

**All of Us Research Program
American Society of Human Genetics–All of Us Educational Session
Q&As**

October 27, 2020

Q: If my institution signed a Data Use and Registration Agreement with All of Us and submitted other required documentation, how do we obtain access to the Researcher Workbench?

A: In addition to completing a Data Use and Registration Agreement with the All of Us Research Program to gain access to the Researcher Workbench, researchers must also have an eRA Commons account and must complete all data access requirements before they can access the Researcher Workbench and Registered Tier data. For more information, please visit the All of Us [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one. Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

Please contact support@researchallofus.org for additional assistance.

Q: Is All of Us storing biosamples?

A: Yes, we store blood and urine samples at a biobank at Mayo Clinic in Rochester, Minnesota. Mayo Clinic created a specialized facility for the All of Us Research Program and the biobank supports the collection, analysis, storage, and distribution of the biosamples that the program collects for research purposes. Currently, we have collected samples from more than 271,000 research participants. See a 2018 press release of our partnership with Mayo Clinic, here: <https://allofus.nih.gov/news-events-and-media/news/mayo-clinic-announces-biobank-will-store-samples-nih-all-us-precision>

Q: Is All of Us participant recruitment family-based? In another way, do you have the pedigree information?

A: For our current recruitment of adults, recruitment is not family-based, and as such we have not collected pedigree information (though we do ask about family medical history in participant surveys).

Q: Sorry if I missed it but will slides (or a recording) be available after the session?

A: All materials from the 2020 ASHG All of Us Educational Session are available to the public, here: <https://allofus.nih.gov/news-events/events>.

Q: Is there a LinkedIn group for your professional partners?

A: Not at this time. You may connect with All of Us on other social media networks, Facebook and Twitter. Our social media handle is @AllofusResearch.

Q: Are you finding your marketing & engagement budgets adequate? Are there funding gaps you would like filled?

A: Yes. Please visit the following link to access an informational webinar about the All of Us Research Program Communications and Marketing Partners, including communications and marketing highlights:

https://allofus.nih.gov/sites/default/files/communication_and_marketing_partners_webinar.pdf

Q: Will permissions-based integrations be created in the future, such as the ability to share research data from the *All of Us* Researcher Workbench to Blockchain or Neo4J infrastructures?

A: The program has looked into integrating external tools, such as Blockchain, into the infrastructure of the Researcher Workbench however these tools are not enabled at this time. We hope to enable researchers with new tools in the future.

Q: Are you performing PCR free WGS?

A: Yes, *All of Us* is performing PCR-free whole genome sequencing.

Q: Will there ever be survey questions on complimentary therapies/health activities such as specific exercise, music-making (like the NIH Sound Health Initiative)?

A: Surveys are valuable medical research tools because they efficiently capture information vital to a variety of research interests. Participants in the *All of Us* Research Program respond to surveys spanning a variety of topics, including demographics, health care, and lifestyle. After participants complete the core surveys (The Basics, Overall Health, and Lifestyle), they may complete additional health surveys on health care access, personal and family medical history, and other topics over time.

Q: What are the specific efforts undertaken to ensure the research data harmonization between different sequencing partners in the program?

A: In addition to the usual process of comparing statistics from 'reference samples' to check for concordance, regulatory requirements from the Food and Drug Administration led to more than 200 samples being processed independently at each of the three *All of Us* Genome Centers to ensure low inter- and intra-center variability.

Q: What is the best way for a student trainee to be involved with the *All of Us* Research Program?

A: To access information about how to become a participant or to join the *All of Us* Research Program, visit <http://joinallofus.org>. To access information about how to explore *All of Us* participant data or how to apply to be a researcher, visit <http://researchallofus.org>. Feel free to check out our public Data Browser to explore participant data.

Also, visit the following link is available to access content presented during the ASHG *All of Us* Educational Session about the *All of Us* Researcher Workbench: <https://allofus.nih.gov/news-events/events> .

Q: What populations are included in the ancestry results and how were they decided? Will they potentially change?

A: Here are the genetic ancestry groups that *All of Us* currently will include in the ancestry results we return to participants:

- The Americas, which includes North, Central, and South America
- Eastern and Northern Asia, such as China or Mongolia
- Europe, including Russia and the Mediterranean
- The Middle East and North Africa
- Oceania, such as Papua New Guinea or Fiji
- Southern and Western Asia, such as India or the Arabian Peninsula
- Sub-Saharan Africa

As we learn more about genetic ancestry, we plan to be able to update these groups or add more specific groups.

Q: Do you share information to research participants on potentially risky genes (e.g., APOE4 linked to Alzheimer's disease)?

A: The Program intends to return to participants any finding of pathogenic or likely pathogenic variants in the genes identified by the American College of Medical Genetics and Genomics (ACMG) as crucial and actionable medical results. These ACMG genes currently are 59 in number. As risk of Alzheimer's disease is not considered actionable, APOE4 is not included in genetic results returned to participants.

To help contextualize results, participants can schedule a phone appointment with a genetic counselor from our Genetic Counseling Resource (GCR). They will discuss the results with you and answer any questions. Note that *All of Us* is a research program and does not provide clinical test results.

Q: Will the *All of Us* Researcher Workbench link out to the pharmgkb.org database?

A: At this time, the Researcher Workbench does not link out to the pharmgkb.org website.

The *All of Us* Research Program Data User Code of Conduct, a component of the Terms of Use and Data Use Researcher Acknowledgement, describes how the program can and cannot be used for research projects. For researchers, this includes agreeing to take full responsibility for any external data, files, or software that you import into the *All of Us* Researcher Workbench and the consequences thereof and agreeing **not** to attempt in any way to copy, download, or otherwise remove any participant-level data from the *All of Us* Researcher Workbench.

As an authorized researcher, you can upload or import external data, codes, or files into your workspace in the Researcher Workbench for the sole purpose of the research that you have described. You are responsible for ensuring that you have the appropriate rights to anything you upload into the system and that you have removed all of the personally identifiable information (PII) from any data or files you upload.

For further details on policies related to the import of external content into a workspace, refer to *All of Us* data use policies governing access to the Researcher Workbench and use of participant data, here: <https://www.researchallofus.org/data-use-policies/>.

Q: Does *All of Us* convey to research participants the uncertainty in determining which variants are "pathogenic"? Are participants allowed to opt-out of receiving genetic results?

A: We still working on the process and timing for reanalyzing previously provided genetic results. Participants will only be notified if reanalysis changes their genetic result and should not expect to receive refreshed genetic results on a regular basis (such as each year). This is distinct from offering new types of genetic results where we will ask participants if you want them. As researchers are constantly learning new things about how to study human genetics, the list of what we will check for may change as researchers make new discoveries. The American College of Medical Genetics and Genomics maintains a list of genes that are associated with the risk of certain serious health conditions. One of the goals of *All of Us* is to learn more about human genetics. As researchers learn more, we may go back and look at a participant's genetics again in a new way.

Please remember that *All of Us* is a research program. If you know you are at risk for certain health conditions, speak with your health care provider.

Participants enrolled in the program are not required to get their genetic results and can opt out of getting genetic results while still allowing researchers to study their genetic data. Participants can change their mind if they decide later that they want to see their results.

Q: How will genetic results returned to *All of Us* participants be shared with hospitals to guide care delivery and will there be any follow-up support for participants' physicians?

A: If a participant shares their genetic results with their health care provider, they can ask our Genetic Counseling Resource (GCR) to consult with their healthcare provider if needed. The GCR can provide educational materials and/or phone support to a participant's health care provider to help them understand their genetic results. If a participant is concerned about specific genetic conditions, we advise that they speak with their healthcare provider. If they do not have a health care provider, our Genetic Counseling Resource (GCR) can connect them with one.

All of Us is first large population research program to offer health-related genetic results to participants as part of being in the program and offer resources to health care providers and communities to help them understand genetic results.

Q: Are institutions outside the United States eligible to complete an institutional Data Use and Registration Agreement to access the *All of Us* Researcher Workbench?

A: The data platform is open to researchers all over the world. Institutions must complete a Data Use and Registration Agreement with the *All of Us* Research Program to gain access to the Researcher Workbench and must have an eRA Commons account. All data access requirements must be completed before obtaining access to the Researcher Workbench and Registered Tier data. For more information, please visit the *All of Us* [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one. Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

Please contact support@researchallofus.org for additional assistance.

Q: Is there any financial aid built in to help participants pay for clinical genetic testing if their insurance won't cover?

A: *All of Us* is not a health care provider and does not offer medical genetic testing (also known as clinical genetic testing). If you are concerned about any results you get from *All of Us*, it is always a good idea to talk with your healthcare provider. Your health care provider will need to do additional tests to make a diagnosis. You or your insurance may be billed for tests your healthcare provider orders.

Q: Could you elaborate on how wearable digital technologies will be used in the *All of Us* Research Program?

A: Digital health technologies, like mobile apps and wearable devices, can gather data (e.g., information about physical activity, sleep, weight, heart rate, nutrition, and water intake) outside of a hospital or clinic which can give researchers a more complete picture of participants' health. The *All of Us* Research Program began gathering this data in early 2020 in addition to surveys, electronic health record information, physical measurements, and blood and urine samples, working to make the *All of Us* resource one of the largest and most diverse data sets of its kind for health research. The collection of data derived from digital health technologies will become a fundamental component of the program and allow the program to better understand the

impact of lifestyle and environment on health outcomes leading to better strategies for keeping people healthy in a very precise, individualized way.

All of Us participants with any Fitbit device who wish to share Fitbit data with the program may log on to the *All of Us* participant portal at <https://participant.joinallofus.org/> and visit the Sync Apps & Devices tab. Participants without Fitbit devices may also take part if they choose, by creating a free Fitbit account online and manually adding information to share with the program. Participants may choose what type of data to share and may stop sharing at any time.

Q: How can participants be assured that their data will be protected (not sold or shared outside of research institutions even as deidentified data) for "all time", now and in the future?

A: Participant privacy is very important to us and we follow privacy and data security rules. The rules lay out the best ways to keep participant's information private and safe. They also guide how we collect data and work with participants. Here are some specific ways we protect participant's privacy:

- We remove names and other identifying information from people's data before researchers can see it.
- We follow all federal, state, and local laws and regulations for keeping information safe.
- We have strict internal policies and procedures to prevent misuse of data.
- Experts regularly check our systems to make sure they're secure.
- We store information on protected computers. We limit and keep track of who can see it.
- To work with your health data, researchers must agree to a number of rules. This includes promising they will not try to find out who you are.
- We will tell you if there is a risk to your privacy because of a data breach.
- We have Certificates of Confidentiality from the U.S. government. They will help us fight legal demands (such as a court order) to give out information that could identify you.

To learn more, read our [Privacy and Trust Principles](#) and [Data Security Policy Principles and Framework](#).

Q: It is really great to see all of the efforts that have been put forth in building a diverse cohort at *All of Us*. How is *All of Us* engaging diverse communities and are there resources for encouraging researchers to leverage this opportunity?

A: Diversity is one of the [core values](#) of the *All of Us* Research Program and the program has employed a number of different engagement strategies to build a diverse cohort. For example, starting with deployment of community engagement studios, which enable community experts to provide feedback on a particular health research topic to meaningfully contribute to research and impactfully provide insights that can inform research studies. *All of us* also engages community organizations that already have a presence in communities underrepresented in biomedical research. By studying data from a diverse group of people, researchers can learn more about what makes people sick or keeps them healthy. What researchers learn could lead to better treatment and disease prevention for all of us.

Visit our [Research Projects Directory](#) to see how researchers are using participant data.

Q: Regarding participant surveys, will *All of Us* include questions related to utilizations of medications in the future, including data about patients' usage of over-the-counter medications and complementary medications?

A: Surveys are valuable medical research tools because they efficiently capture information vital to a variety of research interests. Participants in the *All of Us* Research Program respond to surveys spanning a variety of topics, including demographics, health care, and lifestyle. After participants complete the core surveys (The Basics, Overall Health, and Lifestyle), they may complete additional health surveys on health care access, personal and family medical history, and other topics over time.

Q: How does *All of Us* engage research participants and researchers with pharmacogenomics (PGx) in the context of polypharmacy research participants and their interactions with different medications?

A: As *All of Us* is a research study, the program is not going to import electronic health records data alongside PGx for the return of a clinical report or recommendation. There may be opportunities to bring PGx data to the Researcher Workbench and perform analyses in the future.

Q: When can research participants expect to be contacted to provide their genetic sample if they are enrolled in *All of Us* Research Program?

A: Individuals over the age of 18 who are living in the United States may join the program and provide samples of blood, urine, and/or saliva for lab and genetic results. When we are ready to collect your genetic sample, we will let you know through your *All of Us* account. Please check in regularly for any updates.

Right now, we do not ask everyone to provide a sample. In order to be asked, you must meet certain requirements such as completing The Basics survey. We are also making it a priority to get samples from groups of people who have been historically underrepresented in research. You might not have been asked because there may not be a convenient location near you right now where we can collect your sample. We are working to add locations, but this may take time. You may need to wait before we can collect your sample. But there are other ways you can stay involved. You can fill out health surveys, participate in pilot programs and share your feedback about the program along the way. Check your *All of Us* account for updates.

Q: Is the *All of Us* Data Browser available for participants to look through, or is it specifically for researchers within the program?

A: Anyone can use the Data Browser and no login is required. The Data Browser provides interactive views of publicly available *All of Us* participant data. Visit databrowser.researchallofus.org to learn more. All data in the Research Hub are uncoupled from identifying information to the participant.

Q: I am enrolled as a participant in the *All of Us* Research Program and am working with my Principal Investigator at my university to obtain Data Use and Registration Agreement started for Researcher Workbench access. How can I determine if we have an active account?

A: Access to the Researcher Workbench is currently open to anyone with an electronic Research Administration (eRA) Commons account administered by the NIH Office of Extramural Research and institutions who have signed the Data Use and Registration Agreement and completed all data use requirements. If your institution has an eRA Commons account, you could have an active account. Visit <https://www.researchallofus.org/apply> for more information.

For more information, please visit the *All of Us* [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one.

Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

Please contact support@researchallofus.org for additional assistance.

Q: If participants does not provide a complete genetic dataset, do you follow-up with them to reanalyze their genetic information?

A: We still working on the process and timing for reanalyzing previously provided genetic results. Participants will only be notified if reanalysis changes their genetic result and should not expect to receive refreshed genetic results on a regular basis (such as each year). This is distinct from offering new types of genetic results where we will ask participants if you want them. As researchers are constantly learning new things about how to study human genetics, the list of what we will check for may change as researchers make new discoveries. The American College of Medical Genetics and Genomics maintains a list of genes that are associated with the risk of certain serious health conditions. One of the goals of *All of Us* is to learn more about human genetics. As researchers learn more, we may go back and look at a participant's genetics again in a new way.

Please remember that *All of Us* is a research program. If you know you are at risk for certain health conditions, speak with your health care provider.

Q: Which data types will be longitudinal in the *All of Us* Research Program?

A: *All of Us* is a historic, longitudinal research program established to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, socioeconomics, environment, and biology, researchers will uncover paths toward delivering precision medicine, or individualized prevention, treatment, and care for all of us. *All of Us* collects Participant Provided Information about a participant's health status through self-completed surveys, which include longitudinal data such as personal and family medical history, socioeconomic factors, and health care access and utilization. In addition to these self-completed surveys, *All of Us* launched a new longitudinal COVID-19 Participant Experience (COPE) survey in Summer 2020 which includes questions about COVID-19 related symptoms and treatment, as well as social distancing and mental health factors.

Q: Is the *All of Us* Researcher Workbench an open source data repository? Can researchers utilize the workbench outside of the *All of Us* platform?

A: Access to the Researcher Workbench is currently is open to anyone with an electronic Research Administration (eRA) Commons account administered by the NIH Office of Extramural Research and institutions who have signed the Data Use and Registration Agreement and completed all data use requirements. If your institution has an eRA Commons account, you could have an active account. Visit <https://www.researchallofus.org/apply> for more information.

For more information, please visit the *All of Us* [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one. Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

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Q: Does *All of Us* have plans to incorporate mental health topics and research into the program?

A: A new COVID-19 Participant Experience (COPE) survey, launched by the program in Summer 2020, encompasses questions about COVID-19 related symptoms and treatment, as well as social distancing and mental health factors (e.g., anxiety and depression). Participating in the COPE survey may help researchers around the world understand better the impact of COVID-19 during this challenging time. The *All of Us* Research Program will repeat this survey throughout the COVID-19 pandemic. For more information on mental health topics and research at the NIH, visit: <https://www.nimh.nih.gov/health/index.shtml>.

Q: Are researchers encouraged to recruit participants into the program?

A: Recruitment into the *All of Us* Research Program is open to anyone over the age of 18 and living in the United States. Visit www.JoinAllofus.org to sign up directly.

Q: Are there established data models for researcher access to clinical and electronic health records (EHR) data?

A: *All of Us* adopted a ‘data passport’ model to make participant data broadly accessible to authorized researchers who want to access to the Researcher Workbench Registered Tier. Authorized researchers will receive a ‘data passport’ to gain access to the Researcher Workbench Registered Tier upon completion of a signed Data Use and Registration Agreement and once all data use requirements have been completed. Researchers must also have an eRA Commons account to gain access. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one. Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

For more information about data use requirements, please visit the *All of Us* [Data Use Policies](#) page. For assistance with the Researcher Workbench, please contact support@researchallofus.org.

Currently, participant provided information, including EHRs, surveys and physical measurements taken at the time of participant enrollment are available in the public Data Browser.

Q: How can genetic professionals not affiliated with *All of Us* gain access to and use participant data to contribute to the program?

A: Access to the Researcher Workbench is currently is open to anyone with an electronic Research Administration (eRA) Commons account administered by the NIH Office of Extramural Research and institutions who have signed the Data Use and Registration Agreement and completed all data use requirements. If your institution has an eRA Commons account, you could have an active account. Visit <https://www.researchallofus.org/apply> for more information.

For more information, please visit the *All of Us* [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one.

Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](https://www.researchallofus.org) website.

Please contact support@researchallofus.org for additional assistance.

Q: Who are the awardee partners involved with *All of Us* Genome Centers?

A: The following entities were awarded *All of Us* funding to serve as genomic partners for the generation of genomic data from biosamples contributed by participants and to provide a network of genetic counselors to help participants understand what their genomic results mean for their health and their families:

Genome Center Awardees:

- HudsonAlpha Institute of Biotechnology (Huntsville, Alabama)
- [Baylor College of Medicine](#) (Houston, Texas), with Johns Hopkins University (Baltimore, Maryland) and the University of Texas Health Science Center at Houston (Houston, Texas)
- [The Broad Institute](#) (Cambridge, Massachusetts), with Color Genomics (Burlingame, California) and the Laboratory for Molecular Medicine at Partners HealthCare (Cambridge, Massachusetts)
- [Northwest Genomics Center at the University of Washington](#), Seattle, Washington

Genetic Counseling Resource Awardee

- Color Genomics (Burlingame, California)

Q: Substance abuse is a major issue and affect nearly all common disorders. What is being done to capture issues related to these types of disorders in the Research Hub?

A: The *All of Us* Research Hub will store health data from a diverse cohort of one million or more participants in the *All of Us* Research Program. In the Research Hub, everyone can learn more about the types of data participants are providing and how approved researchers can use our data and tools to conduct studies that may speed up medical breakthroughs, including discoveries related to common disorders. Currently, substance abuse is not a component of data available to researchers in the Research Hub. Visit <https://www.researchallofus.org/> to learn more.

Q: What are best practices for reducing barriers to enrollment and participation in the *All of Us* Research Program? Are there any policy decisions that could help address this issue?

A: An important component of enrollment and participation (as well as identifying and reducing barriers to these actions) in the *All of Us* Research Program is participant engagement. One essential element of participant engagement is building trust and working through trusted entities. The program has made many policy decisions to build trust with communities and their advocates. The program has created a network of both national and local community partners to share the program with their communities. In addition, the program has established participant and community advisory boards (P/CAB) as a best practice throughout the consortium. P/CAB comments, feedback, and insights are used to ensure that the program is best able to serve communities and identify and reduce barriers to enrollment and participation at a local level. Nationally, several participants have also been added to programmatic committees to help support the program's design, implementation, and governance. The program has also partnered with the National Library of Medicine to amplify program messaging by leveraging the extensive infrastructure of the Network of the National Library of Medicine to support the

program and health literacy. The program has also created several mobile vehicles that prior to the pandemic, traveled to communities to meet people where they are. Many of these efforts have shifted virtually so that the program can still engage with participants safely.

Q: Is there any plan to return raw sequencing data to research participants?

A: We plan to be able to give our participants access to their primary whole genome sequencing (WGS) data (i.e., raw genetic data from genome sequencing) sometime in the future. This means that a participant's uninterpreted data (which maintains complete features of their raw health-related data) will be available if they want it. Before we do so, we need to make sure that we can tell participants about the potential risks of sharing their WGS data. Stay tuned for program updates.

Q: Does *All of Us* plan to include dental records in the future as a component of returning health-related results?

A: Returning results in a responsible way is integral to what *All of Us* stands for. At this time, genetic findings tied to 59 genes associated with risk of specific diseases, like breast cancer or heart disease, for which there are established medical guidelines for treatment or prevention will be returned to participants. Currently, there are no plans to return dental records. As researchers are constantly learning new things about how to study human genetics, the list of what we will check for may change as researchers make new discoveries.

Q: If there are changes such as new software or new genome references, will there be 'recalling' of the DNA sequence data as the program proceeds?

A: One of the positive aspects of the program's whole genome sequencing pipeline is its flexibility to adapt to new software or new genome references.

Q: Will *All of Us* provide authorized researchers with access to individual-level research results? How is data curated?

A: Authorized researchers will not be able to access individual-level research results through the Researcher Workbench as research results are available in the Researcher Workbench in aggregate.

Q: Will a common data model be deployed for researchers to utilize for coding genomic data in the Researcher Workbench?

A: In terms of a data model, there is conformity within established standards at *All of Us* as far as file types. The program will be using the human reference genome GRCH38 and will conform with clinical validation standards as well as consider new references in the future.

Q: As a Registered Dietitian, I am thrilled about the new precision nutrition initiatives on the horizon at *All of Us*. How can Registered Dietitians be involved?

A: The new NIH precision nutrition research initiative concept called 'Nutrition for Precision Health' powered by the *All of Us* Research Program will be the program's first ancillary study and there is excitement about using *All of Us* data in this realm, which is foundational. The program is currently developing a diet module that will be available in the future as well.