

# **Consent Issues in Studies Involving the Collection of Biological Material Research**

## **Wake Forest University School of Medicine Institutional Review Board**

### **Background**

With increasing frequency, genomic research is being included in research protocols. Request for subjects to provide biological material including samples of blood, saliva, other tissue, or body fluids for further and often future analysis is becoming a common component of informed consent documents. The Wake Forest University School of Medicine Institutional Review Board has expressed concern regarding the rights of subjects participating in such research. Issues of specific concern include the ability to identify subjects through information linked to the biological material samples, whether subjects retain ownership of samples, the extent to which subjects are informed of potential future uses of the samples, the risks of genetic testing, the disclosure of test results to subjects, and whether patients are provided information on the meaning of any findings. This document and the example consent forms are meant to serve as a guide in developing and reviewing research involving the collection of biological material. Because of the ongoing discussions within the ethics and scientific communities regarding genetic research and research on biological samples these documents should not be viewed as addressing all issues that may arise when developing or reviewing research that involves collection of biological samples for research purposes.

### **Definitions**

Biological material: solid tissues, blood, saliva, and any other tissues or body fluids.

Genetic study: any research protocol involving or proposing in the future to involve the analysis of DNA, RNA, chromosomes, proteins, or certain metabolites which might act as or identify markers associated with a known or suspected predisposition to disease.

Anonymous samples: samples that are impossible under any circumstances for the individual source to be identified. If the researcher cannot identify the source of the tissue but some other individual or institution has this ability, the samples are not anonymous.

Identifiable or linked sample: any sample accompanied by codes or data that could allow the subject to be recontacted or that would allow access to identifiable private information about the subject, such as the subject's medical record or would allow the subject to be identified by pedigree location.

### **Protocol and Consent Form Requirements**

When proposing the collection, storage, and future use of samples for genetic research, the consent form should provide subjects with sufficient information to help them clearly understand the nature of the decision they are about to make. In addition to the points that must be covered in any research informed consent document, there are specific items that should be addressed in

consent for the collection of biological material. These items could be addressed as a separate consent document or as part of the consent form for other interventions associated with the proposed study.

### Purpose of the study

The purpose of the collection of the biological material as part of the study should be provided in simple terms. Potential subject should be told why they have been invited to participate.

### Intervention

Subjects should be informed what will be collected, how it will be collected and why it will be collected. This should include an explanation of the type of sample that will be collected and how they will be collected (i.e. blood draw, skin biopsy, buccal swab, etc.). The test procedures to be used in the analysis of the sample, explained in simple terms may also be appropriate information to provide. Whether the samples or data will be anonymous or identifiable should be included. For identifiable samples, subjects should understand what identifiable means and what information will be linked to the sample. If the samples or data are to be identifiable, describe how confidentiality will be maintained. That there is always a risk of breach of confidentiality should be discussed.

The disposition of the sample, including whether there are any other plans for the use of the sample should be explained. If there are plans for future use of the samples, subjects should be informed as explicitly as possible what future studies are anticipated, how future studies with the samples will be approved, and who will have access to the samples. Subjects should understand if they will be contacted in the future regarding their samples and if so under what circumstances.

### Disclosure of findings

Whether the information derived from the research may be disclosed to the subjects, their physician or family members should be discussed. It is not necessary to disclose the results of the analysis on the samples. If information is to not be disclosed, subjects should understand why. If information is to be disclosed, subjects should understand what information will be provided, under what conditions it may be disclosed, such as only if a serious treatable condition is detected, how notification will be provided, and who the information will be provided to. If provided information on test results subjects should know the implications of the findings, what if any follow up or treatment should be undertaken, and the limitation of the scientific knowledge regarding the implication of the findings. If the information is to be disclosed, the subjects should be offered the opportunity to decide, with the assistance of a genetic counselor or clinical geneticist, whether to receive their results. Subjects should have the option to decline disclosure of the information.

### Risks

Subjects should be informed that there are risks associated with disclosure or knowing the results of the genetic testing. A general description of the psychological, social, and/or economic risks that may result from the subject receiving information derived from the genetic research should be provided. Such risks include the potential of such information to effect future relationships with family members, effect employability and effect insurability. The risk of research findings being included in the subject's medical record, either intentionally or inadvertently should also be discussed. Subjects should understand that any disclosed results might become a part of the subjects' medical records if they tell their physician. Subjects should know that the study might determine that some members of their family are not genetic relatives and that other family members may learn private genetic information about the subject.

The risk of the sample collection procedures should be discussed. A statement of unforeseen risks is recommended.

### Benefits

Subjects should understand what if any benefits they can anticipate from participation.

### Alternatives

A statement of the alternatives to participation in the study should be provided. Subjects should be informed they do not have to participate in the study.

### Confidentiality

How the confidentiality of the samples, any linked information, and all study records will be protected should be discussed. Subjects should know who, such as the FDA and study sponsor, can review the study information and that they will not be identified in any publications.

### Commercial product disclaimer

Subjects should understand whether they have any claim to the profits that may result from the commercialization of their samples.

### Voluntary participation and right to withdraw

Subjects should be informed that participation is voluntary and that they have the right to withdraw from the research at any time prior to the completion of the analysis. Subjects should also understand they can have any linked or identifiable biological samples taken solely for research purposes destroyed upon request or to have identifiers removed. If the samples are anonymous this would not apply. Subjects should also understand that any stored sample can be depleted or destroyed without their consent.

### Whom to contact for more information

The name and phone number of the primary investigator should be provided to address any research related questions. The Chairman of the IRB and the IRB phone number should be provide to address questions regarding the rights of research subjects.

### **Subject Options in Participation**

The IRB feels that subjects should be given options regarding the collection, storage and use of biological material samples. Such options might include: refusing the use of their biological material in research; permitting only anonymous use of their biological material in research; permitting identified use of their biological materials for one particular study only, with no further contact permitted to ask for permission to do further studies; permitting identified use of their biological materials for one particular study only, with further contact permitted to ask for permission to do further studies; permitting identified use of their biological materials for any study relating to the condition for which the sample was originally collected with further contact allowed to see permission for other types of studies; permitting identified use of their biological material for any kind of future study.

Prepared: May 2000

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# **An example of a consent for the collection of biological material with identifying or linked information.**

## *Wake Forest University School of Medicine* Consent for Participation as a Subject in a Research Study

**[Study Title]**  
BG##-####

[Name of primary investigator], Principal Investigator

You are being asked to participate in a research study being conducted by [name of the primary investigator] [and others *add if appropriate*] at the Wake Forest University School of Medicine. You are being invited to take part in this research study because you [have <name of a specific disease>, are currently participating in a study of <name of the specific study>, or other reason the subject has been identified to participate]. The purpose of this research study is to [as specifically as possible, what this study hopes to demonstrate by the collection and analysis of the requested biological material].

### Purpose of the study

*If applicable the scientific significance of the study and further elaboration of the specific outcome measures should be provided. A brief, lay summary of the analysis is recommended.*

### What participating in the study involves

#### **At a minimum the following should be provided:**

*You are being ask to provide [amount] of [biological material]. This will be collected by [a specific description of the method of collection of the biological material].* Knowing background information about you will help [name of the primary investigator] better understand how his findings relate to [specific disease]. As part of this research study he/she is also asking permission to gather information from your health record on your age, sex, ethnic background, medical history and medical care.

If you agree, the [biological material] will be kept and may be used in future research to learn more about [specific disease] and other diseases. The biological material will be stored by [name of the individual or entity responsible for the biological material storage] at [site]. The biological material will be given only to researchers approved by [state who or what entity specifically will provide approval]. An Institutional Review Board (IRB) must also approve any research study using your biological material. *[If the biological material is only being used for the immediate study and will not be stored for future analysis the following may be included: Once <name of the primary investigator> has finished his/her laboratory tests your sample will be discarded. If this is used, other parts of this example consent such as the provisions for future use are not necessary].*

*Additional information on the number of subjects involved, additional procedures, duration of study involvement and other information should be provided if necessary.*

The research that may be done with your biological material is not designed to help you specifically. There is no personal benefit to you from taking part in this research study. It might help people who have [specific disease] or other diseases in the future, but it is not known if this will happen. The results of the research done with your biological material will not be given to you or your doctor. These results will not be put in your health records. The research using your biological material will not affect your care.

Sometimes biological material is used for genetic research that may provide information about diseases that are passed on in families. Even if your biological material is used for this kind of research, the results will not be told to you or members of your family, and will not be put in your health records.

The choice to let your biological material be kept for future research is up to you. [No matter what you decide to do, it will not affect your care in this study. *Included if biological material collection is a subpart of a larger study and the patient is not required to provide biological material in order to participate.*] If you decide now that your biological material can be kept for research, you can change your mind at any time. Just contact your study doctor and let him or her know that you do not want your biological material used and it will no longer be used for research. Otherwise, the biological material may be kept until it is used up or until it is destroyed.

In the future, people who do research may need to know more about your health. While [name of the primary investigator or the individual who will provide approval for additional research on the sample] may give them reports about your health, they will not be given your name, address, phone number or any other information about who you are unless you agree to being contacted in the future.

### Benefits

Participating in this study is not expected to benefit you directly. You may have some personal satisfaction knowing that you are contributing to the scientific knowledge doctors have about [specific disease]. The possible benefits of research from your biological material include learning more about what causes [specific disease] and other diseases, how to detect them, how to prevent them and how to treat them.

### **Risk**

*Include the risks associated with obtaining the biological material.*

The greatest risk to you is the release of information from your health records. [Name of the primary investigator] and his/her assistants will protect your records so that your name, address, phone number and information in your health record will be kept private. The chance that this

information will accidentally be found out by someone else is very small. There will be no cost to you for the collection and storage of your biological material.

*Include other risks as appropriate.*

### Alternatives

You do not have to participate in this research study. Choosing not to participate in this study will in no way effect the care you will receive.

### Confidentiality

Every effort will be taken to protect your confidentiality. Your confidentiality will be protected to the extent allowable by law. Study records may be reviewed by representatives of the Food and Drug Administration (FDA), National Institutes of Health, or the Wake Forest University School of Medicine Institutional Review Board. Your [biological material] will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. You will not be able to share in any profits that may occur as a result of this research. The results of this study may be published, but you will not be identified in any publication.

### Liability

*Either the stand WFUSM liability statement or a sponsor liability statement should be included as appropriate.*

[Should you (your relative) experience a physical injury or illness as a direct result of participation in this study, reasonable necessary medical services will be offered at the usual charges. To the extent of available research coverage maintained by the Wake Forest University School of Medicine, the reasonable cost of these necessary medical services will be paid up to \$25,000. The insurance policy for this coverage is provided by the St. Paul Insurance company, and provides a maximum of \$25,000 for each claim and is limited to a total of \$250,000 for all claims in any one-year. The Wake Forest University School of Medicine and the Wake Forest University Baptist Medical Center do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk Management at 336-716-3467.]

### Voluntary participation and the right to withdraw

Participation in this research study is voluntary. You may withdraw at any time without affecting your treatment. You can ask to have your [biological material] or information removed from the study at any time.

### Whom to contact for more information

[Name of the primary investigator] should be contacted at [primary investigator's contact phone number] for any questions or concerns about the research study or in the event of a research-related injury. The Chairman of the Wake Forest University School of Medicine Institutional Review Board may be contacted at 336-716-4542 for questions about the rights of research subjects.

**Please read each of the following sentences and think about your choices. After reading each sentence, circle YES or NO. If you have questions, please talk to your doctor or nurse.**

1. I agree that my [specify the biological material to be collected] and health records may be kept for use in research on [specific disease].

YES                      NO

2. I agree that my [specify the biological material to be collected] and health records may also be kept for use in future research to learn about, detect, prevent, treat or cure other health problems.

YES                      NO

3. I agree that [name of the primary investigator] or someone he or she chooses may contact me in the future to ask about taking part in more research.

YES                      NO

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Signature of Research Subject

Date

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Printed name or Signature of  
Person Administering Consent

Date

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Witness

Date

# **An example of a consent for the collection of biological material without identifying or linked information.**

## *Wake Forest University School of Medicine* Consent for Participation as a Subject in a Research Study

**[Study Title]**  
BG##-####

[Name of primary investigator], Principal Investigator

You are being asked to participate in a research study being conducted by [name of the primary investigator] [and others *add if appropriate*] at the Wake Forest University School of Medicine. You are being invited to take part in this research study because you [have <name of a specific disease>, are currently participating in a study of <name of the specific study>, or other reason the subject has been identified to participate]. The purpose of this research study is to [as specifically as possible, what this study hopes to demonstrate by the collection and analysis of the requested biological material].

### Purpose of the study

*If applicable the scientific significance of the study and further elaboration of the specific outcome measures should be provided. A brief, lay summary of the analysis is recommended.*

### What participating in the study involves

#### **At a minimum the following should be provided:**

You are being ask to provide [amount] of [biological material]. This will be collected by [a specific description of the method of collection of the biological material]. Knowing background information about you will help [name of the primary investigator] better understand how his findings relate to [specific disease]. As part of this research study he/she is also asking permission to gather information from your health record on your age, sex, ethnic background, medical history and medical care. No information such as your name, address, phone number or health record that specifically identifies you or that the [biological material] came from you number will be kept.

If you agree, the [biological material] will be kept and may be used in future research to learn more about [specific disease] and other diseases. The biological material will be stored by [name of the individual or entity responsible for the biological material storage] at [site]. The biological material will be given only to researchers approved by [state who or what entity specifically will provide approval]. An Institutional Review Board (IRB) must also approve any research study using your biological material. Once the sample and information has been obtained it will not be able to be identified as belonging to you.

*Additional information on the number of subjects involved, additional procedures, duration of study involvement and other information should be provided if necessary.*

### Benefits

The research that may be done with your biological material is not designed to help you specifically. There is no personal benefit to you from taking part in this research study. It might help people who have [specific disease] or other diseases in the future, but it is not known if this will happen.

The choice to let your biological material be kept for future research is up to you. [No matter what you decide to do, it will not affect your care in this study. *Included if biological material collection is a subpart of a larger study and the patient is not required to provide biological material in order to participate.*]

### **Risk**

*Include the risks associated with obtaining the biological material.*

The information gained from the study of your [biological material] cannot be linked to you since no identifying information will be kept. There will be no cost to you for the collection and storage of your [biological material].

*Include other risks as appropriate.*

### Alternatives

You do not have to participate in this research study. Choosing not to participate in this study will in no way effect the care you will receive.

### Confidentiality

Every effort will be taken to protect your confidentiality. Remember that your sample cannot be identified, so you would never be linked to it. Your confidentiality will be protected to the extent allowable by law. Study records may be reviewed by representatives of the Food and Drug Administration (FDA), National Institute of Health, or the Wake Forest University School of Medicine Institutional Review Board. Your [biological material] will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. You will not be able to share in any profits that may occur as a result of this research. The results of this study may be published, but you will not be identified in any publication.

### Liability

*Either the stand WFUSM liability statement or a sponsor liability statement should be included as appropriate.*

[Should you (your relative) experience a physical injury or illness as a direct result of participation in this study, reasonable necessary medical services will be offered at the usual charges. To the extent of available research coverage maintained by the Wake Forest University School of Medicine, the reasonable cost of these necessary medical services will be paid up to \$25,000. The insurance policy for this coverage is provided by the St. Paul Insurance company, and provides a maximum of \$25,000 for each claim and is limited to a total of \$250,000 for all claims in any one-year. The Wake Forest University School of Medicine and the Wake Forest University Baptist Medical Center do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk Management at 336-716-3467.]

Voluntary participation and the right to withdraw

Participation in this research study is voluntary. You may withdraw at any time without affecting your treatment. However, since your sample will not be able to be identified, you will not be able to withdraw it once it has been donated.

Whom to contact for more information

[Name of the primary investigator] should be contacted at [primary investigator's contact phone number] for any questions or concerns about the research study or in the event of a research-related injury. The Chairman of the Wake Forest University School of Medicine Institutional Review Board may be contacted at 336-716-4543 for questions about the rights of research subjects.

I agree that my [specify the biological material to be collected] may be kept for use in research if my name and identifying information is removed from it and no one can identify it as mine.

YES

NO

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Signature of Research Subject Date

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Printed name or Signature of Date  
Person Administering Consent

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Witness Date