

**IRB PROTOCOL APPLICATION**

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| **Study Title and Expected Review** |

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 **Please select the type of review you believe your research requires:** Click here

**Has or will another IRB review this protocol?** Click here

**Section 1: Investigator Information and Sponsor Information**

**Principle Investigator:**

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**Title:**

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**Institutional Affiliation:**

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**Contact Information:**

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Students and individuals who are not employed full-time by PBSC must procure a sponsor. The sponsor must be employed full-time at PBSC and must be agreeable and qualified to oversee the research process. [ ]  **This section is not applicable**

**Sponsor:**

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**Sponsor’s Title:**

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**Sponsor’s Department:**

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**Sponsor’s Contact Information:**

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**Section 2: Study Summary and Procedures**

**Date you plan to begin collecting data**: Click here to enter a date.

**Anticipated end date of the study:** Click here to enter a date.

**Please provide a brief study overview, background, and purpose.** (*300 words max*.)

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**Detail the study procedures. Please describe recruitment, consent, intervention (if any), and duration of contact with participants. Also provide an analysis overview and explain how you will store, protect, and ultimately dispose of the data. Attach all recruitment materials, consent forms, and instruments when you submit your protocol application.** (*750 words max*.)

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| **Section 3: Participants** |

**Sample Size:** 

**Concisely explain the inclusion and exclusion criteria for your sample.**

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**Race/Ethnicity:**

 [ ]  Asian

 [ ]  Black

 [ ]  Hispanic

 [ ]  Native American

 [ ]  White

 [ ]  Mixed Race/Ethnicities

 [ ]  All Races/Ethnicities or not collecting information on Race/Ethnicity

**Gender**:

[ ]  Female

[ ]  Male

[ ]  Transgender

[ ]  All genders or not collecting information on gender

**Age:**

[ ]  Under 18 years of age

[ ]  18 years of age or older

**Vulnerable populations:**

[ ]  Not applicable

[ ]  Minors

[ ]  Pregnant women

[ ]  Individuals with disabilities

[ ]  Homeless persons

[ ]  Prisoners or those on probation or parole

[ ]  Other (please specify) 

**Section 4: Risks and Benefits**

**Please describe the risks associated with participation in the study.** (*150 words max*.)

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**Please succinctly explain this potential, realistic, personal and societal benefits of the research.** (*150 words max*.)

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**Section 5: Attachments**

**Please identify any documents you have submitted with your application below.**

[ ] NIH Protecting Human Research Participants Certificate of Completion

[ ] Consent/Assent Forms

[ ] Data Collection Instruments

[ ] Recruitment Materials

[ ] Copy of other IRB approval letters

[ ] Other (Please specify): 

**Section 6: Certification**

 [ ]  By clicking this box, I certify that the information provided is a complete and accurate description of the research protocol. Should changes need to be made to the protocol, I understand that I am required to submit an amendment and it must be approved by the IRB prior to implementation. I further agree to conduct my research in compliance with all applicable federal and ethical guidelines.

**PI Name:**  Date: Click here to enter a date.

**Co-PI Name:**  Date: Click here to enter a date.

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| **Final Checklist for Submission of Protocol (Include all that are applicable)** |

* Receive approval by your “home” IRB (only applicable if the researcher’s home” institution is not PBSC).
* Complete the NIH Protecting Human Research Participants training (or equivalent).
* Submit in one email to irb@palmbeachstate.edu the following items:
	+ PBSC IRB Protocol Application (*required of all researchers*)
	+ Certificate of Completion of the NIH training or equivalent (*required of all researchers*)
	+ Other study supplemental materials (as applicable):
		- Consent/Assent forms or statements
		- Copy of other IRB approval letters
		- Data collection instruments
		- Recruitment materials
		- Other supplemental materials
* Wait for the PBSC IRB’s decision before conducting the research.