**University of North Carolina at Chapel Hill**  
**Consent to Participate in a Research Study**  
**Adult Participants**-Wave VI Home Exam and Biomarker Components Consent Form  
**Consent Form Version Date:** 09/06/2022  
**IRB Study #** 21-2949  
**Title of Study**: The National Longitudinal Study of Adolescent to Adult Health (Add Health): Wave VI Core Project *also known as* “Add Health Wave VI”

**Principal Investigator**: Robert A. Hummer, PhD, Carolina Population Center

**Funding Source**: National Institute on Aging / National Institutes of Health (NIA/NIH)  
**PI and Study Phone number**: 1-844-509-2835  
**PI and Study Email Address**: AH\_info@unc.edu

**CONCISE SUMMARY**  
The purpose of this study is to visit Add Health Wave VI participants in their homes for a home exam to: learn about recent health history; obtain measurements of height, weight, waist circumference and blood pressure; obtain a blood sample and perform blood tests to learn about current health status as well as indicators of cardiometabolic health, inflammation, immunity and infection.

If you consent to this study, a certified and trained examiner from Add Health’s data collection partner, ExamOne, will contact you to schedule a home exam for these purposes. The home exam can be completed in less than an hour in the privacy of your home or another location of your choosing and on a date and time convenient for you. During the home exam you can skip or decline any questions, measurements, or the blood draw, or stop the home exam at any time for any reason.

There is a slight risk of minor and temporary discomfort and/or bruising from the blood draw. If you participate in the study, you will be provided with free, personalized results from your blood pressure reading. You will also receive free, personalized results for 9 blood tests.

If you consent to this study and provide a blood sample as part of Wave VI, your leftover blood may also be used for future yet-to-be determined Add Health research studies. Future research would be related to health but not used to detect disease. These studies would require review and approval by a human subjects’ protection committee. Add Health would continue to protect your blood sample, your identity and your confidentiality by using the same rigorous set of security measures described for Wave VI in future Add Health projects outside of Wave VI.

If you are interested in learning more about this study, please continue to read below.

**What are some general things you should know about research studies?**  
You are being asked to take part in a research study.  Joining the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future.   You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below.  It is important that you understand this information so that you can make an informed choice about being in this research study. A copy of this consent form is being made available to you. You should ask the researcher named above, or staff members who may assist them, any questions you have about this study at any time.  
  
**What is the purpose of this study?**  
The purpose of this research study is to add to your past participation in the National Longitudinal Study of Adolescent to Adult Health (Add Health) as well as your recent participation in the survey for Add Health Wave VI by taking part in the Wave VI home exam. Add Health has partnered with ExamOne,a professional data collection company. ExamOne will schedule a home exam with you at your home or another location in order to collect new health measures and a new blood sample. The study will use these new measurements and blood sample to learn about your current health as well as how it has changed since our last visit with you, and since adolescence. Wave VI of Add Health is led by the Carolina Population Center at the University of North Carolina at Chapel Hill (UNC-CH), along with ExamOne, part of Quest Diagnostics, and Research Triangle Institute (RTI). The Principal Investigator of this research is Dr. Robert A. Hummer.

**How many people will take part in this study?**

Approximately 15,289 Add Health Wave VI participants are eligible to take part in the home exam for Add Health Wave VI.

**How long will your part in this study last?**  
The home exam will take less than an hour, usually around 45 minutes. This includes time for the ExamOne examiner to: 1) introduce themselves and explain the home exam, 2) answer any questions you may have, 3) ask you some questions about your recent health and medication use and 4) take health measurements and a blood sample. The study will ask a small number of participants if they are willing to schedule a second, repeat home exam within 2 weeks after the first home exam. The same health measurements and blood sample will be collected at this second, repeat exam. This repeat home exam helps the study make sure that our methods are reliable. If you are selected for a repeat home exam, you may decide to agree or decline when you are asked. If you take part in the second, repeat home exam, the two home exams combined (on separate dates) will take just under 2 hours. If you provide a blood sample (during your first and, if selected, second exam) it will be tested at our Add Health study laboratory. We will store any leftover blood long-term in our secure, Add Health freezers located in our study laboratory. Your blood will be tested for measures related to Wave VI as well as for future Add Health studies. Any leftover blood from Add Health research (Wave VI and other projects) will be maintained in secure Add Health partner laboratory freezers and kept indefinitely.

**What will happen if you take part in the study?**

Contact by ExamOne to Schedule Your Home Exam

If you agree to this study, Add Health will securely share your contact information with ExamOne. ExamOne schedulers and/or examiners will contact you directly to schedule your home exam. They will also contact you to share reminders with you about your upcoming exam. Schedulers and examiners from ExamOne will use phone numbers you have provided to Add Health to call you and to send you text messages. They will also use email addresses you have provided to Add Health to send you email communications. Every communication you receive from ExamOne will include the option to opt out of receiving future communications from that mode (email, text, phone).

Home Exam

ExamOne will reach out to you to schedule your Add Health Wave VI home exam for a time and at a location that is most convenient for you. Even if you agree to the home exam now, you can change your mind later and decline the home exam. If you are not sure if you want to participate in the home exam, you may speak with a trained research expert from Add Health who can answer any questions you may have. If you agree to and schedule a home exam, an ExamOne examiner will come to your exam location at the agreed upon time, ask about your health history and use of medications, take health measurements and collect a blood sample as described below.

Health History

The examiner will ask you questions about chronic health conditions as well as recent illnesses and infections. The examiner will also ask about your vaccination status for COVID-19 as well as other conditions, and for information about any special diet you might be following. You may skip/decline any questions.

Measurements

The ExamOne examiner will measure your blood pressure while you are in a seated position, using a cuff that fits your arm. Blood pressure measurements will be taken a few times in a row to make sure the reading is correct. They will also measure your pulse. The examiner will measure your height, waist circumference and weight while you are fully clothed. After the measurements are complete, the examiner will share results with you if you would like. At the end of the home exam the examiner will also give you a Cardiovascular Health sheet containing your blood pressure results and your level of risk for certain heart-related conditions. The sheet also includes resources for more information about cardiovascular (heart) health.

Blood Draw and Blood Tests

The ExamOne examiner, a trained and certified phlebotomist (professional who performs blood draws), will use a fine needle to collect about 2 tablespoons of blood from your arm. Your blood sample will be split into a set of 5 tubes and sent to our research lab for tests related to your health. These tests include looking at markers for various health conditions including indicators of cardiometabolic functioning, inflammation, infection and cognitive wellness. Add Health will securely transfer your blood to our study laboratory for testing as part of Wave VI. Your blood may also be tested as part of other, yet-to-be-determined IRB-approved Add Health research studies. These projects may involve genetic research to study your DNA, including the possibility of whole genome sequencing, gene expression, or epigenetic changes over time. Add Health can do more advanced research by studying the influence of genetics on an array of conditions. Future Add Health research would be overseen by the Add Health team. The tests performed for Wave VI and other Add Health studies are for research purposes only and can’t diagnose disease or any conditions you may have. However, we can share results with you for some of the Wave VI blood tests that are standard indicators of health, such as cholesterol and glucose levels. Your examiner will ask you if you would like to receive those results. We are unable to provide results for other blood tests including those for coronaviruses. If you choose to receive results from your blood tests, you will receive your report by mail within 8 weeks after your home exam. It is up to you to decide if you will share these results with your doctor.

Long-Term Sample Storage

Add Health Wave VI will keep any blood you provide long-term in our secure study freezers at the Laboratory for Clinical Biochemistry Research (LCBR) at the University of Vermont, our study laboratory. Parts of your sample may be shared with one or more other Add Health partner laboratories for specialized testing. Your blood will be labelled with an ID only; your name and other identifying information will not be shared with laboratory personnel. Your blood will be used for tests related to Wave VI as well as tests for other yet-to-be-determined Add Health projects. Your blood will only be available for testing for IRB-approved projects that are overseen by Add Health. Some of these tests may not be started or completed for several years due to the study design, supply chain delays in obtaining laboratory materials and as a result of repeat lab testing to ensure accuracy.

**Will my genetic information from future Add Health research be shared?**

Your blood contains genes that are made of DNA unique to you. To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. With the blood sample you provide in Wave VI, some of your genetic and health information might be placed into one or more scientific databases. Only researchers who receive special approval can access these databases and would be able to view your de-identified information along with information from many other people. There are many different kinds of scientific databases; some are maintained by this institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests.

Researchers with an approved study may be able to see and use your information, along with information from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

**What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge.  Other than receiving results from your blood pressure measurements and blood tests, you will not benefit personally from being in this research study or future Add Health research projects or having your information in a shared database.

**What are the possible risks or discomforts involved from being in this study?**  
The blood draw may cause slight, temporary discomfort and/or bruising from the needle stick. Your ExamOne examiner is fully trained to reduce any discomfort from the blood draw. There may be new or rare risks. You should report any problems to the study’s Principal Investigator. There is a very unlikely risk of privacy breach. Add Health’s strict privacy protections are described below. There is a very unlikely risk of privacy breach. Add Health will use the same privacy protections for the Wave VI home exam to continue to protect your identity, confidentiality and sample throughout all future Add Health research.

**What if we learn about new findings or information during the study?**   
If there are new findings or information about risks and benefits of participation you will be provided with that information.

**How will information about you be protected?**  
You will not be named in any study reports or publications. Every effort will be made to keep records private. There may be times when federal or state law requires release of records, including personal information. This is very unlikely. UNC-Chapel Hill will take all legal steps to protect your personal information. To help ensure your privacy, Add Health has a Certificate of Confidentiality, which was described in the consent information for the Wave VI survey. Add Health uses only IDs to label your data and blood sample. Linkages between these IDs and your identifying information are kept under strict security protocols on specialized servers. Add Health uses several layers of security to protect your identity and confidentiality. Add Health will continue to use the same strict security and privacy protections for Wave VI as well as for future yet-to-be-determined Add Health research projects involving your blood sample.

**Will you receive results from research involving your specimens?**  
For Wave VI, you will receive results from your home exam health measurements including your blood pressure, pulse, height and weight. If you provide a blood sample you will also have the option to receive personalized results by mail for assessment of your blood sugar (glucose and HbA1c), lipids (HDL/LDL, total cholesterol and triglycerides), kidney function (creatinine) and liver function (AST/ALT). It is unlikely that results from future Add Health research involving the use of your leftover blood will yield new information that is meaningful to you. There are no plans to recontact you or other participants with information about research results from those projects.

**What if you want to stop before your part in the study is complete?**

You may change your mind about taking part in the home exam at any point in time and decide not to participate. If you agree to participate, you may choose to skip or decline any questions, parts of the home exam measurements, and/or any tubes of blood you are asked to give. If you are invited to take part in the repeat home exam, you may agree to participate or decline. You can withdraw from this study at any time, without penalty. The research staff also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study, all data and blood sample(s) collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

**Will you receive anything for being in this study?**

Along with results from your in-home measurements and personalized results from your blood sample, you will receive $100 for taking part in the home exam. This amount is the same whether or not you provide a blood sample. This amount is also the same even if you skip any questions or parts of the home exam. If you participate in a repeat, second home exam you will receive an additional $100. You will not receive anything for the long-term storage of your leftover blood or use of your leftover blood for future Add Health research studies.

**Will it cost you anything to be in this study?**  
It will not cost you anything to be in this study or for long-term storage of your blood.

**Who owns the specimens?**

Your specimens-your Wave VI blood sample(s)-are the exclusive property of Add Health at the University of North Carolina at Chapel Hill. Add Health may retain, preserve or dispose of these specimens from our study lab and partner lab locations. Add Health will not use your blood sample (s) for commercial purposes or for profit.

**What if you have questions about this study?**  
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the study phone number listed on the first page of this form.

**What if you have questions about your rights as a research participant?**  
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare.  If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.

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**PI and Study Phone number/Email**: 1-844-509-2835 / AH\_info@unc.edu

**Participant’s Agreement**   
I have read the information provided above.  I have asked all the questions I have at this time.

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| **Q1: HOME EXAM CONSENT: Do you agree to participate in the home exam?** | * Yes, I agree to the Wave VI home exam. I also agree for Add Health to use my leftover blood for future Add Health research after tests related to Wave VI have been completed. (*proceed to sign, date and print your name below*) * No, I am not agreeing to the home exam right now *(proceed to Q2)* |
| **Q2: We understand that you are not agreeing to the home exam right now. Would it be okay to send you information in the next few weeks that includes more details about the home exam? This will also give you more time to think about whether or not you would like to participate.** | * Yes, I am open to learning more about the home exam. At that point I can decide whether or not to participate*(proceed to sign, date, and print your name below)* * No, I am declining*(proceed to sign, date, and print your name below)* |

Signature of Research Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
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Printed Name of Research Participant

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