Guidelines for completing the *IRB Application for Human Participant Research*

These guidelines are developed for first time users who may be unfamiliar with the terminology of the federal regulations for human participant research. Note that "minimal risk," as defined by federal regulations, means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Avoid technical jargon when writing the application.

Attach all supporting material to the application, including any consent documents, advertisements or announcements, and survey instruments. Two copies of the application and supporting material (one original and one copy) should be submitted to the IRB Office (AD 250). Applications must be hand-signed by the Principal Investigator (PI), all co-investigators, and faculty advisor/sponsor (if applicable). The CITI training completion date for all listed investigators and sponsor (if applicable) must be included. If your application is incomplete, the review of your project may be delayed.

The numbered items below match the numbered items on the *IRB Application for Human Participant Research*. If you have further questions, please call the IRB Administrator at 216-397-1527.

1. **PROJECT TITLE:** List the title of your proposed research project.

2. **PROJECT DATES:**
    a. Enter the date that you wish to begin your project and the anticipated completion date of the project. Note that you cannot begin your project until you have received approval from the IRB. In general, your anticipated starting date should be at least three to four weeks after the date you hand in your application to the IRB.
    b. Check "Yes" if you plan to conduct this project on an annual basis, continuing basis, or if you think your project will take more than one year to collect and analyze the data.

3. **PRINCIPAL INVESTIGATOR:**
    a. The principal investigator (PI) is the person in charge of the research project and is expected to be the person to complete and submit the IRB application.
        - ✓ If you are a JCU faculty member, list the name and email address of your department chair.
        - ✓ If you are a JCU administrator or staff member, fill in the name and email address of your immediate supervisor.
        - ✓ If you are a JCU student, fill in the name and email address of your faculty sponsor's department chair.
        - ✓ If you are a department chair, mark these lines as N/A (not applicable).
        - ✓ If you are an external researcher, mark the area requesting supervisor information as N/A (not applicable).

b. Mark the appropriate status for the PI. External PIs should mark "Other." Students and external researchers must also provide their current address.
c. Students and external researchers should fill out this section. External researchers should check the "Other" category for type of project. Note that external researchers must have a John Carroll University faculty or staff sponsor in order to submit an application to the IRB. Faculty and staff sponsors are required to complete CITI training in the ethical conduct of human subjects research. See http://sites.jcu.edu/research/pages/citi/ for more information.

Once an application has been received by the IRB Office, the IRB Administrator will notify the PI and the departmental chair/supervisor by email that the application has been submitted and received. Once the project is approved, the final approval letter will be copied to the PI and the PI's chair/supervisor as well.

4. **FUNDING:** State if the project will be funded (or if funding has been applied for) by marking "Yes" or "No." If "Yes," state the funding source. Note some outside agencies require that a project is approved by the IRB before submission of the grant proposal.

5. **RESEARCH STATEMENT:** Provide a description of your project. Be sure to include the research hypothesis and rationale for the study, and cite previous research where applicable. What do you hope to find out by your research?

6. **RESEARCH RESULTS:** Explain how you will use the information you collect. Will you present the results of your research publicly, for example, at a conference, workshop, or at the Celebration of Scholarship? If this project is being conducted for internal purposes only, or to satisfy the requirements of a class project, and the results will not be shared publicly, IRB approval may not be necessary. Contact the IRB Administrator for clarification of IRB requirements.

7. **PARTICIPANTS:**
   a. Who are your participants? If you plan to include or exclude specific participants that aren't described by these check boxes, please check "Other groups" and describe your participant pool.
   b. If you plan to recruit students you are currently teaching to participate in your research, you must have a procedure in place for ensuring you will not know which students have consented to participate until after semester grades have been posted. Please see IRB guidelines on Faculty Use of Students in Research for suggestions regarding how to mitigate coercion of student participants.
   If you are recruiting JCU employees for your research, you must explain why this population is necessary to the study and how you will protect employee confidentiality. Protecting the privacy and confidentiality of research participants is a significant ethical concern, especially in a small, locally known population.
   c. If you are using a special population, state your reasons for targeting a special group. If you are using single subject population, state why you are excluding others from the research.

d. Indicate the approximate number of participants you plan to recruit for your project. If the participants will be divided by gender, race, age, etc., note how many participants in each group you plan to use (e.g., 10 males & 10 females).
e. How will you recruit your participants? Will you be getting a list from an organization? Will you be contacting people directly or will someone contact potential participants on your behalf? Note that the IRB must review any materials used to recruit participants including printed notices, email announcements, social media posts, and JCU Psych Pool electronic sign-up forms. Verbal scripts for any personal solicitation should be submitted to the IRB also, if used.

8. **INFORMED CONSENT:** Consent documents are closely examined by the IRB and often returned to the researcher with suggestions for revisions. Detailed information on writing an effective informed consent document can be found on the JCU IRB website at **http://sites.jcu.edu/research/pages/irb/informed-consent/**.
   a. Indicate what **type** of consent/assent you are requesting. From whom will informed consent/assent be obtained?
      i. Will you be requesting adult consent? (18 years and older in the state of Ohio)
      ii. Will you be using minors as participants? When minors are used as participants, it may be necessary to obtain both consent from one or both parents/guardians and an assent from minors. Knowing if the child is a proficient reader will help you make a decision on how to best present the study information to the child and obtain his/her assent. See additional information about child asset at **http://sites.jcu.edu/research/pages/irb/informed-consent/assent-information/**.
      iii. Under certain circumstances, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of fully-informed consent. For example, certain aspects of the study (e.g., the true purpose of the study, certain research procedures, etc.) may initially be concealed from the participants in order to avoid influencing their responses. All studies that involve concealment must include a plan to debrief participants.

      Under limited circumstances, the IRB may waive the requirement to obtain informed consent (e.g., participants cannot give their informed consent because of a medical condition, obtaining parental/guardian consent from a neglected or abused child is not a reasonable requirement to protect the child). To request the informed consent or assent process be waived, indicate the category of the waiver from the choices given and justify your request. The IRB will determine if a waiver of informed consent can be used based on federal guidelines and ethical considerations.
   b. If your study design involves any form of deception (i.e., deliberately providing participants with false information), you must provide the IRB with additional information about the nature and purpose of the deception. The use of deception must be fully justified. See IRB guidelines on Concealment and Deception in research.
      i. Describe in detail the nature of the deception you will use. How and when will it take place during the study?
      ii. Explain why the deception is necessary to the research and why the research could not successfully be conducted without the deception.
      iii. You must describe alternative procedures to the deception you considered and why you rejected them.

iv. Deception of participants is only justified when significant prospective scientific, educational or applied value may result from the research. Explain how the benefits of this research outweigh the use of a technique that is not honest and truthful.
v. Describe procedures for debriefing participants. Remember that participants must be given the opportunity to withdraw their data from the research at any time, even after the experiment has concluded.

c. Indicate the **method** you will use to obtain informed consent/assent. A written consent document (i.e., obtaining a written signature from a participant) is the preferred method. A copy of the written consent is generally given to the participant at the time of signing. However, in cases where a breach of privacy is a risk to the participants (e.g., if you are collecting sensitive personal information), written consent (i.e., a written signature) can be omitted. Written consent can also be waived in other minimal risk research (e.g., psych pool studies, Qualtrics surveys). If a waiver of written consent is requested (ii), indicate how participants will be informed (e.g., an information sheet, oral consent, electronic consent), and explain your rationale where requested. The IRB will determine if these methods can be used based on federal guidelines and ethical considerations.

9. **DATA COLLECTION & CONFIDENTIALITY:** How the study data are collected and stored are important factors in reviewing the application.
   a. Indicate in this section how you will collect the data. Check all that apply.
   b. Will the data be collected anonymously, so even you, the researcher, cannot determine who participated? See IRB guidelines on Privacy for more information, including the difference between anonymous and confidential data.
   c. If you answered no to 9.b., describe how you will protect the privacy of the participants (for example, by ensuring that interviews be conducted in a private location, or that employees will not be asked to complete a survey while at work). You must also explain how and where the data will be stored and secured, and who will have access to it. In addition, regulations require that signed consent forms be retained for three years after the study ends. Who will maintain the signed consent forms for the required time?

10. **METHODOLOGY:** Describe how the research will be conducted. Walk the IRB chronologically through the steps you will follow to implement the study. Details such as how you will specifically solicit participants, distribute and collect data instruments, code date, etc. should be included. Refer to the attachments as the steps are described.

11. **RISK FACTORS:** The level of risk is an important factor in determining the approval of the project. Coercion is considered a risk factor. If you are using your own students or employees as participants, they are considered to be at risk. If you are collecting personal, identifiable information such as gender, religion, sexual orientation, salary, place of employment, etc., your participants may be at a higher risk for a breach of privacy. Indicate the appropriate risk factors by checking yes or no for each risk criteria.
   a. Describe any additional risks to participants not indicated above. If none, mark this item as N/A (not applicable).
   b. For all potential risks, evaluate their seriousness and the likelihood of their occurrence. If the participants are not subject to any risks, mark this item as N/A.

c. Describe how you will mitigate or lessen the risks to participants. For example, if there is a chance that participants might be distressed by the study procedures, you can provide them with the contact information for the University Counseling Center. Be sure all risks are acknowledged in the participant recruitment material and/or informed consent documents.

12. **BENEFITS:** Describe any benefit to the participants for taking part in this research study and how this project will add to the generalizable knowledge of the subject field.

13. **COMPENSATION:** If you plan to pay participants to take part in this project, indicate what and when you will be paying them. If you are offering other inducements (a lottery, a free meal, course credit), describe the type of compensation and how it will be offered.

14. **SUBMISSION MATERIAL:** The IRB must review copies of all material that the will be presented to participants. This material should be attached to your IRB application. The IRB cannot approve a project without a complete and accurate application and two final copies of all supporting material. Indicate what material you have attached to the IRB application.

15. **CERTIFICATION:** As the principal investigator (whether student, external researcher, or faculty/staff) you should read the certification statement and hand-sign and date the form. Any adverse effects during the experiment should be reported promptly to the appropriate supervisor and to the Chair of the JCU IRB.

    You as PI and any co-investigators are required to complete CITI training in the ethical conduct of human subjects research. See http://sites.jcu.edu/research/pages/citi/ for more information. You must indicate the date on which you completed CITI training.

    List any other main investigators (i.e., co-investigators) taking part in this research. Provide name, title (e.g., assistant professor, lab assistant, student), affiliation, and date CITI training was completed. Each co-investigator must also provide his or her signature. Add lines if necessary for additional co-investigators.

16. **SUBMISSION INFORMATION:** Make sure you provide two complete copies (one original, one copy) of the IRB application including all attachments. Applications can be mailed or hand delivered to the IRB Office in Room 250 in the Administration Building.

Application Help: The IRB Administrator, Carole Krus, is available for advice on the application process. She is happy to review rough drafts and to answer all your questions.

JCU instructors who teach research methods or other classes in which a student's IRB application may be part of the course, should arrange for the IRB Administrator to give a tutorial presentation on the IRB application process during a class period.

Please stop by AD250 or contact her at ckrus@jcu.edu or (216) 397-1527.

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