STANFORD UNIVERSITY INFORMED CONSENT

Protocol Director: Dr. Agnieszka Kalinowski, M.D., Ph.D.

Protocol: NCT05109065 eP58926

REVISION May 10, 2024

Protocol Title: Peripheral immune system in individuals with schizophrenia

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Agnieszka Kalinowski, MD, PhD. (650) 721-4413. 401 Quarry Road, Stanford, CA 94305.

DESCRIPTION: You are invited to participate in a research study on the immune system in schizophrenia or schizoaffective disorder. The purpose of this research is to understand the ways in which the immune system may be contributing to the disease process in individuals with schizophrenia or schizoaffective disorder. As a part of this study, you will be asked to answer questions about your current and past medical and psychiatric history and symptoms, as well as complete a questionnaire about your recent experience of stress. Then, you will be asked to provide a urine sample for a toxicology screen, allow a measurement of your height and weight and provide approximately five tablespoons of blood under fasting conditions.

This research will not include whole genome sequencing.

Future use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Your specimens will be stored using an assigned study code number and unlinked to your identifying information.

Because your specimens will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the specimens after they are taken.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing

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results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

RISKS AND BENEFITS: The risks associated with this study are uncomfortable thoughts and/or feelings when reflecting on past or current experiences, discomfort of fasting, risk of infection or bleeding with blood draw or risk of potential for legal consequences of a positive urine toxicology screen if the record is requested by the court**.** The benefits which may reasonably be expected to result from this study are none. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately 2-3 hours.

PAYMENTS/REIMBURSEMENTS: You will receive a $30 payment, either a check mailed to you or an electronic deposit, as payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You have the right to refuse to answer particular questions.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

In this study, we are planning to compare the immune system of individuals with schizophrenia or schizoaffective disorder to healthy controls. Your health information will be used to confirm your clinical status and especially against factors that interact with the immune system. For example, what diagnoses you have received to confirm that you are not being treated for a disease of the immune system or are taking a medication that affects the immune system.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Agnieszka Kalinowski, MD, PhD at 401 Quarry Road, Stanford, CA 94305.

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What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to your name, MRN, email address, date of visits, date of birth, emergency contact, your medical conditions with which you have been diagnosed, medications you are or have taken, results from laboratory or radiological testing and clinical notes from providers.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Agnieszka Kalinowski, MD, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health (NIH)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on February 28, 2050 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the study, without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- You do not meet inclusion criteria or meet exclusion criteria, such as a positive urine toxicology screen.
- Pregnancy
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Kalinowski. You may contact her now or later at (650) 721-4413.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Kalinowski at (650) 721-4413.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

SPONSOR

The National Institutes of Health (NIH) is providing financial support and/or material for this study.

FEDERALLY FUNDED RESEARCH

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is

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used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law including reports of abuse, neglect, or intent to hurt self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document including, but not limited to your name, MRN, email address, date of visits, date of birth, emergency contact, your medical conditions with which you have been diagnosed, medications you are or have taken, results from laboratory or radiological testing and clinical notes from providers.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- 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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May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent