Attachment 7: Clinic Examination, Visit 5

Contact Information Update Form

Informed Consent – Clinic

Informed Consent (Proxy) – Clinic

Informed Consent – Home

Informed Consent (Proxy) – Home

Participant Safety Screening Form

Anthropometry

12-Lead Electrocardiogram

Sitting Blood Pressure Form

Biospecimen Collection

Ankle Arm Blood Pressure

Dietary Intake

Medication Survey

Physical Function Tests

Access and Quality of Care

Anxiety domain from the Patient-Reported Outcomes Measurement Information system (PROMIS) using Computer Adaptive Testing (CAT)

Minnesota Living with Heart Failure Questionnaire

Medical History Questionnaire

Physical Ability Questionnaire

Physical Activity

Personal History

Respiratory Questionnaire

SF-12v2 Health Survey Form

OMB#: 0925-0281

Expiration Date: xx/xxxx

CONTACT INFORMATION UPDATE FORM

ID NUMBER: ☐☐☐☐☐☐☐

STUDY YEAR 25

SEQ # ☐

FORM CODE: CIU

VERSION: C – 7/15/10

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *This form should be updated during the participant's visit. Affix the participant ID label above. Note that this form already contains data retrieved from the ARIC study's central database. When the form is administered using the computerized version of the Contact Information Update Form, it is entered in the CHANGE mode of the data entry system. If a paper form should be needed, print the Contact Information Update Form from the study website*.

INTRODUCTION SCRIPT: "Hello Mr/Ms [name of participant]. My name is _____. I would like to verify some of the information we have collected from you over the telephone. First, your personal information; I'll read the information we have and you can let me know if anything needs to be updated."

A. VERIFICATION OF IDENTIFYING INFORMATION

1. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

2. Mailing Address:

a. _____

b. _____

c. _____

d. City: _____

e. State: ☐☐

f. Zip Code: ☐☐☐☐☐

3. Home Phone Number: (☐☐☐) ☐☐☐-☐☐☐☐ (land line)

4. Cell Phone Number: (☐☐☐) ☐☐☐-☐☐☐☐

Does not use cell phone ☐

5. Email Address: _____ Does not use email ☐

6. Administrative use: _____

B. CONTACT PERSON 1

"Now I would like to verify the information we have for your contact persons, to help us get in touch with you if we are not able to reach you. I'll read the information we have and you can let me know if anything needs to be updated."

7. a. Title: _____

b. First Name: _____

c. Last Name: _____

d. Proxy status: Yes ☐ No ☐ [Pre-filled] If No, go to Q 8.

e. Is Mr/Ms [name] still your proxy? Yes ☐ No ☐

8. Mailing Address:

a. _____

b. _____

c. _____

d. City: _____

e. State: ☐☐

f. Zip Code: ☐☐☐☐☐

9. Telephone: (☐☐☐) ☐☐☐-☐☐☐☐

10. Relationship: _____

C. CONTACT PERSON 2

11. a. Title: _____

b. First Name:_____

c. Last Name:_____

d. Proxy status: Yes ☐ No ☐ [Pre-filled] If No, go to Q 12.

e. Is Mr/Ms [name] still your proxy? Yes ☐ No ☐

12. Mailing Address:

a. _____

b. _____

c. _____

d. City:_____

e. State: ☐☐

f. Zip Code: ☐☐☐☐☐

13. Telephone: (☐☐☐) ☐☐☐-☐☐☐☐

14. Relationship: _____

D. PHYSICIAN INFORMATION

15. Do you wish to provide physician information?

Yes.....☐

No.....☐→ **Go to 18**

"Following is the information we have about your physician or provider of medical care."

16. a. First Name: _____

b. Last Name: _____

17. a. Clinic/Building: _____

Mailing Address:

b. _____

c. _____

d. City: _____

e. State: ☐☐

f. Zip Code: ☐☐☐☐☐

"In approximately 6 week's time we will send you a summary of your study results from this exam visit."

18. Who should these results be sent to?.....☐

To the Participant.....A → **Go to QUESTION 19**

To Contact Person 1.....B → **Go to QUESTION 19**

To Contact Person 2.....C → **Go to QUESTION 19**

To Other.....D

Other Mailing Address:

_____

_____

_____

City:_____

State: ☐☐

Zip Code: ☐☐☐☐☐

Telephone: (☐☐☐) ☐☐☐-☐☐☐☐

E. OPHTHALMOLOGIST OR EYE SPECIALIST INFORMATION

“If you agree, today we will take a photograph of the back of one of your eyes. If we find a medical condition in your eye we can send a report to your eye specialist. What is the name of the doctor, ophthalmologist, or eye specialist you see?”

19. Do you wish to provide eye specialist information?

Yes..... ☐

No..... ☐ → **Go to 22**

20. What is the name of the doctor, ophthalmologist, or eye specialist you saw concerning your vision?

a. First Name: _____

b. Last Name: _____

21. a. Clinic/Building: _____

Mailing Address:

b. _____

c. _____

d. City: _____

e. State: ☐☐

f. Zip Code: ☐☐☐☐☐

[Information will be sent with the rest of the study results]

22. Proxy identified in ARIC database*:

[* If (7d=yes and 7e= no) or (7d=no and 11d=no) or (11d=yes and 11e=no)]

Yes.....☐ → **Go to END**

No.....☐

[Give Proxy Card to the participant]

"One of the most important goals for ARIC is to keep track of any major changes in your health. You are the best source of information regarding your health, but there may be times when you are not able to provide these details yourself. We are asking all our ARIC participants to give us the name of a person that can answer questions about your health if you cannot. This person will be considered your "proxy" for the ARIC Study. Only your ARIC center can contact your proxy."

20a. Would you like to identify somebody as your proxy? Yes ☐ No ☐

If yes, complete the ARIC proxy designation form, signed and witnessed. If No, close out CIU

The ARIC Study

Follow-Up by Proxy

A very important goal of the Atherosclerosis Risk in Communities (ARIC) Study is to keep track of any major changes in your health. This information is important for answering scientific questions about heart disease and other health conditions. You are the best source of information regarding your health, but there may be times when you are not able to provide these details yourself. We are asking you to provide us with the name of a person that can answer questions about your health if you cannot. This person will be considered your "proxy" for the ARIC Study. The person you designate would only be contacted once per year, should you be unable to respond. Only your ARIC center can contact your proxy.

What is a proxy?

A proxy is someone who can "stand in" for you and tell us about your health when you cannot because of illness.

Why is a proxy needed?

For almost 20 years you have been providing information about your health to ARIC. This important information should not be lost, even when you are unable to provide it yourself.

What does a proxy do?

Should it be necessary we would ask your proxy to answer questions about your health, just like the questions you have been asked each year by the ARIC staff.

Whom should I name as my proxy?

You should select someone who knows you well enough to provide health information about you. For example, your proxy can be your power of attorney, your legal health care proxy, or your legal next-of-kin (including your spouse, son, daughter, brother, sister, etc).

Am I allowed to change my proxy?

Yes, you may change your proxy at any time by either calling ARIC or by indicating your wishes at your annual ARIC phone call.

Will you give my earlier information to my proxy?

No, all of your information is strictly confidential and will not be provided to your proxy.

What would you like me to do now?

Using the attached form please indicate whom you have chosen to be your proxy. Please indicate his/her name, contact information, relationship to you, sign the form and mail it to the ARIC field center in the enclosed envelope.

We have sent a copy of this form for your own records and one to give to your proxy. This material should be kept by him/her so he/she understands your wishes as a participant in the ARIC Study.

If you have any questions call Mr/Ms. ……. ARIC Study Manager at (xxx) xxx-xxxx

Thank you for your continued dedication ARIC Study!

ARIC Proxy Designation Form

Participant Name: _____ ARIC ID: _____

First Last MI

I have named as my proxy: _____

(Name of person you choose as ARIC Proxy)

Relationship:_____

Proxy Address:_____

_____

_____

Proxy Phone Number:_____

He/she has the authority to provide medical information, and/or to sign a Medical Release Form to obtain hospital records or physician records for the ARIC Study.

_____ _____

Participant's Signature Date

_____ _____

Witness Date

Complete only if participant is physically unable to sign: I have signed the Participant's name above at his/her direction in the presence of the Participant and witness.

_____ _____

(Name) (Street)

_____

(City/Town) (State)

Optional: If my ARIC Proxy is unwilling or unable to serve, then I appoint as my Alternate ARIC Proxy:

_____

(name of person you choose as your alternate proxy)

of_____

(street) (city/town) (state) (phone)

UNIVERSITY OF _____ Department / Division _____

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CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

INVESTIGATORS:

Principal Investigator, _____
Co-Principal Investigator,_____

Project Coordinator, _____

SPONSOR: National Heart, Lung, and Blood Institute, National Institutes of Health

PURPOSE OF THE STUDY

You are invited to participate in this examination of the ARIC study, a national health research project conducted by _____ University under a research contract from the National Institutes of Health (NIH). Your participation in this study is entirely voluntary. Before you give your consent to volunteer, it please read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do in this study.

ARIC is an ongoing study that includes 15,792 participants from four centers across the country. You enrolled in ARIC during 1986-1989, along with several thousand other residents of your community. The main purpose of ARIC study is to investigate diseases of older adults in the population, primarily of the heart, lungs and blood vessels and to monitor the trends of coronary heart disease and heart failure in communities.

PROCEDURES

This new ARIC clinical examination visit takes place at _____, located at _____ and lasts approximately 6 hours and 30 minutes. If you agree to take part in this study, your ARIC exam visit will include the following:

Interviews that will last about 2 hours, with questions about your health, health care, diet, lifestyle, activities of daily living, and family medical history. You will be asked the names and dosages of medications you are currently taking and you will participate in tests of your memory.

An **examination** that will last about 4 hours. You will be asked to participate in the following:

- **Height, weight, waist and hip size, percent body fat,** and **blood pressure measurements on your arms and ankles**. If you have an implanted device your weight will be measured using a non-electronic scale.

- **Blood tests** that will include cholesterol and other blood fats, sugar levels, kidney function, and other factors related to heart disease. About 7 tablespoons of blood will be drawn from your arm. Your blood will be used only for research studies and some of your blood will be stored for future studies. We will not test for illegal substances.

- **Urine sample for kidney function**. While you are at the clinic you will be asked to provide a small amount of urine. We will not do drug testing on your urine. Your urine sample will be used only for research studies and some of your urine will be stored for future studies.

- **Electrocardiogram (ECG)**: We will measure whether your heartbeat and rhythm are regular or if your heart shows possible signs of illness.
- **Stiffness of the blood vessels.** We will estimate the stiffness of your arteries by applying cuffs on your arm.

- **Breathing Test (Spirometry):** You will blow hard into a tube using a new, clean mouthpiece to find out how well your lungs are working. If the test results indicate that you have breathing problems, you will be asked to breathe in a medication that opens up the airways (Albuterol or Ventolin, which is routinely used by persons who have asthma), and then to repeat part of the test. If you have asthma you will be asked to take your own medication in advance of the test. If you had surgery within the last 6 months or your doctor informed you that you had bleeding

inside your eyes, **you will not do this test** and should notify the study personnel to schedule this test for a later time to avoid discomfort.

- **Echocardiogram:** A trained technician will perform a test on your chest using high-pitched sound waves to measure the ability of your heart to pump blood. A computer will pick up echoes of the sound waves off different parts of your heart and turn them into moving pictures of the heart on a video screen.

- **Genetic Research Tests**: The study of genes and gene products has progressed very quickly since ARIC began. If you gave your permission at an earlier exam, ARIC collected DNA, the material that contains the genes, from your blood samples and stored it at that time. Your DNA is used to try to learn whether genes and gene products can help us understand the risk of diseases in middle-aged and older adults, particularly heart disease, stroke, cancer, brain function, lung, and eye disease. ARIC is looking at specific genes and also at wide regions of DNA. ARIC also looks at a material in our cells called RNA, which may help us understand how genes work. If you agree, ARIC will collect DNA and RNA in this examination from the same blood we collect for other tests.

Most people have versions of genes that are safe and cause no disease, but a small number of people may have a version that can carry a greater risk for disease. If you have such a DNA finding, there is a chance that your family members would have the same DNA finding, but it does not mean that you or your family member will in fact get such a disease.

ARIC only looks at DNA and RNA for research studies but does not do clinical genetic testing. That means that ARIC does not examine your DNA to diagnose health conditions nor to do genetic counseling, and that the results will not be reported to you or to others who may request this information.

Sharing of Data and Samples

In order for science to progress, researchers exchange scientific resources and information. We are asking for your permission to allow sharing of data, information and samples that could not be directly identify you, with researchers who are not part of the ARIC Study.

 Use of data and samples: Portions of samples of your blood, urine and DNA, in addition to study information and genetic data, will be stored for use by researchers indefinitely.

The National Institutes of Health will allow researchers who qualify to analyze your data and samples, after your identity has been removed. Researchers can qualify by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.

Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

 Commercial use of data and samples: Researchers from private companies that develop diagnostic lab tests or treatments for diseases may request access to your study information or samples. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

Your samples will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).

Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.

 Genetic research: Very detailed information about your DNA will be stored centrally at the National Institutes of Health, where it will be shared with other investigators for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment. The stored information is de-identified, which means that identifying information such as your name, date of birth, address, etc., is removed. Access to this stored information will be controlled by the National Institutes of Health. The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: http://www.nih.gov/icd/od/foia/efoia.htm

Follow-up Contacts: We will continue to contact you by phone every 6 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask for you to update this person's name in this exam.

Medical Record Review: If you are hospitalized or admitted to a long term care or nursing home, we will ask that institution for your records. We will request your signed permission for ARIC staff to obtain and review a copy of the records from the hospital, or clinic, emergency department/urgent care or cancer registry. We may request records from your doctor for certain office or clinic visits to determine if you have been diagnosed with one of the diseases that ARIC is studying and we will also request Medicare records.

We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting the Study Coordinator listed at the end of this form. In the event of your death, information will be sought from your relatives or other sources, including coroner's report, medical records (if your death takes place in a hospital or long term care facility), and the state health department. In all these instances, your social security number, provided previously to ARIC, may be used to confirm your identity and assure that the correct records are reviewed.

New Information: If new knowledge about the conditions evaluated by ARIC becomes available during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

Option for Additional Studies: You may be contacted to determine if you are interested in participating in other studies done in collaboration with ARIC. The studies may be related to your health or to laboratory information in the ARIC data, or ask for authorization to extend the study to children or other family members. Only ARIC personnel will be authorized to contact you on behalf of this study.

Duration of Participation: Your voluntary participation in ARIC will be for as long as you agree to participate.

Samples: You have the ability to decide how your samples should be used. We will hold them until no longer needed or until you tell us to destroy them. Your blood, urine and DNA samples will be identified only with a number code and sent to a ARIC laboratory for storage, or for detailed analysis. Some of your samples will be stored for unlimited time, for future use in studies related to diseases or in other research projects that have been approved by ARIC.

RESULTS

A report on the results of your exams (with an additional copy to provide to your doctor if desired) will be mailed to you, which can be used for recommended medical treatment. Results from genetic tests will not be reported. It is recommended that you discuss any abnormal findings with your primary care physician. Because ARIC measures your test results at research laboratory the results take a longer amount of time to report than an average medical exam.

POTENTIAL RISKS AND DISCOMFORTS

All of the examinations done by ARIC are routinely done in the clinic and are considered safe. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills during a long exam. If you wear a medical device such as a pacemaker or another implanted device or if you had a mastectomy (surgery to remove one or both breasts) you should notify the study personnel at the start of your exam visit to ensure your safety.

Medical care during the examination: In the unlikely event that during an examination procedure you should require medical care, first aid will be available.

Fasting: There is a chance that your blood sugar levels drop because you are fasting, especially if you have diabetes. You may feel cold sweats, blurry vision, rapid heart rate, shaking of the hands, dizziness, or fainting. These symptoms can be relieved by giving you juice, a snack, and/or lunch after your blood is drawn and a few procedures are performed.

Blood draw: A skilled technician will draw your blood. Minimal bruising, pain, or temporary bleeding may occur as a result of the blood draw. No materials will be injected into your body; blood will only be withdrawn. The technician wears latex gloves when drawing blood. If you have a known latex allergy, inform the technician and he/she will use gloves made from another material.

Interviews: You might experience some embarrassment or anxiety from answering any sensitive background questions. You may refuse to answer any questions that make you uncomfortable.

Breathing test (Spirometry): On rare occasions, a person taking a lung function test may feel lightheaded or may faint. The primary risk involved is injury from falling. Participants asked to

inhale the medication called Albuterol or Ventolin used during lung function testing may notice an increase in heart rate (pulse) or feel jittery or shaky (tremors).

Other Risks and Discomforts: In addition to the risks and discomforts mentioned above, and how they can be decreased, there may be other adverse events associated with any of the procedures that are performed during this examination which the investigators are not aware of. If you experience any other adverse event not mentioned above, it is extremely important that you make us aware of it.

A new health problem: You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. If any important medical problems are found, you may be asked by your insurance company or employer for this information. No personal medical results will be released by ARIC without your approval. If you do not have a personal health provider, the ARIC clinic staff will help you find a medical professional.

Data Sharing: ARIC makes every effort to protect your identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. This is partly because of the possibility of matching your DNA sample with other DNA collections (such as those kept by law enforcement agencies). **However, researchers are strictly prohibited from attempting to identify you.**

ANTICIPATED BENEFITS

There will not be a direct benefit to you from being in this study. You will be given a report of all your results from this examination that may have medical value to identify or treat health conditions. Since this is a research study the examination you receive is not a substitute for care you would receive from your health care provider, and we do not make a diagnosis, provide treatment, or give medical advice. Instead, we will encourage you to share your results with your health care provider. If you do not have regular health care, or you are unable to afford such care, an ARIC staff member will assist you in locating affordable health care. It takes longer for us to report the results back to you than an average medical exam, because this is a research study.

ALTERNATIVES

Your alternative is not to participate in ARIC.

FINANCIAL INFORMATION

There will be no costs to you for participating in this study. If a medical problem is found during the course of the exam that requires diagnosis and treatment, we will inform you of this. A letter with this information (and an additional copy) will also be mailed to you, so that if you desire, you can share it with your primary care physician or clinic. In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by ARIC for compensation or for payment of treatment because of your participation in this study. This does not waive any of your legal rights.

You will receive $75.00 to reimburse your costs of participation.

RESEARCH-RELATED INJURY

If any injuries or complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. _____ University will not pay for any care, lost wages, or provide other financial compensation.

SUBJECT'S RIGHTS

If you choose to be in this study you have the right to be treated with respect, to decide at any time whether or not you wish to continue or stop being in the study, not to answer some questions, or not to complete any of the ARIC exam components. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your the quality of your medical care or your relationship with _____ University. Your participation will not affect your ability to be enrolled in a health care plan or receive related benefits. If you decide to participate and then change your decision, you will have the right to withdraw from this study at any moment without negative consequences.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office of Human Research Protection. You can call them at **XXX-XXX-XXXX**

If you decide to withdraw from the study the information collected about you may still be used in this study, unless you request that your records and test results obtained be removed from study files. You may also request that your DNA/RNA and blood samples be destroyed or that all identifiers be removed (including code numbers) from such samples. Only samples that are stored at the ARIC laboratory could be destroyed. It will not be possible to retrieve information and samples that have already been shared with researchers outside of the study. If you choose to withdraw your samples, you should call the Study Coordinator, Ms/Mr. _____, at **xxx-xxx-xxxx**. Your decision to discontinue participation in the study will not affect the quality of medical care. The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will not be beneficial for you, or the sponsor may stop the study.

CONFIDENTIALITY

Protecting your privacy is a top priority for ARIC. Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law.

- Code numbers - not names: To ensure confidentiality, a code number will be assigned to you and your medical information. Files with your name and other identifying information will be electronically saved separately from your medical information on a secure computer that can't be accessed by an unauthorized person. If your information is printed, it will be kept locked and accessible only to certified ARIC personnel. Only authorized ARIC personnel will have access to your name and identifying information.

- Blood sample confidentiality: Your blood and DNA/RNA sample will have a special code number to protect your privacy. Anyone looking only at this code will not be able to match you. A label with the code number and the date the blood is drawn will be the only information on the blood samples. The coded samples and records will be stored securely, separated from any files that can link your name to the code numbers. No unauthorized individuals will have access to the stored samples or information gained from your stored blood sample or genetic information.

- Risk of you being identified: While we believe that the risks of being identified are very low and the benefits to science and the health of the community are large, there may be risks that we are not aware of at this time. The protected data developed for this project will not contain information that is used to identify you (such as your name, address, telephone number, or social security number), but it is possible that in the future people may develop ways to link your genetic or medical information back to you. If you were identified, your genetic information could potentially be used in ways that may cause you

or your family distress, such as revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative). To protect you, a federal law, the **Genetic Information Nondiscrimination Act** was passed in 2008, making it illegal to discriminate on matters of employment and health insurance in the U.S. based on genetic information.

 Publishing results: When study results are published your name and any other potentially identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by the Office of Human Research Protection of the U.S Government or the Institutional Review Board of _____ University.

 Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from NIH. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you. However, the certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing identifiable information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may provide that information. If the researchers learn of child abuse or your intention to hurt yourself or others, the Certificate of Confidentiality will not prevent ARIC from voluntary providing information that would identify you as a participant in this study. In this case your approval is not needed.

CHILDREN AND RELATIVES OF ARIC PARTICIPANTS

We will ask you if you will allow ARIC personnel to contact your children or other family members in the future, for health-related studies they may be interested in. They will be given the opportunity to agree or decline to participate.

QUALITY-CONTROL/QUALITY ASSURANCE MEASURES

During the ARIC exam we will ask you if you are willing to consent to have your exam audio-recorded (voices only) for quality-control by ARIC supervisors. Quality control means to make sure that all the tests, interviews and exams are done correctly and in the same way to every participant.

REPEAT INTERVIEW/PROCEDURES

We may also invite you to repeat certain interviews or procedures if the information collected during a procedure is incomplete, or to repeat certain interviews or procedures for quality control purposes. This is optional and will be shorter than the original visit. We will let you know how much time this will take when you are contacted.

Note: If you do not wish to participate in any test mentioned above cross it out and print your initials next to it on this form, or have the ARIC staff mark this form according to your instructions.

UNIVERSITY OF _____;

Department / Division _____

CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

I have read or heard the above information and have received answers to all my questions. I agree to participate in this ARIC examination and to allow researchers to store and analyze my data and blood and urine samples now and in the future, in a way that will not identify me, for the research described above. I will be given a copy of this consent form to keep after you sign it.

I also agree to the following (please initial the appropriate place beside each statement shown below):

1) I _____ agree I _____ do not agree	to be contacted twice a year by the ARIC staff to answer questions about my health and to update my address
2) I _____ agree I _____ do not agree	to allow ARIC personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate.
3) I _____ agree I _____ do not agree	to allow my samples (blood, urine) to be used for current and future research by scientists who collaborate with ARIC investigators.
4) I _____ agree I _____ do not agree	to allow my blood to be used to obtain **genetic** material (DNA/RNA) to be stored for current and future use by ARIC and investigators they work with.
5) I _____ agree I _____ do not agree	to be contacted in the future for health–related studies by ARIC personnel.
6) I _____ agree I _____ do not agree	for ARIC personnel to contact my children or other family members in the future for health-related studies. They will be given the opportunity to agree or decline participation.
7) I _____ agree I _____ do not agree	to share my de-identified **non-genetic** data, information, and samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section

	"Sharing of Data and Samples"
8) I _____ agree I _____ do not agree	to share my de-identified **genetic** data, information, and samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples".
9) I _____ agree I _____ do not agree	to allow use of my genetic and non-genetic data, information and samples by **commercial or for-profit companies** that are not part of ARIC to do research on new diagnostic tests and medical treatments that may benefit many people.

The stamp below indicates that _____ University has approved this consent form. My signature below indicates the following:

- That I have read the information in this document / it was read to me
- That I have had a chance to ask any questions I have about the study and that if I have additional questions, I have been told who to contact
- That I agree to be in the study
- That I have been told that I can change my mind and stop participating at any time
- That I have been given a copy of this consent form
- With my signature I also give permission for my hospital and/or health clinic to release any of my health records that ARIC needs and requests. This permission has no expiration date.

_____

Printed Name of Participant Signature Date

_____

Printed Name of Person Obtaining Informed Consent Signature Date

UNIVERSITY OF _____ Department / Division _____

PROXY CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

INVESTIGATORS:

Principal Investigator, _____
*Co-Principal Investigator,*_____

Project Coordinator, _____

SPONSOR: National Heart, Lung, and Blood Institute, National Institutes of Health

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

PURPOSE OF THE STUDY

You are invited to participate in this examination of the ARIC study, a national health research project conducted by _____ University under a research contract from the National Institutes of Health (NIH). Your participation in this study is entirely voluntary. Before you give your consent to volunteer, it please read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do in this study.

ARIC is an ongoing study that includes 15,792 participants from four centers across the country. You enrolled in ARIC during 1986-1989, along with several thousand other residents of your community. The main purpose of ARIC study is to investigate diseases of older adults in the population, primarily of the heart, lungs and blood vessels and to monitor the trends of coronary heart disease and heart failure in communities.

PROCEDURES

This new ARIC clinical examination visit takes place at _____, located at _____ and lasts approximately 6 hours and 30 minutes. If you agree to take part in this study, your ARIC exam visit will include the following:

Interviews that will last about 2 hours, with questions about your health, health care, diet, lifestyle, activities of daily living, and family medical history. You will be asked the names and dosages of medications you are currently taking and you will participate in tests of your memory.

An **examination** that will last about 4 hours. You will be asked to participate in the following:

- **Height, weight, waist and hip size, percent body fat,** and **blood pressure measurements on your arms and ankles**. If you have an implanted device your weight will be measured using a non-electronic scale.

- **Blood tests** that will include cholesterol and other blood fats, sugar levels, kidney function, and other factors related to heart disease. About 7 tablespoons of blood will be drawn from your arm. Your blood will be used only for research studies and some of your blood will be stored for future studies. We will not test for illegal substances.

- **Urine sample for kidney function**. While you are at the clinic you will be asked to provide a small amount of urine. We will not do drug testing on your urine. Your urine sample will be used only for research studies and some of your urine will be stored for future studies.

- **Electrocardiogram (ECG)**: We will measure whether your heartbeat and rhythm are regular or if your heart shows possible signs of illness.
- **Stiffness of the blood vessels.** We will estimate the stiffness of your arteries by applying cuffs on your arm.

- **Breathing Test (Spirometry):** You will blow hard into a tube using a new, clean mouthpiece to find out how well your lungs are working. If the test results indicate that you have breathing problems, you will be asked to breathe in a medication that opens up the airways (Albuterol or Ventolin, which is routinely used by persons who have asthma), and then to repeat part of the test. If you have asthma you will be asked to take your own medication in advance of the test. If you had surgery within the last 6 months or your doctor informed you that you had bleeding inside your eyes, **you will not do this test** and should notify the study personnel to schedule this test for a later time to avoid discomfort.

- **Echocardiogram:** A trained technician will perform a test on your chest using high-pitched sound waves to measure the ability of your heart to pump blood. A computer will pick up echoes of the sound waves off different parts of your heart and turn them into moving pictures of the heart on a video screen.

- **Genetic Research Tests**: The study of genes and gene products has progressed very quickly since ARIC began. If you gave your permission at an earlier exam, ARIC collected

DNA, the material that contains the genes, from your blood samples and stored it at that time. Your DNA is used to try to learn whether genes and gene products can help us understand the risk of diseases in middle-aged and older adults, particularly heart disease, stroke, cancer, brain function, lung, and eye disease. ARIC is looking at specific genes and also at wide regions of DNA. ARIC also looks at a material in our cells called RNA, which may help us understand how genes work. If you agree, ARIC will collect DNA and RNA in this examination from the same blood we collect for other tests.

Most people have versions of genes that are safe and cause no disease, but a small number of people may have a version that can carry a greater risk for disease. If you have such a DNA finding, there is a chance that your family members would have the same DNA finding, but it does not mean that you or your family member will in fact get such a disease.

ARIC only looks at DNA and RNA for research studies but does not do clinical genetic testing. That means that ARIC does not examine your DNA to diagnose health conditions nor to do genetic counseling, and that the results will not be reported to you or to others who may request this information.

Sharing of Data and Samples

In order for science to progress, researchers exchange scientific resources and information. We are asking for your permission to allow sharing of data, information and samples that could not be directly identify you, with researchers who are not part of the ARIC Study.

 Use of data and samples: Portions of samples of your blood, urine and DNA, in addition to study information and genetic data, will be stored for use by researchers indefinitely.

The National Institutes of Health will allow researchers who qualify to analyze your data and samples, after your identity has been removed. Researchers can qualify by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.

Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

 Commercial use of data and samples: Researchers from private companies that develop diagnostic lab tests or treatments for diseases may request access to your study information or samples. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

Your samples will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).

Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.

 Genetic research: Very detailed information about your DNA will be stored centrally at the National Institutes of Health, where it will be shared with other investigators for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment. The stored information is de-identified, which means that identifying information such as your name, date of birth, address, etc., is removed. Access to this stored information will be controlled by the National Institutes of Health. The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: http://www.nih.gov/icd/od/foia/efoia.htm

Follow-up Contacts: We will continue to contact you by phone every 6 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask for you to update this person's name in this exam.

Medical Record Review: If you are hospitalized or admitted to a long term care or nursing home, we will ask that institution for your records. We will request your signed permission for ARIC staff to obtain and review a copy of the records from the hospital, or clinic, emergency department/urgent care or cancer registry. We may request records from your doctor for certain office or clinic visits to determine if you have been diagnosed with one of the diseases that ARIC is studying and we will also request Medicare records.

We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting the Study Coordinator listed at the end of this form. In the

event of your death, information will be sought from your relatives or other sources, including coroner's report, medical records (if your death takes place in a hospital or long term care facility), and the state health department. In all these instances, your social security number, provided previously to ARIC, may be used to confirm your identity and assure that the correct records are reviewed.

New Information: If new knowledge about the conditions evaluated by ARIC becomes available during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

Option for Additional Studies: You may be contacted to determine if you are interested in participating in other studies done in collaboration with ARIC. The studies may be related to your health or to laboratory information in the ARIC data, or ask for authorization to extend the study to children or other family members. Only ARIC personnel will be authorized to contact you on behalf of this study.

Duration of Participation: Your voluntary participation in ARIC will be for as long as you agree to participate.

Samples: You have the ability to decide how your samples should be used. We will hold them until no longer needed or until you tell us to destroy them. Your blood, urine and DNA samples will be identified only with a number code and sent to a ARIC laboratory for storage, or for detailed analysis. Some of your samples will be stored for unlimited time, for future use in studies related to diseases or in other research projects that have been approved by ARIC.

RESULTS

A report on the results of your exams (with an additional copy to provide to your doctor if desired) will be mailed to you, which can be used for recommended medical treatment. Results from genetic tests will not be reported. It is recommended that you discuss any abnormal findings with your primary care physician. Because ARIC measures your test results at research laboratory the results take a longer amount of time to report than an average medical exam.

POTENTIAL RISKS AND DISCOMFORTS

All of the examinations done by ARIC are routinely done in the clinic and are considered safe. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills during a long exam. If you wear a medical device such as a pacemaker or

another implanted device or if you had a mastectomy (surgery to remove one or both breasts) you should notify the study personnel at the start of your exam visit to ensure your safety.

Medical care during the examination: In the unlikely event that during an examination procedure you should require medical care, first aid will be available.

Fasting: There is a chance that your blood sugar levels drop because you are fasting, especially if you have diabetes. You may feel cold sweats, blurry vision, rapid heart rate, shaking of the hands, dizziness, or fainting. These symptoms can be relieved by giving you juice, a snack, and/or lunch after your blood is drawn and a few procedures are performed.

Blood draw: A skilled technician will draw your blood. Minimal bruising, pain, or temporary bleeding may occur as a result of the blood draw. No materials will be injected into your body; blood will only be withdrawn. The technician wears latex gloves when drawing blood. If you have a known latex allergy, inform the technician and he/she will use gloves made from another material.

Interviews: You might experience some embarrassment or anxiety from answering any sensitive background questions. You may refuse to answer any questions that make you uncomfortable.

Breathing test (Spirometry): On rare occasions, a person taking a lung function test may feel lightheaded or may faint. The primary risk involved is injury from falling. Participants asked to inhale the medication called Albuterol or Ventolin used during lung function testing may notice an increase in heart rate (pulse) or feel jittery or shaky (tremors).

Other Risks and Discomforts: In addition to the risks and discomforts mentioned above, and how they can be decreased, there may be other adverse events associated with any of the procedures that are performed during this examination which the investigators are not aware of. If you experience any other adverse event not mentioned above, it is extremely important that you make us aware of it.

A new health problem: You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. If any important medical problems are found, you may be asked by your insurance company or

employer for this information. No personal medical results will be released by ARIC without your approval. If you do not have a personal health provider, the ARIC clinic staff will help you find a medical professional.

Data Sharing: ARIC makes every effort to protect your identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. This is partly because of the possibility of matching your DNA sample with other DNA collections (such as those kept by law enforcement agencies). **However, researchers are strictly prohibited from attempting to identify you.**

ANTICIPATED BENEFITS

There will not be a direct benefit to you from being in this study. You will be given a report of all your results from this examination that may have medical value to identify or treat health conditions. Since this is a research study the examination you receive is not a substitute for care you would receive from your health care provider, and we do not make a diagnosis, provide treatment, or give medical advice. Instead, we will encourage you to share your results with your health care provider. If you do not have regular health care, or you are unable to afford such care, an ARIC staff member will assist you in locating affordable health care. It takes longer for us to report the results back to you than an average medical exam, because this is a research study.

ALTERNATIVES

Your alternative is not to participate in ARIC.

FINANCIAL INFORMATION

There will be no costs to you for participating in this study. If a medical problem is found during the course of the exam that requires diagnosis and treatment, we will inform you of this. A letter with this information (and an additional copy) will also be mailed to you, so that if you desire, you can share it with your primary care physician or clinic. In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by ARIC for compensation or for payment of treatment because of your participation in this study. This does not waive any of your legal rights.

You will receive $75.00 to reimburse your costs of participation.

RESEARCH-RELATED INJURY

If any injuries or complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. _____ University will not pay for any care, lost wages, or provide other financial compensation.

SUBJECT'S RIGHTS

If you choose to be in this study you have the right to be treated with respect, to decide at any time whether or not you wish to continue or stop being in the study, not to answer some questions, or not to complete any of the ARIC exam components. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your the quality of your medical care or your relationship with _____ University. Your participation will not affect your ability to be enrolled in a health care plan or receive related benefits. If you decide to participate and then change your decision, you will have the right to withdraw from this study at any moment without negative consequences.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office of Human Research Protection. You can call them at **XXX-XXX-XXXX**

If you decide to withdraw from the study the information collected about you may still be used in this study, unless you request that your records and test results obtained be removed from study files. You may also request that your DNA/RNA and blood samples be destroyed or that all identifiers be removed (including code numbers) from such samples. Only samples that are stored at the ARIC laboratory could be destroyed. It will not be possible to retrieve information and samples that have already been shared with researchers outside of the study. If you choose to withdraw your samples, you should call the Study Coordinator, Ms/Mr. _____, at **xxx-xxx-xxxx**. Your decision to discontinue participation in the study will not affect the quality of medical care. The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will not be beneficial for you, or the sponsor may stop the study.

CONFIDENTIALITY

Protecting your privacy is a top priority for ARIC. Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law.

 Code numbers - not names: To ensure confidentiality, a code number will be assigned to you and your medical information. Files with your name and other identifying information will be electronically saved separately from your medical information on a secure computer that can't be accessed by an unauthorized person. If your information is printed, it will be kept locked and accessible only to certified ARIC personnel. Only authorized ARIC personnel will have access to your name and identifying information.

 Blood sample confidentiality: Your blood and DNA/RNA sample will have a special code number to protect your privacy. Anyone looking only at this code will not be able to match you. A label with the code number and the date the blood is drawn will be the only information on the blood samples. The coded samples and records will be stored securely, separated from any files that can link your name to the code numbers. No unauthorized individuals will have access to the stored samples or information gained from your stored blood sample or genetic information.

 Risk of you being identified: While we believe that the risks of being identified are very low and the benefits to science and the health of the community are large, there may be risks that we are not aware of at this time. The protected data developed for this project will not contain information that is used to identify you (such as your name, address, telephone number, or social security number), but it is possible that in the future people may develop ways to link your genetic or medical information back to you. If you were identified, your genetic information could potentially be used in ways that may cause you or your family distress, such as revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative). To protect you, a federal law, the **Genetic Information Nondiscrimination Act** was passed in 2008, making it illegal to discriminate on matters of employment and health insurance in the U.S. based on genetic information.

 Publishing results: When study results are published your name and any other potentially identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by the Office of Human Research Protection of the U.S Government or the Institutional Review Board of _____ University.

 Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from NIH. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would

identify you. However, the certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing identifiable information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may provide that information. If the researchers learn of child abuse or your intention to hurt yourself or others, the Certificate of Confidentiality will not prevent ARIC from voluntary providing information that would identify you as a participant in this study. In this case your approval is not needed.

CHILDREN AND RELATIVES OF ARIC PARTICIPANTS

We will ask you if you will allow ARIC personnel to contact your children or other family members in the future, for health-related studies they may be interested in. They will be given the opportunity to agree or decline to participate.

QUALITY-CONTROL/QUALITY ASSURANCE MEASURES

During the ARIC exam we will ask you if you are willing to consent to have your exam audio-recorded (voices only) for quality-control by ARIC supervisors. Quality control means to make sure that all the tests, interviews and exams are done correctly and in the same way to every participant.

REPEAT INTERVIEW/PROCEDURES

We may also invite you to repeat certain interviews or procedures if the information collected during a procedure is incomplete, or to repeat certain interviews or procedures for quality control purposes. This is optional and will be shorter than the original visit. We will let you know how much time this will take when you are contacted.

Note: If you do not wish to participate in any test mentioned above cross it out and print your initials next to it on this form, or have the ARIC staff mark this form according to your instructions.

UNIVERSITY OF _____;

Department / Division _____

PROXY CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

I have read or heard the above information and have received answers to all my questions. I agree to participate in this ARIC examination and to allow researchers to store and analyze my data and blood and urine samples now and in the future, in a way that will not identify me, for the research described above. I will be given a copy of this consent form to keep after you sign it.

I also agree to the following (please initial the appropriate place beside each statement shown below):

1) I _____ agree I _____ do not agree	to be contacted twice a year by the ARIC staff to answer questions about my health and to update my address
2) I _____ agree I _____ do not agree	to allow ARIC personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate.
3) I _____ agree I _____ do not agree	to allow my samples (blood, urine) to be used for current and future research by scientists who collaborate with ARIC investigators.
4) I _____ agree I _____ do not agree	to allow my blood to be used to obtain **genetic** material (DNA/RNA) to be stored for current and future use by ARIC and investigators they work with.
5) I _____ agree I _____ do not agree	to be contacted in the future for health–related studies by ARIC personnel.
6) I _____ agree I _____ do not agree	for ARIC personnel to contact my children or other family members in the future for health-related studies. They will be given the opportunity to agree or decline participation.
7) I _____ agree	to share my de-identified **non-genetic** data, information, and

I _____ do not agree	samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples"
8) I _____ agree I _____ do not agree	to share my de-identified **genetic** data, information, and samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples".
9) I _____ agree I _____ do not agree	to allow use of my genetic and non-genetic data, information and samples by **commercial or for-profit companies** that are not part of ARIC to do research on new diagnostic tests and medical treatments that may benefit many people.

The stamp below indicates that _____ University has approved this consent form. My signature below indicates the following:

- That I have read the information in this document / it was read to me
- That I have had a chance to ask any questions I have about the study and that if I have additional questions, I have been told who to contact
- That I agree to be in the study
- That I have been told that I can change my mind and stop participating at any time
- That I have been given a copy of this consent form
- With my signature I also give permission for my hospital and/or health clinic to release any of my health records that ARIC needs and requests. This permission has no expiration date.

_____

Printed Name of Participant

_____ _____

Signature of Authorized Representative Date

_____ _____

Printed Name of Authorized Representative Relationship to Research Subject

_____

Printed Name of Person Obtaining Informed Consent Signature Date

UNIVERSITY OF _____ Department / Division _____

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

INVESTIGATORS:
Principal Investigator, _____
Project Coordinator, _____

SPONSOR: National Heart, Lung, and Blood Institute, National Institutes of Health

PURPOSE OF THE STUDY

You are invited to participate in this examination of the ARIC study, a national health research project conducted by _____ University under a research contract from the National Institutes of Health (NIH). Your participation in this study is entirely voluntary. Before you give your consent to volunteer, it please read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do in this study.

ARIC is an ongoing study that includes 15,792 participants from four centers across the country. You enrolled in ARIC during 1986-1989, along with several thousand other residents of your community. The main purpose of ARIC study is to investigate diseases of older adults in the population, primarily of the heart, lungs and blood vessels and to monitor the trends of coronary heart disease and heart failure in communities.

PROCEDURES

This new ARIC clinical examination visit takes place at your place of residence. If you agree to take part in this study, your ARIC exam visit will include the items identified below with a check-mark (☐).

☐ A series of **interviews** with questions about your health and activities of daily living and you will be asked the names of **medications** you are currently taking.

☐ Your **blood pressure** will be measured on one arm.

☐ We will measure your **weight** or record the most recent weight from your records

☐ **Blood tests** that will include cholesterol and other blood fats, sugar levels, kidney function, and other factors related to heart disease. About 7 tablespoons of blood will be drawn from your arm. Your blood will be used only for research studies and some of your blood will be stored for future studies.

☐ **Urine sample**. You will be asked to provide a small amount of urine. We will not do drug testing on your urine. Your urine sample will be used only for research studies and some of your urine will be stored for future studies.

☐ **Echocardiogram:** A trained technician will perform a test on your chest using sound waves to measure how well your heart is able to pump blood.

The interviews and exam procedures will last approximately 2 hours.

Note: If you do not wish to participate in any test mentioned above cross it out and print your initials next to it on this form, or have the ARIC staff mark this form according to your instructions

- **Genetic Research Tests**: The study of genes and gene products has progressed very quickly since ARIC began. If you gave your permission at an earlier exam, ARIC collected DNA, the material that contains the genes, from your blood samples and stored

it at that time. Your DNA is used to try to learn whether genes and gene products can help us understand the risk of diseases in middle-aged and older adults, particularly heart disease, stroke, cancer, brain function, lung, and eye disease. ARIC is looking at specific genes and also at wide regions of DNA. ARIC also looks at a material in our cells called RNA, which may help us understand how genes work. If you agree, ARIC will collect DNA and RNA in this examination from the same blood we collect for other tests.

Most people have versions of genes that are safe and cause no disease, but a small number of people may have a version that can carry a greater risk for disease. If you have such a DNA finding, there is a chance that your family members would have the same DNA finding, but it does not mean that you or your family member will in fact get such a disease.

ARIC only looks at DNA and RNA for research studies but does not do clinical genetic testing. That means that ARIC does not examine your DNA to diagnose health conditions nor to do genetic counseling, and that the results will not be reported to you or to others who may request this information.

Sharing of Data and Samples

In order for science to progress, researchers exchange scientific resources and information. We are asking for your permission to allow sharing of data, information and samples that could not be directly identify you, with researchers who are not part of the ARIC Study.

 Use of data and samples: Portions of samples of your blood, urine and DNA, in addition to study information and genetic data, will be stored for use by researchers indefinitely.

The National Institutes of Health will allow researchers who qualify to analyze your data and samples, after your identity has been removed. Researchers can qualify by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.

Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

 Commercial use of data and samples: Researchers from private companies that develop diagnostic lab tests or treatments for diseases may request access to your study information or samples. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

Your samples will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).

Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.

 Genetic research: Very detailed information about your DNA will be stored centrally at the National Institutes of Health, where it will be shared with other investigators for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment. The stored information is de-identified, which means that identifying information such as your name, date of birth, address, etc., is removed. Access to this stored information will be controlled by the National Institutes of Health. The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: http://www.nih.gov/icd/od/foia/efoia.htm

Follow-up Contacts: We will continue to contact you by phone every 6 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask for you to update this person's name in this exam.

Medical Record Review: If you are hospitalized or admitted to a long term care or nursing home, we will ask that institution for your records. We will request your signed permission for ARIC staff to obtain and review a copy of the records from the hospital, or clinic, emergency department/urgent care or cancer registry. We may request records from your doctor for certain office or clinic visits to determine if you have been diagnosed with one of the diseases that ARIC is studying and we will also request Medicare records.

We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting the Study Coordinator listed at the end of this form. In the event of your death, information will be sought from your relatives or other sources, including coroner's report, medical records (if your death takes place in a hospital or long term care facility), and the state health department. In all these instances, your social security number, provided previously to ARIC, may be used to confirm your identity and assure that the correct records are reviewed.

New Information: If new knowledge about the conditions evaluated by ARIC becomes available during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

Option for Additional Studies: You may be contacted to determine if you are interested in participating in other studies done in collaboration with ARIC. The studies may be related to your health or to laboratory information in the ARIC data, or ask for authorization to extend the study to children or other family members. Only ARIC personnel will be authorized to contact you on behalf of this study.

Duration of Participation: Your voluntary participation in ARIC will be for as long as you agree to participate.

Samples: You have the ability to decide how your samples should be used. We will hold them until no longer needed or until you tell us to destroy them. Your blood, urine and DNA samples will be identified only with a number code and sent to a ARIC laboratory for storage, or for detailed analysis. Some of your samples will be stored for unlimited time, for future use in studies related to diseases or in other research projects that have been approved by ARIC.

RESULTS

A report on the results of your exams (with an additional copy to provide to your doctor if desired) will be mailed to you, which can be used for recommended medical treatment. Results from genetic tests will not be reported. It is recommended that you discuss any abnormal findings with your primary care physician. Because ARIC measures your test results at research laboratory the results take a longer amount of time to report than an average medical exam.

POTENTIAL RISKS AND DISCOMFORTS

All of the examinations done by ARIC are routinely done in the clinic and are considered safe. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills during a long exam. If you wear a medical device such as a pacemaker or another implanted device or if you had a mastectomy (surgery to remove one or both breasts) you should notify the study personnel at the start of your exam visit to ensure your safety.

Medical care during the examination: In the unlikely event that during an examination procedure you should require medical care, first aid will be available.

Fasting: There is a chance that your blood sugar levels drop because you are fasting, especially if you have diabetes. You may feel cold sweats, blurry vision, rapid heart rate, shaking of the hands, dizziness, or fainting. These symptoms can be relieved by giving you juice, a snack, and/or lunch after your blood is drawn and a few procedures are performed.

Blood draw: A skilled technician will draw your blood. Minimal bruising, pain, or temporary bleeding may occur as a result of the blood draw. No materials will be injected into your body; blood will only be withdrawn. The technician wears latex gloves when drawing blood. If you have a known latex allergy, inform the technician and he/she will use gloves made from another material.

Interviews: You might experience some embarrassment or anxiety from answering any sensitive background questions. You may refuse to answer any questions that make you uncomfortable.

Other Risks and Discomforts: In addition to the risks and discomforts mentioned above, and how they can be decreased, there may be other adverse events associated with any of the procedures that are performed during this examination which the investigators are not aware of. If you experience any other adverse event not mentioned above, it is extremely important that you make us aware of it.

A new health problem: You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. If any important medical problems are found, you may be asked by your insurance company or employer for this information. No personal medical results will be released by ARIC without your approval. If you do not have a personal health provider, the ARIC clinic staff will help you find a medical professional.

Data Sharing: ARIC makes every effort to protect your identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. This is partly because of the possibility of matching your DNA sample with other DNA collections (such as those kept by law enforcement agencies). **However, researchers are strictly prohibited from attempting to identify you.**

ANTICIPATED BENEFITS

There will not be a direct benefit to you from being in this study. You will be given a report of all your results from this examination that may have medical value to identify or treat health conditions. Since this is a research study the examination you receive is not a substitute for care you would receive from your health care provider, and we do not make a diagnosis, provide treatment, or give medical advice. Instead, we will encourage you to share your results with your health care provider. If you do not have regular health care, or you are unable to afford such care, an ARIC staff member will assist you in locating affordable health care. It takes longer for us to report the results back to you than an average medical exam, because this is a research study.

ALTERNATIVES

Your alternative is not to participate in ARIC.

FINANCIAL INFORMATION

There will be no costs to you for participating in this study. If a medical problem is found during the course of the exam that requires diagnosis and treatment, we will inform you of this. A letter with this information (and an additional copy) will also be mailed to you, so that if you desire, you can share it with your primary care physician or clinic. In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by ARIC for compensation or for payment of treatment because of your participation in this study. This does not waive any of your legal rights.

You will receive $75.00 to reimburse your costs of participation.

RESEARCH-RELATED INJURY

If any injuries or complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. _____ University will not pay for any care, lost wages, or provide other financial compensation.

SUBJECT'S RIGHTS

If you choose to be in this study you have the right to be treated with respect, to decide at any time whether or not you wish to continue or stop being in the study, not to answer some questions, or not to complete any of the ARIC exam components. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your the quality of your medical care or your relationship with _____ University. Your participation will not affect your ability to be enrolled in a health care plan or receive related benefits. If you decide to participate and then change your decision, you will have the right to withdraw from this study at any moment without negative consequences.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office of Human Research Protection. You can call them at **XXX-XXX-XXXX**

If you decide to withdraw from the study the information collected about you may still be used in this study, unless you request that your records and test results obtained be removed from study files. You may also request that your DNA/RNA and blood samples be destroyed or that all identifiers be removed (including code numbers) from such samples. Only samples that are stored at the ARIC laboratory could be destroyed. It will not be possible to retrieve information and samples that have already been shared with researchers outside of the study. If you choose to withdraw your samples, you should call the Study Coordinator, Ms/Mr. _____, at **xxx-xxx-xxxx**. Your decision to discontinue participation in the study will not affect the quality of medical care. The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will not be beneficial for you, or the sponsor may stop the study.

CONFIDENTIALITY

Protecting your privacy is a top priority for ARIC. Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law.

 Code numbers - not names: To ensure confidentiality, a code number will be assigned to you and your medical information. Files with your name and other identifying information will be electronically saved separately from your medical information on a secure computer that can't be accessed by an unauthorized person. If your information is printed, it will be kept locked and accessible only to certified ARIC personnel. Only authorized ARIC personnel will have access to your name and identifying information.

 Blood sample confidentiality: Your blood and DNA/RNA sample will have a special code number to protect your privacy. Anyone looking only at this code will not be able to match you. A label with the code number and the date the blood is drawn will be the only information on the blood samples. The coded samples and records will be stored securely, separated from any files that can link your name to the code numbers. No unauthorized individuals will have access to the stored samples or information gained from your stored blood sample or genetic information.

 Risk of you being identified: While we believe that the risks of being identified are very low and the benefits to science and the health of the community are large, there may be risks that we are not aware of at this time. The protected data developed for this project will not contain information that is used to identify you (such as your name, address, telephone number, or social security number), but it is possible that in the future people may develop ways to link your genetic or medical information back to you. If you were identified, your genetic information could potentially be used in ways that may cause you or your family distress, such as revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative). To protect you, a federal law, the **Genetic Information Nondiscrimination Act** was passed in 2008, making it illegal to discriminate on matters of employment and health insurance in the U.S. based on genetic information.

 Publishing results: When study results are published your name and any other potentially identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by the Office of Human Research Protection of the U.S Government or the Institutional Review Board of _____ University.

 Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from NIH. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would

identify you. However, the certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing identifiable information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may provide that information. If the researchers learn of child abuse or your intention to hurt yourself or others, the Certificate of Confidentiality will not prevent ARIC from voluntary providing information that would identify you as a participant in this study. In this case your approval is not needed.

CHILDREN AND RELATIVES OF ARIC PARTICIPANTS

We will ask you if you will allow ARIC personnel to contact your children or other family members in the future, for health-related studies they may be interested in. They will be given the opportunity to agree or decline to participate.

UNIVERSITY OF _____;

Department / Division _____

PROXT CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

I have read or heard the above information and have received answers to all my questions. I agree to participate in this ARIC examination and to allow researchers to store and analyze my data and blood and urine samples now and in the future, in a way that will not identify me, for the research described above. I will be given a copy of this consent form to keep after you sign it.

I also agree to the following (please initial the appropriate place beside each statement shown below):

1) I _____ agree I _____ do not agree	to be contacted twice a year by the ARIC staff to answer questions about my health and to update my address
2) I _____ agree I _____ do not agree	to allow ARIC personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate.
3) I _____ agree I _____ do not agree	to allow my samples (blood, urine) to be used for current and future research by scientists who collaborate with ARIC investigators.
4) I _____ agree I _____ do not agree	to allow my blood to be used to obtain **genetic** material (DNA/RNA) to be stored for current and future use by ARIC and investigators they work with.
5) I _____ agree I _____ do not agree	to be contacted in the future for health–related studies by ARIC personnel.
6) I _____ agree I _____ do not agree	for ARIC personnel to contact my children or other family members in the future for health-related studies. They will be given the opportunity to agree or decline participation.
7) I _____ agree	to share my de-identified **non-genetic** data, information, and

I _____ do not agree	samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples"
8) I _____ agree I _____ do not agree	to share my de-identified **genetic** data, information, and samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples".
9) I _____ agree I _____ do not agree	to allow use of my genetic and non-genetic data, information and samples by **commercial or for-profit companies** that are not part of ARIC to do research on new diagnostic tests and medical treatments that may benefit many people.

The stamp below indicates that _____ University has approved this consent form. My signature below indicates the following:

- That I have read the information in this document / it was read to me
- That I have had a chance to ask any questions I have about the study and that if I have additional questions, I have been told who to contact
- That I agree to be in the study
- That I have been told that I can change my mind and stop participating at any time
- That I have been given a copy of this consent form
- With my signature I also give permission for my hospital and/or health clinic to release any of my health records that ARIC needs and requests. This permission has no expiration date.

_____

Printed Name of Participant Signature Date

_____

Printed Name of Person Obtaining Informed Consent Signature Date

UNIVERSITY OF _____ Department / Division _____

PROXY CONSENT TO PARTICIPATE
Atherosclerosis Risk in Communities (ARIC) Study

INVESTIGATORS:
Principal Investigator, _____
Project Coordinator, _____

SPONSOR: National Heart, Lung, and Blood Institute, National Institutes of Health

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

PURPOSE OF THE STUDY

You are invited to participate in this examination of the ARIC study, a national health research project conducted by _____ University under a research contract from the National Institutes of Health (NIH). Your participation in this study is entirely voluntary. Before you give your consent to volunteer, it please read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do in this study.

ARIC is an ongoing study that includes 15,792 participants from four centers across the country. You enrolled in ARIC during 1986-1989, along with several thousand other residents of your community. The main purpose of ARIC study is to investigate diseases of older adults in the population, primarily of the heart, lungs and blood vessels and to monitor the trends of coronary heart disease and heart failure in communities.

PROCEDURES

This new ARIC clinical examination visit takes place at your place of residence. If you agree to take part in this study, your ARIC exam visit will include the items identified below with a check-mark (☐).

☐ A series of **interviews** with questions about your health and activities of daily living and you will be asked the names of **medications** you are currently taking.

☐ Your **blood pressure** will be measured on one arm.

☐ We will measure your **weight** or record the most recent weight from your records

☐ **Blood tests** that will include cholesterol and other blood fats, sugar levels, kidney function, and other factors related to heart disease. About 7 tablespoons of blood will be drawn from your arm. Your blood will be used only for research studies and some of your blood will be stored for future studies.

☐ **Urine sample**. You will be asked to provide a small amount of urine. We will not do drug testing on your urine. Your urine sample will be used only for research studies and some of your urine will be stored for future studies.

☐ **Echocardiogram:** A trained technician will perform a test on your chest using sound waves to measure how well your heart is able to pump blood.

The interviews and exam procedures will last approximately 2 hours.

Note: If you do not wish to participate in any test mentioned above cross it out and print your initials next to it on this form, or have the ARIC staff mark this form according to your instructions

- **Genetic Research Tests**: The study of genes and gene products has progressed very quickly since ARIC began. If you gave your permission at an earlier exam, ARIC collected DNA, the material that contains the genes, from your blood samples and stored

it at that time. Your DNA is used to try to learn whether genes and gene products can help us understand the risk of diseases in middle-aged and older adults, particularly heart disease, stroke, cancer, brain function, lung, and eye disease. ARIC is looking at specific genes and also at wide regions of DNA. ARIC also looks at a material in our cells called RNA, which may help us understand how genes work. If you agree, ARIC will collect DNA and RNA in this examination from the same blood we collect for other tests.

Most people have versions of genes that are safe and cause no disease, but a small number of people may have a version that can carry a greater risk for disease. If you have such a DNA finding, there is a chance that your family members would have the same DNA finding, but it does not mean that you or your family member will in fact get such a disease.

ARIC only looks at DNA and RNA for research studies but does not do clinical genetic testing. That means that ARIC does not examine your DNA to diagnose health conditions nor to do genetic counseling, and that the results will not be reported to you or to others who may request this information.

Sharing of Data and Samples

In order for science to progress, researchers exchange scientific resources and information. We are asking for your permission to allow sharing of data, information and samples that could not be directly identify you, with researchers who are not part of the ARIC Study.

 Use of data and samples: Portions of samples of your blood, urine and DNA, in addition to study information and genetic data, will be stored for use by researchers indefinitely.

The National Institutes of Health will allow researchers who qualify to analyze your data and samples, after your identity has been removed. Researchers can qualify by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.

Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

 Commercial use of data and samples: Researchers from private companies that develop diagnostic lab tests or treatments for diseases may request access to your study information or samples. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

Your samples will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).

Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.

 Genetic research: Very detailed information about your DNA will be stored centrally at the National Institutes of Health, where it will be shared with other investigators for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment. The stored information is de-identified, which means that identifying information such as your name, date of birth, address, etc., is removed. Access to this stored information will be controlled by the National Institutes of Health. The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: http://www.nih.gov/icd/od/foia/efoia.htm

Follow-up Contacts: We will continue to contact you by phone every 6 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask for you to update this person's name in this exam.

Medical Record Review: If you are hospitalized or admitted to a long term care or nursing home, we will ask that institution for your records. We will request your signed permission for ARIC staff to obtain and review a copy of the records from the hospital, or clinic, emergency department/urgent care or cancer registry. We may request records from your doctor for certain office or clinic visits to determine if you have been diagnosed with one of the diseases that ARIC is studying and we will also request Medicare records.

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Other Risks and Discomforts: In addition to the risks and discomforts mentioned above, and how they can be decreased, there may be other adverse events associated with any of the procedures that are performed during this examination which the investigators are not aware of. If you experience any other adverse event not mentioned above, it is extremely important that you make us aware of it.

A new health problem: You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. If any important medical problems are found, you may be asked by your insurance company or employer for this information. No personal medical results will be released by ARIC without your approval. If you do not have a personal health provider, the ARIC clinic staff will help you find a medical professional.

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If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office of Human Research Protection. You can call them at **XXX-XXX-XXXX**

If you decide to withdraw from the study the information collected about you may still be used in this study, unless you request that your records and test results obtained be removed from study files. You may also request that your DNA/RNA and blood samples be destroyed or that all identifiers be removed (including code numbers) from such samples. Only samples that are stored at the ARIC laboratory could be destroyed. It will not be possible to retrieve information and samples that have already been shared with researchers outside of the study. If you choose to withdraw your samples, you should call the Study Coordinator, Ms/Mr. _____, at **xxx-xxx-xxxx**. Your decision to discontinue participation in the study will not affect the quality of medical care. The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will not be beneficial for you, or the sponsor may stop the study.

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 Publishing results: When study results are published your name and any other potentially identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by the Office of Human Research Protection of the U.S Government or the Institutional Review Board of _____ University.

 Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from NIH. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would

identify you. However, the certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing identifiable information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may provide that information. If the researchers learn of child abuse or your intention to hurt yourself or others, the Certificate of Confidentiality will not prevent ARIC from voluntary providing information that would identify you as a participant in this study. In this case your approval is not needed.

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UNIVERSITY OF _____;

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I have read or heard the above information and have received answers to all my questions. I agree to participate in this ARIC examination and to allow researchers to store and analyze my data and blood and urine samples now and in the future, in a way that will not identify me, for the research described above. I will be given a copy of this consent form to keep after you sign it.

I also agree to the following (please initial the appropriate place beside each statement shown below):

1) I _____ agree I _____ do not agree	to be contacted twice a year by the ARIC staff to answer questions about my health and to update my address
2) I _____ agree I _____ do not agree	to allow ARIC personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate.
3) I _____ agree I _____ do not agree	to allow my samples (blood, urine) to be used for current and future research by scientists who collaborate with ARIC investigators.
4) I _____ agree I _____ do not agree	to allow my blood to be used to obtain **genetic** material (DNA/RNA) to be stored for current and future use by ARIC and investigators they work with.
5) I _____ agree I _____ do not agree	to be contacted in the future for health–related studies by ARIC personnel.
6) I _____ agree I _____ do not agree	for ARIC personnel to contact my children or other family members in the future for health-related studies. They will be given the opportunity to agree or decline participation.
7) I _____ agree	to share my de-identified **non-genetic** data, information, and

I _____ do not agree	samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples"
8) I _____ agree I _____ do not agree	to share my de-identified **genetic** data, information, and samples available to **investigators not associated to ARIC and specialized laboratories**, as described under the section "Sharing of Data and Samples".
9) I _____ agree I _____ do not agree	to allow use of my genetic and non-genetic data, information and samples by **commercial or for-profit companies** that are not part of ARIC to do research on new diagnostic tests and medical treatments that may benefit many people.

The stamp below indicates that _____ University has approved this consent form. My signature below indicates the following:

- That I have read the information in this document / it was read to me
- That I have had a chance to ask any questions I have about the study and that if I have additional questions, I have been told who to contact
- That I agree to be in the study
- That I have been told that I can change my mind and stop participating at any time
- That I have been given a copy of this consent form
- With my signature I also give permission for my hospital and/or health clinic to release any of my health records that ARIC needs and requests. This permission has no expiration date.

_____

Printed Name of Participant

_____ _____

Signature of Authorized Representative Date

_____ _____

Printed Name of Authorized Representative Relationship to Research Subject

_____

Printed Name of Person Obtaining Informed Consent Signature Date

Participant Safety Screening Form

ID NUMBER:								

FORM CODE: PSA

VERSION: A 7/15/10

Contact Occasion: 2 5

SEQ #: 0 1

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

Administrative Information

0a. Completion Date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐ 0b. Staff ID: ☐☐☐

Instructions: *This safety screening form must be completed before the participant can have their examination either during a reminder phone call for the clinic visit, or immediately prior to the exam. Positive responses to Questions 2 – 10 should be noted on the Exam Itinerary Checklist for routing purposes during the visit.*

***NOTE TO STAFF**: Use appropriate recruitment or clinic scheduling script when completing this form.*

A. Safety and Access Questions

1. Do you need any kind of assistance reading, hearing questions, or getting on an examination table?

Yes ☐ specify: _____

No ☐

2. Do you have either a heart pacemaker or defibrillator (AICD)?

Yes ☐ → **BIA, MRI, Bronchodilator, ambulatory ECG Exclusion**

No ☐

3. Do you have an arrhythmia or irregular heartbeat?

Yes ☐ → **Ambulatory ECG Exclusion**

No ☐

4. Has a doctor or health professional ever recommended that you not take albuterol? Albuterol is also called Ventolin, Proventil, Maxair, or Combivent (when combined with another medicine called ipratropium).

Yes ☐ → **Bronchodilator Exclusion**

No ☐

B. Pulmonary Function Test Exclusion Question

5. Have you had a heart attack, stroke, or eye surgery in the last 6 months?

Yes ☐ → **Pulmonary Test Exclusion**

No ☐

ANTHROPOMETRY FORM

ID NUMBER: | | | | | | | |

STUDY YEAR | 25 |

SEQ # | | |

FORM CODE: ANT

VERSION: F – 7/15/10

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *Enter the answer given by the participant for each response. If a response is unknown or cannot be measured then enter the special missing value, "==", in the item. In order to measure bioimpedence, the participant must be barefoot. Set the Tanita analyzer to report metric units (cm/kg).*

A. DETERMINATION OF ABILITY TO STAND

1. Assessment of ability to stand (choose one):.....☐

   Can stand erectly on both feet. .....A → **GO TO ITEM 3**

   Can stand on both feet, but posture not erect. .....B → **GO TO ITEM 3**

   Cannot stand on both feet. C

B. SELF REPORT

2. a) Self-reported weight (to the nearest lb or kg): .....☐☐☐

   b) Units (check one):.....☐ lb ☐ kg → **GO TO END**

C. MEASURED HEIGHT, WEIGHT, and BIO-IMPEDENCE

3. Standing height (round to nearest cm):.....☐☐☐ cm
4. Weight: .....☐☐☐.☐ kg
5. Fat (%): .....☐☐.☐ %
6. Impedance: .....☐☐☐ Ohms
7. Fat mass: .....☐☐☐.☐ kg
8. Lean body mass (FFM): .....☐☐☐.☐ kg
9. Total body water (TBW): .....☐☐☐.☐ kg

D. BODY SIZE

10. Girth (round to nearest cm)
    a) Waist: .....☐☐☐ cm

    b) Hip: .....☐☐☐ cm

12-LEAD ELECTROCARDIOGRAM

NUMBER: ☐☐☐☐☐☐☐

STUDY YEAR 25 SEQ # ☐☐

FORM CODE: ECG

VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

1. Time of Day: ☐☐:☐☐ ☐ a.m. ☐ p.m.

2. Results of examination:

☐ completed

☐ not completed → a. Reason test incomplete or not done:

- ☐ hardware malfunction or lack of supplies
- ☐ insufficient time available or room not available
- ☐ other, specify _____

_____

3. Heart square measurements:

O-E ☐☐.☐

O-V6 ☐☐.☐

4. Were any alert conditions noted? ☐ Yes → Specify:

☐ No Action Taken:

SITTING BLOOD PRESSURE FORM

ID NUMBER: ☐☐☐☐☐☐☐

STUDY YEAR 25 SEQ # 00

FORM CODE: SBP

VERSION: F 7/15/10

Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *Enter results as measured. If measure is unobtainable, enter the special missing value, "==", in the item.*

A. Arm measurements

1. Arm used for sitting blood pressure measurement (choose one): ☐

Right (preferred).....A
Left.....B
Other {note log}.....C

2. Arm circumference (cm) .....☐☐

3. Cuff size: (arm circumference in brackets) ☐

Small {17-22 cm, CS19}.....A

Adult {22-32 cm, CR19}.....B

Large {32-42 cm, CL19}.....C

X Large {42-50 cm, CX19}.....D

4. Heart rate (30 seconds):.....☐☐

5. Time of measurement

a. Time of day:.....☐☐:☐☐

H H M M

b. AM ☐ or PM ☐

B. Average blood pressure / pulse rate

6. Systolic.....☐☐☐

7. Diastolic.....☐☐☐

8. Pulse: .....☐☐☐

C. First blood pressure / pulse rate

9. Systolic.....☐☐☐

10. Diastolic..... ☐☐☐

11. Pulse: ..... ☐☐☐

D. Second blood pressure / pulse rate

12. Systolic..... ☐☐☐

13. Diastolic..... ☐☐☐

14. Pulse: ..... ☐☐☐

E. Third blood pressure / pulse rate

15. Systolic..... ☐☐☐

16. Diastolic..... ☐☐☐

17. Pulse: ..... ☐☐☐

BIOSPECIMEN COLLECTION FORM

ID NUMBER:								STUDY YEAR	25	SEQ #	

FORM CODE: BIO

VERSION: B – 7/15/10

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *This form should be completed during the participant's clinic or home visit. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry.*

CLINIC VISIT ☐

HOME VISIT ☐

A. URINE SAMPLE

1. Urine sample collected?

Yes.....☐
No.....☐ → **Go to Item 6**

2. Time/date of urine sample:

a. Time of urine sample: .....☐☐**:** ☐☐
h h m m

b. AM or PM?

AM.....☐
PM.....☐

c. Date of urine sample collection: .....☐☐**/** ☐☐**/** ☐☐☐☐
M M D D Y Y Y Y

B. URINE PROCESSING

3. Volume adequate for processing?.....☐

Yes (≥ 30mL).....A

Yes (< 30 mL but at least 15 mL).....B

No (<15 mL, discard).....C

4. Urine pH adjustment made or preservative added?.....☐

Yes, ph adjustment made.....A

Yes, preservative added.....B

No pH adjustment or preservative.....C

5. Date/time that the pH adjustment is made or preservative added and technician ID for urine sample

a. Date.....☐☐/ ☐☐/ ☐☐☐☐

M M D D Y Y Y Y

b. Time .....☐☐: ☐☐

h h m m

c. AM or PM?

AM.....☐

PM.....☐

d. Technician ID for urine sample:.....☐☐☐

C. BLOOD DRAWING

6. Do you have any bleeding disorders other than easy bruising which is often caused by medications like aspirin or plavix?

Yes.....☐
No.....☐ →**Go to Item 7**

Don't Know.…….☐ →**Go to Item 7**

a. Please specify the nature of the bleeding disorder:

_____

_____

7. When was the last time you ate or drank anything other than water?

a. Date.....☐☐/☐☐/☐☐☐☐

M M D D Y Y Y Y

b. Time.....☐☐:☐☐

h h m m

c. AM or PM?

AM.....☐
PM.....☐

8. Time/date of blood drawing:

a. Time of blood drawing: .....☐☐**:** ☐☐

h h m m

b. AM or PM?

AM.....☐

PM.....☐

c. Date of blood drawing: .....☐☐**/** ☐☐**/** ☐☐☐☐

M M D D Y Y Y Y

9. Fasting time (computed by DES)..... ☐☐**:** ☐☐

h h m m

10. Number of venipuncture attempts:.....☐

11. Code number of phlebotomist: .....☐☐☐

a. Code number of assistant:.....☐☐☐

12. Any blood drawing incidents or problems?

Yes.....☐

No.....☐ →**Go to Item 13**

[*Blood drawing incidents: Document problems with venipuncture in this table. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 17*.]

	Tube										
	1	2	3	4	5	6	7	8	9	10	11
a. Sample not drawn	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. Partial sample drawn	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Tourniquet reapplied	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. Fist clenching	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. Needle movement	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
f. Participant reclining	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

13. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here:

_____

_____

_____

D. BLOOD PROCESSING

14. Date/time of processing specimen tubes 3, 4, 5, 7, 8 and 9:

a. Date specimen tubes 3, 4, 5, 7, 8 and 9 were spun: ☐☐**/** ☐☐**/** ☐☐☐☐

M M D D Y Y Y Y

b. Time specimen tubes 3, 4, 5, 7, 8 and 9 were spun: ☐☐**:** ☐☐

h h m m

c. AM or PM?

AM.....☐

PM.....☐

15. Code number of technician processing blood (tubes 3, 4, 5, 7, 8, 9):☐☐☐

16. Date/time of processing specimen tubes 1 and 2:

a. Date specimen tubes 1 and 2 were spun: ☐☐/ ☐☐/ ☐☐☐☐

M M D D Y Y Y Y

b. Time specimen tubes 1 and 2 were spun: .....☐☐: ☐☐

h h m m

c. AM or PM?

AM.....☐

PM.....☐

17. Code number of technician processing blood tubes 1 and 2: ☐☐☐

18. Date/time specimens from tubes 1, 2, 3, 4, 5, 7, 8 and 9 were placed in freezer:

a. Date specimens were placed in freezer ☐☐/ ☐☐/ ☐☐☐☐

M M D D Y Y Y Y

b. Time specimens were placed in freezer:.....☐☐: ☐☐

h h m m

c. AM or PM?

AM.....☐

PM.....☐

19. Date/time tubes with no processing 6, 10 and 11 were packaged for daily shipment out:

a. Date tubes with no processing (6, 10 and 11)
were packaged for daily shipment out: ☐☐/ ☐☐/ ☐☐☐☐

M M D D Y Y Y Y

b. Time specimens were packaged for daily shipment out: ☐☐:☐☐

h h m m

c. AM or PM?

AM.....☐

PM.....☐

d. Code number of technician packaging specimens for daily shipment out: ☐☐☐

20. Any blood processing incidents or problems?

Yes.....☐

No.....☐ →**Go to Item 22**

[*Blood processing incidents: Document problems with the processing of specimens in this table. Place an "X" in box(es) corresponding to the tubes in which the processing problem(s) occurred. If a problem other than those listed occurred, use Item 21*.]

	Tube										
	1	2	3	4	5	6	7	8	9	10	11
a. Broken tube	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. Clotted	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Hemolyzed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. Lipemic	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. Other	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

21. Comments on blood processing or other problems in blood processing: (attach a sheet if needed)

_____

_____

_____

_____

ANKLE ARM BLOOD PRESSURE FORM

ID NUMBER: ☐☐☐☐☐☐☐

STUDY YEAR 25

SEQ # ☐☐

FORM CODE: ABP

VERSION: A - 7/15/10

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *Enter the answer given by the participant for each response. If measure is unobtainable, enter the special missing value, "==", in the item.*

1. Systolic Readings: (*Record in this order*)

	Systolic (mm Hg)
a. Right brachial	☐☐☐
b. Right dorsalis pedis	☐☐☐
c. Right posterior tibial	☐☐☐
d. Left posterior tibial	☐☐☐

e. Left dorsalis pedis ☐☐☐

f. Left brachial ☐☐☐

2. All Procedures were: .....☐

Completed successfully.....A → **END QUESTIONNAIRE**

Not completed.....B

3. Reason procedure was not completed with all measures:

	Yes	**No**
a. Occusion failure.....	☐	☐
If "Yes", (1) R. dorsalis pedis.....	☐	☐
(2) R. posterior tibial.....	☐	☐
(3) L. posterior tibial.....	☐	☐
(4) L. dorsalis pedis.....	☐	☐
b. Amputation.....	☐	☐
c. Discomfort.....	☐	☐
d. Ulceration or lesion.....	☐	☐
e. Other (specify in note log).....	☐	☐ specify:

_____

DIETARY INTAKE FORM

ID NUMBER: | | | | | | | |

STUDY YEAR | 25 |

SEQ # | | |

FORM CODE: DTI

VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: □□/□□/□□□□ (Month / Day / Year)

0b. Staff ID: □□□

"In this part of the clinic visit we want to obtain information on your usual eating habits. We will go over specific foods by groups. I'll name a food and portion size and you tell me how often, on average, you ate that during the past year."

"If your portion was much different from the amount I say, please tell me if it was at least twice as much, or half as much. We have a few sizes of cups and glasses here for reference. [*Explain 4 oz. glass, 8 oz. glass, cup and ½ cup measures, TBSP, Tsp and Bowl*.] **Here are the choices for 'how often.'** [*Show RC 1*.] **The choices are number of times a day or week or month. Please respond with the appropriate letter. For example, 'once a day' would be 'D.' If you ate or drank something less than twelve times a year, that would be the same as 'almost never,' which is 'I.'"**

"It is important that your answer be short in order to save time, but we want you to be as accurate as possible. If we miss food items that you usually eat, we will list those at the end. Feel free to ask questions or have me repeat instructions if I am not being clear."

A. [RC1] DAIRY FOODS

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)
4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

1. Skim or low fat milk; 8 oz. glass..... ☐
   [*item includes ½%, 1%, 2% milk; reconstituted nonfat dry milk; cocoa from mix or vending; buttermilk – low fat or unknown; low fat chocolate milks*]

2. Whole milk; 8 oz. glass..... ☐
   [*item includes whole; "homogenized"; jersey milk; whole milk cocoa; whole buttermilk; unknown milk*]

3. Yogurt; 1 c..... ☐
   [*item includes whole milk yogurts, regular or frozen, 2% or low fat yogurts, regular or frozen*]

4. Ice cream; ½ c..... ☐
   [*item includes all brands, not ice milk - list at end if more than 2/week*]

5. Cottage cheese or ricotta cheese; ½ c..... ☐
   [*item includes any cottage or ricotta cheese Including any in recipes; farmer's cheese*]

6. Other cheeses, plain or as part of a dish; 1 slice or serving..... ☐
   [*item includes processed, cheddar and all hard natural cheeses*]
7. Margarine or a margarine/butter blend; pats added to food or bread..... ☐
   [*at table*]

8. Butter; pats added to food or bread..... ☐
   [*at table*]

B. [RC1] FRUITS

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)

4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

9. Fresh apples or pears; 1..... ☐

10. Oranges; 1..... ☐

11. Orange or grapefruit juice; small glass..... ☐
[*item includes 4 to 6 oz. glass*]

12*. Peaches, apricots or plums; 1 fresh or ½ c. canned or dried..... ☐
[*item includes *dried prunes**]

13. Bananas; 1..... ☐

14. Other fruits; 1 fresh or ½ c. canned, including fruit cocktail..... ☐
[*item includes cantaloupe; grapefruit; strawberries; papaya; raspberries; raisins; grapes; pineapple; kiwi*]

C. [RC1] VEGETABLES

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)
4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

[do not include small amounts in mixed dishes]

15. String beans or green beans; ½ c.....☐
[*item includes frozen or fresh; wax beans; fava beans*]

16. Broccoli; ½ c.....☐
[*item includes raw or cooked*]

17. Cabbage, cauliflower, brussel sprouts; ½ c.....☐
[*item includes raw or cooked; coleslaw; sauerkraut*]

18. Carrots; 1 whole or ½ c. cooked.....☐
[*item includes raw or cooked*]

19. Corn; 1 ear or ½ c. cooked.....☐
[*item includes raw or cooked*]

20. Spinach, collards or other greens, but do not include lettuce; ½ c.....☐
[*item includes raw or cooked; beet greens, chard, kale, mustard greens, turnip greens; romaine*]

21. Peas or lima beans; ½ c. fresh, frozen or canned.....☐
[*item includes mixed vegetables – peas, carrots, corn and limas – frozen or canned butter beans; not dried limas*]

22. Dark yellow, winter squash such as acorn, butternut; ½ c.....☐
[*item includes hubbard, danish, buttercup, delicious, crookneck*]

23. Sweet potatoes; ½ c.....☐
[*item includes pumpkin, yams, fresh or canned*]

24*. Beans or lentils, dried, cooked or canned, such as pinto, blackeye, baked beans, ½ c.☐
[*item includes red; brown; navy; northern; kidney; blackeye; garbanzo; split peas; refried beans; dried limas; *bean or lentil soup**]

25*. Tomatoes; 1 or tomato juice, 4 oz.....☐
[*item includes fresh or canned tomatoes; V-8 juice; *tomato soup**]

D. [RC1] MEATS

Response Categories:

>6 per day (A) 1 per day (D) 1 per week (G)

4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

26. Chicken or turkey, without skin.....☐
[*item includes cornish hen; pheasant*]

27. Chicken or turkey, with skin.....☐
[*item includes cornish hen; turkey roll; pheasant*]

28. Hamburgers; 1.....☐
[*item includes any ground beef in patty form*]

29. Hot dogs; 1.....☐
[*not chicken type*]

30. Processed meats: sausage, salami, bologna, etc.; piece or slice.....☐
[*item includes cold cuts; luncheon meats, packaged or canned; tongue; liver spread goes with liver*]

31. Bacon; 2 slices.....☐
[*not Canadian style: Canadian bacon is coded in next category*]

32. Beef, pork or lamb as a sandwich or mixed dish, stew or casserole, lasagna or in spaghetti sauce, etc.....☐
[*item includes hot dish; meat pies; pizza; meatloaf; meatball; barbeque; chitterlings; Canadian bacon; souse meat; pigs feet*]

33. Beef, pork or lamb as a main dish, steak, roast, ham, etc.....☐
[*includes chops, corned beef*]

34. Canned tuna fish; 3-4 oz.....☐
[*item includes all kinds, about ½ - 2/3 can*]

35. Dark meat fish, such as salmon, mackerel, swordfish, sardines, bluefish; 3-5 oz.....☐
[*item includes canned salmon; lake trout; shad; herring; fresh tuna; Capelin; dogfish; eel; halibut; sablefish; Atlantic sturgeon; Arctic char; lake whitefish*]

36. Other fish, such as cod, perch, catfish, etc.; 3-5 oz.....☐
[*item includes orange roughy; grouper; walleye; crappie; whiting; unknown*]

37. Shrimp, lobster, scallops as a main dish.....☐
[*item includes clams; oysters; crab*]

38. Eggs; 1.....☐
[*item includes boiled; poached; fried; scrambled; omelettes; egg salad; quiche; not egg substitutes such as Egg Beaters*]

E. [RC1] SWEETS, BAKED GOODS, CEREALS

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)
4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

39. Chocolate bars or pieces, such as Hershey's, plain M&Ms, Snickers, Reese's; 1 oz.....☐
[*average bar = about 1 oz. chocolate cream = ½ oz. chocolate fudge; chocolate chips; peanut M&Ms go with nuts, group F*]

40. Candy without chocolate; 1 oz..... ☐
[*about 3-4 = 1 oz. hard candies; gum drops; 1 pkg. life savers; not dietetic*]

41. Pie, homemade from scratch; 1 slice..... ☐
[*item includes any kind or tarts, crust from scratch*]

42. Pie, ready-made or from a mix; 1 slice..... ☐
[*item includes any kind or tarts, bakery, mix or frozen dough or Restaurant; cheese cake; cream puff; pound cake*]

43. Donut; 1..... ☐
[*item includes all kinds*]

44*. Biscuits, cornbread, *pancakes or waffles*; 1..... ☐

45. Danish pastry, sweet roll, coffee cake, croissant; 1..... ☐

46. Cake or brownie; 1 piece..... ☐
[*item includes cupcake; all cakes and bars*]

47. Cookies; 1..... ☐

48. Cold breakfast cereal; ½ c..... ☐
[*item includes all ready to eat; wheat germ*]

49. Cooked cereals such as oatmeal, grits, cream of wheat; ½ c..... ☐
[*item includes all cooked cereals*]

50. White bread; 1 slice..... ☐
[*item includes French; Italian; raisin; ½ bagel; ½ white English muffin; average dinner roll; ½ frankfurter roll; ½ hamburger bun; pita bread; matzoh 4" x 6"*]

51. Dark or whole grain bread; 1 slice..... ☐
[*item includes whole wheat; mixed grain; rye or pumpernickel; 2 graham cracker squares (2 ½"); 3 rye wafers (2" x 3")*]

F. [RC1] MISCELLANEOUS

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)
4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

52. Peanut butter; 1 tbsp..... ☐
[*item includes any kind*]

53. Potato chips or corn chips; small bag or 1 oz..... ☐
[*item includes nachos; 1 oz. = about 1 c.*]

54*. Crackers; 4..... ☐
[*item includes saltines, Wheat Thins®, Triscuits®, Ritz®*]

55. French fried potatoes; 1 serving, 4 oz..... ☐
[*4 oz. = about 1 c.*]

56. Nuts; 1 oz..... ☐
[*item includes all nuts, peanuts; mixed; M&M peanut; 1 oz. = about 3 tbsp*]

57. Potatoes, mashed; 1 c. or baked; 1..... ☐
[*item includes boiled*]

58. Rice; ½ c..... ☐
[*item includes white rice; brown rice; wild rice; Rice-a-Roni*]

59. Spaghetti, noodles or other pasta; ½ c..... ☐
[*item includes macaroni; fettucini; noodles in lasagna*]

60. Home-fried food, such as any meats, poultry, fish, shrimp, eggs, vegetables, etc.;
1 serving.....☐
[*item includes any food fried at home except french fries; include sautéed foods*]

61. Food fried away from home, such as any fish, chicken, chicken nuggets, etc.....☐
[*item includes any deep fried foods; fish sticks; fish patties; McNuggets; do not include french fries*]

62*. How often do you eat chicken-noodle or broth-based soups; 8 oz. serving?
[*Hand participant response card*.].....☐
1/week.....A
2-3/month.....B
1/month or less.....C
Never.....D

63*. How often do you eat cream soups including chowders; 8 oz. serving?
[*Hand participant response card*.].....☐
1/week.....A
2-3/month.....B
1/month or less.....C
Never.....D

G. [RC1] BEVERAGES

Response Categories:

>6 per day (A)	1 per day (D)	1 per week (G)
4-6 per day (B)	5-6 per week (E)	1-3 per month (H)
2-3 per day (C)	2-4 per week (F)	Almost Never (I)

64*. Decaffeinated coffee; 1 c.....☐
[*item includes brewed or instant*]

65. Coffee, regular (caffeinated); 1 c.....☐
[*item includes brewed or instant*]

66*. Decaffeinated or herbal tea, iced or hot; 1 cup.....☐

67. Tea, iced or hot, regular (caffeinated); 1 cup.....☐

68*. Hot chocolate or cocoa beverage; 1 cup.....☐

69*. Decaffeinated low calorie or diet soft drinks, such as diet 7-Up, diet Sprite, diet ginger ale; 1 glass.....☐
[*item includes all decaffeinated low calorie or diet carbonated beverages or sodas*]

70*. Caffeinated low calorie or diet soft drinks, such as any diet Coke, diet Pepsi, diet Mountain Dew; 1 glass.....☐
[*item includes all caffeinated low calorie or diet carbonated beverages or sodas*]

71*. Regular or sugar-sweetened decaffeinated soft drinks, such as 7-Up, Sprite, ginger ale; 1 glass.....☐
[*item includes all decaffeinated non-diet carbonated beverages or sodas*]

72*. Regular or sugar-sweetened caffeinated soft drinks, such as any Coke, Pepsi, Mountain Dew; 1 glass.....☐
[*item includes caffeinated carbonated beverages or sodas*]

73. Fruit-flavored punch or non-carbonated beverages, such as lemonade, Kool-Aid Or Hawaiian Punch; not diet; 1 glass.....☐
[*item includes Tang, Hi-C*]

H. [RC2] OTHER DIETARY ITEMS

74. How often do you eat liver; 3-4 oz. serving?.....☐
1/week.....A
2-3/month.....B
1/month or less.....C
Never.....D

75. Are there any other foods that you usually eat at least twice per week such as tortillas, prunes or avocado? Do not include dry spices or something that has been listed previously.....☐ Y ☐ N→**Go to Item 82**

76. Food #1 eaten at least twice per week [*enter code and specify food and usual portion size below*].....☐☐☐

a. _____

77. **[RC3]** Frequency for food #1:.....☐

>6 / day.....A

4-6 / day.....B

2-3 / day.....C

1 / day.....D

5-6 / wk.....E

2-4 / wk.....F

78. Food #2 eaten at least twice per week [*enter code and specify food and usual portion size below*].....☐☐☐

a. _____

79. **[RC3]** Frequency for food #2:.....☐

>6 / day.....A
4-6 / day.....B
2-3 / day.....C
1 / day.....D
5-6 / wk.....E
2-4 / wk.....F

80. Food #3 eaten at least twice per week [*enter code and specify food and usual portion size below*].....☐☐☐

a. _____

81**. [RC3]** Frequency for food #3:.....☐

>6 / day.....A
4-6 / day.....B
2-3 / day.....C
1 / day.....D
5-6 / wk.....E
2-4 / wk.....F

82. **[RC4]** What do you do with the visible fat on your meat?.....☐

Eat most of the fat.....A
Eat some of the fat.....B
Eat as little as possible.....C
Don't eat meat.....D

83. **[RC5]** What kind of fat do you usually use for frying and sautéing foods at home, excluding "Pam"-type spray?.....☐

Real butter.....A →**Go to Item 85**
Margarine.....B
Vegetable Oil.....C
Vegetable Shortening.....D
Lard.....E →**Go to Item 85**
Bacon Grease.....F →**Go to Item 85**

Not Applicable.....G →**Go to Item 85**
Unknown.....H →**Go to Item 85**

84. Enter code and specify brand and form below.....☐☐☐

a. _____

85**. [RC5]** What kind of fat do you usually use for baking?.....
☐

Real butter.....A →**Go to Item 87**
Margarine.....B
Vegetable Oil.....C
Vegetable Shortening.....D
Lard.....E →**Go to Item 87**
Bacon Grease.....F →**Go to Item 87**
Not Applicable.....G →**Go to Item 87**
Unknown.....H →**Go to Item 87**

86. Enter code and specify brand and form below. .....☐☐☐

a. _____

87**. [RC6]** What brand and form of margarine do you usually use at the table?.....☐

a. Form:

None.....A →**Go to Item 88**
Stick.....B
Tub.....C
Diet (low calorie).....D
Other.....E

b. Code number: .....☐☐☐

c. Brand: .....☐☐☐

88. What kind of cold breakfast cereal do you most often use?.....☐☐☐
[*Enter code and specify brand name below*.]

a. Brand: _____

89*. Do you drink water, tap or bottled, unsweetened?.....☐
Every day.....A
Occasionally.....B
Never.....C

90*. Do you drink meal replacement, energy, or high-protein beverages?
such as Instant Breakfast, Ensure, Slimfast, Sustacal?.....☐
Every day.....A
Occasionally.....B
Never.....C

91. Are you currently on a special diet? .....☐ Y ☐
N→**Go to Item 94**

92. For how many years have you been on it?.....☐☐

93**. [RC7]** What type of diet is it?.....☐
Weight Loss.....A
Low Salt.....B
Low Cholesterol.....C
Weight Gain.....D
Diabetic.....E
Other.....F

94. How many teaspoons of sugar do you add to your food daily? Include sugar
added to coffee, tea, cereal, etc.....☐☐

95**. [RC8]** In cooking vegetables, how often do you add fat such as salt pork, butter
or margarine?.....☐

2-3 times per day.....A
1 time per day.....B

5-6 times per week.....C
2-4 times per week.....D
1 time per week.....E
1-3 times per month.....F
Never.....G
Unknown.....H

96**. [RC8]** How often is salt or salt-containing seasoning such as garlic salt, onion salt, soy sauce or Accent added to your food in cooking?.....☐

2-3 times per day.....A
1 time per day.....B
5-6 times per week.....C
2-4 times per week.....D
1 time per week.....E
1-3 times per month.....F
Never.....G
Unknown.....H

97. How many shakes of salt do you add to your food at the table every day? .....☐

98. **[RC8]** How often do you add catsup, hot sauce, soy or steak sauce to your food?……☐

2-3 times per day.....A
1 time per day.....B
5-6 times per week.....C
2-4 times per week.....D
1 time per week.....E
1-3 times per month.....F
Never.....G
Unknown.....H

99. **[RC8]** How often do you eat special low salt foods such as low salt chips, nuts, cheese or salad dressing?.....☐

2-3 times per day.....A
1 time per day.....B
5-6 times per week.....C
2-4 times per week.....D
1 time per week.....E
1-3 times per month.....F
Never.....G
Unknown.....H

I. ALCOHOL

[Frequency of alcohol consumption is determined as usual weekly intake. The serving sizes are different for beer, wine and hard liquor. Serving sizes are "12 oz. bottles or cans of beer," "4 oz. glasses of wine" and "1 and ½ oz. shots of hard liquor."]

"*Next, I am going to ask you about your consumption of wine, beer and drinks made with hard liquor*."

100. Have you ever consumed alcoholic beverages? ☐ Y ☐ N→**Go to Item 106**

[*If the response is "no," skip to item 101. If the response is "yes," continue with question 92 to determine past alcohol consumption*.]

101. Do you presently drink alcoholic beverages? . .....☐ Y→**Go to Item 103** ☐ N

[*If the participant asks, or if the answer is not explicit, "presently" is defined as within the last 6 months*.]

102. Approximately how many years ago did you stop drinking?.....☐☐

[*Record the response in years, rounding ½ down. For example, "1-1/2 years would be recorded as 1 year. "About a half year ago would be recorded as "0." If the participant stopped more than once, record the years since the most recent stopping. For example, if the participant says: "The last time I quit was two years ago. The first time I quit was twenty years ago," the response would be recorded as "2."*]

103-5. The serving sizes of wine, beer and hard liquor must be clear to the participant. For example,
after asking: "How many glasses of wine do you usually have per week?" indicate that you are referring to 4 oz. glasses and that "per week" includes the weekends. If the participant answers in terms of drinks per month, divide by four to derive the weekly intake. If the number of drinks is "half a drink" or less, record "0." If the number of drinks is more than 99, record as "99." "Wine" includes wine coolers, cordials and "sweet wines." "Liquor" includes liqueurs.

103. How many glasses of wine do you usually have per week? [*4 oz. glasses; round down*].....☐☐

104. How many bottles or cans of beer do you usually have per week? [*12 oz. glasses, bottles or cans; round down*].....☐☐

105. How many drinks of hard liquor do you usually have per week? [*1 ½ oz. shots; round down*].....☐☐

J. ADMINISTRATIVE INFORMATION

106. Interviewer's opinion of information:..... ☐

Reliable.....A
Questionable.....B
Participant Uncooperative.....C
Participant unable to estimate frequencies.....D

[*Evaluate the quality of the interview, emphasizing the dietary portion*.]

MEDICATION SURVEY FORM

NUMBER: | | | | | | | |

STUDY YEAR | 25 | SEQ # | 00 |

FORM CODE: MSR

VERSION: 12/1/2010

Public reporting burden for this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *Enter leading zeroes where necessary to fill all boxes.*

A. Reception

"As you know, ARIC is recording all prescription and over-the-counter medications used by participants in the past four weeks, including cold and allergy medications, vitamins, herbal remedies, and other supplements. These medications include solid and non-solid formulations that you may swallow, inhale, apply to the skin or hair, inject, implant, or place in the ears, eyes, nose, mouth, or any other part of the body. The letter you received about this appointment included a plastic bag for all your current medications and asked you to bring them to the clinic."

1. Did you bring all the medications that you used in the past four weeks, or their containers?

Yes, all of them..... ☐ → **GO TO SECTION B, QUESTION 5**

No, some of them..... ☐ → **GO TO SECTION A, QUESTION 3**

No, none of them.....☐

2. Is this because you forgot, because you have not taken any medications at all in the last four weeks, or because you could not bring your medications?

Took no medication.....☐ → **GO TO SECTION C, QUESTION 34**

Forgot or was unable to bring medication ☐

"That's all right. Since the information on medications is so important, we would still like to ask you about it during the interview."

3. May we follow up on this after the visit so that we can get the information from the other medication labels? *(Explain follow-up options)*

Yes.....☐

No or not applicable…☐

attempt to indicate this

→*Scan/transcribe what you can in Section B and convert refusals; on tracking form.*

4. Describe method of follow-up to be used:_____

B. Medication Record

Copy the MEDICATION UPC / NDC from each medication label. For each medication, begin with the left-most space in fields a-c and the rightmost space in field d. Using upper case letters, carefully copy the MEDICATION NAME. Using periods to indicate decimal points, copy the formulation STRENGTH (weight for solids and concentration for non-solids). Using upper case letters and standard abbreviations, copy the UNITS used to measure strength. For combination medications, use a forward slash (/) to separate active ingredients, corresponding strengths, and units.

#	(a) Medication UPC / NDC		Medication name (b)
5.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
6.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
7.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
8.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
9.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	

10.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
11.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
12.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
13.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
14.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
#	(a) Medication UPC		Medication name (b)
15.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	

16.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
17.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
18.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
19.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
20.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
21.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	

22.	☐☐☐☐☐☐☐☐☐☐☐☐☐	
	(c) Strength:	(d) Units:
23.	☐☐☐☐☐☐☐☐☐☐☐☐☐	
	(c) Strength:	(d) Units:
24.	☐☐☐☐☐☐☐☐☐☐☐☐☐	
	(c) Strength:	(d) Units:
25.	☐☐☐☐☐☐☐☐☐☐☐☐☐	
	(c) Strength:	(d) Units:

#	(a) Medication UPC		Medication name (b)
26.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength:	(d) Units:	
27.	☐☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength:	(d) Units:	

28.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	
29.	☐☐☐☐☐☐☐☐☐☐☐☐		
	(c) Strength	(d) Units	

30. Total number of medications in bag.....☐☐

31. Number of medications in bag unable to successfully scan or transcribe.....☐☐

32. Staff ID number of person scanning / transcribing medications.....☐☐☐

a. Scanner / transcriber (items 5-29):.....☐☐☐

b. Date of scanning / transcription:.....☐☐/ ☐☐/ ☐☐☐☐

Month Day Year

C. Medication Use Interview

"Now I would like to ask about a few specific medications."

33. Were any of the medications you took during the last four weeks for: *(If "Yes", verify that the medication NAME is on the medication record.)*

	Yes	No	Unknown
a. Asthma	☐	☐	☐
b. Chronic bronchitis or emphysema	☐	☐	☐
c. High blood sugar or diabetes	☐	☐	☐
d. High blood pressure or hypertension	☐	☐	☐
e. High blood cholesterol	☐	☐	☐
f. Chest pain or angina	☐	☐	☐
g. Abnormal heart rhythm	☐	☐	☐
h. Heart failure	☐	☐	☐
i. Blood thinning	☐	☐	☐
j. Stroke	☐	☐	☐
k. Mini-stroke or TIA	☐	☐	☐
l. Leg pain while walking or claudication	☐	☐	☐

34. During the last four weeks, did you take any aspirin or aspirin-containing products including Alka-Seltzer, cold and allergy medication or headache powder? This **excludes** acetaminophen (for example, Tylenol), ibuprofen (for example, Advil, Motrin or Nuprin), and naproxen (for example, Aleve).

Show participant List #1: Commonly Used Aspirin or Aspirin-Containing Products

Yes ☐

No ☐ → **GO TO QUESTION 37**

Unknown ☐ → **GO TO QUESTION 37**

35. How many days during the last four weeks did you take aspirin

or aspirin-containing medication? ☐☐ Number of days

If "00" → **GO TO QUESTION 37**

36. For what purpose are you taking aspirin? (*Interviewer: Do NOT read choices.)*

Participant mentioned avoiding heart attack or stroke ☐

Participant did not mention avoiding heart attack or stroke ☐

37. During the past four weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, or cramps? *(Read bracketed "other" unless no medications were reported.)*

Yes ☐

No ☐

Unknown ☐

38. **Excluding** aspirin, acetaminophen (for example, Tylenol), and corticosteroids (for example prednisone), are you NOW taking other anti-inflammatory or arthritis medications on a regular basis? Common examples are shown on this list.

Show participant List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs, NSAIDS

Yes	☐	
No	☐	→ **END QUESTIONNAIRE**
Unknown	☐	→ **END QUESTIONNAIRE**

39. How do you pay for your medications? (Check all that apply)

a. Medicare Part D ☐

b. Medicaid ☐

c. Veteran Administration (VA) ☐

d. Prescription assistance programs ☐

e. Other public programs ☐

f. Private or employer insurance ☐

g. No coverage (self-pay only, entirely out-of-pocket) ☐

40. Think about how you have taken your medications during the past 4 weeks. Did you ever forget to take your medicines?

Yes ☐

No ☐

41. Are you careless at times about taking your medicines?

Yes ☐

No ☐

42. When you feel better, did you sometimes stop taking your medicines?

Yes ☐

No ☐

43. Sometimes if you felt worse when you take your medicines, do you sometimes stop taking them?

Yes ☐

No ☐

44. In the past four weeks, how often have you "stretched" (taken less of) your medicines to make them last longer?

Often ☐

Sometimes ☐

Rarely ☐

Never ☐

45. In the past four weeks, how often have you run out of your medicines?

Often ☐

Sometimes ☐

Rarely ☐

Never ☐

46. In the past four weeks, how often have you missed taking your medicines?

Often ☐

Sometimes ☐

Rarely ☐

Never ☐

47. What percent of the time do you take your medications?

☐☐☐ *If "100"* → **GO TO END**

48. What were the reasons for not taking your medications all the time? Check all that apply:

a. Could not afford ☐

b. Lack of transportation ☐

c. Memory/cannot remember to take medications ☐

d. Ran out of medicine ☐

e. Directions too confusing ☐

f. Felt better ☐

g. Felt worse ☐

h. Too complicated ☐

i. Scared of side effects ☐

j. Don't believe drug(s) will help me ☐

k. Other ☐

PHYSICAL FUNCTION TESTS

ID NUMBER: | | | | | | | |

STUDY YEAR 25 SEQ # 00

FORM CODE: PFT

VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

A. Chair Stands

Single Chair Stand

"This is a test of strength and stability in your legs in which you stand up from a chair without using your arms. Fold your arms across your chest, like this, and stand when I say GO, keeping your arms in this position. Any questions? Ready, Go!"

1. Participant Refused ☐ → Go to **B. Standing Balance**

   Not attempted, unable ☐ → Go to **B. Standing Balance**

   Attempted, unable to stand ☐ → Go to **B. Standing Balance**

   Rises using arms ☐ → Go to **B. Standing Balance**

   Stands without using arms ☐ → Go to **Repeated Chair Stands**

Repeated Chair Stands

"This time I want you to stand up five times as quickly as you can keeping your arms folded across your chest. When you stand up, come to a full standing position each time, and when you sit down, sit down all the way down each time. I will demonstrate two chair stands to show you how it is done. When I say GO stand five times in a row, as quickly as you can, without stopping. Stand up all the way and sit all the way down each time. Ready, Go!"

2. Participant Refused ☐ → Go to **B. Standing Balance**

Not attempted, unable ☐ → Go to **B. Standing Balance**

Attempted, unable to complete 5 stands ☐ → Number completed: 0 ☐

1 ☐

2 ☐

3 ☐

4 ☐

Completes 5 stands ☐ → Enter time for 5 stands: ☐☐.☐☐

Seconds Hundredths

B. Standing Balance

"I'm going to ask you to stand in several different positions that test your balance. I'll demonstrate each position and then ask you to try to stand in each position for 10 seconds. I'll stand next to you to provide support if you lose your balance. Do you have any questions?"

Semi Tandem Stand

"First, I would like you to try to stand with the side of the heel of one foot touching the big toe of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms and body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto my arm while you get in position. When you are ready, let go."

3. Participant Refused ☐ → Go to **Side-by-side Stand**

	Not attempted, unable	☐ → Go to **Side-by-side Stand**
	Unable to attain position or hold for one second	☐ → Go to **Side-by-side Stand**
	Holds position less than 10 seconds	☐ → Go to **Side-by-side Stand**
	Holds position for 10 seconds	☐ → Go to **Tandem Stand**

Side-by-side Stand (only if could not do Semi-Tandem for 10 seconds)

"Now, I would like you to try to stand with your feet together, side-by-side, for 10 seconds. You can use your arms, bend your knees or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Hold on to my arm while you get in position. When you are ready, let go."

4.	Participant Refused	☐ → Go to **C. 6 Meter Walk**
	Not attempted, unable	☐ → Go to **C. 6 Meter Walk**
	Unable to attain position or hold for one second	☐ → Go to **C. 6 Meter Walk**
	Holds for less than 10 seconds	☐ → Go to **C. 6 Meter Walk**
	Holds for 10 seconds	☐ → Go to **C. 6 Meter Walk**

Tandem Stand

"Now I would like you to try to stand with the heel of one foot in front of the and touching the toes of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms and body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto my arm while you get in position. When you are ready, let go."

Trial 1

5.	Participant Refused	☐ → Go to **C. 6 Meter Walk**
	Not attempted, unable	☐ → Go to **C. 6 Meter Walk**
	Unable to attain position or hold for one second	☐ → Go to **C. 6 Meter Walk**

	Holds position less than 10 seconds	☐ → Go to **Trial 2**
	Holds position for 10 seconds	☐ → Go to **C. 6 Meter Walk**

Trial 2

"Let's try this one more time."

6.	Participant Refused	☐ → Go to **C. 6 Meter Walk**
	Not attempted, unable	☐ → Go to **C. 6 Meter Walk**
	Unable to attain position or hold for one second	☐ → Go to **C. 6 Meter Walk**
	Holds position less than 10 seconds	☐ → Go to **C. 6 Meter Walk**
	Holds position for 10 seconds	☐ → Go to **C. 6 Meter Walk**

C. 4 Meter Walks

"I'm going to ask you to do 2 short walks over this 4 meter course. First you will walk at your normal pace, then you will repeat the test at a fast pace. I will demonstrate. Place your feet with your toes behind, but just touching the starting line, like this."

NORMAL PACE WALK

"Now, let's start with the normal pace walk. When I say "Go", please walk at your normal pace. Remember to walk a few steps past the finish line. Do you have any questions? Ready? Go."

Trial 1

7.	Participant Refused	☐ → Go to **D. Grip Strength**
	Not attempted, unable to walk	☐ → Go to **D. Grip Strength**
	Completes with walking aid	☐ → ☐☐.☐☐ → Go to **Trial 2**

Seconds Hundredths

Completes without walking aid ☐ → ☐☐.☐☐ → Go to **Trial 2**

Seconds Hundredths

Trial 2

8. Participant Refused ☐ → Go to **D. Grip Strength**

Not attempted, unable to walk ☐ → Go to **D. Grip Strength**

Completes with walking aid ☐ → ☐☐.☐☐ → Go to **Fast Pace Walk**

Seconds Hundredths

Completes without walking aid ☐ → ☐☐.☐☐ → Go to **Fast Pace Walk**

Seconds Hundredths

FAST PACE WALK

"Now, let's do the fast pace walk. When I say "Go", please walk as fast as you can. Remember to walk a few steps past the finish line. Do you have any questions? Ready? Go."

Trial 1

9. Participant Refused ☐ → Go to **D. Grip Strength**

Not attempted, unable to walk ☐ → Go to **D. Grip Strength**

Completes with walking aid ☐ → ☐☐.☐☐ → Go to **Trial 2**

Seconds Hundredths

Completes without walking aid ☐ → ☐☐.☐☐ → Go to **Trial 2**

Seconds Hundredths

Trial 2

10. Participant Refused ☐ → Go to **D. Grip Strength**

Not attempted, unable to walk ☐ → Go to **D. Grip Strength**

Completes with walking aid ☐ → ☐☐.☐☐ → Go to **D. Grip Strength**

Seconds Hundredths

Completes without walking aid ☐ → ☐☐.☐☐ → Go to **D. Grip Strength**

Seconds Hundredths

D. Grip Strength

"The next test I'll ask you to do is the grip strength test. This device I'll hand you is used to measure the strength in your hand. Even when you squeeze the grip bars as hard as you can, the bars will not feel like they are moving much at all. Before starting, I will ask you a few questions to make sure it is safe for you to do this test."

9. Do you have any pain or arthritis in either hand or wrist?

Yes .....☐

No .....☐→ Go to **Question 10**

Refused.....☐→ Go to **Question 10**

Don't Know .....☐→ Go to **Question 10**

a. Is the pain or arthritis in either hand or wrist?

Right.....☐

Left.....☐

Both.....☐

Refused.....☐

Don't Know.....☐

b. Has the pain or arthritis in your hand(s) or wrist(s) gotten worse recently?

Yes.....☐

No.....☐

Refused.....☐

Don't know.....☐

c. Will the pain or arthritis in your hand(s) or wrist(s) keep you from squeezing as hard as you can?

Yes.....☐

No.....☐

Refused.....☐

Don't know.....☐

10. Have you had any surgery on either hand or wrist in the past 3 months?

Yes .....☐

No .....☐→ Go to **Test**

Refused.....☐→ Go to **Test**

Don't Know .....☐→ Go to **Test**

a. Was the surgery on your right, left or both hands or wrists?

Right.....☐→ Test left side only

Left.....☐→ Test right side only

Both.....☐→ Do not test

Don't Know.....☐→ Do not test

"Please extend your preferred arm for testing out to your side and rest it on the table with your arm straight and wrist on the mouse pad. Grip the two bars in your hand like this and squeeze gently to get the feel of it. Are the bars the right distance apart for a

comfortable grip? We'll do this three times on each side. When I say squeeze, squeeze as hard as you can. Ready? Squeeze! Squeeze! Squeeze! Now, stop."

Hand used: ☐ Right ☐ Left

Trial 1 ☐☐ kg

Trial 2 ☐☐ kg

Completion Status:

Did 1 trial.....☐

Did 2 trials.....☐

Excluded.....☐

Refused.....☐

Unable to do……☐

ACCESS AND QUALITY OF CARE

NUMBER: ☐☐☐☐☐☐☐ STUDY YEAR 25 SEQ # ☐

FORM CODE: AQC

VERSION: 12/8/2010
CORC REVISION

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *This form should be completed during the participant's visit. Affix the participant ID label above.*

Public reporting burden for this collection of information is estimated to average 10minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

1. *Determine whether ARIC has a valid Medicare number for this person. If so, skip to Q. 2. If not, administer the following question:]* We would like to verify that we have the correct Medicare number for you. Can we please see your Medicare card to confirm your number? [QxQ will have more explicit instructions that this question should ONLY be asked of people for whom we do not yet have a valid Medicare number.]

2. Are you covered by any other health insurance besides Medicare or some other kind of health care plan? (*Include health insurance obtained through employment or purchased directly as well as government programs like Medicaid that provide medical care or help to pay medical bills.)*

a.....Yes ☐
b.....No ☐ → **GO TO QUESTION 4**
c.Refused .....☐ → **GO TO QUESTION 4**
d.....Don't know ☐ → **GO TO QUESTION 4**

3. Besides Medicare, what kind of health insurance or health care coverage do you have for services such as physician visits or hospital stays? If you have more than one kind of health insurance, tell me all plans that you have.

	Yes	*No*
a. Private health insurance.....	☐	☐
b. Medigap.....	☐	☐
c. Medicaid.....	☐	☐
d. Veteran's Administration (VA).....	☐	☐
e. Other Military health insurance (TRICARE/CHAMPVA)…….	☐	☐
f. State-sponsored health plan.....	☐	☐
g. Other government program.....	☐	☐
h. Single service plan (e.g., nursing home care, dental, vision)…..	☐	☐
i. Don't know.....	☐	☐

NOTE: SKIP TO "HEALTH CARE SATISFACTION" IF ARIC SAMPLE MEMBER IS IN NURSING HOME.

USUAL SOURCE OF CARE

4. Is there a particular medical person or a clinic you usually go to when you are sick or for advice about your health?
   a. Yes, I go to a specific place or health provider.
   b. No, because I have lots of health problems and see many providers.
   c. No, because I don't use health care services much and don't have a regular provider
   (If c., skip to Q. 8.)

5. What kind of place or provider do you go to most often?

   a. A nurse practitioner.
   b. A primary care physician
   c. A specialist for a medical problem I have
   d. Health center/ambulatory care center/hospital OP with a wide range of providers
   e. Hospital emergency room
   f. Other, specify: _____
   g. Don't go to one place most often
   h. Don't know

6. How do you usually get to this place?

a. walking
b. driving
c. being driven by family/friend
d. bus or other public transportation
e. taxi
f. health care provider usually comes to home
g. senior citizen van/bus
h. ambulance or other special vehicle
i. don't know
j. some other way (specify) _____

7. Does your usual health care provider have office hours at night or on weekends? YES/NO/DON'T KNOW

DIFFICULTY IN OBTAINING CARE

8. How difficult is it to get appointments with your health care provider on short notice, for example, within one or two days?
   Would you say it is:

   a. very difficult
   b. somewhat difficult
   c. not too difficult,
   d. not at all difficult

9. How difficult is it to talk with a medical person/your health care provider over the telephone about a health problem?
   Would you say it is:
   a. very difficult
   b. somewhat difficult
   c. not too difficult,
   d. not at all difficult

10. In the past 12 months, was there any time when you delayed getting, or did not get, medical care when you needed it?

a.....Yes ☐
b.....No ☐ → **GO TO QUESTION 12**
c.Refused ..... ☐ → **GO TO QUESTION 12**
d.....Don't know ☐ → **GO TO QUESTION 12**

11. What were the reason(s) for which you delayed getting, or did not get, medical care in the past 12 months when you needed it?

	Yes	*No*

a. You couldn't get through on the telephone..... ☐ ☐

b. You couldn't get an appointment soon enough..... ☐ ☐

c. Once you got there, you had to wait too long to see the doctor. ☐ ☐

d. The clinic/doctor's office wasn't open when you could get there ☐ ☐

e. You didn't have transportation..... ☐ ☐

f Medical care too far away……..

12. In the past 12 months, was there any time when you needed any of the following, but didn't get it because you couldn't afford it?

	Yes	No
a. To be seen by doctor	☐	☐
c. Mental health care or counseling	☐	☐
d. Nursing home care	☐	☐

HEALTH CARE SATISFACTION

13. In the last 12 months, how often did doctors or other health providers…

	Never		*Sometimes*	*Usually*	*Always*	*N/A*
a. listen carefully to you?.....	☐	☐	☐	☐	☐	
b. explain things in a way you could understand?.....	☐	☐	☐	☐	☐	
c. show respect for what you had to say?.....	☐	☐	☐	☐	☐	
d. spend enough time with you?.....	☐	☐	☐	☐	☐	

(N/A means did not see a health care provider in the last 12 months. If N/A, skip Q. 14)

14. Overall, how satisfied are you with the quality of care you received from your health care providers over the last 12 months? Would you say that you are:

a. very satisfied,
b. somewhat satisfied
c. not too satisfied
d. not at all satisfied

Emotional Distress-Anxiety-Short Form 1

ID NUMBER: | | | | | | | | |

FORM CODE: PRM

VERSION: A

Contact Occasion | | SEQ # | |

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

Instructions: Please respond to each item by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX01	I felt fearful……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

EDANX05	I felt anxious……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX30	I felt worried……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX46	I felt nervous……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54	I felt tense……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE[1]

ID NUMBER:								STUDY YEAR	25	SEQ #	00	FORM CODE: MHQ VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by-	**No**					**Very Little** / **Very Much**
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5

4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate	0	1	2	3	4	5

or remember things?

21. making you feel depressed? 0 1 2 3 4 5

SATISFACTION WITH HEART CARE PROVIDERS

1. In the last 12 months, how often did doctors or other health providers who you see for your heart failure…

	Never	*Usually*	*Sometimes*	*Always*
a. listen carefully to you?.....	☐		☐	☐
b. explain things in a way you could understand?	☐		☐	☐
c. show respect for what you had to say?.....	☐		☐	☐
d. spend enough time with you?.....	☐		☐	☐

MEDICAL HISTORY QUESTIONNAIRE

ID NUMBER: | | | | | | | |

STUDY YEAR | 25 | SEQ # | 00

FORM CODE: MHQ

VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

A. MEDICAL CONDITIONS

1. Has a doctor ever told you that you have arthritis?

Yes.....☐

No.....☐ → **GO TO QUESTION 2**

a. How old were you when you were first told you had arthritis?

☐☐ Age in years

b. Which type or types of arthritis do you have?

Rheumatoid Arthritis.....☐

Osteoarthritis.....☐

Gout.....☐

Other..... ☐, specify: _____
Don't know..... ☐

2. Has a doctor ever told you that you had a thyroid problem requiring treatment with medication?

Yes..... ☐

No..... ☐ → **GO TO QUESTION 3**

a. How old were you when you were first told you had a thyroid problem?

☐☐ Age in years

b. Do you still have a thyroid problem requiring treatment with medication?

Yes..... ☐
No..... ☐
Don't know..... ☐

3. Has a doctor ever told you that you had gallstones?

Yes..... ☐

No..... ☐ → **GO TO QUESTION 4**
Don't know..... ☐ → **GO TO QUESTION 4**

a. Have you ever had medical treatment to dissolve or remove gallstones? Do not include surgery.

Yes..... ☐

No..... ☐
Don't know..... ☐

4. Have you ever had gallbladder surgery?

Yes..... ☐

No..... ☐ → **GO TO QUESTION 5**
Don't know..... ☐ → **GO TO QUESTION 5**

a. How old were you when you had gallbladder surgery?

☐☐ Age in years

5. How many times during the night do you usually get up to urinate? ☐

None.....A

1.....B
2.....C
3 or more.....D

If the participant is male, ask questions 6 and 7.

6. Has the force of your urinary stream or water decreased over the years?

Yes.....☐
No.....☐

7. Have you ever had surgery for your prostate not related to cancer?

Yes.....☐
No.....☐

8. Have you ever been told by a doctor or other health professional that you had weak or failing kidneys? Do not include kidney stones, bladder infections, or incontinence.

Yes.....☐
No.....☐ → **GO TO QUESTION 9**
Don't know.....☐ → **GO TO QUESTION 9**

a. In the past 12 months, have you received dialysis (either hemodialysis or peritoneal dialysis)?

Yes.....☐
No.....☐
Don't know.....☐

9. Have you ever had kidney stones?

Yes.....☐
No.....☐ → **GO TO QUESTION 10**
Don't know.....☐ → **GO TO QUESTION 10**

a. How many times have you passed a kidney stone? ☐☐ Enter number of times

10. Have you ever been told by a doctor or other health care professional that you had an aortic aneurysm, which is a ballooning of the largest artery of your abdomen or chest?

Yes..... ☐

No..... ☐ → **GO TO QUESTION 11**
Don't know..... ☐ → **GO TO QUESTION 11**

a. How old were you when you were first told you had an aortic aneurysm?

☐☐ Age in years

b. Have you ever had surgery to repair your aortic aneurysm?

Yes..... ☐
No..... ☐
Don't know..... ☐

11. Have you ever been told by a doctor or other health care professional that you had psoriasis?

Yes..... ☐
No..... ☐ → **GO TO QUESTION 12**
Don't know..... ☐ → **GO TO QUESTION 12**

a. How old were you when you were first told you had psoriasis?

☐☐ Age in years

12. Do you have any other major medical conditions we did not ask about such as

	No	*Yes*	*If Yes, specify*
a. Stomach ulcer that requires treatment (not gastritis alone).....	☐	☐	_____
b. Mild liver disease, such as hepatitis or fatty liver.....	☐	☐	_____

c. Major liver disease, such as cirrhosis..... ☐ ☐ _____

d. Connective tissue disease, such as lupus or polymyalgia rheumatica..... ☐ ☐ _____

e. Paralysis of one or more arm or leg..... ☐ ☐ _____

f. Cancer that has spread (metastasized)..... ☐ ☐ _____

g. Other major condition that requires ongoing treatment by a physician..... ☐ ☐ _____

B. FALLS

13. In the past 12 months, how many times have you fallen and landed on the ground or floor? ☐

None.....A → **GO TO QUESTION 18**
One.....B
Two or three.....C
Four or five.....D
Six or more.....E
Don't know.....F

14. Did you experience any of the following when you fell in the past 12 months (*check all that apply*)?

	No	*Yes*
a. A fracture or broken bone.....	☐	☐
b. A dislocated joint, head injury resulting in a bleed or loss of consciousness, or bleeding inside your chest or abdomen.....	☐	☐

c. A cut that required stitches, or sprain or strain that was not not a dislocation or fracture..... ☐ ☐

d. An overnight hospitalization..... ☐ ☐

16. Did you limit your activity as a result of any injury sustained from the fall?

Yes.....☐
No.....☐
Don't know.....☐

17. For the most serious fall you sustained in the past 12 months, were you doing any of the following activities when you fell? (*check all that apply*)

	No	*Yes*
Walking.....	☐	☐
Walking up or down steps or curbs.....	☐	☐
Sports activity or exercise.....	☐	☐
Housework (e.g., dishes, cleaning).....	☐	☐
Household repair, gardening, yardwork, ladder climbing.....	☐	☐
Changing position (e.g., getting in/out of a chair, bath, shower, bed, or on/off toilet).....	☐	☐
Other activities (turning, reaching, and/or bending).....	☐	☐
Drinking beer, wine or whiskey.....	☐	☐

18. For this same "most serious" fall, did any of the following conditions contribute to your fall?

	No	*Yes*
Lightheadedness or palpitations.....	☐	☐
Legs gave out.....	☐	☐
Wet or slippery floor or ground.....	☐	☐
Objects on floor or ground (e.g., cords, boxes, pet).....	☐	☐
Uneven ground (e.g., rug, carpet, pavement).....	☐	☐
Poor lighting, excessive glare, or other vision problems.....	☐	☐
Lack of handrail, banister or grab bars.....	☐	☐
Footwear (e.g. high heels, shoes stuck to floor or slippery).....	☐	☐

19. In the past 12 months, did you limit your activities, for example, what you did or where you went because you were afraid of falling?

Yes.....☐
No.....☐
Don't know.....☐

C. OTHER ITEMS

20. In the last year, have you lost more than 10 pounds unintentionally (that is, not due to dieting or exercise)?

Yes.....☐
No.....☐
Don't know.....☐

21. Do you now smoke cigarettes?

Yes.....☐
No.....☐

PHYSICAL ABILITY QUESTIONNAIRE

ID NUMBER:								STUDY YEAR	25	SEQ #			FORM CODE: PAQ VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

"This questionnaire asks about your physical abilities. I will ask about some activities with which some people have difficulty because of a health or physical reason. Do not include difficulties due to a temporary condition like a broken limb."

How much difficulty do you have…

1. Walking for a quarter of a mile (that is about 2 or 3 blocks)?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

2. Walking up 10 steps without resting?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

3. Stooping, crouching or kneeling?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

4. Lifting or carrying something as heavy as 10 pounds?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

How much difficulty do you have….

5. Doing chores around the house (like vacuuming, sweeping, dusting or straightening up? ..... ☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don't know or do not do.....E

6. Preparing your own meals?..... ☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don't know or do not do.....E

7. Managing your money (such as keeping track of your expenses or paying bills)?..... ☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don't know or do not do.....E

8. Walking from one room to another on the same level?..... ☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

9. Standing up from an armless chair?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

10. Getting in or out of bed?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don’t know or do not do.....E

How much difficulty do you have….

11. Eating, including holding a fork, cutting food or

drinking from a glass?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don't know or do not do.....E

12. Dressing yourself, including tying shoes, working zippers

and doing buttons?.....☐

No difficulty.....A

Some difficulty.....B

Much difficulty.....C

Unable to do.....D

Don't know or do not do.....E

13. Because of any impairment or health problem, do you need the help of other persons for personal care needs such as eating, bathing, dressing or getting around your home?

Yes ☐ No ☐

14. Because of any impairment or health problem, do you need the help of other persons in handling routine needs, such as everyday household chores, doing necessary business, shopping or getting around for other purposes?

Yes ☐ No ☐

15. Do you usually use any device to help you get around such as a cane, wheelchair, crutches or a walker?

Yes ☐ No ☐

16. Do you usually use any special eating utensils?

Yes ☐ No ☐

17. Do you usually use any aids or devices to help you dress (such as button hooks, zipper pulls, long-handled shoe horn, etc.?

Yes ☐ No ☐

PHYSICAL ACTIVITY FORM

ID NUMBER:								STUDY YEAR	25	SEQ #			FORM CODE: PHQ VERSION: A – 7/15/10

Public reporting burden for this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

A. SPORTS (Baecke)

1. Do you exercise or play sports? Yes ☐ No ☐ → **Go to Item 19**

2. Which sport of exercise do you do most frequently? ☐☐☐

[*Do not show list. If activity is coded, enter code and go to Item 3. If not coded, enter 499 and specify activity.*]

a. Specify activity

_____

3. How many hours a week do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 2.....B

At least 2 but not quite 3.....C

At least 3 but not quite 4.....D

4 or more.....E

4. How many months a year do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 4.....B

At least 4 but not quite 7.....C

At least 7 but not quite 10.....D

10 or more.....E

5. Do you do other exercises or play other sports? Yes ☐ No ☐→ **Go to Item 18**

6. What is your second most frequent sport or exercise? ☐☐☐

[*Do not show list. If activity is coded, enter code and go to Item 7. If not coded, enter 499 and specify activity*.]

a. Specify activity

_____

7. How many hours a week do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 2.....B

At least 2 but not quite 3.....C

At least 3 but not quite 4.....D

4 or more.....E

8. How many months a year do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 4.....B

At least 4 but not quite 7.....C

At least 7 but not quite 10.....D

10 or more.....E

9. Do you do other exercises or play other sports? Yes ☐ No ☐→ **Go to Item 18**

10. What is your third most frequent sport or exercise? ☐☐☐

[*Do not show list. If activity is coded, enter code and go to Item 11. If not coded, enter 499 and specify activity*.]

a. Specify

*activity*_____

11. How many hours a week do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 2.....B

At least 2 but not quite 3.....C

At least 3 but not quite 4.....D

4 or more.....E

12. How many months a year do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 4.....B

At least 4 but not quite 7.....C

At least 7 but not quite 10.....D

10 or more.....E

13. Do you do other exercises or play other sports? Yes ☐ No ☐→ **Go to Item 18**

14. What is your fourth most frequent sport or exercise? ☐☐☐

[*Do not show list. If activity is coded, enter code and go to Item 15. If not coded, enter 499 and specify activity*.]

a. Specify activity

_____

15. How many hours a week do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 2.....B

At least 2 but not quite 3.....C

At least 3 but not quite 4.....D

4 or more.....E

16. How many months a year do you do this activity?.....☐

Less than 1.....A

At least 1 but not quite 4.....B

At least 4 but not quite 7.....C

At least 7 but not quite 10.....D

10 or more.....E

17. Do you do other exercises or play other sports? Yes ☐ No ☐

B. LEISURE TIME (Baecke)

18. During leisure time, would you say you play

sports or exercise.....☐

Never.....A

Seldom.....B

Sometimes.....C

Often.....D

Very often.....E

19. In comparison with others of your own age do you think

your physical activity during leisure time is.....☐

Much less.....A

Less.....B

The same.....C

More.....D

Much more.....E

20. During leisure time, do you sweat.....☐

Never.....A

Seldom.....B

Sometimes.....C

Often.....D

Very often.....E

21. During leisure time, do you watch television.....☐

Never.....A

Seldom.....B

Sometimes.....C

Often.....D

Very often.....E

22. During leisure time, do you walk.....☐

Never.....A

Seldom.....B

Sometimes.....C

Often.....D

Very often.....E

23. During leisure time, do you bicycle.....☐

Never.....A

Seldom.....B

Sometimes.....C

Often.....D

Very often.....E

C. SITTING

"The following questions are about sitting or reclining while doing things like visiting friends, driving, reading, watching television, or working at a desk or computer. Do not include time spent sleeping."

24. How much time do you usually spend sitting on a typical weekday?

☐☐ Hours ☐☐ Min

25. How much time do you usually spend sitting on a typical weekend day?

☐☐ Hours ☐☐ Min

D. CHAMPS

"You have answered some of these questions already, but the following we are asking about activities you may have done in a typical week for the past 4 weeks."

[Interviewer instructions*: Activities should not be counted under more than one item (e.g,. leisure walking should not be counted under walking to do errands).]*

In a typical week during the past 4 weeks, did you…

26. Dance (such as square, folk, line, ballroom) (do not count aerobic dance here)?

No ☐→ Go to Item 27

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

27. Play golf, carrying or pulling your equipment (count walking time only)?

No ☐→ Go to Item 28

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

28. Play golf, riding a cart (count walking time only)?

No ☐→ Go to Item 29

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

29. Play singles tennis (do not count doubles)?

No ☐→ Go to Item 30

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

30. Play doubles tennis (do not count singles)?

No ☐→ Go to Item 31

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

31. Skate (ice, roller, in-line)?

No ☐→ Go to Item 32

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

In a typical week during the past 4 weeks, did you…

32. Do heavy work around the house (such as washing windows, cleaning gutters)?

No ☐→ Go to Item 33

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

33. Do light work around the house (such as sweeping or vacuuming)?

No ☐→ Go to Item 34

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

34. Do heavy gardening (such as spading, raking)?

No ☐→ Go to Item 35

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

35. Do light gardening (such as watering plants)?

No ☐→ Go to Item 36

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

36. Work on your car, truck, lawn mower or other machinery?

No ☐→ Go to Item 37

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

(*For the following questions about running and walking, include use of a treadmill*)

37. Jog or run?

No ☐→ Go to Item 38

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

38. Walk uphill or hike uphill (count only uphill part)?

No ☐→ Go to Item 39

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

In a typical week during the past 4 weeks, did you…

39. Walk fast or briskly for exercise (do not count walking leisurely or uphill)?

No ☐→ Go to Item 40

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

40. Walk to do errands (such as to/from a store or to take children to school (count walk time only)?

No ☐→ Go to Item 41

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

41. Walk leisurely for exercise or pleasure?

No ☐→ Go to Item 42

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

42. Ride a bicycle or stationary bicycle?

No ☐→ Go to Item 43

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

43. Do other aerobic machines such as rowing or step machines (do not count treadmill or stationary bicycle)?

No ☐→ Go to Item 44

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

44. Do water exercises (do not count other swimming)?

No ☐→ Go to Item 45

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

45. Swim moderately or fast?

No ☐→ Go to Item 46

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

In a typical week during the past 4 weeks, did you…

46. Swim gently?

No ☐→ Go to Item 47

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

47. Do stretching of flexibility exercises (do not count yoga or Tai-chi)?

No ☐→ Go to Item 48

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

48. Do yoga or Tai-chi?

No ☐→ Go to Item 49

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

49. Do aerobics or aerobic dancing?

No ☐→ Go to Item 50

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

50. Do moderate to heavy strength training (such as hand-held weights of more than 5 pounds, weight machines or push-ups)?

No ☐→ Go to Item 51

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

51. Do light strength training (such as hand-held weights of 5 pounds or less or elastic bands)?

No ☐→ Go to Item 52

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

In a typical week during the past 4 weeks, did you…

52. Do general conditioning exercises, such as light calisthenics or chair exercises (do not count strength training)?

No ☐→ Go to Item 53

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

53. Play basketball, soccer or racquetball (do not count time on sidelines)?

No ☐→ Go to Item 54

Yes ☐

How many times a week? ☐

How much total time per week did you usually do it? ☐☐ Hours ☐☐ Minutes

54. Do other types of physical activity not previously mentioned (please specify)?

No ☐→ End Questionnaire

Yes ☐ Specify other activity #1

_____

How many times a week? ☐

How much total time per week did you usually do it?

☐☐ Hours ☐☐ Minutes

Specify other activity #2

_____

How many times a week? ☐

How much total time per week did you usually do it?

☐☐ Hours ☐☐ Minutes

Specify other activity #3

_____

How many times a week? ☐

How much total time per week did you usually do it?

☐☐ Hours ☐☐ Minutes

PERSONAL HISTORY FORM

NUMBER: | | | | | | | |

STUDY YEAR | 25 |

SEQ # | |

FORM CODE: PHX

VERSION: C – 7/15/10

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

A. HOUSEHOLD SOCIODEMOGRAPHICS

"Now I'd like to take a few minutes to ask questions that will update information about your household."

1. Please look at this card. Which of these income groups represents your total combined family income for the past 12 months? Include income from all sources such as wages, salaries, social security, retirement benefits, help from relatives, rent from property and so forth. Please tell me the letter only.

[USE RESPONSE CARD] ☐

Under $5,000..... A

$5,000 - $7,999 ..... B

$8,000 - $11,999 C

$12,000 - $15,999 ..... D

$16,000 – $24,999 ..... E

$25,000 – $34,999 ..... F

$35,000 - $49,000 ..... G

$50,000 – $74,999 ..... H

$75,000 – $99,999 I

$100,000 and over ..... J

Don't know.....K **Go to Item 3**

Refused.....L **Go to Item 3**

2. How many people are supported by this income? ☐☐

3. How hard is it for you (and your family) to pay for the basics like food and heating? Please tell me the letter only.

[USE RESPONSE CARD] ☐

Very Hard..... A

Hard..... B

Somewhat Hard..... C

Not Very Hard..... D

Don't Know..... E

Refused..... F

4. Are you currently caring for a chronically sick or disabled relative?

Yes.....☐

No .....☐

5. This question is about the house or apartment where you live. Do you:

Rent.....☐

Pay a mortgage.....☐

Own free and clear.....☐

Have other living arrangements.....☐

6. Do you or anyone in your household have investments such as stocks, bonds, mutual funds, retirement investments or other investments?

   Yes.....☐

   No .....☐

7. Do you or anyone in your household own any land, business property, apartments or houses other than the one in which you now live?

   Yes.....☐

   Currently buying.....☐

   No.....☐

8. Do you or anyone in your household own a car?

   Yes, 1 car.....☐

   Yes, more than 1 car.....☐

   No.....☐

SES Ladders

*Here is a picture of a ladder. Think of this ladder as representing where people stand in the United States. At the **top** of the ladder are the people who are the best off – those who have the most money, the most education and the most respected jobs. At the **bottom** are the people who are the worst off – who have the least money, least education, and the least respected jobs or no job. The higher up you are on this ladder, the closer you are to the people at the very top; the lower you are, the closer you are to the people at the very bottom.*

9. Where would you place yourself on this ladder? Please show the step where you think you stand at this time in your life, relative to other people in the United States.

*Now, think of this ladder as representing where people stand <u>in their communities</u>. People define community in different ways; please define it in whatever way is most meaningful to you. At the **top** of the ladder are the people who have the highest standing in their community. At the **bottom** are the people who have the lowest standing in their community.*

10. Where would you place yourself on this ladder? Please show the step where you think you stand at this time in your life, relative to other people in your community.

RESPIRATORY QUESTIONNAIRE

NUMBER: | | | | | | | |

STUDY YEAR | 25 | SEQ # | | |

FORM CODE: RSE

VERSION: 7/15/10

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

Administrative Information

0a. Completion Date: □□/□□/□□□□ (Month / Day / Year)

0b. Staff ID: □□□

Instructions: *This form is completed during the participant's visit. ID Number, Contact Year must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly on the paper form, mark through the incorrect entry with an "X." Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.*

A. COUGH

1. Do you usually cough in the winter (during the day, or at night) 4 or more days out of the week?

Yes..... □
No..... □

2. Do you usually cough at other times of the year (during the day, or at night) 4 or more days out of the week?

Yes.....☐
No.....☐

IF 'YES' TO QUESTIONS 1 OR 2:

a. Do you usually cough like this on most days for as much as three months each year?

Yes.....☐
No.....☐

b. For how many years have you had this cough?.....☐☐

3. Do you usually bring up phlegm or sputum when you cough?

Yes.....☐
No.....☐

B. WHEEZING

4. Have you ever had wheezing or whistling in your chest?

Yes.....☐
No.....☐ → **GO TO QUESTION 5**

a. Have you had this wheezing or whistling when you did not have a cold?

Yes.....☐
No.....☐

b. At about what age did the wheezing or whistling start?.....☐☐

c. Do you still have it?

Yes.....☐ → **GO TO QUESTION 4e**
No.....☐

d. How many years has it been since you last experienced wheezing or whistling?☐☐

e. Have you ever had an attack of wheezing that has made you feel short of breath?

Yes.....☐
No.....☐

f. Have you had an attack in the past 12 months?

Yes.....☐
No.....☐

C. BREATHLESSNESS

5. Are you disabled from walking by any condition other than heart or lung disease?

Yes.....☐
No.....☐

6. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?

Yes.....☐
No.....☐

7. Do you have to walk slower than people of your age on the level because of breathlessness?

Yes.....☐
No.....☐

8. Do you ever have to stop for breath when walking at your own pace on the level?

Yes.....☐
No.....☐

9. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level?

Yes.....☐
No.....☐

10. Are you too breathless to leave the house or breathless on dressing or undressing?

Yes.....☐
No.....☐

D. CONDITIONS

11. Has a doctor ever told you that you had emphysema or chronic obstructive pulmonary disease (also called COPD)?

Yes.....☐
No.....☐ → **Go to Item 12**

a. How old were you when the doctor first told you this?.....☐☐

b. Do you still have it?

Yes.....☐
No.....☐

12. Has a doctor ever told you that you had chronic bronchitis?

Yes.....☐
No.....☐ → **Go to Item 13**

a. How old were you when the doctor first told you this?.....☐☐

b. Do you still have it?

Yes.....☐
No.....☐

13. Did you have breathing problems as a child (before age 16)?

Yes.....☐
No.....☐

14. Have you ever had asthma?

Yes.....☐
No.....☐→**Go to Item 15**

a. Was it confirmed by a doctor?

Yes.....☐
No.....☐

b. At what age did it start?.....☐☐

c. Do you still have it?

Yes.....☐→**Go to Item 16**
No.....☐

d. At what age did it stop?.....☐☐

15. Do you have allergies that trigger asthma symptoms?

Yes.....☐
No.....☐

E. ALLERGIES

16. Have you ever had hay fever, nasal allergies, or allergic rhinitis?

Yes.....☐
No.....☐→**Go to Item 17**

a. Have you had it the past 12 months?

Yes.....☐
No.....☐

17. In the past 12 months, have you had a problem with sneezing, runny nose, or blocked nose when you did not have a cold or the flu?

Yes..... ☐
No..... ☐

F. SLEEP

18. How often do you snore now?..... ☐

Never.....A
Rarely (1-2 nights a week).....B
Sometimes (3-5 nights a week).....C
Always or almost always (6-7 nights a week) .....D
Other {note log}.....E

19. How often do you have times when you stop breathing during your sleep?..... ☐

Never.....A
Rarely (1-2 nights a week).....B
Sometimes (3-5 nights a week).....C
Always or almost always (6-7 nights a week) .....D
Other {note log}.....E

20. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

☐☐ Hours of sleep per night

21. Overall, was your typical night's sleep during the past 4 weeks..... ☐

Very sound or very restful.....A
Sound or restful.....B
Average quality C
Restless .....D
Very restless .....E
Other {note log}.....F

22. Have you ever been told by a doctor that you have sleep apnea?

Yes.....☐
No.....☐ →**Go to END**

a. How old were you when you were first diagnosed with sleep apnea?.....☐☐

b. Have you had any treatment for sleep apnea?

Yes.....☐
No.....☐→**Go to END**

c. What type of treatment did you receive for sleep apnea?

	Yes	**No**
a. CPAP.....	☐	☐
b. BILEVEL.....	☐	☐
c. Oral device.....	☐	☐
d. Surgery.....	☐	☐
e. Other.....	☐	☐

specify: _____

SF-12v2™ HEALTH SURVEY

ID NUMBER: ☐☐☐☐☐☐☐

STUDY YEAR 25 SEQ # ☐☐

FORM CODE: SFE

VERSION: 7/15/10

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: *Enter the answer given by the participant for each response.*

"This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can."

1. In general, would you say your health is:

Excellent 1 ☐ Very good 2 ☐ Good 3 ☐ Fair 4 ☐ Poor 5 ☐

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited	Yes, limited a lot	No, not a little	at all
a. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1 ☐	2 ☐	3 ☐	
b. Climbing **several** flights of stairs	1 ☐	2 ☐	3 ☐	

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b. Were limited in the kind of work or other activities	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

b. Did work or other activities less carefully than usual 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all 1 ☐
A little bit 2 ☐
Moderately 3 ☐
Quite a bit 4 ☐
Extremely 5 ☐

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b. Did you have a lot of energy?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c. Have you felt downhearted and depressed?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time 1 ☐
Most of the time 2 ☐

Some of the time	3 ☐
A little of the time	4 ☐
None of the time	5 ☐