REQUEST FOR MODIFICATION OF APPROVED RESEARCH

OKLAHOMA STATE DEPARTMENT OF HEALTH

# INSTITUTIONAL REVIEW BOARD

Do not use this form for changes made prior to IRB approval or in response to an IRB review. The approval of this modification does not change the original period of approval of your IRB application.

1. STUDY INFORMATION

OSDH IRB Number

Study Title

Principal Investigator

E-Mail Address

Phone

1. MODIFICATION REQUEST
   1. Please check the type of modification being submitted.

Change in procedure  Addition  Deletion  Modification

Describe

Change in study personnel  Addition  Deletion  Modification

Describe

Change in research site  Addition  Deletion  Modification

Describe

Change in subject enrollment  Increase  Decrease

Describe

Recruitment Material  Newspaper  Flyer/Brochure/Pamphlet

Radio/Television  Other

Describe

Consent/Assent/Permission form changes

*If this box is checked, attach a copy of the current approved consent document, a copy of the proposed consent document with changes highlighted, and a copy of the revised consent document with all highlighting removed.*

Describe

Other

Describe

* 1. Discuss if the modification(s) will affect research risk and/or benefits (use additional sheet if needed).
  2. Is IRB approval required at other outside sites? Y  N  Specify IRB

If so, has it been obtained? Y  N  If yes, please attach copy of approval.

If not, please submit IRB approval when obtained.

**I understand that I cannot initiate any changes in my approved protocol before I have received OSDH IRB approval and/or complied with all contingencies/stipulations with regards to that approval.**

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**Signature of Principal Investigator Date**

FOR IRB USE ONLY:

* Minor, Non-substantive Change Approved by Expedited Review
* Substantive Change Requiring Convened IRB Review

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Signature of Primary Reviewer Date