SFN 59451 (9-2015)
Version 3.0

REQUEST FOR PROJECT REVIEW FOR COMPLIANCE WITH 45CFR46 (IRB)

NORTH DAKOTA DEPARTMENT OF HEALTH

IRB Use Only
Log#

Name of Project	Date of Application
Principal Investigator for Project	Agency/Dept

ND Department of Health involvement

☐ Initiated the project/research ☐ Part of group project ☐ Provided data/actively involved
☐ Only provided data/not involved in project ☐ DoH employee/project outside of health dept.
☐ Other_____

Role of ND Department of Health Employees

1.	Will the study/data set potentially involve or include any of the following groups, even if inclusion is incidental or not intended?	☐ Yes ☐ No ☐ DK*

If Yes, specify (even if inclusion is incidental or not intended):

1i.	Pregnant women?	☐ Yes ☐ No ☐ DK*
1ii.	Children <18 years old?	☐ Yes ☐ No ☐ DK*
1iii.	Persons not mentally competent?	☐ Yes ☐ No ☐ DK*
1iv.	Prisoners?	☐ Yes ☐ No ☐ DK*
1v.	Persons without English language proficiency?	☐ Yes ☐ No ☐ DK*

1a. Optional explanation

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?	☐ Yes ☐ No
3.	Will the study involve the collection of blood or other biological specimens or use of existing blood samples or other biologic specimens?	☐ Yes ☐ No

If yes, specify special circumstances

3i.	Biologic specimens will be stored with possible use subsequent to completion of this research project	☐ Yes ☐ No
3ii.	HIV testing will be done	☐ Yes ☐ No

*Don't Know

4.	Will the study be preceded by a pilot study?	☐ Yes ☐ No
5.	Does the study involve an investigational drug or device?	☐ Yes ☐ No

6.	Is the researcher requesting a release from IRB oversight under 45CFR 46?	☐ Yes ☐ No

If yes, on what basis is the release requested (mark all that apply)?

STEP 1		**Not research, public health practice only**	☐ Yes ☐ No
STEP 2		**Not human subjects research, because:**	
	i.	All research subjects are deceased, or	☐ Yes ☐ No
	ii.	No interaction between researcher and subjects AND no collection (or use) of confidential identifiers.	☐ Yes ☐ No
STEP 3		**Exempt human subjects research, because:**	
	i.	Evaluation of a public benefit program (See Definition[1]), or	☐ Yes ☐ 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	☐ Yes ☐ 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	☐ Yes ☐ 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.	☐ Yes ☐ 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.

*Don't Know

Request for Release from IRB Oversight

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

7.	Is the researcher requesting waiver of informed consent? If yes, all of the following criteria must be met: 45 CFR 46.116(d)		☐ Yes ☐ 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.	

8.	Is the researcher requesting waiver of written consent based on ONE of the following criteria being met?		☐ Yes ☐ 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.	☐ Yes ☐ 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.	☐ Yes ☐ No

Submission Instructions

If you are **NOT** requesting a release from IRB oversight, you must provide the following in addition to this form:

- ☐ Final protocol, pages consecutively numbered with version and date on each page
- ☐ Final data collection instruments with version and date on each page.
- ☐ Final consent form with version and date on each page
- ☐ Grant proposal if applicable
- ☐ 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.

*Don't Know

☐ By marking this box, I, the principal investigator listed on this form, verify that I have read and understood the NDDoH document "IRB Overview."

_____ Date:_____
Signature of Principal Investigator

Do not fill out. This section reserved for IRB use

Action

No need for IRB review	☐	Date:
Release from oversight granted	☐	Date:
Referred for board review	☐	Date:

Signature of Administrator:_____ Date _____

Signature of Chair: _____ Date _____

Letter of Action sent to PI	☐	Date:

*Don't Know