

IRB APPLICATION FOR HUMAN SUBJECT RESEARCH

1. PROJECT TITLE

Title of Project: _____

2. TYPE OF REVIEW: (See Information Sheets 1 and 2)

This project may fall under an exempt or expedited review category. Yes

3. PROJECT DATES

a. Anticipated starting and completion dates: _____ to _____

NOTE: Project may not start prior to approval from the IRB.

b. This project may be conducted on an annual basis: Yes

4. PRINCIPAL INVESTIGATOR INFORMATION

a. Contact Information

Principal Investigator: _____

Department or Affiliation: _____

Telephone: _____ Email: _____

Name of chair/supervisor: _____

Email of chair/supervisor: _____

b. Status

PI status: Undergraduate: Graduate: Faculty: Staff: Other:

Students and outside researchers must provide their current address:

c. Student / Outside Researcher Information

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

Type of project: Thesis/Essay: Independent Study: Class Project: Other:

Course # & Name: _____

Faculty Sponsor: _____ Dept: _____

Faculty Email: _____ Phone: _____

NOTE: A application by a student or outside researcher must have the following statement signed by a university sponsor:

I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. For student projects, I will take responsibility for informing the student of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.) in a University or computer file.

Signature of University/Faculty Sponsor

Date

5. FUNDING

Is this project being funded? Yes No

If yes, list the funding source: _____

6. RESEARCH STATEMENT: Indicate the reason for the research and a short justification:

7. PARTICIPANTS

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

<input type="checkbox"/> Minors (under 18)	<input type="checkbox"/> Senior Citizens (over 65)	<input type="checkbox"/> Terminally Ill
<input type="checkbox"/> Students	<input type="checkbox"/> Prisoners	<input type="checkbox"/> Cognitively Impaired
<input type="checkbox"/> Non-English Speakers	<input type="checkbox"/> Mentally/Physically Disabled	<input type="checkbox"/> Pregnant Women
<input type="checkbox"/> Institutional Residents	<input type="checkbox"/> Employees	<input type="checkbox"/> No Special Groups
<input type="checkbox"/> Single Subject Populations (by Race, Ethnicity, Sex, or Religion)		
<input type="checkbox"/> Other (specify): _____		

b. If any of the above groups are selected, state the rationale for using special groups.

c. What is the approximate number of subjects to be recruited?

d. How will the subjects be solicited (check all that apply)?

<input type="checkbox"/> Advertisements	<input type="checkbox"/> Letters	<input type="checkbox"/> Random Calls
<input type="checkbox"/> Telephone Lists	<input type="checkbox"/> Notices	<input type="checkbox"/> Direct Solicitation
<input type="checkbox"/> JCU Psych Pool	<input type="checkbox"/> Other (specify): _____	

8. INFORMED CONSENT. See www.jcu.edu/research/irb/consent.htm for detailed information on consent and assent forms, the required consent elements, and to view sample consent forms. If the materials do not meet the requirements for informed consent, a revision may be requested.

a. **Type** of Consent/Minor Assent Requested (check all that apply):

(i)	<input type="checkbox"/> Adult Consent
(ii)	Use of Minors (under 18 years of age)
	<input type="checkbox"/> Parent/Guardian Consent
	<input type="checkbox"/> Child/Minor Assent (Non-readers: Not able to read or not-proficient at reading)
	<input type="checkbox"/> Child/Minor Assent (Proficient readers: Can read & understand a simple assent form)

(iii) In certain circumstances, a waiver of informed consent/minor assent may be requested. In this case, subjects are not informed or only partially informed about a study. To request that informed consent or assent be waived, indicate category below (check all that apply).

<input type="checkbox"/>	Informed consent will not be obtained
<input type="checkbox"/>	Parental consent will not be obtained
<input type="checkbox"/>	Child/minor assent will not be obtained
<input type="checkbox"/>	Partial Consent/Assent: This study involves deception

Justify why informed consent will not be obtained or why deception is necessary for this study. For studies that involve deception please include plans for how and when subjects will be debriefed. If a debriefing statement will not be used, explain why.

b. Method to obtain consent/minor assent.

- (i) Written Consent/Assent (written signature will be obtained from subjects)
- (ii) No Written Consent/Assent Obtained (a written signature will not be obtained from subjects. Documentation of a signature is waived.)

If a waiver of a signature is requested, indicate below how subjects will be informed:

An Information Sheet will be used. Explain rationale below.

Oral Consent will be obtained. Explain rationale below.

Electronic Consent (via Psych Pool Sona Systems)

9. DATA & CONSENT COLLECTION

a. Data collection methods (check all that apply):

<input type="checkbox"/> Questionnaire or Survey <input type="checkbox"/> Web or Internet <input type="checkbox"/> Interview <input type="checkbox"/> Observation <input type="checkbox"/> Video or Audio Taping <input type="checkbox"/> Computer Collected Task Data <input type="checkbox"/> Other: 	<input type="checkbox"/> Archival Data <input type="checkbox"/> Intervention <input type="checkbox"/> Focus Groups <input type="checkbox"/> Testing/Evaluation <input type="checkbox"/> Instruction/Curriculum <input type="checkbox"/> Physical Tasks
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- b. Will the data be collected with identifiers? Yes No
 If yes, will the data be rendered anonymous for analysis? Yes No
 Will the data be rendered anonymous for reporting? Yes No

See www.jcu.edu/research/irb/privacy.htm for an explanation of anonymity, confidentiality, identifiers, and IRB concerns regarding data collection.

- c. Describe how the consent forms and other study material (e.g., data instruments, computer task data, interview questions) will be distributed and collected to protect the privacy of the subjects and how confidentiality/anonymity will be maintained throughout the consent and data collection process.

- d. Describe security of the data, including where the consent forms and other study material will be stored, who will have access, and how and when the material will be destroyed. Note that signed consent forms must be retained for **three years** after the end of the study. State who will maintain the consent forms for the specified three years. (Note: faculty/staff sponsors should retain the original or a copy of signed consent forms collected from student projects.)

- 10. METHODOLOGY:** Describe in detail how the research will be conducted making sure to address (1) how subjects will be identified and the process of contacting, selecting and excluding subjects; (2) how consent will be obtained, and if children will be used, describe how parental consent and child assent will be obtained; and (3) how data will be collected, including how data instruments, if used, will be distributed and collected, and the location where the study will take place. Essentially, describe how the study will be practically implemented step by step.

- 11. RISK FACTORS:** A research participant is considered to be at risk if he or she may be exposed through the procedures of the planned experiment to the possibility of physical or mental harm, coercion, deceit or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants.

a. Risk Criteria	CHECK ONE
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Deceit, coercion or possible embarrassment/humiliation	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Experimental drugs will be used.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Potential for medical problems exist.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Participants may experience physical discomfort.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Participants may experience mental discomfort.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Electrical equipment will be used.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Participants will be tape recorded, photographed, or videotaped.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

b. Does any part of this activity have the potential for coercion of the subject? If yes, explain and describe the proposed safeguards. Yes No

c. Assess the likelihood and seriousness of risks (physical, mental, or other) to the subjects. Describe alternative methods that would not entail comparable risks and why these were not used.

d. Description of the anticipated benefits to subjects and contributions to general knowledge in the field of inquiry:

e. If the research subjects will be compensated or rewarded, indicate the type and amount of compensation and the milestone for each payment. If subjects 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 alternatives are offered to those students who do not wish to participate in the research.

12. SUBMISSION MATERIAL

The IRB must review copies of all final material presented to subjects. The IRB cannot approve a project without a complete and accurate application and final copies of all supporting materials. Please indicate below what materials have been attached to this application (check all that apply):

- Recruitment material (flyer, announcement, oral script, email, letter, etc.)
- Data instruments (surveys, interview questions, tests, web-survey, etc.)
- Informed consent (consent and assent forms, information sheet, oral consent script, psych-pool electronic consent, etc.)

- Debriefing statement
- Video clips, music CDs, photos, etc.
- Other: (specify) _____

13. CERTIFICATION STATEMENT

In making this application, I certify that I have read and understood John Carroll University's policies and procedures governing research with human participants (specifically, those as described in John Carroll University's Institutional Review Board Policy). I shall comply with the letter and spirit of those policies and will not undertake the research without IRB approval. Furthermore, I am aware that certain departments may have their own standards for conducting research, and it is up to me to familiarize myself with them. I further acknowledge my obligation to: (1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations; and (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and the Chairperson or Supervisor of my Department.

Principal Investigator signature

Date

CO-INVESTIGATORS:

a. Name:	_____	Title:	_____
Signature:	_____	Affiliation:	_____
b. Name:	_____	Title:	_____
Signature:	_____	Affiliation:	_____

14. SUBMISSION INFORMATION

Send one original and one copy of this packet (the application and all pertinent supporting materials) to:

**IRB Administrator
John Carroll University
20700 North Park Blvd, AD 250
University Heights, OH 44118**

The submission of handwritten and/or incomplete packets may significantly delay the review process. Forms and policy guidelines are available at: www.jcu.edu/research/irb.

For questions, comments, or assistance in completing the form, contact the IRB Administrator at 216-397-1527 or eparsons@jcu.edu.