



**Consent To Participate In A Research Study
MURDOCK Study Community Registry and Biorepository**

You are being asked to contribute a blood and a urine sample and health information to the MURDOCK Study Community Registry and Biorepository. These types of studies include only people who choose to take part. This consent form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Be sure to ask us as many questions as you want. We urge you to talk with your family, friends, and doctor before making your choice. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

This study is funded by the David H. Murdock Institute for Business and Culture. This Institute provides grant money to Duke University to pay expenses for the study including the salaries for the research staff. The researchers involved with this study will seek additional funding over time to pay the expenses involved in continuing to enroll new subjects and to study the samples and information collected during the study.

Everyone who takes part in research should know that

- Research is meant to gain knowledge that may help in solving problems. You may or may not benefit from taking part. Taking part may also involve some risks.
- Taking part in research is completely voluntary. You can choose not to take part. If you choose to take part, you can quit at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. L. Kristin Newby and Dr. Rowena Dolor from Duke University will be your doctors for the study. No medical care will be provided by this study.

WHY IS THIS STUDY BEING DONE?

Medical researchers are trying to learn more about cancer, heart disease, diabetes, and other health problems. Much of this research is done using health information along with blood and urine. Researchers often study blood, urine and information from people who have health problems and from people who do not.

WHAT IS THE PURPOSE OF THIS PROJECT?

The purpose of this project is to collect and store blood and urine samples and health information. Researchers can then study the stored materials. Through such studies, they hope to find new ways to detect, treat, and maybe even prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. (Genes, which are made up of DNA, have all the information needed to build and operate a human body.) DNA is a short form of deoxyribonucleic acid. DNA contains information needed to construct and operate a human body. The genetic material, in combination with your other health information and blood and urine samples, will be available to researchers studying genetic and other factors that contribute to or cause many different health problems. Some of the studies may lead to new products, such as drugs or tests for diseases. Enrollment into the study is expected to last at least five years and we plan to enroll 50,000 individuals in your community. There is no limit on the length of time we will keep your blood, urine and information. We will keep them as long as they are useful, unless you decide to stop taking part or we close the MURDOCK Study Biorepository.

A "biorepository" is a collection of stored samples and information. This collection is called the MURDOCK Study Community Registry and Biorepository (or just the "MURDOCK Study Biorepository" in the rest of this form). The "MURDOCK Study" is a general name that refers to the MURDOCK Study Biorepository, studies

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that are done with the samples and information stored in the MURDOCK Study Biorepository, and studies that are done with the people who give samples and information for the MURDOCK Study Biorepository.

WHAT IS INVOLVED?

If you agree to take part, you will be asked to sign this consent form. We will give you a signed copy of the consent form to keep. Here is what will happen next:

1. We will ask for some information about you and your health.

First, we will ask you to fill out a MURDOCK Study Participant Registry Questionnaire. This questionnaire asks for some basic information, like your name, age, racial and ethnic groups, and health history. We will contact you no more than once a year to update this information. This will happen for as long as your information is stored in the MURDOCK Study Biorepository.

Second, we will get some information from your medical record. Examples include information about your health problems, lab results, medical procedures, images (such as X-rays), and medicines. This is because future researchers need to know if you have any health problems. They may also need to know about any treatments you have had and how well the treatments worked. We will use your medical record from time to time to update this information. This will happen for as long as your information is stored in the MURDOCK Study Biorepository.

Third, we will collect research data from any future MURDOCK studies in which you decide to take part.

2. We will take vital signs, measure your waist and get a blood and a urine sample from you.

We will measure your blood pressure, pulse and waist circumference. We will draw 50 ml (about 3 tablespoons) of blood from a vein by needle stick and collect about 50 ml of urine.

3. We will store your samples and information in the MURDOCK Study Biorepository.

We will keep your blood, urine and information in the MURDOCK Study Biorepository along with those from all the other people who take part. There is no limit on the length of time we will keep your blood, urine and information. We will keep them as long as they are useful, unless you decide to stop taking part or we close the MURDOCK Study Biorepository.

4. We will let researchers use the materials stored in the MURDOCK Study Biorepository for approved studies.

Researchers can apply to study the samples and information stored in the MURDOCK Study Biorepository. A research committee will review each application. An ethics review will also be done. This kind of review is to make sure that risks are minimized and that the rights and welfare of people who take part in research are protected.

If a study is approved, a part of your blood and/or urine and some information about your health might be distributed to the researchers, along with samples and information from many other people. We will not give researchers your name or any other information that could identify you without your permission.

Materials stored in the MURDOCK Study Biorepository will be used mainly by researchers at Duke University. Researchers from other universities, the government, and drug- or health-related companies may also apply to study them.



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5. Researchers may contact you in the future with offers to take part in other research.

We will not notify you every time your samples and information are used in a study. However, some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to fill out a survey, do a phone interview, or be seen by a researcher or doctor.

If a study like this is approved, the researcher will contact you to tell you more about the study. There will be a new consent process just for that study. You can decide then to take part or not take part. If you do take part, your samples and information from these additional studies will be added to the MURDOCK Study Biorepository and may be used for future research.

We will make sure researchers do not contact you about more than four studies like this per year.

6. Some of your genetic and health information may be placed in Internet databases.

In order to speed research, it is often helpful for researchers to share the genetic information they get from studying blood and urine samples. Other researchers can then compare that information to the genetic information from people in other studies. By sharing information, researchers can learn even more about human health and disease.

Some of your genetic and health information may be released into one or more scientific databases that can be accessed on the Internet. There are many scientific databases where your information may go. Some are kept by Duke University, some are kept by the National Institutes of Health, and some are kept by private companies. Some of these databases can be used by the public. Others are restricted and can only be used by approved researchers.

Your name and other information that could identify you will never be released into an Internet database. Nobody will know just from looking at a database that the information belongs to you.

WHAT ARE THE POSSIBLE RISKS?

Physical Risks. Like any other time you have blood drawn, you may feel brief pain or have some bruising from the needle. Infection, excess bleeding, clotting or fainting is also possible, but unlikely.

Privacy Risks. There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection. We believe the chance of these things ever happening is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. These efforts are described in the part below called "How Will Information About Me Be Kept Confidential?"

Potential Risks and the Genetic Information Non-Discrimination Act (GINA): There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

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The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genome Wide Association Studies (GWAS): Genome-wide association studies (GWAS) look at the genetic differences between individuals that may be found in the human genome (the complete set of all human genes) to find out if there is a relationship between certain traits (such as blood pressure, or weight) and the presence or absence of a disease or condition.

As part of this study, we will be collecting GWAS data about you. The data will not be labeled with any information that can be used to directly identify you. GWAS data may be shared with other researchers around the world. Researchers will have to get approval from an ethics board to use this information for research prior to getting access to the data.

Internet Databases. There is a risk that someone could trace the information in a scientific database back to you. Even though your name or other identifiers will not be included, your genetic information is unique to you. We believe the chance that someone will identify you is very small. But the risk may grow in the future if people come up with new ways of tracing information.

HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

Federal privacy rules give safeguards for privacy, security, and authorized access. We will not give information that identifies you (name, social security number, address, telephone number, or any other direct personal identifier in study records) to anyone without your permission.

We will remove your name and anything that could directly identify you from your samples and replace them with a barcode. These samples will be kept in locked freezers in locked buildings. We will keep the master list that links the code number to your name on secure computers. We will keep health information and research data on secure computers with very limited access. These computers have many levels of password protection. Only a few of the MURDOCK Study staff will have access to the data and all MURDOCK Study staff sign a pledge to keep your identity a secret.

Researchers who study your samples and information will not know who you are. We will give them only a code number and not any information that directly identifies you. The researchers must promise they will not try to find out who you are. They must also promise to keep the coded materials secure.



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Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System, the Duke University Health System Institutional Review Board, Carolinas Healthcare System, or the Carolinas Healthcare System Institutional Review Board. A reviewer who looks at your research record may also need to look at your entire medical record. Your information may be disclosed to outside reviewers for monitoring purposes. If this happens, it may not be covered by federal patient privacy rules (called 'HIPAA'), but it will be protected by other federal privacy rules.

Data and samples in this repository will be maintained indefinitely. This study has a long-range goal to identify factors that contribute to many diseases and illnesses. No end date has been set for analyzing results from the study. As new information about diseases becomes available and new methods of analyzing research results are developed, we hope to use the samples and data over time to continue to advance knowledge about many diseases.

Research records are separate from medical records. We will not place any information that we get or create as part of this project in your medical record.

To further protect you, we obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the Biorepository cannot be forced to disclose information that identifies you, even by subpoena. A "subpoena" is a command to give information to a judge or court. We will use the Certificate to resist any demands for information that could identify you, except as explained below.

- The Certificate cannot be used to resist a demand for information from personnel of the Department of Health and Human Services that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
- In addition, we will disclose information about you without your consent if the information is something that the law says we must report to state health officials or the state attorney's office. For example, we have to report sexually transmitted diseases, domestic violence, child abuse, elder abuse, and threats to harm yourself or others.

You should know that the Certificate does not stop you from giving information about yourself or your involvement in this project.

WHAT ARE THE POSSIBLE BENEFITS?

You will most likely not benefit directly if you decide to take part in this project. The main reason you may want to take part is to help researchers make discoveries that might benefit people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance for taking part in the MURDOCK Study Biorepository. We will give you a \$10 gift card to pay you for the time it took for you to join the Study.

Your samples and information will be used only for research. You should know that research sometimes leads to discoveries that may one day have commercial value. For example, research could lead to new tests, drugs, or other medical products. If you take part in this project, that means you agree to let the MURDOCK Study make your samples and information available for these uses.



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In the event that research using samples and information stored in the Biorepository leads to a product that could be sold commercially, there are no plans for you to share in any profits. Development of new products usually relies on the study of samples and information from hundreds or thousands of people, not on any one person. The Duke University Health System and/or the developers will assert all rights of ownership in the samples and information, as well as all rights arising from use of the samples and information.

WILL I FIND OUT THE RESULTS OF THE RESEARCH?

Research Results. You should not expect to get individual results from research done using your samples and information. Researchers must study materials from many people over many years before they can know if the results have meaning. The results will not affect your care right now. They will not be given to your doctor and will not be put in your medical record.

You can get general news about the kinds of studies being done through the MURDOCK Study at www.murdock-study.org and a quarterly newsletter that you will receive if you join the MURDOCK Study.

Incidental Findings. There is a small chance that researchers could learn something about your health that you and your doctor did not know before. For example, they might find that you have a condition not previously diagnosed. Or they might find that you have a gene or other risk factor that is known to increase the chance you or a member of your family could get a disease in the future.

We will offer to tell you a finding like this only if it is about a serious disease for which a treatment is available. We will send a letter by certified mail asking you to contact Dr. L. Kristin Newby and Dr. Rowena Dolor. Drs. Newby and Dolor will arrange a time for you to meet with them or another health care provider to go over the information. Notification will be sent to the last address you provided to us. Therefore it is important that you inform us of any change in your address. At that time, if you would prefer not to receive the results, you will be asked to inform Dr. Newby or Dr. Dolor of your preference. The staff will not release these specific research findings over the telephone or in the mail.

WHAT ARE MY OPTIONS?

Taking part in the MURDOCK Study is your choice. You can choose to take part or not take part. No matter what you decide, now or in the future, it will not affect your medical care. There will not be any penalty to you and you will not lose any benefits you would otherwise be able to get.

WHAT IF I CHANGE MY MIND?

If you agree to take part in the MURDOCK Study, you are free to change your mind at any time. If you change your mind, please contact the MURDOCK Study office at (704) 250-5861 or (877) 673-2508 and let us know. At that time, we will ask you to indicate in writing on an official MURDOCK Study participant withdrawal form if you want unused blood and urine destroyed or if your samples (having all identifying information that would link the samples to you removed) could be used for further research. Please note that if we have already distributed some of your samples and information for the Study, we cannot call them back. Also, we cannot destroy knowledge already gained from the study of samples and information. But if you change your mind, you can tell us not to give researchers your materials for any more studies.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at the site where your blood and urine samples are being collected in the event that you are injured as a result of your participation in this research study, or you may seek care at

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your local hospital. However, there is no commitment by Duke University, Duke University Health System, Inc., Carolinas Healthcare System or your Duke or Carolinas Healthcare physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

WHAT IF I HAVE QUESTIONS?

You should feel free to ask any questions. Your questions should be answered clearly and to your satisfaction.

For questions about the project, or if you have problems, concerns or suggestions about the research, contact Dr. L. Kristin Newby at (919) 668-8805 or Dr. Rowena Dolor at (919) 668-8627 during normal business hours. You can also call the MURDOCK Study office at (704) 250-5861 or (877) 673-2508. You can leave a message at these numbers after hours, on weekends, and on holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board Office at (919) 668-5111 or the Carolinas Health Care System Institutional Review Board Office at (704) 783-4165 or Carolinas Healthcare System at (704) 355-3158.

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CONSENT STATEMENT

“The purpose of the MURDOCK Study, procedures to be followed, risks and benefits have been explained to me. I have asked all the questions I have now, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions about my rights as a research participant, or to discuss problems, concerns, or suggestions related to the research. I have read this consent form and agree to be in this study, and have been told I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.”

I voluntarily agree to all five of the following:

- My blood, urine and information can be collected and stored at the MURDOCK Study Biorepository. I have been told that it may be used in future research to learn about, prevent, or treat health problems.
- MURDOCK Study staff can contact me once a year to update my personal information.
- MURDOCK Study staff can use my medical record from time to time to get updated information about my health.
- My genetic and health information can be released, with no direct identifiers, into scientific databases that can be accessed on the Internet.
- Researchers with approved projects that require additional consent can contact me with offers to take part in up to four more research studies per year.

Signature of Research Participant	Date	Time
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Signature of the Person Obtaining Consent	Date	Time
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"I am the representative of the subject and am acting on behalf of the subject. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the subject's participation in this study."

Signature of Legal Representative (if applicable)	Date	Time
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Relationship to Participant _____

IMPARTIAL WITNESS STATEMENT

“I confirm that the information in the consent form and any other written information was accurately explained to, and apparently accepted by, the subject, or his/her Legally Authorized Representative. The subject or his/her Legally Authorized Representative freely consented to participate in the research study.”

Impartial Witness's Name	(Signature)	Date	Time
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