

XXX_____ University
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: *Hispanic Community Health Study (HCHS)*
Principal Investigator: _____
Department of
Address
Phone

Co-Principal Investigators:(_____ University)

You have agreed to participate in the research Study mentioned above and have signed a separate informed consent that explained the procedures of the research Study and the confidentiality of your personal health information. This authorization form gives more detailed information about the following:

- What personal health information about you will be collected in this Study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access your personal health information during the Study
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting your doctors and other health care providers, such as Community Health to disclose personal health information collected about you to _____ University and the researcher listed above for purposes of the Study. You are also allowing _____ University and the researcher to disclose that personal health information to outside organizations or people involved with the processing of this Study, as described in the separate informed consent form for this study.

What personal information is collected and used in this Study, and might also be shared (disclosed)?

The following personal contact and personal health information will be collected, used for this research Study and may be disclosed or released during your involvement with this research Study:

- Name
- Address
- Relatives' names or addresses
- Telephone number
- Participant ID number
- Social Security numbers
- Enrollment Date

Other tests and procedures that will be performed in the Study include:

- Height and Weight Measurements
- Blood Pressure
- An electrocardiogram (ECG) an exam of your heart
- A test for lung function and breathing
- A hearing test

- A dental examination
- Blood sugar test for diabetes
- A test for cholesterol levels

It also includes questions about:

- Nutrition
- Stress and depression
- Work and home environment
- Physical activity and eating habits
- Family medical history

Why is your personal information being used?

Your personal contact information is important for _____ University research team to contact you during the Study. Your personal health information (including the results of tests and procedures) is being collected during this research Study for purposes of the Study. The Principal Investigator may also use the results of these tests and procedures to refer you to a medical provider to verify your study results or to treat you.

Who within _____ University may use or disclose your personal health information?

The following individuals and organizations within _____ University may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator’s Study team (other University staff associated with the Study)
- The _____ University Institutional Review Boards (the committees charged with overseeing research on human subjects)
- The _____ University Office for the Protection of Research Subjects (the office which monitors research studies)
- Authorized members of the _____ University workforce who may need to access your information in the performance of their duties (for example: to make sure the research is being done correctly).

Who outside of _____ University might receive your personal health information?

As part of the Study the Principal Investigator, Study team and others listed above, may disclose your personal health information, including the results of the research Study tests and procedures to the following:

- Other academic research center(s) who are also working on the Study
- University of North Carolina Chapel Hill Collaborating Center
- National Heart, Lung, and Blood Institute (NHLBI) who is sponsoring the study
- Government agencies such as the Food and Drug Administration and Office of Human Research Protection
- Other health care providers who are part of the Study (e.g., laboratories who perform tests)

Your personal information that is disclosed in connection with the Study may no longer be protected by the federal privacy protection regulations.

In records and information disclosed outside of _____ University, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research Study.

How long will _____ University be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific Study does not expire. This information may be maintained in a research repository (database). However, _____ University may not reuse or re-disclose your personal health information collected in this Study for another purpose other than the research described in the informed consent document you have signed for this Study, unless it obtains permission to do so from you and the _____ University Institutional Review Board.

Will you be able to access your records?

Results of all tests and procedures done solely for this research Study and not as part of your regular care and will not be included in your medical record. You will be able to request access to your medical record when the Study is completed.

During your participation in this Study, you will have access to your medical record and any Study information that is part of that medical record. The investigator is not required to release to you information in the research records.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research Study may still use your personal information that was collected prior to your withdrawal of permission if that information is necessary to the integrity of the Study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research Study. If you withdraw your permission to use any blood or tissue obtained for the Study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

You are not required to sign this authorization. If you decide not to sign the authorization:

It will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you may not be allowed to participate in the research Study. You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this Study.

By signing this document you are permitting your doctors and other health care providers to disclose your personal health information to _____ University and permitting _____ University to use and disclose personal health information collected about you for research purposes as described above.

Subject's Name **[print]**

Subject's Signature

Date

Person obtaining authorization **[print]**

Person obtaining authorization Signature

Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative **[print]** Authorized subject representative e Date

Provide a brief description of above person authority to serve as the subject's authorized representative.
