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# SAMPLE

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version

## REGARDS INFORMED CONSENT

Reasons for Geographic and Racial Differences in Stroke (REGARDS) Project

Sponsor: National Institutes of Health, National Institute of Neurological Disorders and Stroke,  
grant title: Etiology of Geographic and Racial Differences in Stroke.

Principal Investigator: George Howard

Co-Investigators: Rodney C.P. Go, Virginia Howard, Virginia Wadley, University of Alabama at Birmingham, Alabama; Camilo R. Gomez, Sean C. Orr, Alabama Neurological Institute; Mary Cushman, University of Vermont; Ronald J. Prineas, Wake Forest University, Andra Graham, Examination Management Services, Inc.

### INTRODUCTION/PURPOSE

You have been asked to participate in a medical research project on risk factors for stroke. You are one of about 30,000 people aged 45 and older who has been selected at random (by chance) from the community. For reasons that are not understood, people in some parts of the country develop strokes more often than people in other parts of the country. Also, African-Americans develop strokes more often than whites. The purpose of REGARDS is to study the factors that determine why some people develop stroke and others do not. REGARDS investigators will use medical evaluations and questionnaires to study these factors. This project will follow many people for several years in order to learn why these differences in stroke risk exist.

### PROCEDURES

You have already agreed, by telephone, to participate in the REGARDS project, and you participated in a telephone interview and answered questions about your health.

You are now being asked to have an examination performed in your home by a nurse or health care professional. During this visit, additional information about your health will be collected and medical tests will be done. This in-home visit will take about 45 minutes to an hour. The health care professional will also give you a dietary questionnaire to complete and return by mail. You will also be asked to complete a questionnaire on places you have lived. The dietary questionnaire will take about 30-40 minutes to complete, while the questionnaire on places you have lived takes less than 10 minutes to complete.

UAB-IRB

Consent Form Approved 08-27-04

Expiration Date 08-25-05

Participant Initials:





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This project will include the following:

- a) Health interviews: This will include questions concerning your medical history; personal history, use of tobacco, alcohol, and medications; diet and exercise habits; where you have lived; and family history which may be important to your health.
- b) Physical Examination: This will include measurements of your blood pressure, height, weight waist, and hips.
- c) Electrocardiogram (ECG) - A 12-lead ECG will be performed. This is a recording of the electrical activity of your heart. Small patches or stickers, called electrodes, are placed on different parts of the body. One is put on each arm and leg and your chest. These do not hurt.
- d) Urine test: A urine sample will be collected and stored in a central site where it will be listed under a code number. For some participants it will be used to measure the amount of albumin, a substance that is sometimes secreted by the kidneys. The stored sample may also be used to measure other substances that might be related to stroke. These tests might include measurements of clotting function or certain hormones. These tests are considered research tests and will not be reported back to you unless they have clinical meaning that might benefit you.
- e) Blood test: A 50 ml blood sample (about 4 tablespoons) will be collected for measurement of blood sugar, lipids (cholesterol and fats), kidney function, and complete blood count. Your blood sample will be stored in a central site and listed under a code number. This stored sample may be used to measure other substances that might be related to stroke. These blood tests are considered research tests and will not be reported back to you unless they have clinical meaning that might benefit you.
- f) DNA testing: You will be asked to allow isolation of DNA from your blood sample for testing of different genes. The DNA will be stored in a central site and listed under a code number. DNA may be used to measure inherited factors that might relate to stroke. Results of these tests will not be reported to you without your permission and unless they have a clinical meaning. If we happen to find a gene problem that is linked to a medically treatable genetic disease, we will contact you if you have given us permission to do so. Results from these tests will not be released, placed in your medical record, or shared in any way with your relatives, personal physicians, insurance companies, or any other third party unless you authorize REGARDS staff, in writing, to do so.
- g) Follow-Up information: To complete this project, it is important for us to determine your long-term health status. You will be contacted by phone every six months and asked about your health. If you are hospitalized or admitted to a nursing home, the REGARDS staff may ask you for permission to review your hospital or nursing home records to determine the reason for your admission and verify the diagnosis. If you see a doctor for a stroke or stroke-like symptoms but





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are not hospitalized, we may also ask you for permission to review the records to verify the diagnosis.

If you are unable to answer questions for yourself, REGARDS staff may contact your physician or a person you tell us could answer questions for you. We would also want to obtain information about the cause of death, if you should pass away during the project. To do this, we may request death certificates or coroner's reports from the department of health.

Because of the importance of keeping track of your health status, if you should lose contact with the REGARDS project, we request your permission to contact your relatives or friends whose names and addresses you have provided and/or to use a commercial locator service to find your current address and telephone number. We may also contact you in the future to ask if you would like to participate in studies addressing health issues other than stroke. Your decision to participate or not in any potential future studies has no effect on your agreement to participate in REGARDS. You can withdraw your permission to participate in REGARDS or any other study at any time.

Occasionally, it may be necessary to conduct a second in-home visit to repeat one or more of the procedures such as collecting another blood or urine sample, or performing another ECG. This does not mean that there was anything wrong with the original testing; it usually means there was something wrong with the way the samples were handled, or the way the ECG was done. If it is necessary, we will contact you to schedule a second visit. This visit will be shorter than the first one. You may decline this second visit if you choose to.

### **RISKS OR DISCOMFORTS**

The procedures to be used in this project are considered to be safe. The risks associated with the clinical exams are small. Risks associated with drawing blood are discomfort at the site of needle insertion, bruising or inflammation at the site, and rarely, faintness or infection. Blood will be drawn by an experienced, certified technician using sterile procedures.

### **BENEFITS**

One benefit of participating in this project is an evaluation of certain aspects of your health at no cost to you. Information from the evaluation will be available to you. If a health condition is detected during the evaluation, you will be told. However, the REGARDS project is not intended to provide medical care or interfere with your relationship with your own doctor. You will be referred to your own doctor for follow-up of all medical information obtained by the project.

You will also be given information on the warning signs of transient ischemic attacks (TIAs) and stroke. TIAs are mini-strokes: stroke-like symptoms that last from several minutes to several hours. An additional benefit of participating is that you may help to increase scientific knowledge about the geographic and racial differences in risk factors associated with stroke. This knowledge may help reduce the risk of stroke in others.





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### ALTERNATIVES

You have the alternative to choose not to participate in this project.

### CONFIDENTIALITY

The information gathered during this study will be kept confidential to the extent permitted by law. However, representatives of the National Institute of Health (NIH) and the University of Alabama at Birmingham's Institutional Review Board (IRB) could review your research records and have access to confidential information that identifies you by name. Federal law allows other scientists to request information obtained by the REGARDS Project, including your DNA samples. We will allow this information to be released only after ensuring that your name, social security number, address or other identifying information is removed from your file.

Please understand that we will follow strict rules to protect privacy at all times during and after this project. You will be assigned a unique ID number and only that number will be associated with your medical data. The ID numbers and matching names will be kept in a locked file in a secure area in the REGARDS central office. The coded data will be maintained by the project data center for storage and analysis. The database will be available only to authorized staff of the project.

We will ask for your social security number because data from this project will be linked with data supplied by the National Center for Health Statistics and the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration.) It will be kept confidential according to the Privacy Act of 1974, and will be used only for research purposes. Project records may be kept indefinitely for analysis and follow-up.

The results of the study may be published for scientific purposes, however your identity will not be revealed.

### COST OF PARTICIPATION IN RESEARCH

There will be no cost to you from participation in the research. The project is paid for by the National Institute of Health. The costs of your standard medical care will be billed to you or your insurance company in the usual manner.

### PAYMENT FOR PARTICIPATION IN RESEARCH

You will be paid \$30.00 to cover any inconvenience or expenses such as elder care or childcare. If a second home-visit is conducted, you will be paid \$15 to cover any inconvenience.



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### RESEARCH-RELATED INJURY

The University of Alabama at Birmingham and the National Institute of Health (NIH) have made no provisions for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided but is not free of charge.

In the unlikely event that during the in-home evaluation you should require medical care, first aid will be available. If the examination reveals any medical problems that require medical diagnosis or treatment, you will be so advised. In that case, payment for additional testing must be provided by you and your third party payer ( for example, health insurance or Medicare). It is important to note that the REGARDS project does not provide medical treatment, and the examination you receive does not substitute for a medical examination a doctor might give you.

### WITHDRAWAL

You do not have to take part in this research project. Your decision to be in the project is voluntary. If you should change your mind about participating, you are free to withdraw your consent at any time. If you become uncomfortable during the in-home visit, you can ask the health care professional to leave.

### NEW FINDINGS

Any significant new findings that develop during the course of the study that may affect your willingness to continue in the research will be provided to you by Dr. Howard or his staff.

### QUESTIONS

If you have any questions about the research or a research related injury, Dr. George Howard will be glad to answer them. Dr. Howard's phone number is 205-934-4905. The project manager, Dr. Ella Temple can also be contacted at 205-934-5882 or toll free 1-888-REGARD8 (1-888-734-2738) (Monday-Friday, between the hours of 8:00 am and 5:00 pm Central Time.) If you have questions about your rights as a research participant, you may contact Ms. Sheila Moore, Director of the Office of Institutional Review Board of Human Use (IRB). Ms. Moore may be reached at 205-934-3789 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 (Monday through Friday, between the hours of 8:00 am and 5:00 pm Central Time.)

### LEGAL RIGHTS

You are not waiving any of your legal rights by signing this consent form.





# REGARDS INFORMED CONSENT

Participants's Social Security Number

-  -

## SIGNATURES

Your signature below indicates that you agree to participate in this project. You have been given the opportunity to ask questions about this research project and have received satisfactory answers. You will receive a signed copy of this informed consent.

In addition, you have the right to accept or refuse to participate in certain parts of the study. Please place your initials in the "YES" or "NO" column according to your response to the following questions:

### I give my permission to REGARDS to:

- |    | YES                      | NO                       |   |
|----|--------------------------|--------------------------|---|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | Report the findings from standard medical tests to me.  |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | Prepare DNA from my blood samples.  |
| 3. | <input type="checkbox"/> | <input type="checkbox"/> | Test my DNA for genes related to other diseases of the blood vessels such as renal disease, heart disease, other health conditions related to blood vessel diseases such as diabetes and obesity.   |
| 4. | <input type="checkbox"/> | <input type="checkbox"/> | Test my blood for factors related to other diseases of the blood vessels such as renal disease, heart disease, other health conditions related to blood vessel diseases such as diabetes and obesity.   |
| 5. | <input type="checkbox"/> | <input type="checkbox"/> | Notify me if a potentially treatable genetic condition is identified.   |
| 6. | <input type="checkbox"/> | <input type="checkbox"/> | Allow researchers from private companies who wish to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people to have access to my DNA.<br>(NOTE: neither you, your heirs, nor this study will benefit financially from this, nor will your cell line or DNA be sold to anyone.) |

Please Print Participant's Name here:

Date Example: 12/07/1948

Month Day Year

1A.

1B.  /  /

Signature of Participant or Legally Authorized Representative

Date of Signature

2A.

2B.  /  /

Signature of person obtaining consent

Date of Signature

3A.

3B.  /  /

Signature of Witness

Date of Signature







**REGARDS IN-HOME VISIT**

PHLEBOTOMY (continued)	Yes	No	Partial	Refusal	Hard Stick	Other	Other-State	Reason
Purple Top 3mL EDTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Tiger Top 9mL Serum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Purple Top 10mL EDTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

10. Quality of venipuncture: Clean  Traumatic   
 If traumatic, why? (Choose one or more if applicable)  
 Vein Collapse  Hematoma  Excessive Draw Duration  Hard Stick  Leakage at Puncture Site

**BLOOD PROCESSING**

1. Start time of blood processing:     Please Record in Military Time.  
 Example: 1 pm = 1300

2. Processing of Blood:

Tube	Serum/Plasma	Packed Cells	Completed	Remarks
Tiger Top 9mL (Serum)	Transfer to Red Mailer Tube	Discard to biohazard	<input type="checkbox"/>	<input type="text"/>
Tiger Top 9mL (Serum)	Transfer to 2nd Red Mailer Tube	Discard to biohazard	<input type="checkbox"/>	<input type="text"/>
Purple Top 10mL (EDTA)	Transfer to Purple Mailer Tube	Transfer to Blue Mailer Tube	<input type="checkbox"/>	<input type="text"/>
Purple Top 10mL (EDTA)	Transfer to 2nd Purple Mailer Tube	Discard to biohazard	<input type="checkbox"/>	<input type="text"/>
Red Top 5mL (SCAT-I)	Transfer to Green Mailer Tube	Transfer to Blue Mailer Tube	<input type="checkbox"/>	<input type="text"/>
Tiger Top 4mL (Serum)	Transfer to White Mailer Tube	Discard to biohazard	<input type="checkbox"/>	<input type="text"/>

3. End time of blood processing:     Please Record in Military Time.  
 Example: 1 pm = 1300

**URINE COLLECTION**

1. Was a urine specimen completed? Yes  No   
 If no, why? Refusal  Other  (Please state reason)

2. Time of Collection:     Please Record in Military Time.  
 Example: 1 pm = 1300

3. Processing of urine specimen:

Container Type	Transferred To Plastic Mailer Tube	Completed	Remarks
Plastic Collection Cup <input type="checkbox"/>	Yellow mailer Tube <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>

**ECG**

1. Was an ECG completed? Yes  No   
 If no, why? Refusal  Other  (Please state reason)

2. Processing of ECG:

ECG mounted: Yes  No  If no, why?

Serial # recorded on strips Yes  No  If no, why?

Study ID # recorded on strips Yes  No  If no, why?

3. ECG start time:     Please Record in Military Time (must match ECG reading)  
 Example: 1 pm = 1300





# REGARDS IN-HOME VISIT

## SPECIMEN AND PAPERWORK SHIPMENT

- |                      |  | <u>Done</u>                  |
|----------------------|--|------------------------------|
| <b>1. TO LAB:</b>    |  |                              |
| Specimens:           | Red (2), Purple (2), Green (1), White (1), Yellow (1), and Blue (1) mailer tubes and whole blood plastic 3mL EDTA Tube | Yes <input type="checkbox"/> |
| Consent Form:        | White Copy of the Consent Form _____   | Yes <input type="checkbox"/> |
| Medical Release Form | White Copy of the Medical Release Form _____   | Yes <input type="checkbox"/> |
| Medications Form     | White Copy of the Medications Form _____   | Yes <input type="checkbox"/> |
| ECG Strip:           | All Mounted ECG Strips _____   | Yes <input type="checkbox"/> |
| In-Home Visit Form:  | All Original Copies of the In-Home Visit Form _____  | Yes <input type="checkbox"/> |

## 2. LEAVE WITH PARTICIPANT:

- |                                     |   |                              |
|-------------------------------------|---|------------------------------|
| Places You Have Lived Questionnaire | Leave with the participant to complete and return in envelope _____ | Yes <input type="checkbox"/> |
| Family History Questionnaire        | Leave with the participant to complete and return in envelope _____ | Yes <input type="checkbox"/> |
| Food Questionnaire                  | Leave with the participant to complete and return in envelope _____ | Yes <input type="checkbox"/> |
| Brief Measurement Report            | Leave with the participant to keep _____                            | Yes <input type="checkbox"/> |
| Consent Form                        | Leave Blue copy with the participant to keep _____                  | Yes <input type="checkbox"/> |
| Medical Records Release             | Leave blue copy with the participant to keep _____                  | Yes <input type="checkbox"/> |
| Contact Form                        | Leave with the participant to complete and return in envelope _____ | Yes <input type="checkbox"/> |
| Mailing Envelope                    | Leave with the participant to return to REGARDS _____               | Yes <input type="checkbox"/> |
| "Know Stroke" Brochure              | Leave with the participant to keep _____                            | Yes <input type="checkbox"/> |

## Examiner Comments

1. A. \_\_\_\_\_  
 B. \_\_\_\_\_  
 C. \_\_\_\_\_  
 D. \_\_\_\_\_  
 E. \_\_\_\_\_  
 F. \_\_\_\_\_  
 G. \_\_\_\_\_  
 H. \_\_\_\_\_

(Please Print) Examiner #:  Name:

2. EMSI Examiner Name:

3. Examiner Signature:

(Please Print) EMSI Branch Office #:

(Please Print) EMSI Branch Office Location:

6. End Time of Visit:

Please Record in Military Time: Example: 1pm = 1300



## REGARDS MEDICATIONS FORM

**EMSI STAFF: PLEASE READ.** The REGARDS study is interested in prescription and non-prescription medications participants are taking. These include vitamins, cold remedies, dietary supplements, dermal patches, eye drops, creams, salves, and injections. Please remind participant that the letter the participant received about this appointment asked him/her to have their current medications available. If necessary, remind the participant that this means prescription and non-prescription medications and read the list above.

**Have you taken any medications in the past 2 weeks?** [Please place an "X" in the box beside the appropriate response(s)]

YES ----->Are these all the medications that you have taken in the past 2 weeks?  YES [Complete information below]

NO (why not?) 

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

NO [END FORM]

	Medication Name		Prescription Medicine?
<i>Please Print clearly in all CAPITAL LETTERS.</i>		<i>Please no dosage or frequency</i>	
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			





# REGARDS MEDICATIONS FORM

Medication Name													Prescription Medicine? YES NO	
<i>Please print clearly in all CAPITAL LETTERS.</i>													<i>Please do not list dosage or frequency.</i>	
16.														
17.														
18.														
19.														
20.														

**EMSI STAFF:** *After listing up to 20 medications, please read the following questions to the participant and record the appropriate response.*

1. Do you ever forget to take your medications? \_\_\_\_\_  No  Yes
2. Are you ever careless in taking your medications? \_\_\_\_\_  No  Yes
3. Do you ever miss taking your medications when you are feeling better? \_\_\_\_\_  No  Yes
4. Do you ever miss taking any of your medications because you are feeling sick? \_\_\_\_\_  No  Yes
5. Do you ever miss taking your medications for any reason? \_\_\_\_\_  No  Yes



REASONS FOR GEOGRAPHIC AND RACIAL DIFFERENCES IN STROKE

**HOSPITAL MEDICAL RECORD RELEASE FORM**

**Patient information:**

Please release to the *REasons for Geographic And Racial Differences in Stroke REGARDS) Study:*

All records of hospitalizations, diagnoses, and procedures which occurred during the period from \_\_\_\_\_ to \_\_\_\_\_  
[Date of Inhome Visit] [One year from Date of Inhome Visit]

I authorize the above agency to release copies of my medical records to the *REGARDS Study Operations Center.* This information will be used to statistical purposes only, and will remain strictly confidential.

\_\_\_\_\_  
Signature of Participant or  
Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date