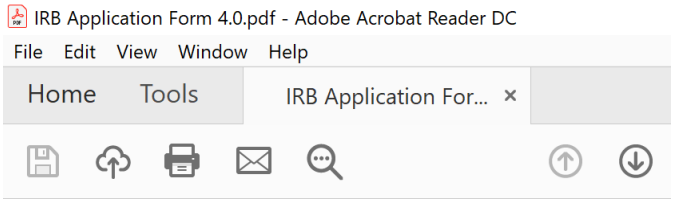
Thank you for downloading the *IRB Application for Human Participant Research*, v. 4.0. This User's Guide is designed to help you successfully complete and submit an application to the JCU IRB. Please contact the IRB Administrator, Carole Krus, ckrus@jcu.edu, with any questions.

Before you begin…
Make sure your computer has the latest version of **Adobe Acrobat Reader DC.** It's available as a free download on the Adobe website for Windows or Mac. If you're working on a JCU-owned desktop computer, look for "Acrobat Reader DC" by clicking the Start Menu. The *IRB Application* is a fillable Adobe PDF form. We have found that the form does not work reliably on an iPad, even if Acrobat Reader is used, so standard laptop or desktop computers are required.

Go to the IRB Forms & Templates webpage and click on "*IRB Application Form 4.0*". Even if you've submitted an application before, please download a new application form to assure that you are using the most up-to-date version. Student investigators and external (outside JCU) investigators should also download "*IRB Research Sponsor Signature Form*." (More information to follow.)

Don't start filling it out now! First download the form by saving it to your computer. It will be named *IRB-Application-Form-4.0.pdf,* but you should rename it using your last name.

Always open, edit, and save your application form using Adobe Acrobat Reader. If you save or edit the form in preview mode or with any other PDF viewer, especially the Apple PDF viewer, the file will be corrupted. In Adobe Acrobat Reader, the top left hand side of the screen will look something like this:



Google Drives: Unfortunately, you cannot edit this form or see the electronic attachments while it is in a Google drive. The form can be shared with others in a Google drive, but it must be downloaded from the drive and then opened with Adobe Reader in order to edit or view attachments.

If you suspect your form has become corrupted (e.g., the fields are no longer fillable, or the pull-down menus no longer work) please contact Carole Krus at ckrus@jcu.edu. This problem is very easily fixed, but any edits you do after it's been corrupted may not be saved. When in doubt, ask!

USER'S GUIDE CONTENTS:

Line-by-Line Directions for Completing the Form:

In each section, 1 through 16, make note of the required fields marked with a red asterisk *.

1. PROJECT TITLE*

This might be the title you will use for a future publication, presentation, thesis, or poster, but it doesn't have to be. Do not use "Capstone Research Project" or "PS301 Research" as the title of your IRB application. Provide a descriptive title for your specific topic of study.

The **IRB log number** will be assigned by the IRB Office. Leave this field blank.

If you are familiar with IRB review categories, you may complete the **Review Category** field. Otherwise you may leave this blank, and the category will be assigned by the IRB Office. Review category guidance can be found on the IRB website, Types of IRB Review.

2. PROJECT DATES*

No research activity can begin until you've received an approval or exemption notice from the IRB. Please note that research activity *includes recruiting potential participants*.

Please indicate the **start** and **end dates** that you anticipate for your research. You can estimate your project starting date based on when you anticipate gaining IRB approval.

Timing:

Minimal risk human research projects classified as **expedited** or **exempt** usually take 2-3 weeks after the initial submission to be approved. If few revisions are needed, or if the revisions are completed quickly, this time may even be shorter!

Higher risk research is often classified as **full board** and must be approved by the fully convened IRB during a scheduled meeting. A list of scheduled meeting dates can be found on the IRB Members & Meetings page. Full board approval can take 6-8 weeks. Students who wish to complete a project in one semester are cautioned against research that would require full board approval. Please see Types of IRB Review for more information about expedited, exempt, and full board project classification.

Indicate if you anticipate your research lasting longer than one year or if you plan an annual project. Protocols that are reviewed by the IRB may be given an approval

expiration date. If your protocol has been assigned an expiration date, it will be indicated on the *Notice of Approval*. Some very low risk expedited protocols are not given an expiration date, and exempt research never has an approval expiration. When an approval period is nearing its end, researchers must apply for Continuing Review.

3. PRINCIPAL INVESTIGATOR INFORMATION*

In section **3.a.**, please provide the name, department, and contact information for the principal investigator (PI). For student group projects, designate one researcher to be the PI. The other group members will be co-investigators (Co-I). All Co-I will be listed in Section 15.

In section **3.b.**, please indicate the PI status. If the PI is a student or external investigator, please provide a current mailing address, such as a house, apartment, or JCU mailbox number.

Section 3.c. Student/External Investigator Information (The blue box)

This section is required only for students and external investigators. Indicate the type of research project you are proposing and the JCU/St. Mary Seminary course number and name, if applicable. All students and external investigators must provide the name of your JCU or St. Mary research sponsor. This could be your course instructor, thesis advisor, independent study mentor, or JCU faculty sponsor. Please provide the name and contact information of this sponsor.

NEW for the '20-'21 Academic Year! The IRB Research Sponsor Signature Form:
Student and external investigators are required to submit an *IRB Research Sponsor Signature Form* with your completed application. This form is also found on the IRB Forms & Templates page of our website. Just like the *IRB Application*, the signature form requires that you download it to your computer and then use Adobe Acrobat Reader each time you edit and save.

After the sponsor has read your entire IRB application and is familiar and satisfied with the research methods, your sponsor must provide either a **digital signature** or a **written signature** under the *Sponsor Statement*. More information about providing a digital signature is found on the *IRB Research Sponsor Signature Form*. If the form is printed out and hand-signed, please scan it into a PDF before submitting. The final signed *IRB Research Sponsor Signature Form* should be attached electronically (see Section 14) to your application before it is submitted.

All research sponsors are required to complete the CITI training course "IRB Researchers and Sponsors – Basic Course." Sponsors of student investigators must complete the "Students in Research" module from the list of elective modules. The sponsor's CITI training completion date is required on the *IRB Research Sponsor Signature Form*. See CITI Training for more information.

4. FUNDING*

Indicate if you are receiving money from a source outside of JCU to financially support the proposed research efforts. If "Yes," list the name of the source or the name of the sponsor.

All grant and external funding administration must be managed through the Office of Sponsored Research. Please see the Director of Sponsored Research for more information.

5. RESEARCH STATEMENT*

Please provide an abstract or brief summary of your research. Include information about the background and rationale for the study, your motivation, the hypotheses, and the goal(s) of the study. Cite previous research done by you or others, where applicable. Remember that IRB reviewers have diverse backgrounds in various scientific and non-scientific fields, so avoid specific or technical jargon unless they are clearly defined.

Research with human subjects involves putting research participants at risk. In the Research Statement, you should offer your justification for this risk by explaining why this research is important and beneficial. Remember: the benefits must outweigh the risks.

HINT: This is where you "sell your idea" and make a first impression with the IRB. Sloppy grammar, careless spelling, or unfocused writing could taint an otherwise brilliant research proposal.

6. RESEARCH RESULTS*

Indicate what you plan to do with the results of this research. Your plans might include: submitting for publication, presenting at a conference or on a poster, uploading the results to an online or cloud-based platform, archiving the data for a future project, or submitting for a graduation requirement. Contact the IRB Administrator first if the project will NOT be shared outside your immediate classroom.

7. PARTICIPANT POPULATION

7.a.* Check all the groups that will be represented in the participant population. If you need to give more specific description, check "Other groups" and specify who will be in your study population.

In the next box, if necessary, please describe the study population characteristics, including the selection criteria. Give justification for including or excluding specific groups or characteristics, if applicable.

7.b.* Research with Students:

If you are faculty or staff member and you plan to recruit students from courses that you are teaching or your advisees, please indicate "Yes." Coercion to participate is a significant concern when instructors do research with their students or advisees. Please see Faculty Use of Students in Research for instruction on ensuring you will not know which of your students have consented or have not consented to participate until *after* semester grades are posted.

7.c.* Research with Employees:

Indicate whether you will specifically recruit employees of JCU or of another organization. When studying employees in their workplace, they are considered vulnerable subjects, and a breach of confidentiality could potentially put their reputation and employability at risk. Describe your procedures for protecting employees' confidentiality in their workplace.

7.d.* Population Size:
Indicate the approximate total number of participants to be recruited. Then, if applicable, describe the targeted number or percentage for each arm of the study. For example: "50:50 male: female" or "1/3 experimental group A; 1/3 experimental group B; 1/3 control group."

7.e.* Recruitment:
Check all the ways that you plan to recruit participants into your study. You will be required to submit a copy of any recruitment materials. These may include: the study announcement flyer, the SONA posting, the text of a proposed social media post, a proposed recruitment email, or an oral script for telephone solicitation. Remember that participants cannot be recruited until the study has been approved. Any written recruitment material must be free from all spelling, grammar, and typographical errors.

In the box below **7.e.**, describe your recruitment process, if necessary, including your methods for insuring that your participants will fulfill the inclusion/exclusion criteria described in **7.a.**

8. INFORMED CONSENT*

8.a. Type of Informed Consent Obtained:
Check all that apply to your study. In the state of Ohio, a minor is defined as someone under the age of 18. Minors cannot legally give informed consent; minors give *assent*. A minor in a research study would need a parent or legal guardian to provide consent for them. See the IRB Forms & Templates page for parental consent and child assent templates.

8.b. Waiver of Informed Consent:
There are very *specific circumstances* in which informed consent can be waived. For example: some research about natural behavior may require that subjects be unaware that the research is taking place. Research on previously collected, de-identified private data can also be done without informed consent from each of the subjects. If informed consent will not be obtained, please indicate this in **8.b.** Boxes must be checked in either **8.a.** or **8.b.**

If you have checked one of the boxes in **8.b.**, you must justify why informed consent will not be obtained. Please see the IRB Administrator for more information on consent waivers.

8.c. Partial Consent: Concealment/Deception:
The use of concealment and deception are used often in social and behavioral research.

- Concealment is when some specific information about the study is *initially withheld* from the participants. For example, in conducting surveys or interviews to assess the prevalence of racial prejudice in a given population, researchers may not want to disclose the study's true purpose, since doing so could prompt the study participants to shade their responses, leading to inaccurate results.
- Deception is when researchers *deliberately give participants false information* about some aspect of the study. Dr. Stanley Milgram used deception in his infamous obedience studies in the 1960's when he told participants that they were administering a painful electric shock to a person by pushing a button.

Both are a form of *partial informed consent*, which will be cause for concern, so the use of

concealment or deception must be justified, and all participants must be fully debriefed at the end of the experiment.

In section **8.c.i.**, please describe the type of concealment or deception being proposed. In section **8.c.ii.**, explain why concealment or deception is a necessary component of your experimental design. In section **8.c.iii.**, describe the debriefing procedure, when all truth will be revealed to the participants. Make sure the debriefing materials are included in the supporting materials attached to the application.

8.d.* Method to Document Informed Consent:
Will you document informed consent with signatures? You must check **(i)** yes or **(ii)** no. If you check **(ii)** and are requesting a waiver of signature on an informed consent document, indicate how the participants will be informed and will grant consent. Common options:

- An **Information Sheet** is similar to a traditional informed consent document, but it is not signed by the participant or guardian. It can be used in minimal risk research. Each participant is given a copy to read and sometimes keep.
- **Oral Consent** is often obtained in cases when participants are unable to read or write or with non-English speakers, but a signature from a witness must be collected. (See the IRB Administrator for details about gaining oral consent.)
- **Electronic Consent** is common with minimal risk online surveys or on-screen data collection methods such as SONA studies. Participants do not give a signature, but they often "click" to grant consent after reading the study information.

If you check **(ii)** and you will not collect a signed informed consent document, please explain your rationale in the text box.

9. DATA COLLECTION & CONFIDENTIALITY ISSUES
9.a.* Check all the methods you will use to collect data. If you need to check "Other," please describe your special data collection methods.

9.b.* If you will collect data anonymously so that no one, not even the investigators, could connect data to a specific participant, then check "Yes." In JCU SONA studies, when Psych pool members appear in person to participate in the experiment and the researchers *see* the participants, there is visual identification, even if names are not collected. Therefore, most SONA studies are not anonymous.

9.c. If you have checked "No" in **9.b.**, then describe how you will keep the collected personal data confidential and secure. Please include your methods for collecting, storing, and protecting the data throughout the entire study.

10. METHODOLOGY*
Please describe each step of your research project chronologically. It's often very helpful to write each step separately in a numbered or bulleted list, while referring to your supporting documents so the IRB reviewer can follow along. Be sure to include, when applicable:

- How potential participants will be identified and contacted
- The recruitment and screening process

- Informed consent procedures
- The location(s) of the study
- All data collection methods and instruments used
- How data will be recorded, stored, and shared among co-researchers
- Any "timing" issues (# of interactions, time between interactions, follow ups, etc.)
- If you're using an electronic survey, include the link
- Methods for ensuring the safety of the participants
- Plan for stopping the study in case of an unanticipated problem or adverse event
- Debriefing process, if applicable
- Data analysis methods (general description)

This section should be clear and make sense even to someone who is unfamiliar with your project. If any part of this Methodology description is unclear or incomplete, revision will be required!

11. RISK FACTORS*

Please consider very carefully all the ways that risk could enter into your study. Err on the side of caution. *Risks cannot be mitigated unless they are acknowledged.*

11.(i)* Describe any other potential physical, psychological, social, or legal risks to the participants of your study.

11.(ii)* For all potential risks, discuss the likelihood and seriousness of these risks occurring. The IRB will be very concerned that you fully understand and respect the level of risk in your study.

11.(iii)* Describe all the procedures you will put in place to mitigate these risks, including any necessary professional intervention in the event of a distressed or injured participant.

12. BENEFITS*

Briefly describe the anticipated benefits to the participants, if any, to the general knowledge in your area of study, or to society in general. Compensation is not a benefit.

13. COMPENSATION*

Describe how participants may be compensated. This might include any food or drink provided to study participants or prizes (such as gift cards) awarded to participants chosen in a lottery. If students are receiving course credit, extra credit, or SONA credits for participating, describe this compensation, and indicate what alternatives are offered to those students who do not wish to participate in the research.

14. SUPPORTING MATERIALS*

All supporting materials must be submitted with the application or else the application is considered incomplete. These materials may include: all recruitment materials, informed consent/assent documents or scripts, data instruments (including surveys, interview questions, photos, music, videos, or anything else used in the data collection process), letters of support, and debriefing statement, if applicable. If you've created an online survey, include the link in this section. Any study material viewed or experienced by the

study participants, including electronic surveys, must be free of spelling, grammar, and typographical errors.

Student and external investigators must attach a signed *IRB Research Sponsor Signature Form*.

Any investigator who completed **CITI training** through JCU does not need to attach a completion certificate; the completion date is all that's required. However, if an investigator completed CITI, NIH, or any other type of human subject research training through another institution, please attach a certificate or some other proof of completion with the date of completion.

These materials should be attached as electronic files in .doc, .pdf, .jpeg, .wav, or any other commonly used file format. Please give these files names that clearly indicate what they are so they can be easily identified by the IRB reviewer. Click on the yellow "ATTACH" button, and you will be prompted to select the file from your computer. Repeat the process until all your supporting files are attached.

To view and manage your list of attachments, click the light blue "View Attachments" button. You can also click on the little paperclip icon along the left hand side of the screen. When the Attachments Pane opens up on the left hand side of the screen, you will see the list of files that you've attached to the application. You can delete or add files, as needed.

15. CERTIFICATION STATEMENT*

The PI and all co-investigators (Co-Is) engaged in this research project should carefully read the **Certification Statement**. The PI should type their name beneath this Statement, enter the date, and their CITI training completion date.

Anyone engaged in contacting or interacting with participants or has access to identifiable study data should be included as a Co-I. Each Co-I's full name, email, affiliation (if not with JCU), and CITI training completion date should be entered in the **CO-INVESTIGATORS** section. Please include "Dr.", "M.D.", "Ph.D.", or any relevant title or licensure with the name, if applicable.

Each Co-I should also SAVE the completed file to their computer. All project-related communication between the IRB Office and the research team should include all the names on this application. Investigators should be mindful to cc: all the co-investigators, including the research sponsor, if applicable, when sending emails.

16. SUBMISSION INFORMATION

The PI must make sure all sections of the application are complete, especially the required fields* and the CITI training completion dates. All supporting documents should be attached electronically. Student and external investigators must also include a signed *IRB Research Sponsor Signature Form*.

Please give the application a **file name** that includes the last name of the PI. (For example: *Smith_IRB_Application.pdf*) Please do not submit an application with the originally downloaded file name *IRB Application Form 4.0.pdf.*

The completed application should be emailed by the PI to IRB@jcu.edu. The entire research team will receive an email acknowledgment when the application has been received and logged into the IRB Office. This will not be an automated email, but you should hear from the IRB Office within two working days. You will also be given an IRB log#. The IRB Office processes ~100 applications per year, often several from the same investigators. To avoid confusion, please use your application's log# in all correspondence with the IRB Office.

The Review and Revision Process:

After an application has been reviewed, the IRB Office will send the investigator(s) a response that might include questions, comments, required revisions, and suggested changes:

1. Depending on the review category and level of risk, the IRB Office may ask for specific revisions so that the research protocol complies with federal regulations.
2. Using only the most *recently updated version* of the application (see the **File Revision Names** section below), the PI should make their edits and resubmit the application to IRB@jcu.edu.
3. Any document or media that is seen by study participants (or potential participants) must be free from all grammatical, spelling, and typographical errors. It should also be composed and formatted clearly and professionally.
4. The IRB Office reserves the right to ask for revisions in the content and formatting of the protocol materials in order to maintain a high level of quality within the JCU research community.

Communication with the IRB Office:

1. Always use the IRB log # in your email correspondence with the IRB Office. Put the log # in the email subject line.
2. Always cc: all members of your research team, including the research sponsor if applicable, when corresponding with the IRB Office. Hit "Reply All" when replying to emails.
3. Please email (ckrus@jcu.edu), call (216-397-1527), or visit (AD250) the IRB Office with questions or problems. This is a complex and often confusing process, and we're here to help!

File Revision Names:

When your submitted application file is logged in, your file will be given a new file name in this format: **<YYYY-000 PI name_advisor name.pdf>**.

> For example: in the 2021 academic year, the 1st application, submitted by student John Smith who is advised by Dr. Mary Jones, will have an application file initially logged in as: **<2021-001 Smith_Jones.pdf>**.
>
> Faculty and staff PIs will not have a research advisor, so Dr. Mary Jones' application would be named: **<2021-001 Jones.pdf>**.

NEW for 2021 Academic Year: In order to better keep track of subsequent revisions, your application will be given dated file names by the IRB Office each time it is revised.

> For example: the version of the application that was most recently updated on September 16, 2020 will be named: **<2021-001 Smith_Jones 091620.pdf>.**

These dated file names will be given by the IRB Office, but the research team should take care to always use the most recent work-in-process version (which is why everyone needs to be included in all emails!) Always download and use the most recent revision of your application throughout the revision and approval process.

Once your application has been **approved** by the IRB, it will be given a file name with the word "Protocol."

> For example, John Smith's application that was approved on 09/16/20, will be named **<2021-001 Smith_Jones Protocol 091620.pdf>.**

And further revisions to an approved protocol will be given updated protocol names.

Problems and Questions?

If you have any problems completing or submitting the IRB form, please contact the IRB Administrator, Carole Krus, at ckrus@jcu.edu or 216-397-1527.