

**IRB Application for
 Human Participant Research**

**v. 6.4**

For IRB Office use only:

|  |  |  |
| --- | --- | --- |
| Date Received: date rec’d | Sent to Review: date rev’d  | Date Approved/Exempted: date approved |
| CR Required? Yes or No | Expiration Date: CR date | VERSION DATE CODE: date code |

# INSTRUCTIONS: This is a Microsoft Word form. Please complete all fields, and enter “N/A” to any field that does not apply to your protocol. Do not use this form as a Google Doc.

# 1. PROTOCOL TITLE

|  |  |
| --- | --- |
| Title of Project: | Please enter the full title of your protocol |
| IRB Log No.: *Assigned by the IRB* | Review Category: *Assigned by the IRB* |
| Revision No.: *Assigned by the IRB* |  |

# PROJECT DATES

NOTE: Project work may **not begin** prior to approval or exemption from the IRB.

|  |  |  |
| --- | --- | --- |
| Anticipated starting and completion dates: Start date | to | Comp date |
| Will this project be conducted on an annual basis? Yes [ ]  | No [ ]  |

# PRINCIPAL INVESTIGATOR INFORMATION

|  |
| --- |
| Principal Investigator: Please enter the name of the PI |
| Department or Affiliation: Please enter your JCU dept or the name of your institution |
| Email: Please enter PI email | Phone: Please enter PI phone |

**PI Status:** Choose from the dropdown menu.

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

|  |
| --- |
| If you are a student researcher, please provide the following, as applicable: |
| Type of project: Choose from the dropdown menu |
| Course Name and #: Enter the name and # of the course, if applicable |
| Research Advisor: Please enter the name of your research advisor |
| Department: Research advisor’s department |
| Advisor Email: Please enter advisor’s email | Advisor’s CITI training date: enter date |
| **NOTE:** When this application is complete, research sponsors must review it, read **Section 16**, and then email this form and any supporting documents to IRB@jcu.edu from their JCU email address. |

# FUNDING

|  |  |
| --- | --- |
| Will this project be funded by a source external to JCU? Yes [ ]  | No [ ]  |
| If yes, list the funding source and/or sponsor name: Please enter funding source |

**RESEARCH STATEMENT:** Provide a brief summary or abstract of your project. Include information about your motivation, research hypothesis, and goal(s) of the study. Specific or technical jargon should be avoided or explicitly explained. Maximum 500 words.

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| --- |
| Enter your Research Statement here in 500 words or less. |

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, archive the data for a future project, etc.) Contact the [IRB Administrator](http://sites.jcu.edu/research/pages/contacts/) first if the project will NOT be shared outside the classroom.

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| --- |
| Please describe your plans for sharing data and disseminating results. |

# PARTICIPANT POPULATION

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | Adults | [ ]  | Senior Citizens (over 65) | [ ]  | Terminally Ill |
| [ ]  | Minors (under 18) | [ ]  | Non-English Speakers | [ ]  | Prisoners or parolees |
| [ ]  | Students | [ ]  | Mentally/Physically Disabled | [ ]  | LGBTQ+ |
| [ ]  | JCU Psych Pool | [ ]  | Cognitively Impaired | [ ]  | Homeless Persons |
| [ ]  | Employees in a work setting | [ ]  | Institutional Residents | [ ]  | Addicts |
| [ ]  | Single Subject Populations (e.g. by Gender, Race, Ethnicity, or Religion) |

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

|  |
| --- |
| Please describe your study population, if applicable. |

# Research with Students

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Will you recruit students from courses you are teaching or your advisees? | [ ]  | Yes | [ ]  | No |

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

|  |
| --- |
| Please explain how you will avoid potential coercion with students |

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.

|  |
| --- |
| How will you protect employees who are being studied at their workplace? |

1. **Population Size**

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| --- | --- |
| What is the approximate number of participants to be recruited? | Number recruited |

If applicable, please describe the targeted number or percentage for each arm of the study:

|  |
| --- |
| Please describe your study population, if applicable |

# 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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| --- |
| Please describe your recruitment processes |

1. **INFORMED CONSENT**

See the [IRB Guidelines on Informed Consent](http://jcu.edu/research/pages/irb/informed-consent/) for more information and for helpful templates. Please use a template 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*.
Submit ALL applicable consent and assent materials with this form.

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

|  |  |
| --- | --- |
| [ ]  | Adult Consent |
| [ ]  | Consent from an adult’s Legally Authorized Representative (LAR), if applicable |
| Use of Minors (under 18 years of age): |
| [ ]  | Parental/Guardian consent |
| [ ]  | Child/Minor Assent for non-readers (not able to read or not proficient at reading) |
| [ ]  | Child/Minor Assent for proficient readers (can read and understand a simple assent form) |

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

Indicate if participants will not be informed and consent will not be obtained prior to the study. See the IRB Administrator for the *very specific circumstances* in which informed consent may be completely waived. If consent will not be obtained, please offer justification in the box below.

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

If any of the items in **8.b** are checked, please justify why informed consent will not be obtained. Please see the IRB Administrator for guidance on this specific situation. Refer to [45CFR46.116(d) and 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) for the federal guidelines regarding waivers of informed consent.

|  |
| --- |
| Please explain your justification for a complete waiver of informed consent. |

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

Concealment is when some 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*, and in both cases, participants must be fully debriefed at the end of the study. If your research involves concealment or deception, you must provide the following information:

* + - 1. Specifically describe the type of concealment/deception being used (Enter N/A if not applicable.)

|  |
| --- |
| Please describe the concealment or deception used in your study |

* + - 1. Why is concealment or deception a necessary component of the experimental design?

|  |
| --- |
| Please justify the use of concealment or deception in your study |

1. How will participants be debriefed? (Debriefing materials must be submitted)

|  |
| --- |
| Please describe the debriefing procedure |

# Method to Document Informed Consent: Please check (i) or (ii)

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

If **(ii) is checked**, a *waiver of signature* 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 participants will be informed and will grant consent.

|  |  |
| --- | --- |
| [ ]  | A paper **Information Sheet** will be presented to participants. Explain rationale below. |
| [ ]  | **Oral Consent** will be obtained from participants. Explain rationale below. |
| [ ]  | **Electronic Consent** will be obtained. (for online surveys or other on-screen experiments) Study information will be presented and consent will be given electronically. |

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

|  |
| --- |
| Please explain, if applicable |

# DATA COLLECTION & CONFIDENTIALITY ISSUES

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Yes | [ ]  | No |

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

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| --- |
| Please explain how you will keep data confidential |

1. **METHODOLOGY**

Describe in detail *how* the research will be conducted, step by step. Be sure to address: how participants will be identified, contacted, and recruited; how informed consent will be handled; the location where the study will take place; how all the data will be collected; how participants will be debriefed, if applicable, and how the data will be analyzed. If you are using an electronic survey (Qualtrics, Google Forms, etc.), provide the link to the survey. If the research will be conducted by several co-investigators, specify *who* will be responsible for *what* step(s). Reference all attachments when applicable. Max. 1000 words.

|  |
| --- |
| Describe your Methodology in 1000 words or less. |

1. **RISK FACTORS**Does your study 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 | [x]  | No |
| Biomedical procedures, including the use of drugs or EEG recorder | [ ]  | 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 should carefully consider all potential physical, psychological, social, legal, or other risks.

|  |
| --- |
| Please describe all other potential risks |

* 1. For all potential risks, assess both the likelihood of their occurring and their seriousness, even if you think these risks will be avoided.

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| --- |
| Please describe the likelihood and seriousness of risks |

1. Describe the procedures you will use to mitigate these risks as well as any provisions for ensuring necessary professional intervention in the event of a distressed participant or other adverse event.

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| --- |
| How will you mitigate risks? |

1. **BENEFITS**

Describe the anticipated benefits to study participants and contributions to general knowledge in this field of inquiry. **NOTE:** compensation is not a benefit.

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| --- |
| Please describe the benefits of your study |

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:

|  |
| --- |
| Please describe how your participants will be compensated, if applicable |

1. **SUPPORTING MATERIALS**

All supporting documents must be submitted with this application. The IRB must review all materials that are presented to or seen by participants during the study. Indicate below what materials will be submitted with his application. Check **ALL** that apply:

|  |  |
| --- | --- |
| [ ]  | Recruitment materials (flyer, social media post, recruitment email, 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): Enter survey link(s), if applicable |
| [ ]  | Letters of support from data collection sites |
| [ ]  | Résumé or CV from the members of the research team |
| [ ]  | Other (specify): Describe other supporting documentation, if applicable |

Supporting material files should be emailed to IRB@jcu.edu along with this completed application form. Please name your documents so that they clearly 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 human subject data, must be listed on this application and must read and agree to the following Certification Statement:

|  |
| --- |
| *By providing my name below, I certify that I have read and I 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 will not conduct any research activities without IRB approval. I further acknowledge my obligation to:**obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations;**Immediately report all adverse events of the study to the* [*Chairperson*](http://sites.jcu.edu/research/pages/contacts/) *of the Institutional Review Board and the Research Sponsor, if applicable.* |

|  |
| --- |
| **[ ]  I agree to the above Certification Statement** |
| **Name of Principal Investigator:** Please enter your full name |
| **Today’s Date:** Click or tap to enter today’s date |
| **CITI Training Completion Date:** Click or tap to enter a date |

**CO-INVESTIGATORS:**

All communication with the IRB Office must include all members of the research team listed on this application, as well as the research sponsor, if applicable. All the co-investigators listed below must read and agree to the **Certification Statement** above.

|  |  |
| --- | --- |
| Name: Co-Investigator 1 Name | Email: Co-Investigator 1 Email |
| Affiliation: Choose JCU or type in affiliation |
| CITI Training Completion Date: Click or tap to enter a date. |
|  |
| Name: Co-Investigator 2 Name | Email: Co-Investigator 2 Email |
| Affiliation: Choose JCU or type in affiliation |
| CITI Training Completion Date: Click or tap to enter a date. |
|  |
| Name: Co-Investigator 3 Name | Email: Co-Investigator 3 Email |
| Affiliation: Choose JCU or type in affiliation |
| CITI Training Completion Date: Click or tap to enter a date. |
|  |
| Name: Co-Investigator 4 Name | Email: Co-Investigator 4 Email |
| Affiliation: Choose JCU or type in affiliation |
| CITI Training Completion Date: Click or tap to enter a date. |
|  |
| Name: Co-Investigator 5 Name | Email: Co-Investigator 5 Email |
| Affiliation: Choose JCU or type in affiliation |
| CITI Training Completion Date: Click or tap to enter a date. |
|  |

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

# DUTIES OF FACULTY or STAFF ADVISORS of STUDENT RESEARCHERS

# Faculty or staff advisors of students conducting human subject research must take an active part in preparing their students for the role of researcher. They must instruct them in the ethical conduct of research and assist in the preparation of this application for IRB approval. Research advisors must take an active role in ensuring that the conduct of 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 accordance with JCU and IRB policies and procedures.

When completed, student applications must be submitted by their research advisor from the advisor’s JCU email address. By submitting this application, the research advisor is confirming that they have reviewed the complete protocol and they are ultimately responsible for the protection of human subjects in their student’s research.

*To be completed by the advisor:*

|  |  |
| --- | --- |
| Name of Advisor: | Please enter your full name |
| Date Approved: | Please enter the date |  |
| [ ]  | I confirm that I have reviewed my student’s (or students’) research plan and have read this application and all supporting documents. I understand my responsibilities as described above. |

# SUBMISSION INFORMATION

# Faculty or Staff Principal Investigators:

# Submit this completed form as an email attachment to IRB@jcu.edu. All supporting documents must also be submitted by email.

# Student Principal Investigators:

# When ready to submit, you must review this application with your research advisor. Your advisor must read and complete Section 16. and then submit this completed form as an email attachment to IRB@jcu.edu. All supporting documents must also be submitted by email by your advisor.

# PLEASE DO NOT SEND AS A GOOGLE DOC. Save this file as an MS Word document.

Within two working days, you will receive an email acknowledgment when the application has been received and processed for review. You will also be given an **IRB Log #**.

For questions or assistance in completing this application, see the [JCU IRB website,](http://sites.jcu.edu/research/) or contact the [IRB Administrator](http://sites.jcu.edu/research/pages/contacts/) at 216-397-1527.

**Version 6.4 / January 2024**

# For IRB Office Use Only:

|  |  |
| --- | --- |
| Review Notes: | Click or tap here to enter text. |
| Revision History: | Click or tap here to enter text. |
| Continuation History: | Click or tap here to enter text. |
| UAE/Protocol Deviations: | Click or tap here to enter text. |
| Project Closed: | Click or tap here to enter text. |