IRB APPLICATION INSTRUCTIONS

Making Changes to an Unsubmitted IRB Application

- **Do not Submit** your application by clicking on the "Submit" button at the end of the application!
- Use the **"Save and Resume Later"** button at the bottom of the application.
    - When you use the "Save and Resume Later" option, you will get a link to take you back to the application.
    - Each time you make changes/additions and use the "Save and Resume Later" option, you will get a new link. Be sure to save the new link as the old one will not show your latest changes.
    - You can use this option to forward the link to your chair and dean for approval and possible suggestions.
    - HINT: Attachments will not be saved to this form until you "Submit". While using the "Save and Resume Later" option, attach your documents to the e-mail you send to your chair and dean with the link. Be sure to let them know to use the latest link if they make any changes to the application.
    - **The link is only good for 30 days.** You can go in and "Save and Resume Later" just to get a new link which will be good for 30 days. If there is no activity on an unsubmitted IRG application for 30 days, the form disappears.

Completing a New IRB application

IRB Application Section	Instructions
I.A. PI Name	
I.B. Student PI?	If so, the faculty sponsor will submit the form with the attachments when it is ready.
I.C. Co-investigators	All information for co-PIs and research team is under Section II.K.
I.C.1. Other authorizers	Dept. chair and dean need to approve the study. Forward an approval e-mail to research@fgcu.edu.
I.D. Project Title	
I.E. Location of Project	Where will the participants be participating?
I.F.1. Regulatory Compliance	Is this study sponsored? Complete the sponsor information.
I.F.2. Regulatory Compliance	Include anything that may require monitoring, training, or licensing.
I.G Cooperating Institution or Entity	Do you need a letter of cooperation?
I.H. Collaborating Institution or Entity	Do you need a letter of collaboration or will this be a single IRB with another institution or entity
I.I. Sponsored Funding	Include information and copy of the grant if ORSP does not have this grant.
I.J. Level of IRB Review Requested	The IRB may change the requested status based on risk to participants.

IRB Application Section	Instructions
I.K. Conflict of Interest	
II.A. Description 1. Abstract 2. Literature Review 3. Major research question and Hypothesis 4. Please identify the outcome measure.	**Abstract** – a paragraph or 2 describing what you plan to do? This is not the Lit Review. **Lit Review** – Literature review to explain why this study is important. Why should people take their time and any risk involved to participate in the study? **Question and Hypothesis** – What do you expect to gain from your research question? **Outcome measure –** How will you measure the data?
II.B Data Collection	Explain your data, what, how and how will you protect your subject's identifiable private information, i.e. number of participants, demographics, information from survey/interview, findings from testing, etc.
II.C. Participant Population	Are you planning to recruit from a vulnerable population? Your exclusion criteria should mirror your inclusion criteria. You will recruit from this population and you will not recruit form outside this population.
II.D. Participant Recruitment	How do you plan to recruit participants? How will you advertise your study? Will participants be paid? If so, how will you avoid possible coercion among potential participants?
II.E. Informed Consent	If you are using an on-line consent form you will request a waiver of consent # 2. This is still an informed consent, but participants will not sign, they will give consent by moving on to a survey. If you ask for no informed consent, explain in detail why a consent is not required.
II.F Use of Device, Dietary Supplement, Product	Attach all information and any documentation that describes the item and how it will work within your study. How will the participant be involved with this activity?
II.G. Protocol	How do you plan to plan to do this? This can be a numbered list or bullet points. Starting with participant recruitment, consent, data gathering, etc. Give time references, frequency of participation and location/setting.
II.H. Confidentiality and Data Security.	Data should be secured in encrypted software or locked cabinets in the PI's office. If the PI is a student, it should be stored in the Faculty Sponsor's office or computer.

IRB Application Section	Instructions
II.I. Risks	What potential risks will your participants encounter? Check all that apply or # 16 – "no risks above those experienced in daily life". Know where to report disclosures required by law to be reported, i.e., child abuse, elder abuse, self-harm.
II.J. Benefits	What benefits do you hope to prove through this study? If there are risks, how will the benefits outweigh them? Why is it worth the participant taking the risk to support the benefit?
II.K Research Team	All team members information should be included here. If you have more than 3 co-PIs you will need to add a document with their information. Include all information, name, Academic unit, position (faculty, student, staff), Role in the Project, and training on the document. Attach to the application when you submit it. Documents will not be saved when using "Save and Resume Later".
III. Additional Attachments	Any extra documentation that may help explain your study can be added here.
Form Submission	Do NOT Submit application until all answers and documents are ready for submission. Use the "Save and Resume Later" button to send a link to the form to your chair and dean for review. An e-mail approval from both is required for IRB approval.