John Carroll University | INSTITUTIONAL REVIEW BOARD

How to Download and Complete the John Carroll University IRB Application Form

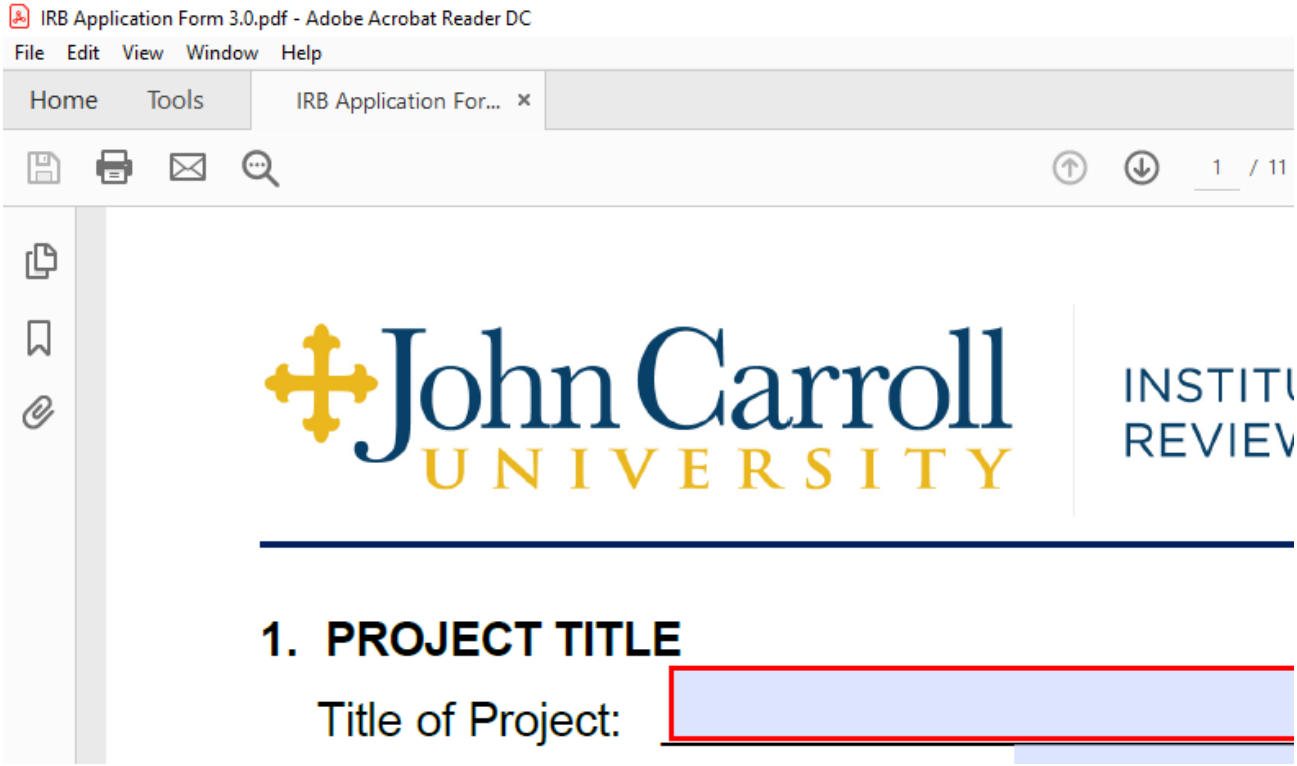
Updated: November 2019

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 are working on a JCU-owned desktop computer, look for "Acrobat Reader DC" by clicking the Start Menu.

Click on the "IRB Application Form" on the IRB Forms & Templates webpage. Even if you've submitted an application before, please download a new application with each submission to assure that you are using the most up-to-date version of the form.

Don't start filling it out now! First download the form by saving it to your computer. It will be named *IRB-Application-Form-3.0.pdf* but you should rename it.

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



Line-by-Line Directions for Completing the Form:

Complete the form by filling out the indicated fields under each section.

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 approval or an exemption 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.

Human research projects that involve low or minimal risk and are classified as expedited or exempt usually take 2-3 weeks after the initial submission to be approved. Higher risk research is often classified as full board and must be approved by the fully convened IRB. Full board approval can take 6-8 weeks. Students who wish to complete a research 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, the approval period will be indicated on the *Notice of Approval*. Some very low risk expedited protocols are not given an expiration date. Exempt research never has an approval expiration. When a project approval period is nearing its end, researchers must apply for a Continuation.

3. PRINCIPAL INVESTIGATOR INFORMATION:

In section 3.a., please provide the name and contact information for ONE principal investigator (PI). For student group projects, designate one researcher to be the PI. The co-researchers will be listed in Section 15. All names listed on the application will be

included by the IRB Office in all project related correspondence. Likewise, the PI should

include (cc:) all co-researchers in their communications with the IRB Office.

JCU or St. Mary Seminary students, faculty, and staff members who are part of an academic department, please list the name and email of your *department chair;* researchers who are department chairs or other employees who do not report to an academic chair, please list the name and email of your *supervisor* at JCU or St. Mary Seminary. In section 3.b., please indicate the PI status. If the PI is a student or external researcher, please provide a current mailing address.

Section 3.c. Student/External Researcher Information (The blue box)
This section is required only for students and external researchers. 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 researchers must provide the name of your JCU or St. Mary research sponsor. This could be your course instructor, thesis advisor, independent study mentor, or co-researcher. Please provide the name and contact information of this sponsor.

The research sponsor must provide a **digital signature** under the Sponsor Statement. After the sponsor has read the entire application, including the Sponsor Statement, and is satisfied with the research methods, the sponsor should click on the digital signature box. If the sponsor has never digitally signed an Adobe PDF before, they will be instructed to establish a password-protected, digital signature. After the digital signature and password are established, these will be saved to the sponsor's computer, and they will be able to sign all subsequent Adobe digital forms by using their password. This will be a date-stamped, verified electronic signature. After completing the digital signature, the sponsor will be prompted to SAVE the form to their computer. After the application is signed, the sponsor should email the form back to the PI.

All research sponsors are required to complete the CITI training course "IRB Researchers and Sponsors – Basic Course." Sponsors of student researchers must complete the "Students in Research" module from the list of elective modules. Please provide the sponsor's CITI training completion date in this section. 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 research hypothesis, and the goal(s) of the study. Cite previous research done by yourself 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.

6. RESEARCH RESULTS:

Indicate what you plan to do with the results of this research. Please include plans that might include: publishing, presenting publicly 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 the classroom.

7. PARTICIPANT POPULATION:

7.a. Check all the groups that will be represented in the research 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. For each method, you must attach a copy of the recruitment materials. These may include: a copy of the study announcement flyer, the SONA study posting, the text of a proposed social media post, a copy of the proposed recruitment email, or an oral script for telephone solicitation. Remember that participants cannot be recruited until the study has been approved.

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:
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 provide consent. See the JCU website for parental consent and child assent templates for you to use.

If your study will use **concealment** or **deception** (see **8.b.** for definitions), you will be collecting *partial informed consent* because your participants will not be fully informed. If you check either of the boxes in **8.a.iii.**, please explain your use of concealment or deception in **8.b**.

There are very specific circumstances when informed consent can be completely 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 you check **8.a.iv.**, please explain in **8.c**. (see below).

8.b. Partial Consent: Concealment/Deception:
The use of concealment and deception are often used 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.b.i.**, please describe the type of concealment or deception being proposed. In section **8.b.ii.**, explain why concealment or deception is a necessary component of your experimental design. In section **8.b.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.c. Complete Waiver of Informed Consent:
If you have checked one of the boxes in **8.a.iv.**, you must justify why informed consent will not be obtained. The specific requirements for a waiver of informed consent are found at §46.116(f)(3) of the federal regulations.

8.d. Method to Document Informed Consent:
You must check **(i)** or **(ii)**. 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, if applicable. An **Information Sheet** is similar to a traditional informed consent document, but it is not signed by the participant or guardian. **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 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 **8.d.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 researchers, 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 researcher(s) *see* the participants, there is visual identification, even if names are not collected. Most SONA studies are not anonymous.

9.c. If you have checked "No" in **9.b.**, then describe how you will keep the data that you will

collect confidential and secure. Please include your methods for collecting, storing, and protecting the data throughout the study.

10. METHODOLOGY:

Please describe each step of your research project chronologically. Be sure to include your recruitment process, informed consent procedures, the location(s) of the study, data collection methods, debriefing (if applicable), and data analysis methods. 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.a. Describe any other potential physical, psychological, social, or legal risks to the participants of your study.

11.b. For all potential risks, discuss the likelihood and seriousness of these risks occurring.

11.c. 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. The IRB will be very concerned that you fully understand and respect the level of risk in your study.

12. BENEFITS:

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

13. COMPENSATION:

Describe how participants will be compensated. This might include any food or drink provided to study participants or prizes (such as gift cards) awarded randomly to participants chosen in a lottery. It 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. Any material viewed or experienced by the study participants must be submitted as part of the application. This would 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), and debriefing statement, if applicable.

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. Click on the "ATTACH FILE" button, and you will be prompted to select the file you would like to attach. Repeat the process until all your supporting files are attached.

To view and manage your list of attachments, click the yellow "VIEW Attachments" button or the little paperclip icon along the left hand side of the screen, and the Attachments Pane will open up. You will see the list of files that you've attached to the application.

NOTE: once the form is digitally signed, Adobe Acrobat does not allow attached files to be removed, but new files can be attached. The IRB Administrator is able to override this limitation. If you need to make revisions to your attachments after the form is digitally signed, please contact the IRB Administrator for help.

15. CERTIFICATION STATEMENT:

The PI and all co-researchers engaged in this research project should read the **Certification Statement**. The PI should type their name beneath this Statement, enter their initials, the date, and their CITI training completion date.

Each co-researcher should enter their name, email, affiliation (if not with JCU), CITI training completion date, initials, and the date as a sign that they agree to the Certification Statement. Each co-researcher should also SAVE the file to their computer. Once all co-researchers have initialed the application, it should be sent back to the PI.

16. SUBMISSION INFORMATION:

The PI must make sure all sections of the application are complete, especially the required fields outlined in red. All supporting documents should be attached electronically. Student Researchers and external researchers must also include a digital signature from their research sponsor in section 3.c., the blue box.

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 file name *IRB Application Form.pdf* or *ResearchProject.pdf.*

Completed application should be emailed by the PI to IRB@jcu.edu. You will receive an email acknowledgment when the application has been received and processed for review. 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#. Use this log# in all correspondence with the IRB Office concerning your application.

Communication with the IRB Office:

1. Please *always* use the IRB log# in your email correspondence with the IRB Office. Put the Log # in the email subject line.
2. Always include (cc:) all members of your research team when corresponding with the IRB Office. Hit "Reply All" when replying to emails.
3. Once your application has been submitted and logged in, your file will be given a file name in this format: <YYYY-000 PI name_Advisor name.pdf.> For example, in the 2020 academic year, the 12th application, submitted by student John Smith who is working with Dr. Mary Jones, will have an application file named: **<2020-012 Smith_Jones.pdf>**. Faculty and staff PIs will not have a research advisor, so Dr. Mary Jones' application would be named: **<2020-012 Jones.pdf>**.
4. ALWAYS DOWNLOAD AND USE THE UPDATED VERSION of your application throughout the revision and approval process. The IRB Office will enter data into some of the fields, and your application might go through several changes, so use the updated version with each communication. Don't go back to your original IRB application version!

The Review and Revision Process:

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

1. Using only the most *recently updated version* of the application, the PI should make their edits and resubmit the application to IRB@jcu.edu. The file name should be in the <2020-000 Smith_Jones.pdf> naming format.
2. Depending on the review category and level of risk, the IRB Office may ask for revisions so that the research protocol complies with federal regulations.
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.

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.

Version 2.0
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