|  |
| --- |
| For IRB Office Use Only: |
| Date Rec’d:  |  | Sent to Review:  |  | Date Approved/Exempted: |  |
| CR Required? |  | Expiration Date:  |  | VERSION DATE CODE: |  |

# INSTRUCTIONS: Please read all the instructions carefully. Complete all fields by typing in the boxes, and enter “N/A” when it does not apply to your project. If you have questions or are unsure how to complete a section, contact Carole Krus at ckrus@jcu.edu.

# PROTOCOL TITLE

|  |  |
| --- | --- |
| Title of Project: |  |
| IRB Log No.: | *Assigned by the IRB* | Review Category: | *Assigned by the IRB* |
| Revision No.: | *Assigned by the IRB* |  |

# PRINCIPAL INVESTIGATOR INFORMATION

|  |  |
| --- | --- |
| Principal Investigator:  |  |
| Department or Affiliation:  |  |
| Email:  |  | Phone:  |  |

**PI Status (check ONE):**

|  |  |  |  |
| --- | --- | --- | --- |
|  | JCU Faculty |  | Student, Undergraduate |
|  | JCU Staff |  | Student, Graduate |
|  | St. Mary Seminary Researcher |  | Other (explain below): |
|  |
|  |

**Student Researcher Information** (*JCU faculty/staff researchers,* ***SKIP*** *the blue boxes below)*

|  |  |
| --- | --- |
| Research Advisor: |  |
| Department.:  |  |
| Type\* of project:  |  |
| \* Examples: Honors research project, Capstone project, SURF, Independent Study, PS301/401, etc. |

**IMPORTANT NOTE to STUDENT RESEARCHERS:** When this application is complete, your research advisor must review this form and all your supporting documents. Next, they must complete **Section 16** at the end of this application. Finally, they must email this form and all supporting documents to IRB@jcu.edu from the advisor’s JCU email address. Do not submit your application to the IRB directly.

# PROJECT DATES

NOTE: Project work, including recruitment, **may** **not begin** before IRB approval or exemption.

|  |  |  |  |
| --- | --- | --- | --- |
| Anticipated starting and completion dates: |  | to |  |
| Comments? (anticipated project phases, specific timelines, deadlines, etc.:)  |
|  |

# FUNDING: Please contact the [Director of Sponsored Programs](https://www.jcu.edu/research/contact-us) with all funding questions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Will an external source (not JCU) fund this project?  | Yes: |  |   | No: |  |  |
| If yes, list the funding source or sponsor name: |  |

1. **RESEARCH STATEMENT:** Provide an abstract or summary of your project. Briefly describe your motivation, research hypothesis, and goal(s) of the study. Avoid specific or technical jargon unless explicitly defined or explained in lay terms. Maximum 500 words**.**

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1. **RESEARCH RESULTS:** What will you do with the results of the study? (e.g., publish, present publicly, share the data with collaborators or sponsors, write a thesis or capstone, etc.)
**NOTE:** If you will NOT share the results of this project outside a classroom, please contact the [IRB Administrator](https://www.jcu.edu/research/contact-us) BEFORE completing this form.

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# PARTICIPANT POPULATION

* 1. Indicate which of the following groups will be research participants (check **ALL** that apply):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Adults |  | Senior Citizens (over 65) |  | Terminally Ill |
|  | Minors (under 18 in Ohio) |  | Non-English Speakers |  | Prisoners |
|  | Students |  | Mentally/Physically Disabled |  | LGBTQ+ |
|  | JCU Psych Pool |  | Cognitively Impaired |  | Unhoused Persons |
|  | Employees in a work setting |  | Institutional Residents |  | Addicts |
|  | Single Subject Populations (e.g., by gender, race, ethnicity, or religion) |

Describe the study population characteristics, including inclusion/exclusion criteria, if applicable:

|  |
| --- |
|  |

# Research with Students

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Will you recruit students from courses you are teaching or advisees? | Yes: |  | No: |  |

If “Yes,” consult [Faculty Use of Students in Research](https://www.jcu.edu/research/irb/special-guidance/faculty-use-students-research) on the JCU website. Explain below how you will ensure you will not know which students have or have not consented to participate in your study until ***after*** you have submittedsemester grades.

|  |
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1. **Research with Employees**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Will you specifically recruit JCU employees? | Yes: |  | No: |  |
| Will you specifically recruit employees of other organizations? | Yes: |  | No: |  |

If “Yes” to either question above, describe procedures for protecting employees’ confidentiality in their workplace. When studying employees in their workplace, a breach of confidentiality could potentially put participants’ reputations and employability at risk.

|  |
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1. **Population Size**

|  |  |
| --- | --- |
| What is the approximate number of participants you will recruit? |  |
| If applicable, describe the targeted number or percentage for each arm of the study: |
|  |

# Participant Recruitment

How will your study participants be recruited? Check **ALL** that apply and include all applicable recruitment materials with your submission.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Recruitment Emails |  | Advertisements |  | SONA/JCU Psych Pool |
|  | Direct Solicitation |  | Social Media |  | Snowball / Word of Mouth |
|  | Flyers or Posters |  | Oral Scripts |  | Other (describe below) |

Please describe your recruitment process, including your methods for ensuring that your population fulfills the inclusion/exclusion criteria described in **section 7.a**.:

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1. **INFORMED CONSENT** ([45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116))

Submit all consent and assent materials with this form. Use a [consent template](https://www.jcu.edu/research/irb/irb-forms-templates) or refer to [45CFR46.116(b) and (c)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116) for *The General Requirements for Informed Consent*.

\*\*\* If NO consent or assent will be obtained, leave **8.a.** and **8.b.** blank and complete **8.c.** below.

* 1. **Type of Informed Consent Obtained** (check **ALL** that apply):

|  |  |
| --- | --- |
|  | Adult Consent |
|  | Consent from an adult’s Legally Authorized Representative (LAR), if applicable |
|  | Passive Consent (also known as “Opt-Out” Consent) |
| Use of Minors (under the age of 18 in Ohio) |
|  | Parental/Guardian consent |
|  | Child/Minor Assent for non-readers (not able to read or not proficient at reading) |
|  | Child/Minor Assent for proficient readers. |
|  | Passive Assent (also known as “Opt-Out” Assent) |

1. **Partial Waiver or Alteration of Consent: Concealment and Deception**

Concealment is when specific information about the study is *initially withheld* from participants. Deception is when researchers deliberately give participants *false information about some aspect of the study*. Both are forms of *partial informed consent*; in both cases, participants must be fully debriefed at the end of the study. You must complete this section if your research involves concealment or deception. Otherwise, skip this section.

* + - 1. Specifically, describe the type of concealment/deception you will use:

|  |
| --- |
|  |

* + - 1. Why is concealment or deception necessary for this experimental design?

|  |
| --- |
|  |

1. How will participants be debriefed? (You must submit the debriefing statement.)

|  |
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|  |

1. **Complete Waiver of Informed Consent**:

If you do not plan to obtain any form of informed consent/assent, you must complete this section. Otherwise, skip to **Section 8.d.** Contact the IRB Office to discuss the *very specific circumstances* in which informed consent may be waived entirely.

|  |  |
| --- | --- |
|  | Adult informed consent will not be obtained.  |
|  | Parental/Guardian consent will not be obtained. |
|  | Child/Minor assent will not be obtained. |

If any items in **8.c.** are checked, you must justify below why informed consent will not be obtained. Refer to [45 CFR 46.116(d) and §46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116) for the federal guidelines regarding waivers of informed consent. You may skip **Section 8.d.** below.

|  |
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# Method to Document Informed Consent ([45 CFR 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117))

# You must check (i) or (ii) below:

|  |  |  |
| --- | --- | --- |
| (i) |  | Written Consent and/or Assent with signature(s) will be obtained. |
| (ii) |  | No signed Consent/Assent will be obtained from participants. |

If **(ii) is checked** above, a *waiver of documentation of consent* is requested. (See [§46.117(c)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117) for requirements) Indicate below how study participants will be informed and will grant consent and give a rationale for not collecting signatures in the text field below.

|  |  |
| --- | --- |
|  | A paper **Information Sheet** will be presented. Explain the rationale below. |
|  | **Oral Consent** will be obtained from participants. Explain the rationale below. |
|  | **Electronic Consent** will be obtained. (e.g., online surveys) Study information  |
|  | will be presented, and consent will be obtained electronically. |

If **8.d.(ii)** is checked, explain the rationale for NOT collecting a signed informed consent form:

|  |
| --- |
|  |

# DATA COLLECTION & CONFIDENTIALITY ISSUES

* 1. Data collection methods, check ALL that apply:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Questionnaire or Survey |  | Collecting archived data or databases |
|  | Web / Internet |  | Intervention |
|  | Interview |  | Focus Groups |
|  | Observation |  | Testing / Evaluation |
|  | Video or Audio Taping |  | Instruction / Educational Curriculum |
|  | Computer Collected Task Data |  | Physical Tasks |
|  | Other:  |  |

* 1. Will the data be collected **anonymously** so that no one, *not even the researchers*, can determine who participated? **NOTE:** JCU SONA studies conducted in person in the Psychology Department labs are NOT completely anonymous because researchers will visually identify the participant.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

* 1. If you answered **NO** to **9.b.** above, describe procedures for keeping all data confidential and secure. Explain how the data will be stored or shared throughout the study.

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1. **METHODOLOGY**

Describe step by step *how* you will conduct this research. Address how you will identify, contact, and recruit your participants; how you will obtain informed consent; the location and duration of your data collection; how you will collect data; what data you will collect; how you will debrief your participants, if applicable; and how you will analyze the data. If you use an electronic survey (Qualtrics, Google Forms, etc.), provide the link to the completed survey. If several co-investigators will conduct the research, specify *who* will be responsible for *what* step(s). Reference all attachments when applicable.

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1. **RISK FACTORS**

You must acknowledge all potential risks, even if they are unlikely. Do your research methods involve any of the following elements?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Coercion or undue influence, or the *potential* for coercion …………. |  | Yes |  | No |
| Procedures that might cause mental discomfort ………………………... |  | Yes |  | No |
| Procedures that might cause physical discomfort …………………....... |  | Yes |  | No |
| Collection of information that, if disclosed, could be embarrassing or harmful to the participant’s reputation, employability, financial standing, or insurability or place the participant at risk for  |  |  |  |  |
| criminal/civil liability ………………………………………………………. |  | Yes |  | No |
| Procedures that might cause physical harm to participants …………… |  | Yes |  | No |
| Biomedical procedures, including the use of drugs or EEG recorders  |  | Yes |  | No |
| Participants will be audio or video-recorded or photographed ……....... |  | Yes |  | No |
| Participants who are members of a vulnerable population ……………... |  | Yes |  | No |

* 1. Describe any other potential risks to participants besides those above. You must consider all potential physical, psychological, social, legal, and other risks.

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* 1. Assess and explain the likelihood and seriousness of all potential risks, even if you think they will be avoided.

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1. Describe the procedures you will use to mitigate risks and any provisions for ensuring necessary interventions in the event of a distressed participant or other adverse event.

|  |
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1. **BENEFITS**

Describe the anticipated direct benefits to study participants and/or contributions to general knowledge in this field of inquiry. **NOTE:** compensation or SONA points are not benefits.

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1. **COMPENSATION**

If the research participants will be compensated or rewarded, indicate the type and amount of compensation. If participants are being recruited from JCU classes or the Psych Pool, indicate whether students are receiving course credit (extra credit or SONA points) and, if so, what alternatives are offered to those students who do not wish to participate in the research:

|  |
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1. **SUPPORTING MATERIALS**

All supporting documents must be submitted with this application. The IRB must review all materials presented to or seen by participants during the study. These materials must be free of spelling and grammatical errors and formatted neatly and professionally. Indicate below what materials will be submitted with his application. Check **ALL** that apply:

|  |  |
| --- | --- |
|  | Recruitment materials (invitation email, flyer, social media post, SONA page, etc.) |
|  | Informed Consent documentation (all formats) |
|  | Data instruments (surveys, interview questions, tests, links to internet surveys, etc.) |
|  | Debriefing statement |
|  | Electronic survey link(s):  |  |
|  | Letters of support from data collection sites |
|  | Résumé or CV from the members of the research team |
|  | Other (specify):  |  |

Supporting material files should be emailed to IRB@jcu.edu along with this completed application form. It is very helpful if you name your documents so that they identify what they are. (e.g. *RecruitmentFlyer.pdf, Informed\_Consent.doc*, *Debrief\_page.pdf,* etc.)

# CERTIFICATION STATEMENT

# ALL investigators who are engaged in this research, including the analysis of data, must be listed on this application and must read and agree to the following Certification Statement:

|  |
| --- |
| *By providing my name and initials below, I certify that I have read and understand John Carroll University’s policies and procedures governing human subject research as described in John Carroll University’s Institutional Review Board Policy. I will fully comply with those policies and not conduct any research activities without IRB approval. I further acknowledge my obligation to:**Obtain written approval of significant deviations from the approved protocol BEFORE making those deviations;**Immediately report all adverse events of the study to the* [*Chairperson*](https://www.jcu.edu/research/contact-us) *of the Institutional Review Board and my research advisor, if applicable.* |

|  |  |  |
| --- | --- | --- |
| *PI initial here:* |  | **I agree to the above Certification Statement.** |
| **Name of Principal Investigator:**  |  |
| **Today’s Date:**  |  |
| **CITI Training Completion Date:**  |  |

**CO-INVESTIGATORS:**

All the co-investigators listed below must read and agree to the **Certification Statement** above. CITI training is required for all researchers engaged in human subject research. When applicable, please provide full names and titles (Ph.D., M.D., LCSW, BCBA, etc.).

|  |  |
| --- | --- |
| Name:  |   |
| Email: |  |
| CITI Training Completion Date:  |  |
| Affiliation (if not JCU):  |  |
|  |
| Name:  |   |
| Email: |  |
| CITI Training Completion Date:  |  |
| Affiliation (if not JCU):  |  |
|  |
| Name:  |   |
| Email: |  |
| CITI Training Completion Date:  |  |
| Affiliation (if not JCU):  |  |
|  |
| Name:  |   |
| Email: |  |
| CITI Training Completion Date:  |  |
| Affiliation (if not JCU):  |  |
|  |
| Name:  |   |
| Email: |  |
| CITI Training Completion Date:  |  |
| Affiliation (if not JCU):  |  |

If more co-investigators need to be listed, please add names in an attachment.

# ADVISORS of STUDENT RESEARCHERS (all other researchers skip this section)

# Faculty or staff advisors of students conducting human subject research must actively participate in preparing their students for the role of researcher. They must instruct them in the ethical conduct of research and assist in preparing this application for IRB approval. Research advisors must also ensure that the research meets the highest ethical standards.

# Responsibilities of the Advisor:

# Research advisors shall ensure their advisees do the following:

* Minimize the risks to human participants,
* Plan and accomplish appropriate recruitment strategies for identifying participants,
* Understand the elements of the informed consent process,
* Develop readable, error-free recruitment materials and consent forms,
* Establish and maintain strict guidelines for protecting anonymity and confidentiality, and
* Conduct their research in compliance with JCU and IRB policies and procedures.

Student applications must be submitted by their research advisor using the advisor’s JCU email address. By submitting this application, the research advisor confirms that they have reviewed the complete protocol and are ultimately responsible for protecting human subjects in their students' research.

***Must be completed by the advisor:***

|  |  |
| --- | --- |
| Name of Advisor: |  |
| Date Approved: |  | CITI Training Date: |  |
|  |
| *Initial here:*  |  | I have reviewed my student’s (or students’) research plan and read this application and all supporting documents. I understand my responsibilities as described above. |

# SUBMISSION INSTRUCTIONS

# Faculty or Staff Principal Investigators:

# Submit this form with all supporting documents as email attachments to IRB@jcu.edu.

# Student Principal Investigators:

# You must first review this application with your research advisor. Your advisor must read and complete Section 16 (above) and then submit this form and all supporting documents as email attachments to IRB@jcu.edu. The email submission from your advisor’s JCU address is the “signature” verifying that they approve your application.

Within two working days, the PI, co-investigators, and advisor (if applicable) will receive an email acknowledgment when the application has been received and processed for review. You will also be given an **IRB Log #**.

If you have questions or need assistance completing this application, contact the [IRB Administrator](http://sites.jcu.edu/research/pages/contacts/) at IRB@jcu.edu or 216-397-1527 or visit SIH250.

# For IRB Office Use Only:

|  |  |
| --- | --- |
| Review Notes: |  |
| Revision History: |  |
| Continuation History: |  |
| UAE/Protocol Deviations: |  |
| Project Closed: |  |