

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Michael Snyder

*IRB Use Only*Approval Date: February 10, 2016Expiration Date: October 14, 2016

Protocol Title: A community-based personalized omics profiling to assess the population's molecular variation and dynamics

Date _____ Valid through: _____ Interviewer ID: _____

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY 06/2015**Title: A community-based personalized omics profiling to assess the population's molecular variation and dynamics****Institution: Stanford University****Principal Investigator: Michael Snyder, Ph.D.**Are you participating in any other research studies? _____ **YES** _____ **NO****INTRODUCTION**

We invite you to take part in a research study to achieve a better understanding of blood integrative omics at the personal and population level on its variation and dynamics for health monitoring and preventative medicine. The study is being directed by Dr. Michael Snyder at Stanford University, Stanford, California, with sponsorship from the Stanford University Department of Genetics.

Personalized medicine is expected to benefit from combining genomic information with regular monitoring of physiological states with multiple high-throughput methods. To achieve this, we developed an integrative monitoring approach named iPOP (integrated personal omics profiling), which includes genomic (including whole genome sequencing, which tells us your DNA sequence and some of your genetic disposition to diseases), epigenomic (this shows how your genes are regulated at the DNA level), transcriptomic (this informs us how your genes are expressed at the RNA level), proteomic (this allows us to know the details of all your proteins in your sample), metabolomic (this measures all the metabolites in your sample) and autoantibodyomic (this gives us information about whether your immune system) profiling, as well as integrative analyses (where we combine the information above to try to learn more about health) of individuals, preferentially over a period of time. Our previous study shows that this approach will not only reveal personalized medical risks, but also uncover extensive, dynamic profiles in diverse molecular components and biological systems. Our goal for this study is to profile 40 individuals as part of a pilot study, after which we hope to enroll up to 2,000 more participants. This will allow us a better understanding of variation and dynamics of iPOP profiles at both personal and population levels. This study will play a critical role in setting a baseline for the advent of personal health monitoring and personalized medicine.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. You **must** sign this form to participate in this study, and a copy of this consent will be emailed to you. You are free to withdraw your consent at any time by notifying Dr. Michael Snyder at

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mpsnyder@stanford.edu or (650) 736-8099.

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

Please take your time to decide whether to participate or not. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in this study:

- The study will ask for one-time blood draw, urine and stool samples. Including initial screening consenting, and filling out surveys, the active participation in the study is up to two hours. Dependent on the length of research activities, we might follow up with you within half year to five years after this study.
- As part of this study, we will have access to personal health information you provide via questionnaires, including a questionnaire about your health history, and we may also ask for you to provide copies of your medical records.
- Personal benefit to you may or may not result from taking part in this research. However, knowledge may be gained from your participation that might eventually benefit you and others.
- The nature of the research study, including possible benefits, risks, discomforts, and other information are discussed below. Any new information we discover that might affect participation in the research study will be provided to you. You are urged to ask any questions you have about this research with the staff members, who will explain it to you in detail. The Principal Investigator (person in charge of this research study) is Dr. Michael Snyder.
- We will ask for your contact information to allow us to reach out to you if we have follow-up questions. For example, our study might identify a sub group of participants who show interesting (research or clinic wise) omics patterns compared to general population, therefore being interesting candidates for future studies. In this regard, being able to follow up with those participants is a key factor for a continuous long-term study, in order to gain more scientific understanding of the underlying physiology.

PURPOSE OF RESEARCH

We intend to establish an extensive iPOP database to obtain more defined variation and dynamics of iPOP profiles at the personal and population levels. We will recruit 40 participants for this pilot study. We believe the results of our study will substantially benefit personalized health monitoring and personalized medicine.

ELIGIBILITY OF PARTICIPATION

Persons eligible for this study must (look at this carefully):

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- Be 18 years of age or older;
- Not be pregnant, if female;
- Be generally healthy without severe medical conditions;
- Be willing to provide written informed consent for all study procedures.
- Be willing to provide contact information for reconnection and follow-ups.
- Be willing to make de-identified omics data public

You may not participate in this study if any of the following applies to you:

- Any medical condition that physicians believe would interfere with study participation or evaluation of results.
- Mental incapacity and/or cognitive impairment on the part of the patient that would preclude adequate understanding of, or cooperation with, the study protocol.
- Understanding of written and spoken English language is not sufficient to facilitate adequate understanding of, or cooperation with, the study protocol.

EXPECTED NUMBER OF PARTICIPANTS AND DURATION OF STUDY

Forty participants will be enrolled in the study at the pilot phase. Extended enrollment, however, might be considered for future phase to allow more extensive research studies.

PROCEDURES

If you decide to participate, you will be asked for one-time blood draw, urine and stool samples. We will draw 30 ml (about 6 teaspoon) of blood during your visit (within the ml/kg limits per federal minimal risk regulation). We will also ask you to fill in a questionnaire about your physical status at the time of blood draw.

TESTS TO BE PERFORMED WITH BLOOD, URINE AND STOOL SAMPLES COLLECTED: We will perform iPOP analysis on the samples collected, including genomic (including whole genome sequencing, this tells us your DNA sequence and some of your genetic disposition to diseases, as well as the transcriptomic (this informs us how genes are expressed at the RNA level), proteomic (this allows us to know the details of all the proteins in your samples), metabolomic (this measures all the metabolites in your samples), autoantibodyomic profiling (this gives us information about your immune system) and microbiome (this allows us to identify bacteria in the gut), as well as integrative analyses (this will enable us to analyze you and your health with all the molecular information above). Additionally, if you choose to give permission we will make your blood, urine and stool samples available for future researches to develop inducible pluripotent stem cell (iPSC) line. You will then be consented separately to the future study, which is out of the scope of current study. Please indicate your choice to question 2 on page 12.

As part of this study, we will collect your name, medical history, and answers to questionnaires. We will also record your iPOP profiles (including genomic, epigenomic, transcriptomic, proteomic, metabolomics, autoantibodyomic as well as integrative profiles) that we generate in our research lab. All participants for this study will be anonymized and assigned to a coded identification number and only the

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core personnel of the study will have access to the key. Data may also be looked at by groups who regulate all research, including the Institutional Review Board (IRB), the Food and Drug Administration (FDA), or the federal Office for Human Research Protections.

All the above analyses, similar to standard hospital lab tests, will generate a comprehensive molecular profile of you. This is a snapshot of your physiological status on a specific date, the day on which your samples are collected.

Please note that any information obtained for this study is NOT intended to replace your standard medical care.

GENETIC COUNSELING

Genetic counseling will be provided before your participation in this study, through our Genetic Counselor, Shannon Rego, MS, LCGC.

- 1) Genetic counseling will occur prior to the consent in the format of a presentation to a group of individuals interested in participating in the study.
- 2) You will be asked to provide consent electronically. If that is not possible, a paper consent will be provided.
- 3) If you have any questions or concerns prior to providing consent, a genetic counselor will be available to answer questions at the group session, via email, and in-person for private discussion at designated times throughout the conference.

SAMPLE STORAGE FOR RESEARCH

Research using biological samples is an important way to try to understand human disease. You have been given this information because the investigators want to include your samples in a research project and because they want to save the samples for future research. There are several things you should know before allowing your samples to be studied.

Your samples will be stored with coded identification numbers in our -80°C freezers.

You have the right to refuse to allow your samples to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research. Please choose whether you authorize to store your sample for future studies on page 12.

TISSUE SAMPLING FOR GENETIC TESTING

As part of the analysis on your samples, the investigators will 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. We do not intend to return any results to participants in this

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study. However, there is a very small chance that in the process of analyzing your omics data we will come across a genetic mutation or other omics information indicating that you have or are at risk for developing a potentially life-threatening condition for which treatment or preventative measures are available. In this case, we will contact you with this information unless you opt out. Please indicate if you wish to opt out of learning such information on page 13. Please note that looking for such information is not the primary objective of this study, and if you are not contacted regarding a disease-causing mutation, it does not mean you do not have such a mutation. If you are concerned about a potential genetic condition in your family, you should pursue genetic testing in a clinical setting. Genetic research raises certain questions about informing you of any results. Possible risks of knowing 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.

Your DNA sample and information will be kept in a secured place in Dr. Michael Snyder's laboratory at the Alway Building of the Stanford University School of Medicine, or another site until it is used up or destroyed. If you give permission, your banked DNA may be used in future studies of genetic factors related to health and 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.

DATA STORAGE AND ACCESS PRIVILEGE

The National Institutes of Health (NIH) has established a national database of Genotypes and Phenotypes (dbGAP) that was developed to archive and distribute the results of studies that have investigated the interaction of genotypes and phenotypes. These studies include genome-wide association studies, medical sequencing, molecular diagnostic assays, as well as association between genotype and non-clinical traits. dbGaP provides two levels of access - open and controlled - in order to allow broad release of non-sensitive data, while providing oversight and investigator accountability for sensitive data sets involving personal health information. Controlled-access data can only be obtained with authorization by the NIH Data Access Committee (DAC) and includes de-identified genotype and phenotype information. Your tissues contain genes which are made of DNA that is unique to you. Coded information about you may be sent to this national database. Access will be controlled and limited to other researchers.

We will be making your omics data, including your genomic data, accessible to the public. Your name and personal information would not be posted, but the results of sequencing and other biological assays will be available. There is the possibility that you could be identified through your genome sequence which means others could have access to your genetic information. **If you are not willing to have your de-identified data made public, you should not enroll in this study.**

Please note that even in the secure database, there is a risk of breach of confidentiality. When data are

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stored electronically, there is also a risk of breach of computer security. Since you and your relatives and other members of your ethnic group share some of the same genetic make-up, there is a small chance for breach of their privacy, as well.

While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. We believe that the benefits of learning more about diseases outweigh these potential risks.

Psychological or social risks associated with loss of privacy:

- Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
- While neither the public nor controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic information in our databases with information from you (or a blood relative) in another database and be able to identify you (or a blood relative). It also is possible that there could be violations to the security of the computer systems used to store codes linking your genetic and medical information to you.
- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation can also be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a blood relative).
- There may be other privacy risks that we have not foreseen.

Every effort will be made to keep research records private. There may be times when federal or state law requires the disclosure of those records, including personal information. This is very unlikely. If disclosure is required, we will take all steps allowed by law to protect the privacy of your personal information.

RIGHTS AND RESPONSIBILITIES OF PARTICIPANTS**Rights:**

1. Your participation is completely voluntary;
2. You have absolute freedom to withdraw from the study;
3. You have the right to ask for answers to your questions on the content of this consent, as well

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as the experimental details of the study;

4. You have the right to refuse to answer particular questions;

Responsibilities:

1. Follow the instructions of the Protocol Director and study staff;
2. You should complete your questionnaires as instructed;
3. You need to ask questions as you think of them;
4. You should notify the Principal Investigator (Dr. Michael Snyder) or research staff if you change your mind on participation;
5. You should not participate in any other research projects without the approval from all of the Project Directors when you are part of this study. This is to protect you from potential harm and injuries resulting from possible incompatibility of different research projects (such as excessive blood draw), as well as influence of the other project(s) on the collection and interpretation of your iPOP data.
6. You should notify your regular physician about participation in this study.

POSSIBLE RISKS OF THE STUDY

Risks from taking blood from your arm is minimal, which may involve a little pain, a bruise or local infection at the site.

Moreover, if the Protocol Director sees that continued participation might be harmful to your health you may be withdrawn from the study. You might also be withdrawn due to administrative reasons, study cancellation, unanticipated situations, or if you fail to follow the instructions of the Protocol Director and study staff.

POTENTIAL BENEFITS OF THE STUDY

The goal of this kind of research is to eventually benefit various aspects of personalized medicine. We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative is not to participate.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed. We plan to deposit the data in dbGAP,

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which is de-identified and has controlled access, and also to make the data public.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

If you have any questions about your rights as a research participant, please contact Dr. Michael Snyder at mpsnyder@stanford.edu or (650)736-8099.

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?

The purpose of this research study is to establish an extensive iPOP database to obtain more defined association of iPOP profiles at personal and population levels. Personalized medicine is expected to benefit from combining genomic information with regular monitoring of physiological states with multiple high-throughput methods. To achieve this, we developed an integrative monitoring approach named iPOP, which includes genomic, epigenomic, transcriptomic, proteomic, metabolomic, and autoantibodyomic profiling of individuals, preferentially over a period of time. Our previous study shows that this approach will not only reveal personalized medical risks, but also uncover extensive, dynamic changes in diverse molecular components and biological pathways. During this study, we will recruit up to 40 participants for this pilot study for healthy individuals with no apparent symptoms at the time of enrollment. Your de-identified health information will become part of our iPOP database, which will help us obtain a more accurate association between iPOP profiles and physiological states. We believe the results of our study will substantially benefit personalized health monitoring and personalized medicine.

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.

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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: Dr. Michael Snyder at 300 Pasteur Drive, Alway M344A, Stanford University School of Medicine, Stanford, CA 94305-5120, USA.

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, medical history, sample related records, results of your physical examinations and answers to questionnaires. We will also record your iPOP profiles, including genomic, epigenomic, transcriptomic, proteomic, metabolomics as well as integrative profiles, that we generate in our research lab.

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 (Dr. Michael Snyder).
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.
- Other investigators on the research team, such as the study coordinator and lab personnel, and any other unit of Stanford University as necessary.

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:

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- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

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 December 31, 2112.

Name of Adult Participant

Signature of Adult Participant

Date

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FINANCIAL CONSIDERATIONS

Payment

You will not be paid to participate in this research study. Participation is free and voluntary for our study.

Costs

There is no cost to you for participating in this study.

Sponsor

The Department of Genetics of Stanford University is providing financial support and/or material for this study.

Consultative or Financial Relationships

Dr. Michael Snyder is a founder and member of the scientific advisory board of Personalis, the company that is performing sequencing for this study.

COMPENSATION FOR RESEARCH-RELATED INJURY

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

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. Michael Snyder at (650)736-8099. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

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Alternate Contact: If you cannot reach the Protocol Director, please contact Drs. Sara Ahadi at (650)723-3277, Wenyu Zhou and Brian Piening at (650)723-9914.

EXPERIMENTAL SUBJECT'S 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.

1. **YES** **NO** Do you authorize us to use your blood samples to generate iPSC line for future research?
2. **YES** **NO** Do you authorize us to store the samples for future research upon the completion of this study? If your answer is no, we will destroy your samples when the study is complete.
3. Please check this box if you do NOT wish to be told in the event that we identify a genetic mutation or other omics information indicating that you have or are at high risk for developing a potentially life-threatening disease for which preventative measures or treatment is currently available.

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STATEMENT BY PARTICIPANT

- I volunteer to donate blood, urine and stool samples to be used for this project.
- I know I can stop taking part at any time without being disadvantaged.
- I understand that my genetic and medical information will be anonymized and will be stored securely.
- I am aware of any possible risks and discomfort.
- I agree to inform the researchers immediately if I am in pain, or if I feel uncomfortable.
- I have had the chance to ask questions.

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

Signed: _____ **Date:** _____

Print name: _____

Telephone number: (____) _____

E-mail address: _____

Address: _____

City: _____ **State:** _____ **Zip Code:** _____

Signature of Person Obtaining Consent

Date

Copies to: **Subject**
 Researcher's file