



Obafemi Awolowo University Teaching Hospitals Complex – ARGO Biobank Center

P.M.B. 5538

Ile-Ife, Osun State

Nigeria

BROAD CONSENT FORM

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|----------------------------|--|
| BSS Name and Number | |
| IRB# | |
| Consent form approved | |
| This consent valid through | |

What is the ARGO biobanking?

The ARGO biobanking is a research biobank created by the three-member consortium—Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), African Research Group for Oncology (ARGO), and Memorial Sloan Kettering Cancer Center (MSKCC). A biobank is a place where small amounts or "samples" of tissue, blood, and other human material, and related medical information, are collected and stored for future use in medical research. The ARGO biobanking will collect and store samples and information from people Nigeria and send them to research scientists who may be in country or outside the country.

OAUTHC collects samples and related medical information for the ARGO biobanking and is asking you to donate your samples and related medical information for future medical research. It is up to you whether or not to donate to the ARGO biobanking. Saying no will not affect your medical treatment or insurance benefits at OAUTHC.

This form explains what will happen if you say yes. You can learn more about this project by first reading the fact sheet “Questions and Answers about the ARGO biobanking.” Please ask questions if something is not clear or if you would like more information.

Why are you asking me to donate to the ARGO biobanking?

OAUTHC is asking you to donate to the ARGO biobanking because your tissue samples could help scientists find, prevent, and treat cancer and other diseases. You need to have tissue removed for medical reasons. Your doctor will examine the tissue samples removed and keep what is needed for your medical care. The tissue samples not needed by your doctor are the ones you can now choose to donate to the ARGO biobanking

What will happen if I say yes?

Note: Specific details in this section may vary if additional biospecimens (i.e., urine, saliva) are collected or additional collection procedures (i.e., extra blood draw) are undertaken.

If you say yes, you are giving permission for OAUTHC to:

- Send your samples to the ARGO biobanking. Samples may include small amounts of healthy as well as diseased tissue removed by your doctor for medical reasons.
- Send about 3 tablespoons of your blood to the ARGO biobanking. The blood will be collected during your surgery. You will not have any additional needle sticks to obtain this blood.
- Send information from your medical record to the ARGO biobanking. This information may include your age, ethnic background, diagnosis, disease history, family medical history, medical treatment, and response to treatment. It will not include your name, national ID number, or other information that could identify you.

How will the ARGO biobanking respect my privacy and confidentiality?

The ARGO biobanking values your contribution to research. The ARGO biobanking will take several steps to respect your privacy and keep your information confidential.

- OAUTHC will label your samples and information using a code number instead of your name. For example: Rotimi Musa Chukwudum becomes RMC/P418
- The ARGO biobanking will use this code to keep track of your samples and information and will not know your name, address, social security number, or other information that identifies you or your family.
- Only a few people at OAUTHC will be able to link your code to your name. OAUTHC needs to keep the link so it can contact the ARGO biobanking to update your medical information or to let them know if you decide to stop participating in the ARGO biobanking. The link between your code and your name will be stored on secure, password-protected computers at OAUTHC.
- The ARGO biobanking will ensure that your samples are stored in a locked freezer in a secure building.
- Information about you and your samples will be stored in a secure database.
- The ARGO biobanking is partially sponsored by the MSKCC and US National Institute of Health (NIH) grant; and must follow federal rules and laws to protect your privacy. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of the kinds of genes you have.

Who can use the samples and information in the ARGO biobanking?

The ARGO biobanking will give samples and related information only to researchers who need high-quality samples for medical research. The researchers may be from any country in the world. They could be doctors, scientists in universities, or researchers from companies that make new drugs or tests for diseases.

Researchers will need to get approval to use samples and information from the ARGO biobanking. A committee of experts and patient advocates will review each request to make sure the proposed research is ethical, useful, and based on good science.

After a project is approved, the ARGO biobanking will give researchers samples and related information from one or more people. You will not be contacted when your samples or information are sent to researchers.

How will my samples and information be used?

Researchers will use your samples and information to study cancer and other diseases. You should not donate to ARGO biobanking unless you are willing to allow your samples and

information to be used for all types of medical research. Scientists may use the samples and information to study how genes affect human health. Genes are instruction manuals for our bodies. Genes carry information about diseases and medical conditions that run in families, like diabetes or Alzheimer's disease. Some tissue samples may be treated so that they grow forever and can be studied for many years.

Researchers who receive samples and medical information from the ARGO biobanking are asked to share their research results with other scientists so that research moves forward as quickly as possible. The ARGO biobanking will store your samples and information safely and confidentially and send them out to researchers for approved studies. Since the ARGO biobanking does not know your name or contact information, it cannot give them to researchers. Many samples will be used right away but there is no limit on how long the ARGO biobanking may store your samples and information for research.

Will the researchers tell me if they learn something about my health?

Research using your samples and information is not likely to show anything about your disease. You will not receive the results of studies that use your samples and information. But you may visit the ARGO biobanking Web site *[insert the web address]* to learn about the kinds of research being done.

In the unlikely event that a researcher found something directly relevant to your medical care, OAUTHC would contact you. The ARGO biobanking researchers will never contact you directly.

Can anything bad happen if I say yes?

Blood draw risk

The risks of drawing additional blood include pain, bruising, or infection at the site of the needle stick. These are the same risks you face any time you have blood drawn in a doctor's office.

Privacy risks

Although the ARGO biobanking will take all measures to protect your private medical information, there is a very small risk that private information could be disclosed outside OAUTHC. The ARGO biobanking will not release your private medical information to employers or insurers.

Will donating to the ARGO biobanking help me in any way?

You will not personally benefit from donating samples and medical information to the ARGO biobanking. You should not donate to try to learn information about your own health. But your samples and medical information might help future patients.

Will there be a cost to donating to the ARGO biobanking?

No.

Will I be paid for donating to the ARGO biobanking?

No. You will not be paid to donate to the ARGO biobanking. Your samples and medical information will be used only for medical research and will not be sold for profit. It is possible

that research using your samples or information could lead to new tests, drugs, or other commercial products. The ARGO biobanking was developed to support medical research and will not reimburse donors whose samples were used to develop a commercial product.

Do I have to donate to the ARGO biobanking?

No. It is your choice to donate or not. No matter what you decide, your care at OAUTHC will not change. You will still be able to join other research studies in the future.

If I say yes now, can I change my mind later?

Yes. You have the right to stop participating in the ARGO biobanking. You may do so by sending a letter to:

Department of Surgery
Obafemi Awolowo University Teaching Hospitals Complex,
Ile-Ife
Osun.

OAUTHC will notify the ARGO biobanking of your request. The ARGO biobanking will stop using the samples and information you have left in the bank. This means your samples and information will no longer be available for future studies.

If you decide to leave the project, please note that:

- You cannot stop your samples and information from being used in studies that have already started.
- ARGO biobanking staff cannot get back samples or information already shared with other researchers. Results from studies that used your samples and information will not be destroyed.

Who can answer my questions?

- Professor Olusegun Isaac Alatise
- ARGO biobanking team

You can learn more about the ARGO biobanking in the fact sheet “Questions and Answers about the ARGO biobanking” which is available at Department of Surgery, OAUTHC.

Summary and consent statement

You have been asked to donate samples and related information to the ARGO biobanking. This form describes the ARGO biobanking and the risks and benefits of donating samples and information for research. Its purpose is to help you decide if you want to donate. You will only be able to donate to the ARGO biobanking if you sign this form.

Participant’s Consent Statement

By signing this form, I confirm that:

- I know enough about the ARGO biobanking and the risks and benefits involved to decide that I want to donate.
- I know that giving samples and related information to the ARGO biobanking is voluntary, and I agree to do so.
- I know that the ARGO biobanking cannot predict all future research that will use my samples and information. Research topics are likely to include cancer and other diseases.
- I know that future studies may include genetic research.

- I know that I can always ask to stop participating in the ARGO biobanking by writing to the address listed in this form.
- I have read this form and received a copy of “Questions and Answers about the ARGO biobanking.” I have had a chance to ask questions, and they have been answered to my satisfaction. I know who to contact for any questions I might have in the future.

(Date/Time) (Printed Name of Participant) (BSS Number)

(Signature of Participant)

(Date/Time) (Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)