ADDENDUM TO CONSENT FORM FOR PARTICIPATING IN A RESEARCH STUDY
(HIPAA Authorization for use of Protected Health Information)
University of North Carolina at Chapel Hill

IRB Study Number: GCRC # 2140
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Title of Study: Environmental Polymorphisms Registry

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Sponsor: National Institutes of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services

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What is the purpose of this form?
You have been asked to take part in a research study. The consent form for this study describes your participation, and that information still applies. This extra form is required by the federal "Health Insurance Portability and Accountability Act" (HIPAA). The purpose is to get your permission (authorization) to use health information about you that is created by or used in connection with the research. If you are signing on behalf of someone other than yourself, this permission applies to that person's health records.

What if I don't want my personal health information to be used in this research study?
You may refuse to give this permission. A decision not to sign this form will not change your ability to get health care outside of this research study. However, you may not be able to participate in this research study unless you sign this permission form. You should discuss this, and any other questions, with the investigators.

Who will be allowed to use my personal health information for this research? And why?
The investigators named above and their assistants will be allowed to see and to use your health information for this research study. We may use it to check on your progress during the study, or analyze it along with information from all other subjects. Sometimes research information is shared with collaborators at other institutions, or with labs running additional tests. Your research records may also be reviewed by other employees of the University of North Carolina at Chapel Hill or representatives of the research sponsor or funding agency in order to check for quality, safety or effectiveness.

What personal health information am I allowing to be used for this research study?
The information we might use includes:

- Your contact information: name, address, phone numbers for home, work, or any other phone number we can use to contact you

Where will investigators go to find my personal health information?
This study does not involve accessing your medical records.

What are the privacy protections for my health information used in this research study?
The federal privacy regulations (HIPAA) apply to personal health information in the records of health care providers and other groups that share such information. There are some differences in how these regulations apply to research, as opposed to regular health care. One difference is that you may not be able to look at your own records that relate to this research study, at least until the study is over. The HIPAA privacy protections may no longer apply, once your personal health information has been shared with others who may be involved in this research.

How long does this permission allow my personal health information to be used?
If you decide to be in this research study, your permission to access and use your health information in this study will not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the study or up to 25 years.

What if I change my mind after I give this permission?
You have the right to cancel this permission to use your personal health information for research. In this case, we will not get any more of your health information for use in this research. However, canceling this authorization will not reverse uses of your personal health information that have already happened, or uses that have already been promised and cannot reasonably be reversed. If you want to cancel this permission, you must put this in writing and deliver to the Principal Investigator at the mailing address listed at the top of this form. You should clearly state that you want to cancel this permission to use your personal health information in this particular research study (attaching a copy of this form would be very helpful).

SUBJECT'S AUTHORIZATION
I have read the information provided above. By signing this form, I am giving permission for my personal health information to be used in research as described above. I will be given a copy of this authorization form after I have signed it.

_____	_____	_____
Printed Name of Research Subject (or Authorized Representative*)	Signature	Date
_____	_____	_____
Printed Name of Person Obtaining Authorization	Signature	Date

*Only if consent/authorization by someone other than immediate subject was approved by IRB. If used, also include description of Representative's relationship to subject, and their authority to act on subject's behalf (parent, legal guardian, etc). IRB Version 3-7-03