

**THE ROTHBERG INSTITUTE**  
**530 Whitfield Street**  
**Guilford, CT 06437**  
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### **“Methuselah Project”**

Why did Methuselah live to be 900 years old? We are going to try to answer this age-old question.

#### **Purpose of the Project**

We would like to invite you to participate in a research project called the Methuselah Project, which is sponsored by The Rothberg Institute (TRI), a non-profit research organization in Guilford, CT. The purpose of the Methuselah Project is to discover the genetic basis for good health and longevity in humans. We hope that this will lead to a better understanding of the genes that offer protective properties for a long, healthy life.

Body tissues are made up of cells. Cells contain DNA, which is your unique genetic material that carries the instructions for your body’s development and function. Many diseases can result from changes in a person’s genetic material that causes cells to not work properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know what genetic changes affect overall health and longevity.

We will compare the DNA from people with certain diseases to the DNA from people, who have lived long, healthy lives, to uncover the differences. By combining this information with information from your medical records and your life choices, it may be possible to identify the genetic changes that are associated with your health and longevity as well as genes that may cause disease, which will provide invaluable information about methods to help others live long and healthy lives as well.

#### **Description of the Research**

##### **Collection of Samples and Medical Information**

- We will collect a saliva sample (2 ml) from you by asking you to spit into a collection vial after rinsing your mouth with water.
- We will collect a medical history form from you, including your age, ethnic background, disease history, medical treatments, and response to treatments.
- We also will ask you questions about your social history and how you lead your life.

##### **Coding of Tissue Samples and Medical Information**

- Your saliva sample and medical information will be labeled with a code.
- Only the lead researcher currently, Dr. Sarah E.W. Finch at (TRI) will have the information that matches the code to your actual identifying information, such as your name, address, or phone number. Dr. Finch will keep the information that matches the code to your identifying information in a locked database.

##### **Storage and Release of Samples and Medical Information**

- Your coded saliva samples will be sent to a TRI laboratory for detailed analysis. Remaining portions of your samples will be stored for an unlimited period of follow-up use in the Methuselah project.
- Information from analyses of your coded samples and your coded medical information will be put into controlled-access databases along with information from the other research participants.

### **Recontact**

- In the future, we may want to use your samples for other future research, obtain additional samples, or obtain follow-up information about your health or medical care. Should this be needed, a person from The Rothberg Institute will contact you to ask whether you would be interested in participating in this additional research.

### **Financial Compensation/Costs**

You will not be paid to participate in this project, nor will you incur any expenses from your participation in this project. Your saliva samples and your medical information will be used only for research purposes and will not be sold. It is possible that some of the research conducted using your samples or information eventually will lead to the development of new diagnostic tests, new drugs or other commercial products. Should this occur, you will not receive any part of the profits generated from such products.

### **Potential Benefits of Participating in the Project**

You may not personally benefit from this research. Your participation may help researchers and health professionals around the world to better understand the causes of disease so that they can find better ways to prevent, detect, treat, and cure illnesses. We hope that you will feel good knowing that you may be helping future patients.

### **Potential Risks of Participating in the Project**

#### **Physical Risks**

- If a saliva sample is not taken from you, there are no physical risks associated with this project.
- If a saliva sample is taken from you, possible side effects from collection are minimal and may include a temporary feeling of a dry mouth.

#### **Psychological or Social Risks Associated with Loss of Privacy**

- Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measure that we will use, we cannot guarantee that your identity will never become known.
- While the controlled-access databases developed for this project will NOT contain information that is traditionally used to identify you, such as your name, address, or telephone number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law

enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by 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).

- There also may be other privacy risks that we have not foreseen.
- While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. There are some state laws that protect against genetic discrimination by employers or insurance companies, but there is no federal law yet that prohibits such discrimination. We believe that the benefits of learning more about diseases outweigh these potential risks.

### **Confidentiality**

We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. We will carefully follow the coding, storage, and release plan explained in the *Description of the Research* section on pages 1-2 of this document.

### **Project Results**

In general, results from this research project will not be given back to you or put into your medical records. In some situations, the results might be important to your health or medical care. If this occurs, we will contact you to see if you want to learn more. If research from this project is published in professional journals, no identifying information, such as your name, address, or telephone number, included in the publications.

### **Alternatives to Participating in the Project**

The alternative option is not to participate.

### **Voluntary Participation**

The choice to participate in this research by donating your tissues and medical information is completely up to you.

### **Withdrawal from the Project**

Once data are generated from the samples you provided, and those data are placed in the database as described elsewhere in this consent, you will not be able to withdraw the data, only the samples. If you would like to withdraw from this project you can contact Dr. Sarah E.W. Finch (203-458-7100 or [sfinch@childhoodiseases.org](mailto:sfinch@childhoodiseases.org)) at TRI and any remaining saliva samples will be destroyed. In addition, the link between you and your genetic and medical information will also be destroyed.

### **Contact Information**

If you have any questions about the project or your participation, please contact Dr. Sarah E.W. Finch at TRI via phone at 203-458-7100 or email at [sfinch@childhoodiseases.org](mailto:sfinch@childhoodiseases.org). If you have any questions about your rights as a research volunteer, please contact Ellen Kelso of Goodwyn Institutional Review Board, Ltd. (Goodwyn IRB) at 877-793-8900 (toll free).

**Agreeing to Participate in the Project**

**To participate in this research, you must agree to ALL of the following statements:**

- I voluntarily agree to donate a saliva sample to be used for experiments as part of the Methuselah project at TRI.
- I agree to release information from my medical records for the Methuselah project.
- I agree to have my coded genetic information and coded medical information placed in controlled-access databases, as described in the *Storage and Release of Samples and Medical Information* section on page 2 of this document.
- I have been told that my coded genetic information and coded medical information in the databases will be used in this project.
- I have been told that there is a risk that someone in the future might be able to use information in these databases to identify me or possibly my blood relative(s).
- I agree to be recontacted in the future to see if I am willing to provide additional samples or follow-up information about my health or medical care.

Please sign your name here if you agree with the above six statements.

Your signature: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Doctor/Nurse/Other Witness \_\_\_\_\_