

## **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). If two copies are not submitted or if your application is incomplete, handwritten, or difficult to understand, 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. **TYPE OF REVIEW.** Read *Information Sheet 1* and *Information Sheet 2* (available on the IRB forms page) to see if your project may fall under an exempt or expedited review category. If you think your projects can be reviewed under one of these categories check the “Yes” box. **If you are uncertain, you may skip this question.**

### *Exempt Review (Information Sheet 1):*

A complete list of federally designated exempt categories is available on the website [www.jcu.edu/research/irb/exempt.htm](http://www.jcu.edu/research/irb/exempt.htm). An exempt review is usually the quickest type of review since it generally involves fewer reviewers (1 or more) but is reserved for certain categories of minimal risk, such as review of previously collected data, anonymous minimal risk survey research, and general program evaluations. Your project is unlikely to receive an exempt review if it involves greater than minimal risk to the participant, if the participants are considered members of a special population group, or if the project involves video or audio taping. The final determination for qualification of exempt status rests with the IRB.

### *Expedited Review (Information Sheet 2):*

A complete list of federally designated categories is available on the website [www.jcu.edu/research/irb/expedited.htm](http://www.jcu.edu/research/irb/expedited.htm). An expedited application requires fewer reviewers (2 or more) than a full board review but is restricted to minimal risk projects falling within specified categories such as survey research, focus groups, or interviews. The major difference between an exempt review and an expedited review for survey research lies in the degree of risk and the issue of anonymity and confidentiality. Confidential minimal risk survey research is usually processed as an expedited review. The final determination for qualification of expedited status rests with the IRB.

**3. 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.

**4. 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 outside researcher, mark the area requesting supervisor information as N/A (not applicable).
- b. Mark the appropriate status for the PI. Outside PIs should mark “Other.” Students and outside researchers must also provide their current address.
- c. Students and outside researchers should fill out this section. Outside researchers should check the “Other” category for type of project. The signature of the faculty sponsor is required before submitting the application to the IRB.

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 received and submitted. Once the project is approved, the final approval letter will be copied to the PI and the PI’s chair/supervisor as well.

5. **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 before submission of the grant proposal.
6. **RESEARCH STATEMENT:** Briefly describe your project and purpose. What do you hope to find out by your research? Provide a short justification for your project.
7. **PARTICIPANTS:**
  - a. Who are your participants?
  - b. 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.
  - c. 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).
  - d. 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 printed materials or computer generated materials used to recruit participants including printed notices, email announcements, 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 [www.jcu.edu/research/irb/consent.htm](http://www.jcu.edu/research/irb/consent.htm).
  - 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?
    - 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 assent at [www.jcu.edu/research/irb/consentassent.htm](http://www.jcu.edu/research/irb/consentassent.htm).
    - 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 informed consent, or waive the requirement to obtain informed consent (e.g., participants must be deceived for the study to be successful, 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. Studies that involve deception must include plans to debrief participants and a debriefing statement must be given to each participant. The IRB will determine if a waiver of informed consent can be used based on federal guidelines and ethical considerations.
  - b. 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, when justified, written consent (i.e., a written signature) can be omitted; indicate how participants will be informed (e.g., an information sheet, oral consent, electronic consent – Psych Pool Sona Systems) 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 & CONSENT COLLECTION:** How consent forms and data are collected and stored are important factors in reviewing the application.
  - a. Indicate in this section how you will be collecting data. Check all that apply.
  - b. Will the data be collected confidentially but analyzed anonymously? Will it be collected and analyzed confidentially but rendered anonymous for reporting? See [www.jcu.edu/research/irb/privacy.htm](http://www.jcu.edu/research/irb/privacy.htm) for the difference between anonymous and confidential.

- c. For this item, describe how you will handle the data instruments and consent documents to protect the privacy of the participants. For example, will a participant be asked to seal the consent form and survey together in an envelope before returning them or will consent documents be collected separately from data instruments so the consent forms cannot be linked to the data?
  - d. It is important to explain how the data, once it is collected, will be stored and who will have access to it. Indicate how you will keep the data confidential. Will it be kept in an unsecured area? In a locked file cabinet? Will the raw data be available to an entire class? Will the consent forms and/or identifier codes be stored in the same file cabinet as the rest of the data? Will the data be stored on a hard drive of a computer with multiple users? Who will have access to the names of the participants? 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 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 data, etc. should be included.
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, then they are considered at risk. If you are requesting identifiable information such as sex, religion, salary, place of employment, your participants may experience loss of privacy.
- a. Indicate the appropriate risk factors by checking yes or no for each risk criteria.
  - b. Comment here on any possible coercion which may be experienced by potential and actual participants. Describe any safeguards.
  - c. If the participants will be subject to serious risk, explain the rationale for not using alternative methods. Explain any safeguards in case of any anticipated adverse effects. If the participants are not subject to serious risk, mark this item as N/A (not applicable).
  - d. 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.
  - e. If you plan to pay participants to take part in this project, indicate what you will be paying them and how often 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.
12. **SUBMISSION MATERIAL:** The IRB must review copies of all final material that 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 final copies of all supporting material. Indicate what material you have attached to the IRB application.
13. **CERTIFICATION:** As the principal investigator (whether student, outsider researcher, or faculty/staff) you should read the certification statement and 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. List any other main investigators (i.e., co-investigators) taking part in this research. Provide name, title (e.g., assistant professor, lab

assistant, student), and affiliation. Each co-investigator should also provide his or her signature. Add lines if necessary for additional co-investigators.

14. **SUBMISSION INFORMATION:** Make sure you provide two complete copies (one original, one copy) of the IRB application including all attachments. If you are in a hurry, you can hand deliver the application to IRB Office in Room 250 in the Administration Building.