prospective collection of biological specimens for research purposes by noninvasive means.

4) Collection of data through noninvasive and nonsedative procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5) Non-exempt research involving materials data, documents, records, or specimens that have been collected, or will be collected solely for non-research purposes.

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Non-exempt research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Project neither qualifies for “Exempt” nor “Expedited IRB Review.” Applicant must work with IRB Chair to submit additional information for the full committee review.

**If approved…**

**Date Research May Begin:** Enter information

**Date Research Must Conclude:** Enter information

**IRB Tracking Number:** Enter information

**Signature of IRB Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:** \_\_\_\_\_\_\_\_\_\_\_\_

1. References: Code of Federal Regulations Title 45 Public Welfare Department of Health And Human Services Part 46, Protection Of

   Human Subjects [↑](#footnote-ref-1)