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### Annual Approval of an Exempt Research Project

*This form is for annual review of a research project that had been approved as exempt from IRB review*

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 change or no change where appropriate for the study:

1. Project No. & Title:

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

Name, Academic/professional degree(s):

Signature and Date:

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

Telephone number: E-mail:

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

Name, Academic/professional degree(s):

Signature and Date:

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

Telephone number:       E-mail:

. Coinvestigator

Name, Academic/professional degree(s):

Signature and Date:

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

Telephone number:       E-mail:

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*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.

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| ***In regard to procedures/protocols since the last annual review:*****Any change to subject recruitment?** No [ ]  Yes [ ] , describe amendment.      **Any change to confidentiality?**No [ ]  Yes [ ] , describe amendment.      **Any change to informed consent?** No [ ]  Yes [ ] , describe amendment.      **Any change to subject handling/treatment protocols?** No [ ]  Yes [ ] , describe amendment.       Any change to handling of subject records? No [ ]  Yes [ ] , describe amendment.       **Any change to risk/benefit ratio?** No [ ]  Yes [ ] , describe amendment.      **Describe any other changes to the project**:       |
| ***Overall status of the project since the last annual review:*****Has recruitment begun?** No [ ]  Yes [ ] **Has recruitment ended?** No [ ]  Yes [ ] **Have there been any adverse events or complaints?** No [ ]  Yes [ ] , attach description.      **Is data collection complete?** No [ ]  Yes [ ] **Has study been completed, including manuscripts?** No [ ]  Yes [ ] **Is study on hold?** No [ ]  Yes [ ]  |
| Comments       |
| ***[ ]*** Close the study and remove from IRB review (In doing so, all PHI identifiers must be removed from the data and given to the IRB administrator along with identifier key. For a complete list and description of PHI, see 45 CFR 164.514(e)). |