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| **Study Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****For all applicants:****Principal Investigator’s Agreement**As Principal Investigator, I understand that I have the fundamental responsibility to conduct this study in accordance with ALL Fairleigh Dickinson University IRB policies and federal, state, and local laws that relate to research involving human participants.I agree: 1. That submitted information in this application is accurate and complete.
2. To conduct this study in accordance with ALL FDU’s IRB policies, guidelines, and approvals and federal, state, and local laws that relate to research involving human participants.
3. To complete the Human Participants Protection Tutorial required by the IRB prior to conducting the research, in accordance with the IRB guidelines. If this application is for a proposal submitted to an external funding agency and the project is funded, the tutorial must be completed by the project start date or immediately upon award notification, whichever comes first.
4. To ensure that all research staff, who will have contact with human participants and/or their data, complete the Human Participants Protection Tutorial required by the IRB prior to conducting the research, in accordance with the IRB guidelines.
5. That all research staff will be qualified to conduct the research.
6. To promptly supply the IRB with requested information.
7. To promptly implement any requested changes by the IRB during the review process.
8. Not to begin the study until AFTER IRB WRITTEN APPROVAL is granted.
9. That when applicable, protocol information approved by FDU’s IRB for this study will be consistently represented in **ALL** funding applications and processes.
10. That after initial IRB approval is granted, to obtain WRITTEN APPROVAL from the IRB prior to implementing ANY requested changes during the research covered by the approval for this Application. Changes must be sent to the IRB following the submission instructions found at (insert website address once it’s available.)
11. That, during emergencies, only necessary study changes will be made to ensure the participants’ well being without getting prior IRB approval.
12. That the IRB will be notified within 48 hours of any changes that were made to the project in the event of an emergency.
13. To immediately report to the IRB, sponsors, Data Safety and Monitoring Boards, and other agencies, any problems (e.g., complaints, injuries, adverse events) involving risks to participants.
14. That if research **must** continue in my absence (during vacations, sabbaticals, etc.), I will arrange for another PI carry out my responsibilities. The designated PI will have completed the tutorial and forwarded a copy of their certification to the Grants Office (mail code T-BE2-02.)
15. To submit a revised application to the IRB at least annually as noted in the IRB approval letter.
16. That if a revised application is not submitted by the expiration date, the study becomes inactive and I will ensure that ALL research activities will cease on the study’s expiration date.
17. To notify the IRB via email when the project and all research aspects have concluded.
18. To comply promptly with IRB requests to completely suspend, withdraw, or terminate this study’s research activities.

**By signing your name below, you agree to abide by the above conditions:**PI Name (please print or type) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PI Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_**For applicants seeking external funding only:**Name of Funding Source \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Agency Award Number \_\_\_\_\_\_\_\_\_\_\_\_\_I certify that the research plan and safeguards to human participants described in this application conform to the plan and safeguards that have been submitted/will be submitted to an external funding source. PI Initials \_\_\_\_\_\_ |