UNIVERSITY OF MINNESOTA

Change In Protocol Request

Route this form to: See instructions below. | **Rev:** Nov 2012

Instructions:
Use this form when submitting change requests on IRB protocols. This form is for use when the changes are initiated by the PI. Do not use this form to respond when changes are requested by the IRB. Please do not use this form when responding to changes requested in a stipulation letter.

Submit this form to the Human Research Protection Program:

U.S. Mail Address: **or**
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

Electronic Submission:
Submit to: irb@umn.edu
PI must submit request using University of Minnesota e-mail Account.

The UMN IRB reviewed and APPROVED this submission including all attachments listed on this form by expedited review.

By Christina Dobrovolny on Feb 26, 2013

IRB Protocol Information

IRB Study Number:	**1209M21047**
Principal Investigator:	**Lyn M. Steffen, PhD**
Primary StudyTitle:	Salt Sources Study
Date of this Submission	February 18, 2013
Study Includes	☒ Drug(s) / Biologic(s) ☐ Device(s)

Indicate the type of change: :
☐ Protocol Amendment: Version , Dated
☐ Revised Investigator Brochure: Version , Dated
☐ Recruitment Changes/Advertisements
☐ Notice of Closure to Accrual
☐ Change(s) to Study Procedures
☒ Other:Change grade level of language in Consent form to 8th grade level

1. **Briefly summarize the change(s). For protocol amendments, do not say "See summary of changes provided with amendment." Rather, summarize the nature of the significant revisions.**

The CDC requested that we lower the grade level of the Consent Form from 11th grade to 8th grade level.

2. **Describe the rationale for the change(s):**

CDC would not approve the 11th grade level of the Consent form - requested that the language level change to 8th grade.

3. **In your opinion as principal investigator, how will these changes affect the overall risk to subjects in this study?**

The subjects will better understand the information imparted to them.

4. **Do the changes to the study prompt changes to the consent form(s)?**

☐ **No.** ☒ **Yes.** **If yes:**

- **Attach a copy of the revised consent form(s) with changes tracked or highlighted as well as a clean copy.**

- **Confirm whether currently enrolled subjects will notified of the changes and how they will be notified (i.e. subjects will be re-consented with the updated form once approved, subjects will be provided with an information sheet, subjects will be told of changes at next study visit, etc.).**

Recruitment has not started yet.

5. List and attach all documents included with this request, including version dates:

Consent form attached (version date 1/14/2013).

Lyn M. Steffen (steff025) — 2/18/2013

Principal Investigator's Signature (x500) — **Date**