

DFCI IRB RECOMMENDED CONSENT LANGUAGE RELATING TO RETURN OF RESEARCH RESULTS

This Information Sheet provides investigators with sample language addressing the return of research results that can be incorporated into a research consent form.

A. Investigators Who Envision the Possibility of Offering Individual Results:

Return of Individual Research Test Results

Will the Results of the Tests Done During this Study be Returned to Me?

It is possible that the genetic tests done as part of this research study may reveal important information about your health that was previously unknown. Therefore, we are asking you to consider whether or not you would like to be informed about some of the results of these genetic tests.

Results from the genetic tests may relate to cancer or to other diseases and medical conditions. The tests may or may not provide information that can be used to improve your health or prevent future health problems. Additionally, some of the tests may have implications for the health of your family members.

As examples, the test results might reveal changes in your genes (called “alterations”), which could indicate: *[Include the following examples, as applicable, or provide alternative examples using lay language]*

- That your cancer may be more or less likely to respond to specific therapies.
- That you may have a better or worse outlook (prognosis) for your type of cancer.
- That you may have an increased risk of developing certain cancers such as colon, lung, or breast cancer. If you are found to have such an alteration, some of your family members may also share it. If so, they may also have an increased risk of developing certain cancers.
- That you may have a higher than average risk of developing heart disease. In this example, there might be proven interventions or treatments to help you prevent heart disease (such as changes to your diet or taking medication).
- That you may have a higher than average risk of Alzheimer’s disease. In this example, there are no proven interventions or treatments to help you prevent Alzheimer’s disease.
- That you may carry an alteration for a condition that you might pass on to your child. This is possible even if you do not have the condition yourself. For example, tests might show that you carry a gene alteration for cystic fibrosis that could be passed on to your child.

How Would Test Results be Returned to Me?

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If you choose to be informed about some of the results of genetic tests done during this study, or if we need to inform you about them as described below, then we will *[Describe how results would be returned. E.g., “provide them to your primary doctor who will discuss them with you” or “provide them to you directly” (if given to participants directly, then specify whether this will be done in writing, over the phone, in person, etc.) Note that, in general, the IRB requires that results be returned to the participant’s physician]*.

[When applicable, include the following:] We will offer genetic counseling, if you wish, to help you understand the potential implications of this kind of genetic information for you and for your family members.

At the end of this form, we will also ask you to provide the name and contact information for an individual, such as a friend or family member, with whom you would like information about your genetic tests to be shared in case you are not able to receive it yourself.

What are the Risks of Receiving Test Results?

There may be risks of receiving your test results. Learning that you or your family members have an increased risk of disease or poor disease outlook (prognosis) may cause you emotional and psychological distress. Family members could also be upset to learn that they may be at risk for cancer or other diseases and that they learned this through your participation in this study. If you find the information you receive upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

Another risk is that your test results could lead to genetic discrimination. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

The tests done during this study will not detect every possible gene alteration. You may still have an alteration that is important to your health but which the test results do not show. Therefore, one risk is that you may be falsely reassured about your health if we do not report specific findings to you. There is also a possibility that the test results may be inaccurate. We try to reduce this possibility by only reporting results from tests performed in a laboratory that is certified by the government for consistency and accuracy (called a CLIA-certified laboratory).

Additionally, there may be risks from receiving the results that are not known at this time.

Participant Options

Please think about whether or not you would like to be informed of the results of your genetic tests. If you decide not to receive the test results, you can still participate in the research study and you will not be penalized or lose any benefits to which you are otherwise entitled.

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We will honor your choices as best we can, and in general, the results from genetic tests will only be given to you if you have given us permission to do so. However, if the tests reveal information about a gene alteration that can significantly compromise your health in the near future, and if we have proven ways to treat or reduce that health risk, then we may tell you about the test results in order to give you the best medical care possible. If this situation arises, the study investigators may tell you information about this alteration even if you have not previously given us your permission to do so.

You may change your response(s) to the question(s) below at any time. If you would like to change your response(s), then please contact your research doctor.

*Investigators may ask participants a **single global question** regarding return of test results. For example:*

Please indicate whether or not you want to be informed of the results of your genetic tests which could be important for your health.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

*Alternately, investigators may identify a **set of relevant categories** of findings and ask participants to indicate their preferences within each category. For example (**include each of the following only if applicable**):*

1. Please indicate whether or not you want to be informed of results of your genetic tests *related to cancer* that...

a. Might tell you that you have a **better** than average outlook (prognosis) for your type of cancer.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

b. Might tell you that you have a **worse** than average outlook (prognosis) for your type of cancer.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

c. Might identify you (and possibly your family members) as having an increased risk of developing certain cancers.

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Yes _____ Initials _____ Date

No _____ Initials _____ Date

d . Might tell you about how your body handles chemotherapy or other cancer medications.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

e . Might qualify you for a clinical study of an investigational drug.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

2. Please indicate whether or not you want to be informed of results of your genetic tests *unrelated to cancer* that...

a . Might identify you (and possibly your family members) as having a condition, or having an increased risk of developing a condition, *other than cancer*, that **can** be treated or prevented.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

b . Might identify you (and possibly your family members) as having a condition, or having an increased risk of developing a condition, *other than cancer*, that **cannot** be treated or prevented.

Yes _____ Initials _____ Date

No _____ Initials _____ Date

c . Might identify you as carrying a gene alteration for a non-cancer-related condition that you might pass on to a child (even if you do not have the condition yourself).

Yes _____ Initials _____ Date

No _____ Initials _____ Date

d . Might tell you about how your body handles non-cancer-related medications.

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Yes _____ Initials _____ Date

No _____ Initials _____ Date

We would like to ask you to provide the name and contact information for an individual, such as a friend or family member, with whom you would like information about your genetic tests to be shared in case you are not able to receive it yourself. This person would be given the information described above which you have indicated that you would like to receive.

Name: _____

Relationship: _____

Phone Number: _____

Other Contact Information (such as email address or mailing address, if available):

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B. Investigators Who Do Not Envision the Possibility of Offering Individual Results:

Return of Individual Research Test Results

It is possible that the genetic tests done as part of this research study may reveal information about your health that was previously unknown. There are no plans to provide this information to you or your doctor. However, if the tests reveal information about a gene alteration that can significantly compromise your health in the near future, and if we have proven ways to treat or reduce that health risk, then we may tell you and your doctor about the test results in order to give you the best medical care possible. If this situation arises, the study investigators may tell you and your doctor information about this alteration even if you have not previously given us your permission to do so.

We would like to ask you to provide the name and contact information for an individual, such as a friend or family member, with whom you would like the information described above to be shared in case you are not able to receive it yourself.

Name: _____

Relationship: _____

Phone Number: _____

Other Contact Information (such as email address or mailing address, if available):
