

DGIM Project Summary

(1 page preferred, 2 pages maximum)

Name of Project: *All of Us* Research Program / Precision Medicine Initiative

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

Principal Investigator: Dr. Robert A. Hiatt, Robert.Hiatt@ucsf.edu

Program Manager: Emily Scott, escott@psg.ucsf.edu

Research question(s): By combining health-related information from one million or more diverse participants, the *All of Us* Research Program will have the right scale and inclusive scope to enable research for a wide range of diseases, both common and rare. The *All of Us* Research Program will create a curated dataset that will be made available to support a wide variety of scientific investigations. The *All of Us* Research Program will encourage future researchers to “bring the analysis to the data” rather than bringing “the data to the analysis.”

Brief Background/Significance: A cohort of this size will have the statistical power to detect associations between genetic and environmental exposures and a wide variety of health outcomes. Outcomes of this research could include novel prevention and screening strategies, earlier and more precise diagnoses, new and more rational use of therapies and improved understanding of why some people remain healthy despite exposures and risk factors for disease.

Inclusion/exclusion criteria (list): Per the *All of Us* Research Program Protocol (https://allofus.nih.gov/sites/default/files/allofus-initialprotocol-v1_0.pdf):

Inclusion criteria:

1. Adults 18 and older with decisional capacity to consent
2. Currently residing in the United States or a territory of the United States

Exclusion criteria:

1. Prisoners at the time of enrollment

Method of contact/recruitment (be specific):

1. UCSF Research Informatics Analyst identifies eligible DGIM patients who have upcoming appointments in next 1-5 weeks.
2. UCSF *All of Us* staff send an invitation email or letter to eligible patient.
3. UCSF *All of Us* staff call the eligible patient 3-5 days later to invite participation in the *All of Us* Research Program.
4. If patient refuses to participate in the program the refusal is documented in the study database and there will be no further contact with the individual.
5. If patient accepts to participate in the program the acceptance is documented in the study database, and an *All of Us* visit is scheduled to occur after their upcoming DGIM medical appointment, or at another time of the participant's choosing.

Benefits/burden for participants (clearly identify potential for harm): Per the *All of Us* Research Program Protocol:

Benefits:

1. The *All of Us* Research Program invites participants to become partners in the data gathering and research process through various means, including through data return and as citizen scientists investigating the data. Substantive participant involvement will occur at all levels of the *All of Us* Research Program including oversight, design, implementation, and evaluation.
2. Participants will receive their personal data (Participant-provided Information (PPI) & physical measurements), along with information about the normal ranges for the physical measurements. They will be told when their measurements are outside the norm.

3. Participants will receive a \$25 pre-paid debit card upon completion of the *All of Us* visit.
4. As new information types are collected, the *All of Us* Research Program will seek to provide access to participants via the online Participant Portal.
5. Eligible participants may be contacted about opportunities to participate in research studies relevant to their health or interests. They may also be invited to participate in clinical trials of targeted interventions and therapies of which they otherwise would not be aware.

Risks/burdens:

1. Potential loss of a participant's privacy and the loss of confidentiality of a participant's personal health information & EHR.
2. Sensitive information may be revealed during the screening process and/or during the program
3. Participants may feel uncomfortable with some of the physical measurement procedures and/or results from those measurements. Physical measurements include blood pressure, heart rate, height, weight, waist circumference, and hip circumference.
4. The modest amount of blood drawn should not have any adverse physiological effects, nor should it lead to any long-term distress. Blood sampling risks include bruising of the arm and fainting. Risks for bloodborne pathogens from accidental needle sticks and during sample processing exist.

Any benefits or burden to DGIM practitioners? No burden. Benefit: UCSF *All of Us* staff will assist UCSF DGIM researchers as much as possible to gain access to the data once it is available for use.

Timeline for recruitment (projected start and stop dates): Current projected enrollment start date is February 12, 2018. Enrollment may last up to 5 years (February 2023).

Funding source: NIH.

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular) Per the *All of Us* Research Program Protocol, the data analysis platform (*All of Us* Research Program Research Portal) will be built and available for use by qualified researchers within the second year and available for the life of the program. Researchers based at institutions participating in the program will not have privileged access. As mentioned above, UCSF *All of Us* staff will assist UCSF researchers as much as possible to gain access to the data once it is available for use.

Do you agree to notify us when recruitment is completed? Yes.

Date form completed: October 16, 2017

Attachments enclosed:

1. DGIM Practice Impact Survey (Allofus_DGIMPracticeImpact_20171016.doc)
2. IRB Approval (AoU_v1.5_IrbApproval_052017.pdf)
3. Protocol (allofus-initialprotocol-v1_0.pdf; also available online at https://allofus.nih.gov/sites/default/files/allofus-initialprotocol-v1_0.pdf)
4. Online questionnaires:
 - The Basics (AoU_ppi_module_basics.pdf; also available online at https://allofus.nih.gov/sites/default/files/ppi_module_basics.pdf)
 - Overall Health (AoU_ppi_survey_overall_health.pdf; also available online at https://allofus.nih.gov/sites/default/files/ppi_survey_overall_health.pdf)
 - Lifestyle (AoU_ppi_survey_lifestyle.pdf; also available online at https://allofus.nih.gov/sites/default/files/ppi_survey_lifestyle.pdf)
5. Provider handout example (AoU_ProviderHandout_DraftExample.pdf)
6. Participant brochure example (AoU_Brochure_DraftExample.pdf)