



Memorandum

Date December 31, 2012

From Barbara R. DeCausey, MPH, MBA
Chief, Human Research Protection Office

Subject HRPO Exemption Determination for Protocol #6398.0, " Perceptions of Health Risk from Smokeless Tobacco Products and Nicotine Replacement Therapy among Pregnant Women and Women Planning a Pregnancy "

To Lucinda England
NCCDPHP/OSH

On behalf of the CDC Human Research Protection Office (HRPO), I have reviewed the request to exempt protocol #6398.0, "Perceptions of Health Risk from Smokeless Tobacco Products and Nicotine Replacement Therapy among Pregnant Women and Women Planning a Pregnancy " and find that this research activity is exempt under 45 CFR 46.101(b)(2). This determination is valid for a period of three years through **12/30/2015**. However, we strongly encourage investigators to close out exempt protocols as soon as CDC staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Please be aware that changes to this protocol may not be implemented until they are reviewed by HRPO and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised that investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact your Associate Director for Science, your National Center Human Subjects Contact, or HRPO at huma@cdc.gov, or by telephone at 404-639-7570.

cc:
Joan Redmond Leonard