

## **For IRB Members:** ***How to Review the new Electronic IRB Applications***

Please use the following guidelines for reviewing the new electronic IRB Applications. You are free to print out any application documents that I send you, but we are trying to keep the review process as paperless as possible.

If there are ever any problems with opening or viewing an application or any of the attachments, please don't hesitate to contact me at [ckrus@jcu.edu](mailto:ckrus@jcu.edu) or even on my cell phone, 216-952-7717. We are still ironing out the wrinkles in this system, so feedback is welcome!

### **1. Get “Adobe Acrobat Reader DC”, version 10:**

Make sure you have the PDF viewing program Adobe Acrobat Reader DC, better known as just Adobe Reader loaded on the computer(s) that you will use to review applications. If you do not have Adobe Reader on your personally owned computer(s), it is available as a free and easy download for both Windows and Mac: [ADOBE DOWNLOAD](#).

JCU employees are restricted from downloading programs onto JCU-owned computers, so I have placed a request with Information Technology Services to make sure all IRB Members are given Adobe Reader on your JCU-owned office computers. If Adobe Reader does not appear on your desktop or if you have any problems with it on your JCU office computer, please let me know and I will follow up with ITS.

### **2. Download the Application File:**

When you are sent an IRB Application to review, and agree to review it, please download the application and save it to your computer. Don't just click and start reading – you must download it so you can use Adobe Reader. The application file name will be in this format: *IRB 2019-xxx LastName.pdf* where “LastName” is the PI's last name. For student applications, the file name will be *IRB 2019-xxx StudentName\_AdvisorName.pdf*. The file will always be in the PDF format.

### 3. Open the Application file with Adobe Reader:

Open the Adobe Acrobat Reader DC program by clicking on the icon or choosing the program on your computer. Once Reader is running, open up the application file to review.

Alternatively, Windows users can right-click on the saved application file and choose the “Open with >” option then select “Adobe Reader DC”. Many of you may have Adobe Reader as your default PDF viewing program. If this is the case, when you open up any PDF, your computer will automatically open it with Adobe Reader. However you choose to open the application file, make sure you’re viewing it with Adobe Reader and not just a PDF preview window. In Reader, the application will look like the window below. Note that the top of the screen will indicate “Adobe Acrobat Reader DC”.

The screenshot shows the Adobe Acrobat Reader DC interface. The title bar indicates the file is "Electronic IRB Application Form for Download.pdf - Adobe Acrobat Reader DC". The window title is "Electronic IRB Appli...". The toolbar shows various navigation and editing tools. The document content includes the John Carroll University logo and the text "Institutional Review Board" and "IRB Application for Human Participant Research".

**1. PROJECT TITLE**  
Title of Project:   
IRB Log No. (Assigned by IRB):  Review Category:

**2. PROJECT DATES**  
NOTE: Project work may **not begin** prior to approval or exemption from the IRB.  
a. Anticipated starting and completion dates:  to   
b. Will this project be conducted on an annual basis?  Yes  No

**3. PRINCIPAL INVESTIGATOR INFORMATION**  
a. Contact Information  
Principal Investigator:   
Department or Affiliation:

On the right side of the window, there is a sidebar with options: Comment, Fill & Sign, Send for Signature, and More Tools. At the bottom right, there is a message: "You have a free Document Cloud account Upgrade Now".

#### 4. Review the Attachments

The new application file will include all the supporting documents as attachments within one PDF document. This means that all the attachments are already part of the file that you've downloaded. To view the attachments, you can scroll down to page 9 of the application, the SUPPORTING MATERIALS section, where you'll see a yellow box labeled "VIEW". By clicking this button, the Attachments Pane will open up on the left-hand side of the screen:

**14. SUPPORTING MATERIALS**

All supporting documents must be submitted with this application. The IRB must review all materials that are presented to or seen by any participants during the study. Indicate below what materials will be attached to this application. Check ALL that apply:

- Recruitment Materials (flyer, ad copy, social media post, recruitment email, SONA study page, etc.)
- Informed Consent (consent and assent forms, information sheet, electronic consent page, oral consent script, translated informed consent documents for non-English speakers, etc.)
- Data Instruments (surveys, interview questions, tests, links to internet surveys, etc.)
- Debriefing statement
- Other: (specify) \_\_\_\_\_

Attachments Pane: **VIEW** **ATTACH FILE**

(will appear on the left)

Electronic files should be attached to this form by clicking **ATTACH FILE**. You will be asked to choose files from your computer that you wish to attach. Please give your documents names that clearly identify what they are. (e.g. AppendixA.doc, RecruitmentFlyer.pdf, Informed\_Consent.doc, etc.)

The other way to open up the Attachments Pane is to click on the little paperclip icon that you'll see along the left hand screen margin:

Please fill out the following form. When finished, click Submit Form to return the completed form.

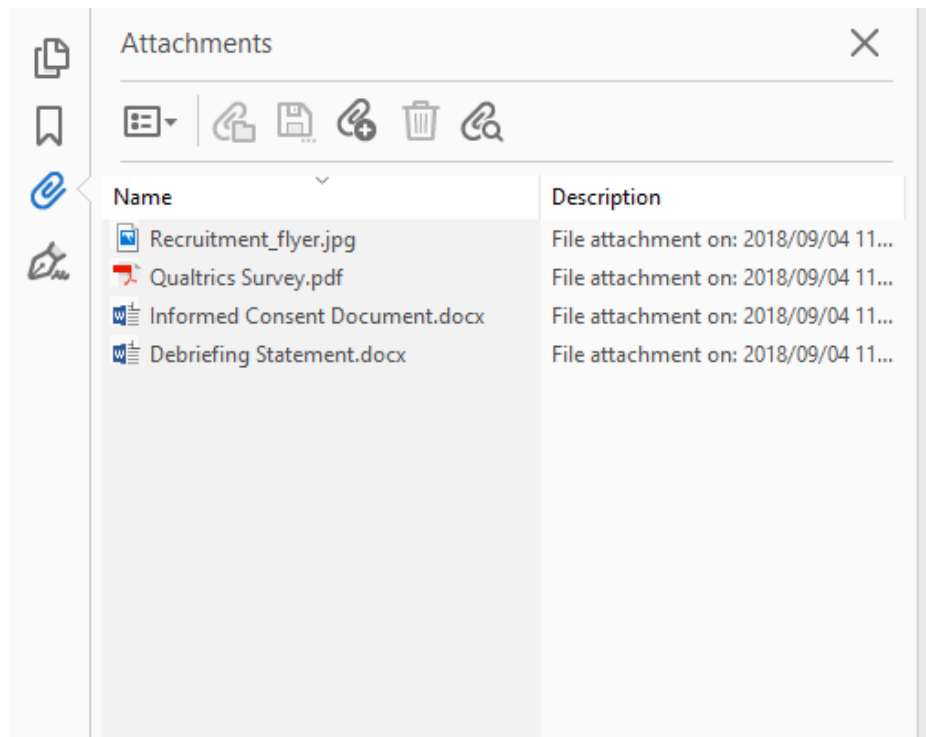


## 1. PROJECT TITLE

Title of Project:

IRB Log No. (*Assigned by IRB*)

Either method will open up the Attachments Pane, which will look like this:



Informed Consent (consent ar  
 consent script, translated infor  
 Data Instruments (surveys, int  
 Debriefing statement  
 Other: (specify)

**Attachments Pane:** [VIEW](#)  
 (will appear on the left)

Electronic files should be attached t  
 files from your computer that you wi  
 what they are. (e.g. AppendixA.doc,

Each of the documents listed in the Attachments Pane are included in the file and should be considered part of the application. You can open and view each document by clicking on it. If you'd like, you could save documents to your computer or print them, but it isn't necessary. They will remain attached and always be there to click, open, and view. By clicking the "VIEW" button or the paperclip icon again, you can close the Attachments Pane.

### 5. Signatures and CITI Training:

You will notice that the electronic applications are not signed by the PI. When the PI sends their completed form to the IRB inbox, we verify that it's sent from the PI's password-protected account. This is their "signature". All the co-researchers add their initials to the protocol, but the PI is the only one who is signing the **Certification Statement** and is ultimately responsible for the ethical conduct of the protocol.

When applications are submitted, I make sure all the CITI training dates are filled in and are correct, but if I miss one and you see a blank "CITI training" field, please don't hesitate to point it out in your review.

Student researchers and external researchers must have their research sponsor provide a digital signature to the application. Directions for completing a digital signature are found on page 11 of the application and on the JCU website. Make sure student researchers and external researchers have completed **Section 3.c** (the blue box) on page 1 of the application and that the research sponsor has provided a digital signature. It will look like this:

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

Type of project:

Course # & Name:

JCU Faculty/Staff Sponsor:

Department:

Sponsor Email:  Phone:

**Sponsor Statement:**

*By signing below, I confirm that I am familiar with the project proposed on this IRB application, and I have fully reviewed this completed form. I am satisfied with the proposed research design and the measures proposed for the protection of human participants. As the sponsor, I assume responsibility for conduct of ethical human subject research and applicable and/or required data security measures.*

Electronic Signature of Faculty/Staff Sponsor:  Digitally signed by Carole Moran Krus  
Date: 2018.09.04 13:00:36 -04'00' (See p.11 for signing instructions)

All faculty/staff sponsors are **required** to complete [CITI training](#) and choose the “Students in Research” module as one of the course electives.

Sponsor’s CITI Training Completion Date:

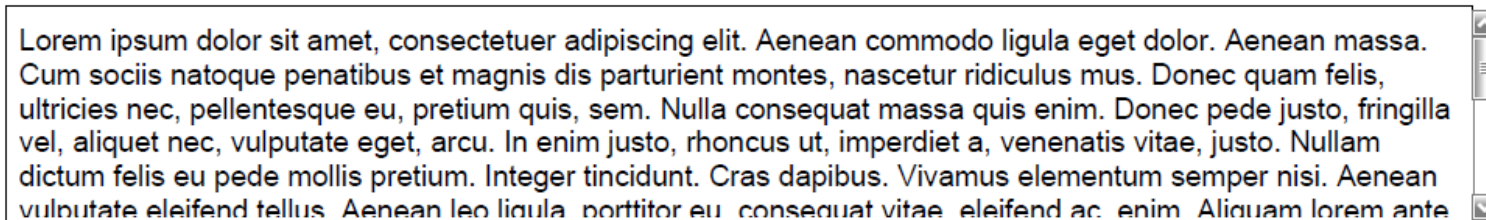
## 6. Review the Application:

Read through the application and all the attached documents as you would a paper application.

In some of the sections, the PI might have written an answer that is larger than the text box that was provided. In this case, you'll see a scroll bar along the right-hand side of the box that will allow you to scroll up and down to read everything that is written in the text box.

- a. Describe any other potential risks to participants besides those above. You should consider potential physical, psychological, social, legal or other risks.

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aenean commodo ligula eget dolor. Aenean massa. Cum sociis natoque penatibus et magnis dis parturient montes, nascetur ridiculus mus. Donec quam felis, ultricies nec, pellentesque eu, pretium quis, sem. Nulla consequat massa quis enim. Donec pede justo, fringilla vel, aliquet nec, vulputate eget, arcu. In enim justo, rhoncus ut, imperdiet a, venenatis vitae, justo. Nullam dictum felis eu pede mollis pretium. Integer tincidunt. Cras dapibus. Vivamus elementum semper nisi. Aenean vulputate eleifend tellus. Aenean leo ligula porttitor eu. consequat vitae eleifend ac enim. Aliquam lorem ante



Otherwise, review the documents of the application as you always have. For Expedited Reviews, use the [Expedited Review Checklist](#) to submit your review.

**Questions or Problems?** Please contact me by phone, email, or text. I really appreciate all of your support in working toward an efficient paperless IRB review system!

Carole  
[ckrus@jcu.edu](mailto:ckrus@jcu.edu)  
216-397-1527 (office)  
216-952-7717 (cell)