

**MAINE BUREAU OF HEALTH  
INSTITUTIONAL REVIEW BOARD (IRB)  
REQUEST FOR CONTINUATION APPROVAL OF PROTOCOL**

Instructions: Use this form when submitting protocols for continuing review. Review is required AT LEAST annually; however, the IRB may have determined that your protocol will need to be reviewed more often. Please submit this form along with the current consent form and a copy of the protocol (if changed since last year) and any supporting documents (if changed since last year) to the IRB Chairperson. Consecutively number all pages, beginning with the title page of the protocol (if applicable), followed by any consent form(s) and any applicable ancillary documents. Complete all applicable items or the form will be returned.

**Date Submitted by Investigator:** \_\_\_\_\_

**PROTOCOL NO.** \_\_\_\_\_ **Date**  
**Rec'd MBOH IRB**

(For Human Subjects Office Use)

**Title of Protocol:**

Proposed Dates for Project - Begin: \_\_\_\_\_ End: \_\_\_\_\_

**Name of MBOH Employee Serving as Principal Investigator (PI) and Degrees:**

\_\_\_\_\_

Telephone.: \_\_\_\_\_

Email Address: \_\_\_\_\_

**Names of Other MBOH Employee Co-investigators (use supplemental page if > than 3):**

- 1.
- 2.
- 3.

**1. Current Status**

\_\_\_\_\_ Study not yet begun (Provide explanation in item 4. Complete item 6, if applicable)

\_\_\_\_\_ Active research; contact with subjects continuing (Complete items 2-9)

\_\_\_\_\_ Active research with subjects completed; study activities involve only data analysis and/or report writing (Complete items 2,5,6,7,9)

\_\_\_\_\_ Study does not involve contact with subjects (e.g., research using existing records); study activities involve only data analysis and/or report writing (Complete items 5,6,7,9)

**2. Study Population**

\_\_\_\_\_ Enrolled this past year

\_\_\_\_\_ Declined enrollment this past year

\_\_\_\_\_ Total number of subjects to date

\_\_\_\_\_ Withdrawn from project this past year

**For individuals who were enrolled this year:**

Gender distribution:

\_\_\_\_\_ % Female

\_\_\_\_\_ % Male

**Race/ethnicity distribution of enrolled subjects for domestic studies:**

\_\_\_\_\_ % American Indian or Alaskan Native

\_\_\_\_\_ % Hispanic

\_\_\_\_\_ % Asian or Pacific Islander

\_\_\_\_\_ % White, not of Hispanic Origin

\_\_\_\_\_ % Black or African American, not of Hispanic origin

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

**Vulnerable Populations** - Have any of these populations been added to the study? \_\_\_\_\_ YES \_\_\_\_\_ NO

If YES, please check all that apply

\_\_\_\_\_ Pregnant women (as a SPECIFIC target group)

\_\_\_\_\_ Children 17 years of age or younger  
(Ref: 45CFR46, Subpart D)

\_\_\_\_\_ Fetuses (Ref: 45CFR46, Subpart B)

\_\_\_\_\_ Mentally disabled

\_\_\_\_\_ Prisoners (Ref: 45CFR46, Subpart C)

\_\_\_\_\_ Educationally or economically disadvantaged

**3. Collaborating Sites** (Use additional sheets if necessary)

3a. List any collaborating sites by name and location (including state) that were added since last continuation approval:

\_\_\_\_\_ None added

**OPRR Assurance No.:**

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3b. List any collaborating sites by name and location (including state) that were deleted since last continuation approval:

\_\_\_\_\_ None deleted

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**4. FUNDING** (check one)

\_\_\_\_\_ 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 **MBOH** investigators performing study

\_\_\_\_\_ Collaborative (Non-**MBOH** investigators & **MBOH** investigators; no funding involved)

**5. Summary of Activities to Date** (Use additional sheets as necessary):

**6. Summary of Study Modifications Reviewed and Approved This Past Year** (Use additional sheets as necessary):

\_\_\_\_\_ None

**7. Summary of Any New Literature, Findings, or Other Relevant Information** (Use addition sheets as necessary):

\_\_\_\_\_ None



**8. Summary of Adverse Events or Unanticipated Problems** (Use additional sheets as necessary):

\_\_\_\_\_ None

**9. Consent Documents** (Attach a copy of each current consent form, telephone consent text, and/or letter):

consent

**10. Summary of Remaining Activities** (Use additional sheets as necessary):

<b>Approvals</b> (Signature and Position Title):	<b>Date:</b>	<b>Remarks:</b>
Program Manager:		
Division Director:		
MBOH IRB Chairperson:		