**HUMAN SUBJECTS RESEARCH APPLICATION FORM**

* IRB USE ONLY: **Pre-review Date App. Type**:  Board  Exempt  Expedited

OKLAHOMA STATE DEPARTMENT OF HEALTH

INSTITUTIONAL REVIEW BOARD

### RESEARCH PROPOSAL

### Study Title

*Does this IRB Application replace and/or continue an existing IRB approved study?* *[ ]  Yes* *[ ]  No*

*If yes, please provide OSDH IRB Number of this existing IRB project.*

Principal Investigator (include degree)

Title

Department

Address

Phone  Fax Email

Has PI submitted IRB Investigator Training completion certificate to OSDH IRB Office? [ ]  Yes [ ]  No

Co-PI (include degree)

Title

Department

Address

Phone  Fax  Email

Has Co-PI submitted IRB Investigator Training completion certificate to OSDH IRB Office? Yes [ ]  No [ ]

Collaborating Investigators (include OSDH researchers or employee(s) engaged in the research)

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OSDH program and personnel contacts (if OSDH is not engaged with the research)

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Sponsor (specify federal/state agency funding this research in part or whole or other funder)

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Study Sites (list all applicable sites and specify OSDH-related sites)

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*Is IRB approval required at other outside sites?* *[ ]  Yes* *[ ]  No If yes, specify IRB*

 *If so, has it been obtained?* *[ ]  Yes* *[ ]  No If yes, please attach copy of approval.*

*If no, please submit IRB approval when obtained.*

## STUDY POPULATION

Age Range  to  (include low/high age) Gender: [ ]  Males [ ] Females [ ] Both

Special Qualifications

Source of Subjects

Number of Subjects

Exclusions (attach separate sheet if necessary)

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### PROTECTED GROUPS

# Please check any protected groups included in the study.

[ ]  Children (under 18)\*\* [ ]  Pregnant Women [ ]  Fetuses

[ ]  Mentally Disturbed [ ]  Elderly (65 & older) [ ]  Prisoners

\*\* With few exceptions, the consent of both parents is required by regulation where the research involves greater than minimal risk and will not directly benefit the individual child research subject. If both parents' consent is not going to be obtained, please explain why:

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The assent of the child is required by regulation, if the child is capable of providing such assent (typically age 7 to 17). If the assent of the child is not going to be obtained, please explain why:

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1. PROTOCOL/CONSENT FORM REFERENCES

Please indicate page numbers within the protocol and consent form(s), which address the following:

PROTOCOL CONSENT PROCESS

Inclusion/Exclusion Criteria  Purpose

Duration of Participation  Status of Drug/Device Procedure

Early Termination Criteria  Description of Study

Drugs and Dosages  Costs

Devices  Risks

Surgical Procedures  Benefits

Data Collection  Alternative to Participation

Data Analysis  Compensation and Injury

Confidentiality of Data  Subject's Assurances

 Contact for questions about rights

1. INVESTIGATIONAL DRUGS AND DEVICES

|  |  |
| --- | --- |
| IND/IDE Number(s) | IND/IDE Name(s) |
|  |  |

## REQUEST FOR EXEMPT STATUS OR EXPEDITED REVIEW

I request this application be considered for Exempt status or Expedited review. [ ]  Yes [ ]  No

|  |  |
| --- | --- |
| Exempt #  | Expedited #  |

Please refer to the list of Exempt/Expedited Categories in the OSDH 1-40 Administrative Procedures and **indicate the specific number** thatapplies to your study. The IRB Administrator may grant exempt or expedited approval, but reserves the right to require convened Board review of any IRB application.

1. CERTIFICATION/SIGNATURE

**I certify that the information contained herein (application, research protocol, and consent form, if required) is true and correct, and that I have received approval to conduct this research project from all persons named as collaborating investigators and from officials of the project sites. All investigators will comply with IRB policies and procedures and all federal regulations.**

**Signature of Principal Investigator Date**

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**Signature of Co-Principal Investigator Date**