# Cover Letter

<u>[Final version with letterhead & signature added.]</u>


Dear Ms. Irene Haas,

Open Humans is an online nonprofit platform that seeks to connect its members to the All of Us Research Program.

Open Humans combines technology and community to enable individuals to contribute to research. Our members are invited to join diverse studies and aggregate diverse data in an ongoing manner. We facilitate data access, exploration, and sharing – with researchers and citizen scientists. We also aim to expand dramatically in coming years.

Our members are already committed to contributing to research. This is the purpose of our community – our raison d'être. Some have explicitly asked about the All of Us program – and whether Open Humans is part of it. I would like that answer to be "Yes".

Our ability to foster and support citizen science and patient-led efforts has the potential to create important stories of empowerment and discovery related to the All of Us program. This strengthens engagement and enrollment beyond our own platform, benefiting enrollment and engagement in other participant communities.

I believe Open Humans is a unique opportunity for the All of Us program engagement efforts.


Sincerely,


Madeleine Ball, PhD

Open Humans Foundation, Director of Research
Co-founder of Open Humans

## Community Served

Open Humans is an online, US-based community of individuals that actively contribute to and participate in research, via data donation and other forms of participation.

It is a national scale project that currently has a relatively small core demographic, but plans to grow significantly in coming years and has the resources to do so.

**Community size:** Our core community consists of people who have made accounts in our platform. We are also connected to a larger audience via collaborations with other groups.
- 3,100 people with accounts as of March 2017.
    - These individuals are highly engaged, and have already created an account for the purpose of contributing to research.
    - >6,000 accounts anticipated in 2018 based on our current growth rate.
- Broad audience of over 15,000 in diverse collaborating projects.

Because Open Humans is online, it has very low per-member costs. It is well-positioned to support a much larger membership base, and seeks to grow in coming years.

**Target enrollment:** We aim to have 10,000-20,000 individuals enrolled in All of Us and highly engaged via Open Humans by the end of the three year engagement plan.

**Demographics:** Open Humans does not target any specific demographic. Its online modality biases towards demographics that are more engaged with technology and internet use.
- Languages: Primarily English-speaking
- Sex/gender: Both
- Race/ethnicity: Any
- Ages: Any (children must engage via parent/guardian)

**High response rates.** Our newsletter is subscribed to by 82% of our members, and our engagement rate for email communications is 50-100% above industry norms.

**Highly engaged.** The community has an online chatroom and diverse member-created projects, reflecting a highly engaged community. These include an open source iOS app to connect Apple HealthKit data, and patient-led data commons run by Nightscout and OpenAPS type 1 diabetes communities (which share data with groups at Univ of Mich, Stanford, and Johns Hopkins).

**Participant advocates.** Because they are explicitly interested in contributing to research, we believe Open Humans members are likely to be enthusiastic and committed participants if enrolled in All of Us. Furthermore, their interest in furthering research makes them more likely to disseminate information about the All of Us study with their family, friends, and communities, which are distributed across the United States.

## Organization Description

**Annual budget.** The annual budget of Open Humans Foundation is $420,000, with 60% supporting the Open Humans program (2016 data).

Open Humans Foundation is a 501(c)(3) nonprofit organization dedicated to making a wide spectrum of data about humans accessible to increase biological literacy and improve human health. Founded by Jason Bobe and George Church in 2008 as "PersonalGenomes.org", the name was changed in 2016 to better reflect our mission. The nonprofit currently supports three core programs: Open Humans, the Personal Genome Project, and the GET Conference.

It is the Open Humans program, in particular, that we are proposing as an engagement partner for "All of Us". Open Humans is a platform and community that launched in 2015, co-founded by Madeleine Ball and Jason Bobe. Open Humans has been supported through grant funding from the Robert Wood Johnson Foundation, the John S. and James L. Knight Foundation, and the Shuttleworth Foundation. Academic use of the platform spans various institutions, including researchers at Harvard Medical School, Stanford University, New York University, University of California San Diego, and University of Michigan.

Open Humans uses continuous engagement with members via projects, newsletters, and social media, and invites them to join new projects on an ongoing basis. Researchers can easily access accumulated data from participants and invite members to contribute additional data (e.g. via surveys). Projects can engage members anonymously, if desired, via random identifiers and in-platform messaging, increasing participant privacy and security. Data is private by default in Open Humans. Individuals have ongoing control over how they share their data, and we make it easy for participants to decide whether and how to share with new projects.

Ongoing accounts that transcend specific studies allow individuals to aggregate research data across projects. This enables decentralization of research within a shared cohort.This approach facilitates ongoing engagement from diverse projects - including academic and patient-led efforts - and invites members to contribute to research in new and exciting ways.

Open Humans is in a strong position to connect an ongoing, highly-engaged participant community contributing to the All of Us program – indeed, this is almost explicitly what the platform is built to support.

# Engagement approach

## Engagement timeline

Our engagement timeline is split into three phases over the three years. Each phase builds upon work in the previous phase, as well as anticipated developments within the All of Us Research Program. We expect the number of individuals recruited and engaged to be relatively low at the outset, with an aim for exponential growth - in particular during our third phase.

**Phase 1 / Year 1: Focused recruitment within the Open Humans member community**

In this phase, we plan to build an initial core of Open Humans members that join the All of Us Research Program. The Open Humans member community consists of highly-engaged individuals interested in contributing to research. Community members tend to be tech-savvy and highly educated, with a strong interest in personal data and contributing to research. These members are ideal "beta testers" – a starting point for developing our long term engagement strategy that leverages individual data sharing for research, data exploration, and citizen science.

We expect the first phase to be relatively low cost, as our recruitment strategies rely on our existing techniques, features, and resources for member engagement.

Phase 1 / Year 1 targets
- Create a project representing All of Us within Open Humans.
- Share 3-6 invitations with the Open Humans community, statistics on response rates.
- Connect 500 - 1,000 Open Human members to All of Us via our project.
- Share 6+ updates regarding our work with All of Us with these members.
- Collect information to enable targeted engagement & alternate contact methods.

Phase 1 / Year 1 assessment plan
We will review Open Humans community engagement, enrollment, and All of Us program developments to confirm that we're well-positioned to proceed to the next phase.

The second phase should occur when the following aspects are aligned:
- Positive response and support in the Open Humans community
- All of Us Research Program implements data sharing with participants

If these factors are not met – but remain anticipated – we may extend the phase one strategy and budget until ready to proceed.

**Phase 2 / Year 2: Connect All of Us data and fund data exploration projects.**

The second phase focuses on connecting All of Us Research Program data to Open Humans, and supporting data exploration tools. We plan to continue to encourage enrollment, with an increased focus on individuals who wish to connect and explore personal data produced by All of Us.

The All of Us Research Program has stated a plan to share data with participants. Our phase two plan is to build on this feature: connecting All of Us data to Open Humans accounts and encouraging downstream uses: research, citizen science, and data exploration. We believe enabling participants to explore their All of Us data (as well as other potential downstream data use opportunities) renders their ongoing participation meaningful and engaging.

We expect the second phase to have increased costs. Open Humans already has a powerful platform for data aggregation and management, but some additional work will be needed to connect All of Us data to member accounts and support new data exploration features.

Phase 2 / Year 2 targets
- Connect data from All of Us program (via API if possible, or by file uploads).
- Share 4+ quarterly invitations, with statistics on response rates.
- 1,000 - 2,000 Open Humans members connected to All of Us through OH project.
- Share 8+ updates regarding our work with All of Us with these members.
- 400+ members with All of Us data in Open Humans accounts.
- 3-4 projects enabling exploration of All of Us data.

Phase 2 / Year 2 assessment plan
We will review community engagement, data exploration efforts, and other engagements via downstream data use to confirm that we're well-positioned to proceed to the next phase.

The third phase should occur when the following aspects are aligned:
- One or more "success stories" in downstream uses for All of Us data
- Positive feedback and response rates to data exploration

Successfully meeting these goals will indicate that our data features are likely to have broad appeal and may be relevant to other communities. We will be ready to perform outreach seeking to significantly expand our cohort of engaged All of Us members.

**Phase 3 / Year 3: Expand outreach beyond Open Humans to appropriate communities.**

The third phase focuses on expansion. Building upon and extending our work with All of Us data, we plan to greatly expand our engaged All of Us participant community.

We expect the third phase to have two facets: (a) further expanding All of Us enrollment by recruiting individuals interested in personal data generated by the program, (b) expanding engagement of existing All of Us participants interested in exploring their existing data, including patient advocacy groups and other communities interested in self-organizing projects using their data.

We expect the third phase to have costs reflecting increased outreach efforts, user support, and support to assist citizen science and patient-led community efforts.

Phase 3 / Year 3 targets
- 10,000-20,000 Open Humans members connected to All of Us through OH project.
- 1,000+ members with All of Us data in Open Humans accounts.
- 5+ new projects created by citizen scientists and patient advocacy communities.
- Share 6+ news and updates with Open Humans community.

## Engagement method

Our primary method for ongoing engagement is to create a project representing the All of Us Research Program within Open Humans.

**Background: "Projects" in Open Humans.**

The Open Humans platform enables "projects" that engage the online member community. Each project is an activity, app, or research study within our online platform. Our flexible, powerful format provides both APIs and online features for working with individuals and their data – including anonymous messaging, surveys and form data, and secure data management.

Open Humans members elect to join projects. Projects can consent and enroll members within the Open Humans site – or can perform consent and enrollment through external methods. Once members join a project, the project facilitators can work with these members on an ongoing basis by sending emails, inviting data donations, adding data to members' accounts, inviting members to complete surveys or fill out forms, etc.

**Overview: An All of Us project in Open Humans.**

An All of Us project within the Open Humans platform and community would be managed by our nonprofit, and created as part of our partnership with All of Us as an engagement partner.

We expect this project to perform the following:

1. Enrollment invitations via newsletter and other communication channels.
   (Phases 1 and 2)

2. Ongoing updates & targeted communications.
   (Phases 1, 2, and 3)

3. Collect demographics and additional contact information.
   (Phases 1, 2, and 3)

4. Connect All of Us data.
   (Phases 2 and 3.)

5. Encourage data exploration and citizen science.
   (Phases 2 and 3.)

6. Enable downstream research.
   (Phases 2 and 3.)

7. Recruit and engage individuals beyond the Open Humans community.
   (Phase 3.)

We aim to enroll 500 to 1,000 highly-engaged individuals in the Open Humans All of Us project in our first year. Working with All of Us program management, we plan to assess our engagement results (from the All of Us perspective, as well as our own community) at the end of this year, potentially aiming to expand this work to 1,000-2,000 individuals in year 2, and 10,000-20,000 individuals in year 3.

**1. Enrollment invitations via newsletter and other communication channels.**

The All of Us project in Open Humans will have a page on the site, as is standard for projects in the platform. This provides an online entry point for engagement via Open Humans. It is publicly visible, enabling both members and non-members to learn about All of Us and decide to join.

We plan to promote this project in our Open Humans newsletters, which share regular updates relevant to Open Humans members. These newsletters typically include new and

ongoing opportunities to contribute to research projects. On a regular basis (quarterly at minimum), we would use our newsletter to provide updates on this project with our community and how it relates to topics of interest to them. As mentioned previously, the newsletter is subscribed to by 82% of our members, and our engagement rate for email is 50-100% above industry norms. We also share newsletters via social media: on our blog, in Twitter, and on Facebook.

Furthermore, the All of Us project would be highlighted continuously within our online platform, which uses responsive design to enable engagement through desktop and mobile devices.

We will also have the opportunity to highlight our All of Us project with communities and venues that are likely to be receptive and interested in connecting to All of Us through Open Humans – *e.g.* research studies, citizen scientists, data enthusiasts, and patient advocacy groups. These include groups that have connected as "projects" within Open Humans, as well as communities with similar interests. If the All of Us project is successfully deployed within our core community, we would plan to extend outreach to these groups via appropriate channels (online and face-to-face events, presentations, and more).

**2. Collect demographics and additional contact information.**

Open Humans projects are able to invite members to complete surveys and forms.

We plan to use this feature to collect additional information with two specific goals:

1. Demographic data. In many cases, we expect that All of Us projects, partners, and events will seek to work with a specific subset of individuals. This may be due to a geographical limitation, for instance research that requires in-person engagement. In other cases, the goal may be to find individuals meeting specific eligibility criteria – sex/gender, age, or health conditions.

2. Alternate communication channels. To enable direct mail, we plan to request project members share their mailing address with us. These addresses will be used to share an immediate reward: stickers advertising the All of Us project. Stickers are fun, affordable, and act as an ongoing advertisement for the program.

   Since response rates to direct mail often outperform digital methods, we may increase our use of this communication channel in the long term. We may also pursue collecting information for other communication channels, e.g. phone numbers, which would enable phone calls and text messaging.

**3. Ongoing updates & targeted communications.**

Members who join the All of Us project in Open Humans will be able to receive messages from the project, and send messages to it. Messages are typically received as emails, but projects can engage individuals anonymously via random identifiers (if this is desired).

In contrast to our newsletter and social media, which provide channels for initial engagement and somewhat broad publicity, our project messaging feature enables strong, ongoing interaction with individuals who have joined the All of Us program. We plan to use this feature to share exclusive, in-depth updates and commentary regarding the All of Us program, as well as notify individuals of specific All of Us events and subprojects that may be appropriate to them. Recruitments may be shared broadly, or targeted to individuals meeting inclusion criterion (based on demographic data - see section 2).

**4. Connect "All of Us" data.**

The All of Us Research Program has committed to giving individuals access to personal data.

Open Humans is positioned to leverage this data access to enable data exploration and citizen science. This is a core, unique strength that we offer as an engagement partner.

Open Humans would facilitate participant access, management, and downstream use of their All of Us data, empowering them and encouraging ongoing engagement with the All of Us Research Program. We are prepared to support participant-authorized data imports from All of Us members via API or user-mediated upload. These imports would create more comprehensive bodies of data on participants, which could then be used to drive further research.

**5. Encourage data exploration and citizen science.**

Open Humans provides a unique and promising retention strategy for All of Us participants through its support for data exploration and citizen science.

Our nonprofit organization's mission is to promote biological literacy as well as advance health. One major method through which we achieve this is technically facilitating data exploration projects and citizen science efforts.

Within Open Humans, we currently support the ability of citizen scientists and others to create projects that invite individuals to explore their data and put it to new uses. In the coming years, we plan to continue to expand this facet. (For example, one project currently planned will enable individuals to use Jupyter notebooks to share "analysis code" that others can privately run on their own data using a cloud-based server.)

We plan to highlight how All of Us data can be used by citizen scientists, and to leverage a small amount of funding to support development of projects and tools for data exploration. This may take the form of a contest with prizes, contracted work, and/or a summer student internship.

These efforts will encourage the engagement of Open Humans individuals in the All of Us program, and also create important stories of empowerment and discovery that will boost and support engagement in All of Us programs beyond Open Humans.

## 6. Enable downstream research.

In its most mature form, ongoing engagement mean maximizing the longitudinal, cumulative contributions that individuals make to research.

Open Humans does this with its "open cohort" approach. Researchers can create projects that invite members to join – including participants enrolled in other studies connected to our platform. Projects can securely access accumulated data of participants (research and personal data), and can invite members to share additional information and further engage.

This goes beyond merely enabling data sharing between studies – the cohort itself is shared. Even a brief follow-up survey can leverage pre-existing data in powerful, new ways. Individuals can also be invited to perform sample collection or otherwise engage a research team.

The ability for individuals to aggregate data and share data across specific studies is a key format for ongoing engagement that aligns perfectly with All Of Us program goals. As with citizen science and patient-led uses, this contributes to success stories for the All of Us program, benefitting the program's overall engagement.

## 7. Recruit and engage individuals beyond the Open Humans community.

Once the All of Us project is successfully deployed within our core community, we plan to extend outreach to communities and venues that are likely to be receptive and interested in connecting to All of Us through Open Humans. These include research studies, citizen scientists, data enthusiasts, and patient advocacy groups, as well as groups already connected to All of Us that want ongoing engagement with their data.

Using appropriate channels - online and live events, presentations, strategically-placed advertisements, etc. - we will highlight "success stories" from the project in order to demonstrate the broad appeal and value of joining the Open Humans All of Us project.

## Past Performance

When Open Humans was launched in 2015, our primary goal was to establish a community of users to build longitudinal, integrated research profiles with existing data generated by our three pilot research partners: the Harvard Personal Genome Project, American Gut and GoViral. We met our goal mainly through digital outreach to our partners' communities coupled with strategically-timed press releases and news coverage by a dozen key media venues (Forbes, Newsweek, Scientific American, and more). We now have a highly engaged community with over 3,100 members.

Since launch, we have iterated our design to make it easy to create new projects that engage members and their data. It is open source, flexible, and powerful, with APIs and on-site tools.

This has enabled diverse uses, facilitating academic research across the nation. We have collaborations with researchers at Arizona State University, Harvard Medical School, New York University, UC Berkeley, UC San Diego, UC San Francisco, and Wellesley College.

Open Humans also uniquely enables citizen science and patient-led projects, which can spark their own academic collaborations. Citizen-led efforts can include citizen-supported data sources (e.g. an open source iOS app that adds Apple HealthKit data to Open Humans) as well as data exploration and visualization (e.g. a tool for discovering errors in genetic data) and patient-led efforts that engage the research process.

To explain this, we will highlight a specific project which has won a Sage Bionetworks Young Innovator/Investigator Award and will be presented at the 2017 Assembly ("Mapping Open Research Ecosystems"). This project centers on data produced by Nightscout, an open source project developed by type 1 diabetes patients and their caretakers.

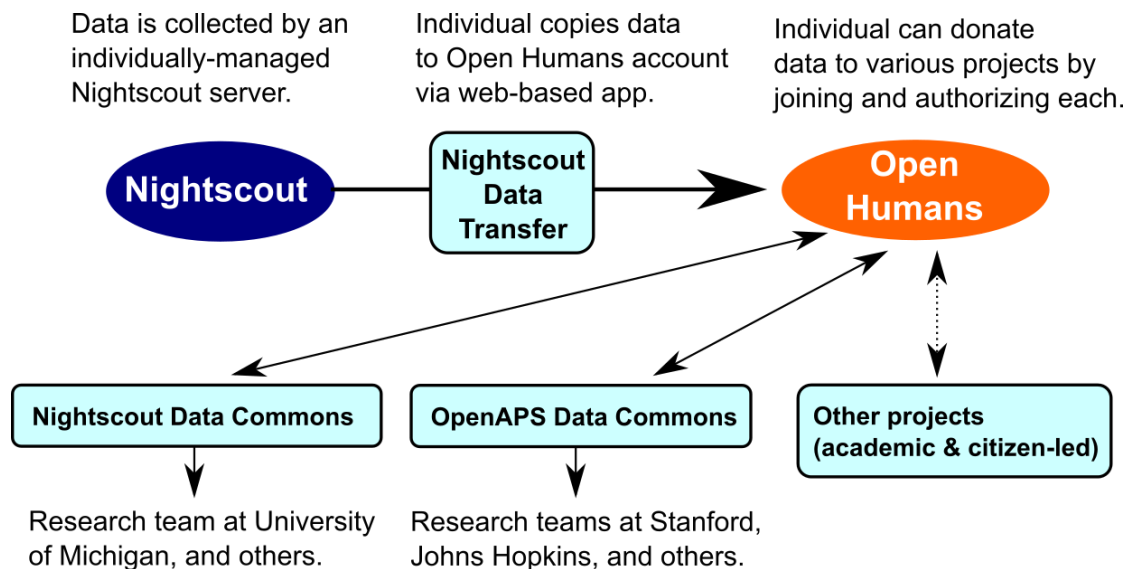**OpenAPS Data Commons: a citizen-driven project enabled by Open Humans.**

Nightscout enables individuals to get real time access to continuous glucose monitor (CGM) and other diabetes data. Nightscout community members were interested in enabling their data to be used in research. Open Humans worked with Nightscout developers to help individuals connect their Nightscout CGM data to Open Humans. The Nightscout Foundation now has an app that adds CGM data to Open Humans, where it can be shared with research studies and citizen science projects.

Building on this, the Nightscout Foundation is also developing a "Nightscout Data Commons" project in Open Humans which will invite their user community to aggregate data. This data is to be shared with research teams according to community terms, including specifically planned work with Dr. Joyce Lee's pediatrics research team at the University of Michigan.

Dana Lewis, founder of the Open Artificial Pancreas System (OpenAPS) movement, has also extended this work to create a similar project. Lewis is inviting the OpenAPS community to contribute the same CGM data to the OpenAPS Data Commons. She is working with research teams at Stanford and Johns Hopkins to analyze this community's data.

What is transformational about this work is how Open Humans has enabled a citizen community to engage and aggregate data, connect it to researchers at leading institutions. The opportunity to collaborate and work with data is open-ended: other citizen scientists and research teams can get involved and create new projects.

**Diagram illustrating Nightscout data & associated commons in Open Humans**

Data is collected by an individually-managed Nightscout server.

Individual copies data to Open Humans account via web-based app.

Individual can donate data to various projects by joining and authorizing each.

**Nightscout** → **Nightscout Data Transfer** → **Open Humans**

**Nightscout Data Commons** → Research team at University of Michigan, and others.

**OpenAPS Data Commons** → Research teams at Stanford, Johns Hopkins, and others.

**Other projects (academic & citizen-led)**

As mentioned previously, Dana Lewis and Madeleine Ball were co-awarded a Young Investigators/Innovators Award from the Sage Bionetworks 2017 Assembly for their collaborative efforts with Nightscout and academic partners. We expect to see this work further develop in the coming year.

This project aptly demonstrates how Open Humans has an exceptional combination of community and data-centered features that makes us a uniquely valuable engagement partner. We believe All of Us and the data it produces can be connected to Open Humans to produce an ongoing engagement of All of Us participants through diverse projects, citizen science, and patient-led efforts.

Numerous other stakeholders are also using our web-based platform to quickly and affordably launch projects that recruit members to share data and participate in a wide range of activities. We remain focused on user interface design and user experience that constantly improves our front and back-end design to make the Open Humans platform easier and more approachable for both participants and researchers.

**Key Personnel**

**Madeleine Ball:** Project director.

Anticipated time on project:
>        Year 1: 5% FTE
>        Year 2: 15% FTE
>        Year 3: 15% FTE

Madeleine Ball, PhD is Director of Research at Open Humans Foundation. She is supported by a Shuttleworth Foundation Fellowship for her work in supporting health data access and sharing through the Open Humans platform. She is co-founder of the Open Humans platform and a member of the Board of Directors of Open Humans Foundation.

Through Open Humans and previous work as Director of Research at the Harvard Personal Genome Project, Dr. Ball has extensive experience with highly engaged participatory research, data sharing, technology solutions, and citizen science. Through Open Humans, Dr. Ball has extended this focus to work closely with human subjects research studies at a variety of institutions, including ASU, Harvard, NYU, UCSD, UCSF, UMich, and Wellesley. These studies represent a diverse range of research topics, including genome and microbiome research, health behavior research, human computer interaction and mobile health.

Dr. Ball has been invited to speak about her work at past and upcoming events:

- Health Data Exploration Project 2017 Network Meeting "Promoting Social Justice in the Use of Personal Health Data" (May 2017)
  *Invited speaker.*

- Sage Bionetworks 2017 Assembly "Mapping Open Research Ecosystems" (April 2017)
  *Young Innovator/Investigator Award recipient & invited speaker.*

- Health Data Exploration Project 2016 Network Meeting "Enabling Personal Data Donation for Public Good Research" (May 2016)
  *Invited speaker, "Enabling Personal Health Data Donation: Models that Work" session.*

- Quantified Self 2016 Public Health Symposium. (May 2016)
  *Panelist, "A Public Infrastructure for Data Access".*

- PRIM&R 2015 Advancing Ethical Research Conference. (Nov 2015)
  *Panelist, "Picked Out of a Crowd: Privacy and Re-Identification Research".*

**Hope Kroog:** Outreach, communications, and project operations.

Anticipated time on project:
      Year 1: 20%
      Year 2: 20%
      Year 3: 50%

Hope Kroog manages member outreach and support for Open Humans.

Ms. Kroog's outreach work centers on creating newsletters and blog posts for the Open Humans community, including interviews with researchers and participants for our popular "Spotlight" series. Ms. Kroog also maintains the Open Humans Facebook and Twitter feeds, tracks Google Analytics, and handles direct mailing campaigns that distribute stickers to our members.

In addition public outreach, Ms. Kroog also responds to private support questions and operational issues that arise, providing assistance to participants, citizen scientists, researchers, and other members. She is familiar with standard study engagement methods and is trained in ethical research conduct. She has a history in performing arts and is comfortable with face-to-face outreach and public speaking.