John Carroll UNIVERSITY | Institutional Review Board

IRB Application for Human Participant Research

1. PROJECT TITLE

Title of Project: _____

IRB Log No. (*Assigned by IRB*): _____ Review Category: _____

2. PROJECT DATES

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

a. Anticipated starting and completion dates: _____ to _____

b. Will this project be conducted on an annual basis? ◯ Yes ◯ No

3. PRINCIPAL INVESTIGATOR INFORMATION

a. Contact Information

Principal Investigator: _____

Department or Affiliation: _____

Email: _____ Phone: _____

Dept. Chair/Supervisor: _____ Email: _____

b. PI Status: Choose One

c. Student / External Researcher Information (*JCU faculty/staff researchers may skip the section below)*

If you are a student or external researcher, please provide the following, as applicable:

Type of project: Select Project Type

Course # & Name: _____

JCU Faculty/Staff Sponsor: _____

Department: _____

Sponsor Email: _____ Phone: _____

Students and External Researchers must provide their current mailing address:

_____

Research Sponsor's Statement:

By signing below, I confirm that I am familiar with the project proposed on this IRB application, and I have fully reviewed this completed form. I am satisfied with the proposed research design and the measures proposed for the protection of human participants. As the sponsor, I assume responsibility for conduct of ethical human subject research and applicable and/or required data security measures.

Electronic Signature of Faculty/Staff Sponsor:  (See p.11 for signing instructions)

All faculty/staff sponsors are **required** to complete CITI training and choose the "Students in Research" module as one of the course electives.

Sponsor's CITI Training Completion Date: _____

4. FUNDING

Is this project being funded by an external source? ◯ Yes ◯ No

If yes, list the funding source/sponsor name: _____

(See the Director of **Sponsored Research** for more information about funding sources and grant administration.)

5. RESEARCH STATEMENT: Provide a brief summary or abstract of your project. Include information about the motivation, research hypothesis, and goal(s) of the study. Cite previous research where applicable. Specific or technical jargon should be avoided or explicitly explained.

6. RESEARCH RESULTS: What will you do with the results of the study? (e.g. publish, present publicly, upload results onto an online or cloud-based platform, archive the data for a future project, etc.) Contact the IRB Administrator first if the project will NOT be shared outside the classroom.

7. PARTICIPANT POPULATION

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

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

Please describe the study population characteristics, including the selection criteria and the rationale for including or excluding specific groups, if applicable:

b. Research with Students

Will you recruit students from courses you are teaching or your advisees? ◯ Yes ◯ No

If "Yes", explain why this population is necessary to the study. Coercion to participate is a significant concern when instructors do research with their students or advisees. 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 on the JCU website.

c. Research with Employees

Will you specifically recruit JCU employees? ◯ Yes ◯ No

Will you specifically recruit employees of other organizations? ◯ Yes ◯ No

If "Yes", explain why this population is necessary to the study. When studying employees in their workplace, a breach of confidentiality could potentially put participants' reputation and employability at risk. Describe procedures for protecting employees' confidentiality in their workplace.

d. Population Size

What is the approximate number of participants to be recruited? _____

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

_____

e. Recruitment

How will participants be recruited? Check ALL that apply and attach all applicable recruitment materials.

☐ 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 insuring that your population fulfils the inclusion/exclusion criteria described in **section 7.a**.:

8. INFORMED CONSENT

See the IRB Guidelines on Informed Consent for more information and several helpful informed consent/assent templates. Attach ALL applicable consent and assent materials.

a. Type of Informed Consent (check ALL that apply):

(i) ☐ Adult Consent

(ii) Use of Minors (under 18 years of age)

☐ Parent/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 & understand a simple assent form

(iii) Informed Consent will be **partially waived**: participants will be only *partially* informed about some aspects of the study. Please also complete **8.b.** below.

☐ Concealment/Partial Consent: Some information will initially be withheld from participants

☐ Deception/Partial Consent: Participants will be deliberately given false information

(iv) Informed Consent will be **completely waived**: 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 waived. Please also complete **8.c.** below.

☐ Informed Consent will not be obtained

☐ Parental consent will not be obtained

☐ Child/minor assent will not be obtained

Refer to 45CFR46.116d and 46.117 for the federal guidelines regarding waivers of informed consent. See the IRB Administrator for more information.

b. Partial 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:

(i) Specifically describe the type of concealment/deception being used.

(ii) Why is concealment/deception a necessary component of the experimental design?

(iii) How will participants be debriefed? (Debriefing materials must be attached)

c. Complete Waiver of Informed Consent (Please see the IRB Administrator for guidance.) If any item under **8.a.iv** is checked, please justify why informed consent will not be obtained.

d. Method to Document Informed Consent: check (i) or (ii)

(i) ☐ Written Consent/Assent with signature(s) will be obtained from participants

(ii) ☐ No signed Consent/Assent Obtained (Documentation of Signature is waived)

If **(ii)**, a *waiver of signature* is requested (see §46.117(c) 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 obtained from participants. Explain rationale below:

☐ **Electronic Consent** will be obtained. (JCU SONA experiments, online surveys, or other on-screen experiments, etc.) Study information will be presented electronically.

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

9. DATA COLLECTION & CONFIDENTIALITY ISSUES

a. Data collection methods, check ALL that apply:

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

b. Will the data be collected **anonymously** so that no one, *not even the researchers*, can determine who participated? See the IRB Privacy page for an explanation of anonymous vs. confidential.

○ Yes ○ No

c. If you answered NO to **9.b.**, describe procedures for keeping data confidential and secure. Be sure to explain how the data will be stored both during the data collection process and after the study is conducted since this will affect the confidentiality of the data.

10. METHODOLOGY: Describe in detail how the research will be conducted, step by step. Be sure to address (1) how participants will be identified, contacted, and recruited; (2) how informed consent will be handled; (3) the location where the study will take place; (4) how all the data will be collected; (5) how participants will be debriefed, if applicable, and (6) how the data will be analyzed.

If the research will be conducted by several co-investigators, specify *who* will be responsible for *what* step(s). Please use attachments if more space is needed. Reference all attachments when applicable.

11. 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 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 recorder	◯ Yes	◯ No
Participants will be audio or video recorded, or photographed	◯ Yes	◯ No

a. Describe any other potential risks to participants besides those above. You should consider potential physical, psychological, social, legal or other risks.

b. For all potential risks, assess both the <u>likelihood</u> of their occurring and their <u>seriousness</u>, even if you think these risks will be avoided.

c. 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.

12. BENEFITS: Describe the anticipated benefits to participants and contributions to general knowledge in this field of inquiry:

13. 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 (regular or extra credit) and, if so, what alternative are offered to those student who do not wish to participate in the research:

14. SUPPORTING MATERIALS

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

- ☐ Recruitment Materials (flyer, ad copy, social media post, recruitment email, SONA study page, etc.)
- ☐ Informed Consent (consent and assent forms, information sheet, electronic consent page, oral consent script, translated informed consent documents for non-English speakers, etc.)
- ☐ Data Instruments (surveys, interview questions, tests, links to internet surveys, etc.)
- ☐ Debriefing statement
- ☐ Other: (specify) _____

Attachments Pane: (will appear on the left) VIEW Attachments ATTACH FILE

Electronic files should be attached to this form by clicking **ATTACH FILE**. You will be asked to choose files from your computer that you wish to attach. Please give your documents names that clearly identify what they are. (e.g. *AppendixA.doc, RecruitmentFlyer.pdf, Informed_Consent.doc*, etc.)

15. CERTIFICATION STATEMENT: must be initialed by ALL investigators engaged in this research.

*By providing my 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 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:*

(1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations;

*(2) immediately report all adverse events of the study to the **Chairperson** of the Institutional Review Board and the Research Sponsor, if applicable.*

Name of Principal Investigator: _____

PI's initials: _____ Date: _____

Principal Investigator's CITI Training Completion Date: _____

Once this form is completed and SAVED, the PI should email the file to each co-investigator in order for it to be read, saved, and initialed by each member of the research team.

CO-INVESTIGATORS:

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 initial the **Certification Statement**. All co-investigators must also provide their CITI training completion date.

When you receive this form to be initialed, you must review the proposed research protocol, the attachments, and the **Certification Statement**. Type your name, email, and affiliation (if not JCU) in one of the spaces below. Next, enter your CITI (or equivalent) training completion date.

Enter your initials and the date below your name, then **SAVE** the file to your computer. Finally, send it as an email attachment back to the Primary Investigator or to the next co-investigator. When all names have been listed and initialed, the PI is responsible for submitting the completed form to the IRB Office.

1. Name: _____ Email: _____

Affiliation (if not JCU): _____

CITI Training Completion Date: _____

Initials: _____ Date: _____

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2. Name: _____ Email: _____

Affiliation (if not JCU): _____

CITI Training Completion Date: _____

Initials: _____ Date: _____

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3. Name: _____ Email: _____

Affiliation (if not JCU): _____

CITI Training Completion Date: _____

Initials: _____ Date: _____

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4. Name: _____ Email: _____

Affiliation (if not JCU): _____

CITI Training Completion Date: _____

Initials: _____ Date: _____

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

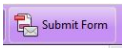
To **SAVE** this form, at any point, to your computer: **SAVE**

*This form will be saved to your computer as a PDF. Please give your file an **appropriate and easily recognizable name,** not "IRB Application Form". We strongly suggest the file name contain the PI's last name.*

16. SUBMISSION INFORMATION:

This application is complete when all required fields are filled, all supporting documents are attached (see **Section 14**), and all investigators engaged in this research have read and initialed the **Certification Statement**. Student researchers and external researchers must also have a digital signature from a JCU faculty advisor/sponsor (see **Section 3.c.**). **SAVE and name this form BEFORE YOU SUBMIT!**

There are two ways to SUBMIT a completed form:

1. Click the 

button at the top right hand side of this file window or...
2. Send an email with this completed application attached to: **IRB@jcu.edu**

You will receive an email acknowledgment when the application and supporting documents have 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, or contact the IRB Administrator at 216-397-1527.

To **PRINT** a hard copy of this form: **PRINT**
(Please, think twice and save paper!)

For IRB Office Use Only:

Date Received: Sent to Review: Date Approved:

Revision History:

Project Closed:

Instructions for Faculty Advisors and Research Sponsors:

Providing an electronic signature:

All faculty advisors of student researchers and JCU sponsors of external researchers are required to sign **Section 3.c** of this application. After you have read this application, have become familiar with the protocol, and are satisfied with the research methods, click on the digital signature box under the Sponsor Statement.

If you haven't done so before, you will be instructed to establish your own password-protected, digital signature. After your digital signature and password are established, they will be saved to your computer, and you will be able to sign all subsequent Adobe digital forms by using your password. This will be a date-stamped, verified electronic signature.

After completing the digital signature, you will be asked to SAVE the form to your computer. Please email the form back to the Primary Investigator.

If you have any questions about digital signatures in Adobe forms, please contact the IRB Administrator.

CITI Training

All faculty advisors of student researchers and JCU sponsors of external researchers are required to complete CITI training in ethical conduct of Human Subjects Research and to keep their certification current. Faculty/Staff advisors of student researchers are also required to complete "Students in Research" as one of the elective modules of the "IRB Researchers and Sponsors" course.

If you have any questions about CITI training, please contact the IRB Administrator.