

**APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 30, 2019**

**RESEARCH INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY**

Name of Sponsor Company: Diagnomics Inc.

Protocol Number and Title of Study: DR_CPLX_001; “Comparison study of genetic predisposition and prediction for diseases and traits by the analysis of individual genome using different computational algorithms”

Name of Person in Charge of the Research Study (Study Doctor/Investigator): Min Seob Lee, Ph.D.

Telephone Number(s), Daytime: (858) 345-4817
After Hours: (925) 997-4666

INTRODUCTION

You are deciding if you would like to volunteer for a scientific research study. Human genetics is a very rapidly developing field led by highly sophisticated genomics technologies. However, the participation of consumers like you is essential in making genetic studies more accurate and discovering the genetic factors related to traits and diseases. With your consent, we hope to contribute to the scientific research that will help scientists better understand human traits, population history and diseases.

Your consent to participate in the research is voluntary and you can withdraw this consent if you decide to do so in the future. When you withdraw the consent, your health history and genetic information will not be used except for the research that is in progress or completed. You can withdraw your consent at your account management page at www.genomatch.me website.

Your genetic data and any other personal information we collect may be analyzed in the research. However, your Registration Information such as your name, contact information, and credit card information will not be used for research. The investigator is the sponsor, and is paying for this study.

CONSENT DOCUMENT

What is the research project Diagnomics conducts? (“Purpose”)

One of Diagnomics’ missions is to advance research related to the study of human genetics and health. For that goal, we will be offering you the opportunities to participate in research which are designed for:

- Discovering links between genetic markers, non-genetic markers, traits, diseases, behaviors and other characteristics
- Understanding the human genetic factors for various human traits
- Developing new diagnostic and therapeutic tools for human diseases and health
- Understanding human history and migration
- Understanding how people use and understand the genetic information which they receive to help improve the experience of obtaining and using genetic information.

We refer to all research focused on the Purpose that Diagnomics or others may do over time as the Diagnomics Research Project (the “**Project**”). We may partner with academic research institutions,

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collaborative partner companies and government institutions as part of the research. We refer to Diagnostics Inc. and its affiliated companies collectively as “**Diagnostics**,” “us,” “we,” or “our.”

What does Diagnostics do if I consent?

You are agreeing that all health and family information and Biological Samples you share with Diagnostics through your use of our websites, mobile applications, and products including current products and future products (“**Services**”) can be collected, stored and used for research. The research project will be consistent with the Purpose, and your information will be used for the period of the Project. Any customer of Diagnostics can voluntarily participate in the Project.

Who conducts the research?

Diagnostics will perform some of the research. Diagnostics also works with other researchers from other institutions and companies sharing the same Purpose. This may include schools as well as non-profit, for-profit businesses or government institutions (“**Collaborators**”).

These Collaborators may also work with other entities to conduct research associated with our Purpose (“**Collaborator Partners**”). The research for the Project may be performed solely by us, or by Collaborators with or without help from Diagnostics researchers or Collaborator Partners. All researchers, whether affiliated with Diagnostics, our Collaborators, or Collaborator Partners are referred to in this Informed Consent as “**Researchers**.” Diagnostics will review all research requests for Biological and DNA Samples. In some instances, Diagnostics receives compensation from Collaborators who work on the Project.

How long will the study last and how many people will be in the study?

Your participation in the study will last for three years from the time you agree to participate. The study may be extended beyond three years if Diagnostics contacts you and obtains your consent to extend the study. Up to 10,000 men and women ages 18 and older will be enrolled in the study.

What data is used?

With your consent, Researchers may use all health information and genetic data that you provide to us when you use our Services, including Biological Samples and any data derived from those samples (the “**Data**”). Data includes:

- **Biological Samples:** means samples (“blood, saliva, or swab Samples”) and the nucleic acids such as (DNA and RNA) obtained from the samples (“**Nucleic acids Samples**”) that you voluntarily provide to us now or in the future;
- **Genetic Data:** Genetic information derived from processing your Nucleic acids Sample through genomic, molecular, and computational analyses using various technologies, such as genotyping and whole or partial genome sequencing. Genetic Data is broader than just the results delivered to you when you use the Diagnostics test and includes a range of DNA markers such as those associated with your health or other conditions;
- **Self-Reported Health and Trait Data:** Information that you voluntarily share with us about the health, medical conditions, diseases, lifestyle or other traits of you and your family members through surveys, forms and other features in our website;

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- **Other Personal Data:** information that you share with us when you register, create a profile, or use your account. Your name and contact information may be used to communicate with you but are not analyzed in combination with your genetic and other personal information.
- **Additional Data that may be shared in the future:** New surveys and features may be added on a continuing basis as we expand our Services. If new surveys or features are added, you may receive an email update or see an announcement when you sign in to your account. We might invite you to participate in a specific study if your Genetic & Self-Reported Information matches the area of interest. You are under no obligation to share additional data with us. However, if you do and you have given consent to participate in the Project, it may be used by the Researchers and collaborating partners.

We take your privacy seriously. Our privacy statement describes how we manage and handle your data in compliance with applicable laws and privacy protection standards.

How can I provide Biological Samples?

You will receive one of the kits for saliva or buccal swab collection. If you prefer providing the blood, you may need to visit a clinic to draw the sample. Diagnostics does not cover the cost for the blood drawing. Free return shipping label will be included in the package with the kit. Place collection tube in the box and ship using appropriate mail carrier.

Saliva Sample:

- 1) Rinse mouth with water 30 minutes before providing the saliva sample. Do not eat, drink, smoke, or chew gum during the 30 minutes before the saliva collection.
- 2) Just before the saliva collection, gently rub the outside of your cheeks.
- 3) Attach the included funnel to the saliva collection tube and spit until your saliva (not bubbles) reaches the red line marked on the bottle.
- 4) Add the preservation buffer into the saliva collection tube as shown in the picture in the kit.
- 5) Close the tube tightly with the white screw cap included with your kit.
- 6) Shake the tube 5-7 times to mix the contents.
- 7) Put the saliva collection tube back in the box and seal the box with the yellow sticker under the box cover. It is now ready to ship or store at room temperature.

Swab Sample:

- 1) Thoroughly rinse your mouth 30 minutes before collection. Do not brush your teeth, eat food, drink beverages, chew gum or use tobacco 30 minutes before collection.
- 2) Carefully open the tube and do not touch the swab head.
- 3) Swab both sides of the cheeks inside your mouth 15-20 times.
- 4) Break the swab into the collection tube containing preservation buffer.
- 5) Screw the lid onto the tube and gently shake 10 times.
- 6) Place collection tube into the self-addressed envelope and return using appropriate mail carrier.

Blood Sample:

- 1) Blood sample should be collected in a provided blood collection tube by a phlebotomist or other medical professional in a clinic.

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- 2) There may be a charge for blood collection services by the phlebotomist, clinic or lab. You will be responsible for payment of these charges. They are not included in the study and will not be covered as costs of the study.
- 3) You will send the blood sample in the collection tube placed in the provided box using the provided label as in kit instructions.

How is my Data used and shared if I give consent?

Researchers may use your Data, including your sample, for:

- Research that is consistent with our Purpose; and
- Publication of research results in scientific or medical journals and in other publications and presentations. No personal information will be included in the publications.
- Data and Biological Samples may be shared with Collaborators and Collaborator Partners, but your name, contact information or other common identifying information will not be shared. When your Biological Sample is shared, it is labelled only with a code.
- Your data may be shared with others who review the quality and safety of the research such as U.S. Food and Drug Administration or Institutional Review Board, IntegReview IRB. We will never knowingly disclose or share your data for use by employers or insurers for employment or insurance purposes.
- When we collaborate with government agencies on research, we take all necessary steps to protect the privacy and integrity of your Genetic Data and Biological Samples in accordance with laws and regulations pertaining to government funded research. In some instances, if we partner with, or our research is funded by, certain U.S. agencies like the National Institutes of Health, we may be required to contribute certain Data to a national database that will be accessible by other researchers. In the event such contribution is required, we will only provide Data that has had identifying information removed in accordance with U.S. federal regulations.

How is my Data protected?

We use industry-standard data protection measures including multiple layers of physical, technical, and administrative procedures to protect your Data. This protection applies to every aspect of Diagnostics operations including providing the Service and performing research projects within Diagnostics and among Collaborators and Collaborator partners. The samples will be stored in Diagnostics' repository under strictly controlled conditions depending on the type of the specimen for the full period of the research. The destruction of the biological specimens will be conducted according to health and safety guideline. The biological samples and the data will be stored in Diagnostics' secure server for the full period of research. The genetic information will be destroyed according to data safety guideline.

Will I be at any risk?

Other than the risks of having blood drawn (if you choose to submit a blood sample), there are no physical risks involved with providing a Sample and having your Data used in this Project. The risks of having blood drawn include fainting, redness, pain, bruising, bleeding, nerve damage and a chance of infection at the site where your blood is drawn. If you feel faint, tell the person drawing your blood right away.

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There are some potential non-physical risks to participating in the Project as follows:

- If we were to provide you with information about your Genetic Data, you may learn information about you or your genetic relatives that you do not expect or that makes you uncomfortable, such as potential health risks. There is a possibility of psychological injury from learning your genetic information. Diagnostics does not cover the cost/treatment of any such injury.
- If you have concern about a research-related psychological injury, please do not participate in this study or contact us as indicated below.
- Research publications may include your data but only as a part of aggregated results across many participants to minimize the possibilities of identifying personal information. But it is possible that third parties could identify you from research publications even though it will require combining the genetic data in the publication with other personal information from different sources. The chance of identifying your individual data is extremely small.
- Biological Samples can be lost or stolen while in transit to Collaborators or storage. However, your Biological Samples are not transferred with your personal information.
- Your Data could become public as the result of a security breach. Even though we have strong policies and processes to minimize a security breach, we cannot guarantee that a security breach won't happen.
- If your Data is somehow made public or made available through a security breach, it may be used to identify you, and may negatively impact your ability to obtain certain types of insurance coverage, or used by law enforcement agencies to identify you if they have additional DNA data to compare to your Data. In addition, if you or a family member has Data linked to your name or your family member's name in a public database, someone who has access to your Data might be able to link that data to your name or your family member's name through the publicly available data.

However, in the United States, a federal law called the Genetic Information Non-Discrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to seek your genetic information without your consent, and to discriminate against you based on your genetic information. GINA does not protect you from discrimination with regard to life insurance, disability insurance, long-term care insurance, or military service.

In addition, there are laws in certain states and laws outside the United States that prohibit discrimination against an individual based on genetic data, which further minimize the risk of potential negative impacts to you or a relative through a third party identifying you based on publicly available information and your Data. Diagnostics will never disclose your Data to insurance providers, employers or law enforcement (unless compelled by valid legal process).

There may be additional risks to participation that are currently unknown or unforeseeable.

Are there any costs to participate in the Project?

No. There is no cost for the participating in Project.

If you choose to submit a blood sample, the cost of collection of the sample is outside the scope of the research project and will be your responsibility.

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How will I benefit from this Project?

You will not receive any direct benefit by participating in this study. There may be an indirect benefit to you as scientific knowledge increases, and/or new drugs or tests are developed. You may also have the opportunity to acquire additional information about genetics, genetic research or the Diagnostics study.

Are there any compensations?

No financial compensation will be provided to you for participating in this study or for any commercial developments related to the Project that may be developed by Researchers and collaborative partners.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Employees of the investigator or sponsor are allowed to participate in this study. If you are an employee:

- The decision to participate or not will not affect your performance evaluation.
- The decision to participate or not will not affect possible promotions.
- The decision to participate or not will not affect your pay.

Do I have to consent to the Project?

Your participation is voluntary. No one is required to participate in the Project. If you choose not to participate in the Project, you can still use our Services, including activating your DNA test and receiving your DNA results.

LEGAL RIGHTS

You will not lose any of your legal rights by consenting to this project.

Can I withdraw from the Project?

Yes, you can withdraw your consent at any time from your account setting page in www.genomatch.me website. If you withdraw, we will cease using your Data for the Project within 30 days and the Data will not be used in future research. **However, Data cannot be withdrawn from research already in progress or completed by Diagnostics or our collaborative partners, or from published results and findings. In those cases, Researchers may have access to such Data about you indefinitely.** There is no negative impact to you for withdrawal of your consent, and you will continue to be able to use our Services as before. Withdrawing your consent will not result in destruction of your DNA Sample or deletion of your Data from Diagnostics products and services, unless you direct us otherwise. If you want your DNA Sample destroyed or your Data deleted from Diagnostics products/services or research, we will promptly do so at your request. Please contact Diagnostics at info@diagnostics.com or at +1(858) 345-4817.

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The investigator, the collaborator, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

New Findings

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

Who can I contact about the Project?

Please contact us if you have any concerns, complaints, or questions about the Project.

In accordance with applicable law, you may have a right to seek access to, rectification of, or object to use of your Data. You may contact us should you wish to lodge a complaint about our handling of your Data.

This Informed Consent is also available on our Diagnostics website.

Contacts

Phone: +1(858) 345-4817
Email: info@diagnomis.com

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

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IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?

The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study

IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

Subject's Bill of Rights

California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

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6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study.

Please answer **YES** or **NO** to the following questions:

- A. Is this document in a language you understand? _____
- B. Do you understand the information in this consent form? _____
- C. Do you think you received enough information about the study? _____
- D. Do you volunteer to be in this study of your own free will? _____
- E. Do you know that you can leave the study at any time without giving a reason? _____
- F. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

**IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT PARTICIPATE IN THIS STUDY.**

Printed Name of Adult Study Subject

Signature of Adult Study Subject Date

Printed Name of Person Explaining Consent Form

Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form to keep.

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