

Comprehensive Genome Profiling Test Informed Consent Form (model document)

1. Purpose of comprehensive genome profiling test

The purpose of comprehensive genome profiling test is to characterize your cancer by comprehensively examining the characteristics of your cancer cells by genomic analysis and determining the status of many cancer-related genes. The expert team evaluates appropriate drugs/treatments and clinical trials in which you may be able to participate, and notifies you of the results.

2. Advantages and limitations of comprehensive genome profiling test

Comprehensive genome profiling test may provide useful information for your future treatment.

Research on cancer-related genes has been advancing rapidly, and the interpretation of the test results is complicating. Experts evaluate the results with the latest and reliable information. However, possibility remains that no useful information for your cancer treatment is provided. [To be specified after discussion between the company providing the test and the Hospital for Cancer Genomic Medicine] Only about 10% to 20% of patients who take the test is assumed to receive treatment based on the test results. In other words, the test may not result in treatment in 80% to 90% of patients who take the test.

Genomic analysis may fail depending on the quality and/or quantity of the sample used for the analysis. Even if an appropriate drug for you is found, it may not be selected as your treatment when:

- the drug is not approved for marketing in Japan;
- the drug is not indicated for your cancer; and
- the drug is used only in clinical trials for which you are not eligible, etc.

3. Test method [to be specified at each Hospital for Cancer Genomic Medicine. (1) sample used, (2) sample collection method, (3) sample analysis institution (please specify whether it is in Japan or overseas) and (4) information sharing among Hospitals for Cancer Genomic Medicine should at least be included. The description should be in about 6 to 7 lines at the longest.]

[Example] Your cancer cells and normal cells are needed for comprehensive genome profiling test. When the cells collected and stored from the past clinical practice are available, these cells are used. When new cell collection is considered necessary, you need to have biopsy

or blood collection. “○○○○○○○○○○” of ○○ is used for the test. Your sample and clinical information will be sent to the analysis institution of ○○ (in the United States). Your post-analysis data and clinical information will be shared among Hospitals for Cancer Genomic Medicine to appropriately interpret the results and decide your treatment policy through discussion with experts. They may also be used as reference for educating medical professionals in cancer and for caring other patients.

4. Possibility that cancer-related gene information (hereditary tumor) is revealed

Various genes are thoroughly examined in this test to characterize your cancer cells. In this process, [to be specified after discussion between the company providing the test and the Hospital for Cancer Genomic Medicine] there is a few percent possibility that the association of your cancer with your genetic predisposition (hereditary tumor) is revealed, apart from useful information for your cancer treatment. We would like to inform you of any beneficial result for your and your relatives' health management, such as the presence of prevention and treatment, but we respect your wishes. If you do not wish to know such results at this time, please let us know. If you wish to obtain more detailed information, genetic counseling and genetic testing are required, for which additional costs may be incurred.

[Please add the following at institutions where only tumor tissues are used for the test] However, please be advised that information about your genetic predisposition revealed by this test solely shows the possibility and may not be a definitive diagnosis. If you wish to obtain more detailed information, additional costs may be incurred for genetic counseling and genetic testing.

5. Explanation of comprehensive genome profiling test results

Results regarding your treatment will be delivered by your doctor [to be specified at each Hospital for Cancer Genomic Medicine] in about ○○ days. Results regarding the association with your genetic predisposition may be delivered later than that. We recommend that your family also hear the results in case that your health condition suddenly changes or any result related to your family is found.

6. Costs of comprehensive genome profiling test [to be specified based on the cost burden for the test]

Comprehensive genome profiling test is performed as ○○○.

If you wish to have genetic counseling and genetic testing to obtain more detailed information about genetic predisposition to hereditary tumors, additional costs may be incurred. If your

relative becomes interested in the genetic predisposition, genetic counseling and genetic testing are required, for which additional costs may be incurred.

7. Handling of data and information used in comprehensive genome profiling test [please make sure to include the part in blue]

If you provide consent, data and information obtained from comprehensive genome profiling test will be used for the purposes shown below. We provide information and genome data with your name coded and made unidentifiable.

(1) We provide your genome data, clinical information, medical chart number and health insurance number (*1) to Center for Cancer Genomics and Advanced Therapeutics (C-CAT) (Chuo-ku, Tokyo) established by Ministry of Health, Labour and Welfare, Japan.

The testing company will send your genome data to C-CAT, and we will send the other pieces of information to C-CAT [Change to “We will send the information to C-CAT” for some profiling tests]. C-CAT creates a large database of genome and clinical information of Japanese cancer patients as an information infrastructure necessary for future cancer genomic medicine. There is a possibility that useful information for your treatment could be added if you provide your data.

(2) Part of data accumulated by C-CAT may be provided to academic institutions and companies (including those overseas [*2]) for the purpose of academic research and pharmaceutical development. Before the data provision, C-CAT will conduct a strict review with third parties under applicable laws, regulations and guidelines, depending on the purpose of using the data. C-CAT will also update clinical information as needed to keep the database accurate and may verify the information with various medical/nursing care databases in the future including the cancer registry. If you withdraw consent to data provision, the subsequent use of the data is stopped. However, the data already used will not be deleted.

(*1) It is currently under consideration that the health insurance number should be assigned as an individual identification number. The health insurance number is planned to be used to accelerate maintenance of data collected by C-CAT.

(*2) Countries/regions establishing a personal information protection system recognized to have equivalent standards to that in Japan

Handling of the above data is associated with the risk of leakage but are managed in a highly secure manner.

(3) [To be specified after discussion between the Hospital for Cancer Genomic Medicine and the company]

8. Contact

[Please specify the contact of the applicable institution]

Version 1 (190218)

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[To be specified at each institution] Dear Director of ○○ Hospital,

I have received a sufficient explanation about comprehensive genome profiling test and understood the purpose and details of the test. I wish to take comprehensive genome profiling test.

■ Providing your information and genome data to Center for Cancer Genomics and Advanced Therapeutics (C-CAT), in a way you are not identifiable directly, to find useful information for your treatment and create a cancer treatment database (Item 7 (1))

Agree · Disagree

■ Providing information about genetic predisposition to cancer (hereditary tumor) (Item 4)

I wish to receive information · I do not wish to receive information

■ Informing your family, etc. of comprehensive genome profiling test results (Item 5)

I allow you to inform my family · I do not allow you inform anyone except myself

Contact of the person whom you wish to be informed of the results of comprehensive genome profiling test

Name _____ Relationship _____

Contact _____

■ Providing your information and genome data provided to C-CAT to a third party wishing to use them for the purpose of academic research and/or pharmaceutical development after a strict review. If you withdraw your consent to provision, the subsequent use of your data is stopped. Data already used cannot be deleted. (Item 7 (2))

Agree · Disagree

■ [For company (testing company) use: To be specified after discussion between the Hospital for Cancer Genomic Medicine and the company] (Item 7 (3))

Agree · Disagree

Consent date (Year/Month/Day) _____

Patient (signature) _____

Legal representative (signature) _____

Relationship _____

Explanation date (Year/Month/Day) _____

Explainer (signature) _____

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Comprehensive Genome Profiling Test Consent Amendment Request Form (model document)

[To be specified at each institution] Dear Director of ○○ Hospital,

I amend my consent for tumor profiling test/comprehensive genome profiling test I took.

● Providing your information and genome data to Center for Cancer Genomics and Advanced Therapeutics (C-CAT), in a way you are not identifiable directly, to find useful information for your treatment (Item 7 (1))

I change from “disagree” to “agree”

I answered “agree” but wish to stop the future data provision and use

● Possibility that genetic predisposition to cancer (hereditary tumor) is revealed (Item 4)

I change from “I do not wish to receive information” to “I wish to receive information”

I change from “I wish to receive information” to “I do not wish to receive information”

● Informing your family, etc. of comprehensive genome profiling test results (Item 5)

I change from “I do not allow you to inform anyone except myself” to “I allow you to inform my family”

* Contact of the person whom you wish to be informed of tumor comprehensive genome profiling test results

Name _____ Relationship _____

Contact _____

I change from “I allow you to inform my family” to “I do not allow you to inform anyone except myself”

● Providing your information and genome data provided to C-CAT to a third party wishing to use them for the purpose of academic research and pharmaceutical development after a strict review (Item 7 (2))

I change from “disagree” to “agree”

I answered “agree” but wish to stop the future data provision to a third party

● Use/disclosure of data, etc. by the company that conduct comprehensive genome profiling test (Item 7 (3))

[To be specified after discussion between the Hospital for Cancer Genomic Medicine and the company]

I change from “disagree” to “agree”

I answered “agree” but wish to stop the future data provision to a third party

Request date (Year/Month/Day) _____

Patient (signature) _____

Legal representative (signature) _____

Relationship _____

Recipient (signature) _____