

INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR NEW PROTOCOL APPROVAL

Instructions: Use this form when submitting new protocols to the IRB. Please send the original and two copies of all documents. Consecutively number all pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.

Date submitted by Investigator: _____

PROTOCOL NO. _____

*(For
IRB Use)*

Title of Protocol: _____

Date Rec'd _____

Proposed Dates for Project – Begin: _____ End: _____

Name of Maine Center for Disease Control and Prevention Employee Serving as Principal Investigator (PI) and Degrees:

Name: _____

Location: _____

Program: _____

Telephone: _____

Division: _____

Email Address: _____

Names of Other Maine Center for Disease Control and Prevention Employee Co-investigators (use supplemental page if >than 3):

1. _____

2. _____

3. _____

STUDY POPULATION – Estimated number of subjects

Gender:

_____ Female

_____ Male

Ethnicity:

_____ Latino/Hispanic

_____ Not Latino/Hispanic

Race:

_____ American Indian or Alaskan Native

_____ Asian

_____ Black or African American

_____ Native Hawaiian or other Pacific Islander

_____ White

_____ Some Other Race

If an international study, provide race and ethnicity of subjects by estimated percentages:

VULNERABLE POPULATIONS – Do the subjects include: _____ YES _____ NO

If YES, check all that apply:

_____ Pregnant women and/or fetuses as SPECIFIC targets group (Ref: 45 CFR 46, Subpart B)

_____ Prisoners (Ref: 45 CFR 46, Subpart C)

_____ Children 17 years of age or younger (Ref: 45 CFR 46, Subpart D)

_____ If YES, are you requesting a waiver of parental permission?

_____ Mentally disabled

_____ Economically or educationally disadvantaged

STUDY DESIGN ISSUES (Check all that apply)

- Will MAINE CENTER FOR DISEASE CONTROL AND PREVENTION investigators have personal identifiers?
- Is a waiver or alteration of informed consent being requested in this project? (Ref: 45 CFR 46.116)
- Is a waiver of documentation of consent being requested for this project? (Ref: 45 CFR 46.117)
- If specimens are collected, will they be stored for future use?
- Is HIV testing being performed as part of the study?
- Is genetic testing planned?
- Does the study involve the use of a drug or device? (See FDA Regulations)
 - If YES, will the study be carried out under an Investigational New Drug (IND) or device (IDE)?

FUNDING (Check one)

Federal Funding Mechanism Used:

- Cooperative Agreement No(s):
- Contract No(s):
- Grant:
- Purchase Order (a.k.a. Simplified Acquisition):

Other Funding Mechanism:

- Memorandum of Understanding (MOU) (With whom):
- Interagency Agreement (IAA) (Name of other agency):
- Other (Specify type and with whom):

- Only MAINE CENTER FOR DISEASE CONTROL AND PREVENTION investigators performing study
- Collaborative (Non-MAINE CENTER FOR DISEASE CONTROL AND PREVENTION investigators and MAINE CENTER FOR DISEASE CONTROL AND PREVENTION investigators; no funding involved)

LOCATION OF THIS RESEARCH (Use additional sheets if necessary)

- U.S. or its territories? Foreign country (countries?)

List All Collaborating Sites by Full Name and Location (include state):	OPRR Assurance No.:
1.	
2.	
3.	
4.	
5.	
6.	

7.	
8.	
9.	
10.	
11.	
12.	

Approvals (Signature and Position Title):	Date:	Remarks:
Program Manager:		
Division Director:		