

Procedures/Risks: Genetic_testing

Biomarkers

Purpose: The purpose of [the additional tests in] this research study is to look at genes (DNA) in blood. DNA (deoxyribonucleic acid) carries hereditary (inherited) information such as eye and hair color. Genes are pieces of DNA. Differences in genes and proteins can affect the way a disease develops, the way drugs act on diseased cells, or the way drugs are used by your body. These genetic tests may:

- Show how subjects respond differently to the study drug
- Help develop other treatments for people whose disease does not respond to study drug
- Help understand causes of the disease and how the disease changes over time

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If you decide to participate in this research study, a small sample of your blood will be drawn. DNA (genetic material) will then be removed from the cells in your blood. Your DNA sample will be stored in a DNA Repository. Samples in the DNA Repository will be used in research to study the links between subject's DNA (genetic material), the illnesses they get, and the way they respond to medicines. Information from this research study will be from all of the subjects who take part in the study as a group, not just from your sample.

The information collected by studying your DNA sample, along with many other samples, will help researchers to:

- Better understand why certain subjects are more likely to respond to medicines or study drugs
- Better understand how and why [name of disease] acts differently in different subjects
- Develop new treatments for [name of disease]
- Find reasons why certain subjects are more likely to develop side effects to the study drug
- Develop better ways for preventing [name of disease] or related diseases or treating diseases earlier.
- Develop diagnostic tests (tests to detect or understand disease) related to the study drug, [name of disease].

It may take many years to complete this DNA research, so your DNA sample will be stored in the DNA Repository indefinitely or until it is all used up. Your sample will be used by

researchers and other researchers partnering for future research on the study drug, side effects, [name of disease], and related diseases.

Procedure: The identification of key biomarkers should improve the understanding of disease processes and improve clinical decision making. Such biomarkers may serve to improve diagnosis, help predict therapeutic response, and better focus the selection of treatments. Biomarkers that reflect the how a new therapy works or predict treatment response offer numerous advantages. [including: a) more directed testing of new treatment in economically feasible smaller trials, b) early change in therapy and hence saving patients further accumulation of disability and saving cost, c) rational development and testing of therapeutics. Specifically, genomic and proteomic approaches are capable of identifying broad patterns that cannot be appreciated when focusing on a small number of gene or proteins.]

A “biomarker” is something that can be measured (for example cholesterol level is a biomarker for heart health) to better understand disease and treatments. The purpose of this study is to identify potential biomarkers for [name condition/disease]. For this study, comparison subjects are needed to ensure that the researchers are looking at “real” biomarkers that actually measure the disease progression in individuals [with disease/condition]. There is no drug treatment involved in this study, but information from this study may help prepare for future drug trials.

In this study, biomarkers will be looked for in blood [and urine] samples. The biomarkers will come from protein and metabolites – molecules that can be commonly found in these body fluids.

[What do these metabolites do in your body?] Every cell in your body contains a set of genes. Genes are made up of deoxyribonucleic acid (DNA). Genes are inherited and carry instructions for the body to direct growth and development (e.g., eye and hair color). Ribonucleic acid (RNA) carries information from your genes and tells your body how to make proteins. Proteins control how the body works. Differences in genes and proteins can affect the way a disease develops, the way drugs act on disease cells, or the way drugs are used by the body. Metabolites are small substances in the body or molecules that are made by cells. Metabolites, proteins and RNA are all gene products. In this study, gene products are being investigated as potential biomarkers which are signals if the disease is present or what affect it might have on the body before a person is aware of any symptoms.

Genetic testing (general):

Introduction: DNA is the genetic material that determines such things as hair color, eye color or other more complex traits. The DNA samples for this study will be used in an attempt to find genes that may cause an increased risk for a person to develop.... A sample of your DNA will also be sent to ...a DNA Repository where it will be stored for possible use by other scientists in future studies [related to]

Every cell in you [and your child's body] contains a set of genes. Genes are made up of pieces of deoxyribonucleic acid, or DNA for short. Genes are inherited and carry instructions for the body to direct growth and development. For example, some genes control eye and hair color.

Ribonucleic acid, or RNA for short, carries information from your genes and tells your body how to make proteins. Proteins control how the body works. Differences in genes and proteins can affect the way a disease develops, the way drugs act on disease cells, or the way drugs are used by the body. Metabolites are small substances in the body or molecules that are made by cells. Metabolites, proteins and RNA are all gene products. In this study, gene products are being studied to see if they are associated with someone being at risk for [name disease/condition].

This protocol includes an optional and completely separate informed consent form that allows for the collection and storage of DNA and messenger RNA (mRNA) isolated from blood samples as part of this study. Further details are found in the separate informed consent form. **You may decide not to participate in the storage of blood samples research project and still be able to take part in the main [clinical] research trial.**

I wish to participate in the optional study to collect and store my samples for future testing

I do NOT wish to participate in the optional study to collect and store my samples for future testing

Procedure: Blood will be collected in order to obtain DNA (deoxyribonucleic acid). DNA is the genetic material that determines such things as hair color, eye color or other traits. The DNA samples for this study will be used in an attempt to find genes that may cause [increase the risk for] a person to develop...[or be at risk for...]

The researchers will use frozen samples of your white blood cells which are a source of DNA. Your white blood cells will be used to create a cell line, which is living tissue, which will be studied for its DNA and used for future genetic studies.

Neither you nor your doctor will receive the results of your DNA testing. If you decide that you want to pursue genetic testing in the future based on results reported for this study [but not your individual results as they will not be reported to you], it will be at your expense [and you will be referred to the genetic testing and counseling services in the OSU Medical Center]. [It may be a long time (months or years) before results from this study are available. If you wish to be notified about the results of this study as they become available, you should make sure that the researchers are notified of any address changes so they can mail the study results to you.]

Risk: Despite all efforts to keep this information confidential, there remains the possibility that there may be social, economic (e.g., insurance, employment), psychological (related to mind or emotions) and other unforeseen risks associated with collecting DNA. Testing could identify

additional genetic abnormalities (something not normal) not already known. This information could have psychological or other consequences [including discrimination and/or ineligibility for insurance] to you if you were to know such results. This also may include information about your status with regard to disease severity.

Since you will not be receiving your personal results from this study, most of the usual psychological risks associated with genetic testing do not apply to you. If you decide, at your expense, to undergo clinical genetic testing in the future based on discoveries made as part of this study, the applicable risks of receiving genetic test results will be discussed with you at that time.

The results of the testing used for this study will be kept confidential to the fullest extent possible. Although the specimens will be stored with a code number, if this confidentiality were broken, a researcher could learn something about you that you would not want them to know (i.e., name, address, or other personal information you do not want them to have).

Because changes in genes or proteins may affect the outcome of a disease, or may affect or influence one's health, information as to any changes in your genes [or proteins] may be of interest to employers or insurance companies in determining future health risks, and could be used in a discriminatory fashion. [However, the researchers do not expect results from this study to provide information that could affect you in any way or cause you any discrimination]. In order to protect your confidentiality as a participant in this study, you (and the data that we collect on you) will be assigned a code number. Research samples will be labeled only with this code number. All of your demographic information will be kept in locked files, and/or on a password-protected computer database. The only individuals that will have access to the data will be the research personnel on this project. These precautions should significantly reduce or eliminate the risk of your data being released to unauthorized parties. You may request withdrawal of your samples from the study at any time, at which time the samples will be destroyed.

Confidentiality: Samples of your DNA will be sent to [another laboratory]... for analysis for this study,[and to a... DNA Repository], will not contain any information could e directly identify you. Samples will be coded with a number which could only be linked to your name by the Principal Investigator for the study, or his/her designee.

Commercial Products: The Principal Investigator (PI) for this study will be responsible for deciding how your DNA specimen and the information derived from it will be used. Successful research using the specimen, DNA, or other derivatives could result in a commercial or therapeutic project with significant [monetary] value, such as a product for the medical treatment of ... or for diagnosing a mutation responsible for the disease. You will not share in any financial benefits of these uses. If you later decide that you do not want the specimen already collected from you to be used in future research, you may tell the researchers who will use their best efforts to stop any further [use of your DNA] studies. However, in some cases, it may be impossible to locate and stop such future research once the materials already have been shared with other investigators.

By consenting for this study, you are giving your DNA sample to the researchers conducting this study. They will own the results of this research and of any use or development of the research records (including your sample) that are in keeping with this consent. In the [unlikely] event that any discoveries which could make money are made, using your biological material, you will not receive any personal financial benefit. If there are any patent or commercial uses of your DNA data, identifiers that would link it to you will be destroyed (for example, your name, address, phone number, and social security number).

Disclosure of results: The tests will be performed in a research laboratory. Results from a research laboratory may not always be exact. They cannot be used to make a diagnosis about your health. Also, research laboratories cannot give advice on health or health risks. For these reasons, the results of your DNA tests will not normally be given to you or your study doctor (or his/her staff).

[However, you have the right to ask your study doctor *in writing* for your results. The Sponsor will give your results to your study doctor to give to you. The Sponsor has no control over the privacy of your results after they are sent to your study doctor to give to you. The Sponsor cannot give an interpretation of the test results nor provide genetic counseling. If you ask for your test results, it would be up to your study doctor to decide what to do next. For example, you may be sent to have the tests performed by a specialized laboratory. You may also be sent for genetic counseling. The Sponsor would not pay for any such further procedures. Even if you or your study doctor asks, the Sponsor will not do any additional DNA tests.]