REQUEST TO CONDUCT STUDIES WITH HUMAN SUBJECTS (IRB-Form 1)

(IRB Form 1)

Use this form when submitting a new protocol or five-year renewal. Annual renewals for a previously approved protocol require "*Request to Renew Human Subjects Protocol (IRB-2)*" form. All information must be typed.

1. Protocol Title:

2. Date Research will begin: **Date of expected completion:**

3. Administrative Contact (the individual responsible for completing the paperwork)

Name: E-mail:
Phone: FAX:
Campus Address:
Department/Section:

4. Study Coordinator

Name: E-mail:
Phone: FAX:
Campus Address:
Department/Section:

5. PBA Principal Investigator

Name: E-mail:
Phone: FAX:
Campus Address:
Department/Section:

6. Associated Personnel Check One: ☐ Co-Investigator ☐ Mentor/Advisor ☐ Non PBA Project PI

1) Name: E-mail:
Phone: FAX:
Campus Address:
Department/Section:
Institution:

Check One: ☐ Co-Investigator ☐ Mentor/Advisor

2) Name: E-mail:
Phone: FAX:
Campus Address:
Department/Section:
Institution:

(Use the "Additional Personnel" form if necessary)

7. Sponsor (funding source):

8. Location(s) of Research: (place an "X" within sets of brackets)

- ☐ Palm Beach Atlantic University
- ☐ Behavioral Learning Center
- ☐ Good Samaritan Medical Center
- ☐ Palm Beach Gardens Medical Center
- ☐ St. Mary's Medical Center
- ☐ Other (specify):
- ☐ Columbia Hospital
- ☐ Columbia Hospital - Mental Health Services
- ☐ Wellington Regional Hospital
- ☐ South County Mental Health Center
- ☐ Palms West Medical Center

9. Tissue only: ☐ Yes ☐ No

(Please note: discarded tissue - no identifying link to subject and/or no possibility of need of cell line wavier).

10. Subject sex: ☐ Male ☐ Female ☐ Both

11. Subjects' age: ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Geriatric

12. For initial submission, please note the expected number of subjects to be enrolled in the investigation:

a) Total # of subjects included locally (i.e., on-campus):

b) If multi-center study, total # of subjects included at all centers:

13. One-year renewal, number of subjects enrolled last year? Total to date:

14. What type of study is proposed?

- ☐ **Survey**
- ☐ **Compassionate Use**
- ☐ **Cohort (Longitudinal) Study**
- ☐ **Retrospective (case-control)**
- ☐ **Other:**
- ☐ **Cross-sectional**
- ☐ **Laboratory Experiment**
- ☐ **Program Policy Study**
- ☐ **Clinical trial**
- ☐ **Multicenter Investigation**
- ☐ **Community Intervention**
- ☐ **Pilot study**

15. Keywords (used to describe the research in this protocol):

I certify that this protocol conforms with the OSHA/HHS guidelines for HIV/HBV occupational safety.

(Remember to attach the Human Consent forms.)

16. Description of the Research (Provide Sufficient Detail):

a. Statement of problem:

b. Data collections methods:

c. Instruments to be used: (Send in new or nonstandards ones.)

d. Method of recruitment of participants: (Send in any advertisements.)

e. Incentives, follow ups, compensation to be used:

f. Detail stress, psychological, social, legal, or physical harm that might occur to participants. How are these held to the absolute minimum? What remediation is offered?

g. Benefits of the research: University policy requires that any risk associated with participation be outweighed by potential benefits to participants and to humankind in general.

a. Identify any benefits to participants resulting from this research.

b. Identify any benefits to humankind in general resulting from this research.

h. Consent Form: How will legally effective informed consent be obtained from all participants (or their parent(s) or guardian(s))? Include form(s) to be used. If deception is necessary, please justify, and describe and submit debriefing procedures.

i. Minors And Others: If minors or other vulnerable participants are involved,

please outline procedures to be used in obtaining their agreement (assent) to participate, in addition to the consent of the parent(s) or guardians).

j. **Future Risk: How are all participants protected from the potentially harmful future use of the data collected in this research? Describe measures planned to ensure anonymity or confidentially. If audio or video tapes are used, when will they be erased?**

k. **Illegal Activities: Do the data to be collected relate to illegal activities? If so, please explain.**

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FOR RESEARCH CONDUCTED BY STUDENTS OR NON-FACULTY STAFF: This research involving human participants, if approved, will be under my direct supervision.

Name of faculty Advisor (type or print)	**Signature (original signature only)**	**Date**

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17. Signature Page: By signing below, you agree that you have read the University's "*Assurance of Compliance with HHS .... Excerpts*" and agree to provide proper guidance of this research to ensure that the rights and welfare of the human participants ("subjects") are protected. You also agree to submit significant changes in procedures and/or instruments to the Institutional Review Board for prior approval.

Signature of Principal Investigator (original signature only)	**Date**
Signature of Student Investigator (if applicable; original signature only)	**Date**
PI Department Chair (original signature only)	**Date**
Co-Investigator Department Chair (original signature only) (if different from PI)	**Date**