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### Annual Approval of an Approved Research Project

*This form is for expedited or full annual review of a research project involving human subjects*

In order to fulfill the responsibilities of the Institutional Review Board (IRB) to human subjects, all research projects must be reviewed at least on an annual basis. In order to facilitate this annual review, please take a few minutes to review the following and indicate amendments or no change where appropriate for the study:

1. Project No., Title, & Type of Initial Review (Full or Expedited):

2. NUHS Contact Person (Check one): [ ]  NUHS Investigator of Record/Faculty Sponsor [ ]  Project Principal Investigator

Name, Academic/professional degree(s):

Signature and Date:

Telephone number:       E-mail:

Date of most recent IRB approved training for the Protection of Human Subjects from Research Risks:

3. (Check one) [ ]  Coinvestigator [ ]  Project Principal Investigator

Name, Academic/professional degree(s):

Signature and Date:

Telephone number:       E-mail:

Date of most recent IRB approved training for the Protection of Human Subjects from Research Risks:

. Coinvestigator

Name, Academic/professional degree(s):

Signature and Date:

Telephone number:       E-mail:

Date of most recent IRB approved training for the Protection of Human Subjects from Research Risks:

*For additional Co-investigators, please provide contact and training information on a separate piece of paper*.

4. Estimated project completion:

**5.** Is this project funded by the US Public Health Services (example: NIH, NSF, HRSA, etc.)?

**[ ]**  No, the project is NOT funded by USPHS.

Do any investigators, or family members thereof (spouse, dependent children) have a significant financial interest ($5000 compensation in the past 12 months, including salary, consulting, honorarium, or 5% ownership of company) with the project sponsor?

**[ ]**  No.

**[ ]** Yes. Attach a description of the significant financial interest and present a plan for managing the conflict, minimizing its effect on the design, conduct, or reporting of the research, and maintaining the rights and welfare of the research participants.

**[ ]**  Yes, the project is funded by USPHS.

Have any investigator’s disclosure been determined to be a financial conflict of interest (FCOI) under the NUHS Financial Conflict of Interest in Research policy?

**[ ]** No. Annual disclosure was submitted to the Dean of Research and no FCOI was found.

**[ ]** Yes. Attach a copy of the FCOI management plan signed by the Dean of Research with this annual review.

***In regards to procedures/protocols since the last annual review describe any amendments to the following*:**

1. Subject recruitment: No Change**[ ]** Amendment**[ ]**

Describe the amendment(s):

* 1. Number of subjects recruited since last report to IRB:
		1. Is this on target? No**[ ]** Yes[ ]

 If no, please explain and provide revised projections:

* 1. Number of subjects withdrawn since last report to IRB:

If known, please describe reasons for the withdrawals:

1. Confidentiality: No Change**[ ]** Amendment**[ ]**

Describe the amendment(s):

1. Informed consent: No Change**[ ]** Amendment **[ ]**

Describe the amendment(s):

1. Subject handling/treatment protocols: No Change**[ ]** Amendment **[ ]**

Describe the amendment(s):

1. Handling of subject records:
	1. Are identifiers (Protected Health Information ) linked or maintained with the records:

[ ]  No

[ ]  Yes. Describe ALL locations of hardcopy data, electronic data on desktop computers or networks, and portable computing devices (laptops, flash drives, external drives, CDs, etc) and security for storage and transmission of the identified records.

* 1. Describe the procedure(s) for maintaining confidentiality of records and protecting the data from access by unauthorized individuals and who is currently supervising this information?
	2. Is this the procedure that was approved by the IRB in the new project application?

[ ]  Yes.

[ ]  No. Describe the change(s) to the procedures.

1. Risk/benefit ratio: No Change**[ ]** Amendment **[ ]**

Describe the amendment(s):

1. Any other changes: No Change**[ ]** Amendment **[ ]**

Describe the amendment(s):

***Overall status of the project since the last annual review:***

1. Has recruitment begun? No[ ]  Yes[ ]  Not Applicable[ ]
2. Has recruitment ended? No[ ]  Yes[ ]  Not Applicable[ ]
3. Is data collection complete? No[ ]  Yes[ ]
4. Has the study been completed, including

manuscripts? No[ ]  Yes[ ]

1. Is the study on hold? No[ ]  Yes[ ]
2. Have there been any adverse events or complaints? No[ ]  Yes[ ]

Describe the adverse event or complaint and the action taken or to be taken.

1. Is there any new information that might change the benefit or risk to research participants or necessitate revision of the protocol and/or informed consent document? No[ ]  Yes[ ]
2. Did the study require a data safety monitoring plan ? No[ ]  Yes[ ]

If yes, please describe the DSM activity since the last annual review.

[ ]  Please submit a copy of the informed consent document currently in use; if IRB waived the requirement for signed consent, please submit the information provided to participants.

[ ]  This study requires Clinical Trial Registration.

If so, Registry and trial registration number:

[ ]  Close this study and remove from IRB review (In doing so, all PHI identifiers must be removed from the data and given to the Research Coordinator along with the identifier key(s). For a complete list and description of PHI, see 45 CFR 164.514(e)).