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| <i>IRB Use Only</i> Log# |
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| Name of Project | Date of Application |
| Principal Investigator for Project | Agency/Dept |
| PI Phone Number and email | |
| ND Department of Health involvement <input type="checkbox"/> Initiated the project/research <input type="checkbox"/> Part of group project <input type="checkbox"/> Provided data/actively involved <input type="checkbox"/> Only provided data/not involved in project <input type="checkbox"/> DoH employee/project outside of health dept. <input type="checkbox"/> DOH Employee doing school project <input type="checkbox"/> Other _____ | |
| Role of ND Department of Health Employees | |

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| 1. Will the study/data set potentially involve or include any of the following groups, even if inclusion is incidental or not intended? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |
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If Yes, specify (even if inclusion is incidental or not intended):

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|---|---|
| 1i. Pregnant women? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |
| 1ii. Children <18 years old? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |
| 1iii. Persons not mentally competent? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |
| 1iv. Prisoners? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |
| 1v. Persons without English language proficiency? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK* |

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| 1a. If you answered yes or don't know (DK) to number 1, please provide explanation: |
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| 2. Will confidential identifiers be collected or existing identifiers used? This would include name, address, telephone number, identifying number (e.g., medical record number, social security number) or any linkage to an identifier? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Will the study involve the collection of blood or other biological specimens or use of existing blood samples or other biologic specimens? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

*Don't Know

If yes, specify special circumstances

| | | |
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| 3i. | Biologic specimens will be stored with possible use subsequent to completion of this research project | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3ii. | HIV testing will be done | <input type="checkbox"/> Yes <input type="checkbox"/> No |

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| 4. | Will the study be preceded by a pilot study? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. | Does the study involve an investigational drug or device? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

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| 6. | Is the researcher requesting a release from IRB oversight under 45CFR 46? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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If yes, on what basis is the release requested (mark all that apply)?

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| STEP 1 | Not research, public health practice only | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| STEP 2 | Not human subjects research, because: | |
| | i. All research subjects are deceased, or | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | ii. No interaction between researcher and subjects AND no collection (or use) of confidential identifiers. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| STEP 3 | Exempt human subjects research, because: | |
| | i. Evaluation of a public benefit program ¹ (See Definition), or | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | ii. Use of existing data recorded by the researcher without identifiers or any possible access to a code that the researcher could use to reconstruct subject identity, or | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | iii. Data collected (or use of existing data) from adults by educational test, survey, interview, or observation which, even if revealed, would not reasonably place any participant at risk for criminal or civil liability or be damaging to any participant's financial standing, or employability, or | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | iv. Data collected (or use of existing data) from adults by educational test, survey, interview, or observation with no collection of any confidential identifiers. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

¹ A public benefit program is defined for purposes of this IRB as an established process administered by a public health agency that 1) is not offered as a benefit of this investigation or dependent on this investigation for existence, 2) existed prior to this investigation and will continue after this investigation, 3) does not require participation in this investigation for full benefit eligibility, and 4) offers specific persons resources (e.g., money, food), counseling, education or clinical services to improve their health.

Request for Release from IRB Oversight

Because the board may not agree to release the project from oversight, complete the following:

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| 7. | Is the researcher requesting waiver of informed consent? If yes, <u>all</u> of the following criteria must be met: 45 CFR 46.116(d) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7i. | The research involves no more than minimal risk to the subjects | |
| 7ii. | The waiver or alteration will not adversely affect the rights and welfare of the subjects; | |
| 7iii. | The research could not practicably be carried out without the waiver or alteration; | |
| 7iv. | Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | |

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| 8. | Is the researcher requesting waiver of <u>written</u> consent based on ONE of the following criteria being met? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, specify: | | |
| 8i. | The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8ii. | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Submission Instructions

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| If you are NOT requesting a release from IRB oversight, you must provide the following in addition to this form: | |
| <input type="checkbox"/> | Final protocol, pages consecutively numbered with version and date on each page |
| <input type="checkbox"/> | Final data collection instruments with version and date on each page. |
| <input type="checkbox"/> | Final consent form with version and date on each page |
| <input type="checkbox"/> | Grant proposal if applicable |
| <input type="checkbox"/> | Documents from review by another institution's IRB if applicable |

If you ARE requesting a release from oversight you must attach a summary of the proposed project, including information which would support your request. See documentation outline located on page 5.

If you ARE requesting an exemption based on **6 (STEPS 1, 2 or 3)** you must attach a summary of the proposed project, including information which would support your request for exemption and a copy of the data collection instrument. See documentation outline located on page 5.

By marking this box, I, the principal investigator listed on this form, verify that I have read and understood the NDDoH document "IRB Documentation and Guidance – What Principal Investigators need to know."

Signature of Principal Investigator

Date: _____

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| <i>Do not fill out. This section reserved for IRB use</i> | |
| Action | |
| No need for any IRB review | <input type="checkbox"/> Date: _____ |
| No IRB review, project sent to HIPAA officer | <input type="checkbox"/> Date: _____ |
| Project NOT Approved/Denied | <input type="checkbox"/> Date: _____ |
| Project Tabled, resubmission required | <input type="checkbox"/> Date: _____ |
| Approved as is, exempted | <input type="checkbox"/> Date: _____ |
| Approved with changes, exempted | |
| ■ Changes made, project approved | <input type="checkbox"/> Date: _____ |
| Approved as is, IRB oversight required | <input type="checkbox"/> Date: _____ |
| Approved with changes, IRB oversight required | |
| ■ Changes made, project approved | <input type="checkbox"/> Date: _____ |
| Signature of Administrator: _____ | Date: _____ |
| Signature of Chair: _____ | Date: _____ |
| Letter of Action sent to PI | <input type="checkbox"/> Date: _____ |