

Nutrition for Precision Health

powered by the *All of Us* Research Program

Pre-Application Webinar

February 11, 2021
11 am EST

This meeting is being recorded



Webinar Best Practices

- Please turn off VPN
- Ask questions in the Q and A box only
- Refrain from using chat



National Institutes of Health

Webinar Outline

- Presentation
 - Panelist introduction
 - NIH Common Fund
 - Nutrition for Precision Health (NPH) overview
 - *All of Us* Research Program
 - Key points for all RFAs
 - Key points for specific RFAs
- Q&A



Submit Questions via the Q&A panel

Q&A

All (0)

Ask: All Panelists

Select a panelist in the Ask menu first and then type your question here. There is a 256-character limit.

Send

Be sure that “All Panelists”
is selected

Do not use “chat” for Q
and A



Panelists: Program Officers



Ashley Vargas

Research Coordinating Center
Clinical Centers



Padma Maruvada

Microbiome and
Metagenomics Center



Christopher Hartshorn

Artificial Intelligence, Multimodal Data
Modeling, and Bioinformatics Center



Jill Reedy

Dietary Assessment Center



Pothur Srinivas

Metabolomics and Clinical
Assays Center



Pam Jeter

Research Coordinating Center SRO



Panelists: NPH Coordinators



Holly Nicastro



Christopher Lynch



Felicia Qashu



Ananda Roy



Danyelle Winchester



Samantha Adas



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Panelists: *All of Us* and CFDE



Romey Azuine
Data and Research
Center Program Officer



Mark Caulder
Biobank Program Director



James McClain
Participant Technologies
Program Director



Holly Garriock
Acting Director of Division
of Scientific Programs



Sheri Schully
Acting Chief Medical
and Scientific
Officer



Haluk Resat
Common Fund Data Ecosystem (CFDE) Data Coordinating
Center Engagement Directors



Christopher Kinsinger

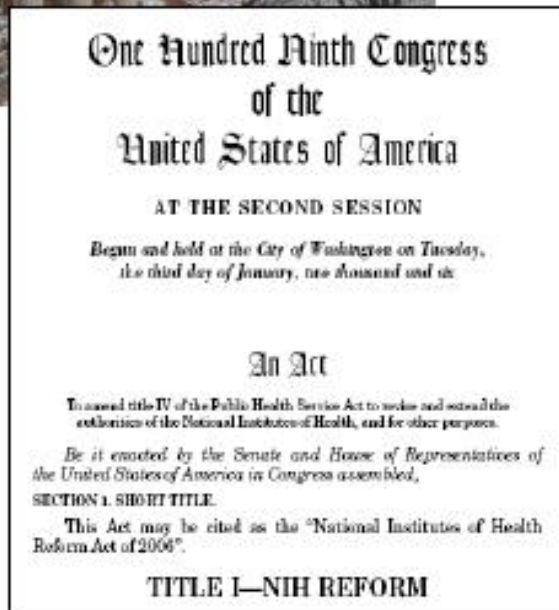


NIH Common Fund



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What is the Common Fund



2004: NIH Roadmap is launched

2006: Congress unanimously reauthorizes the
NIH



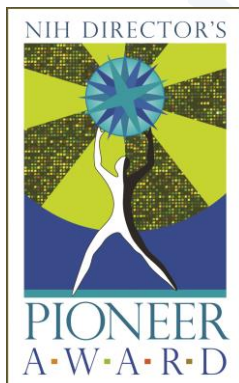
Establishes the Division of Program Coordination,
Planning, and Strategic Initiatives (DPCPSI) within
Office of the Director and the **NIH Common Fund**
to provide a dedicated source of funding to
enable goal driven *trans*-NIH research.

Separate budget line for the Common Fund.



Common Fund Programs

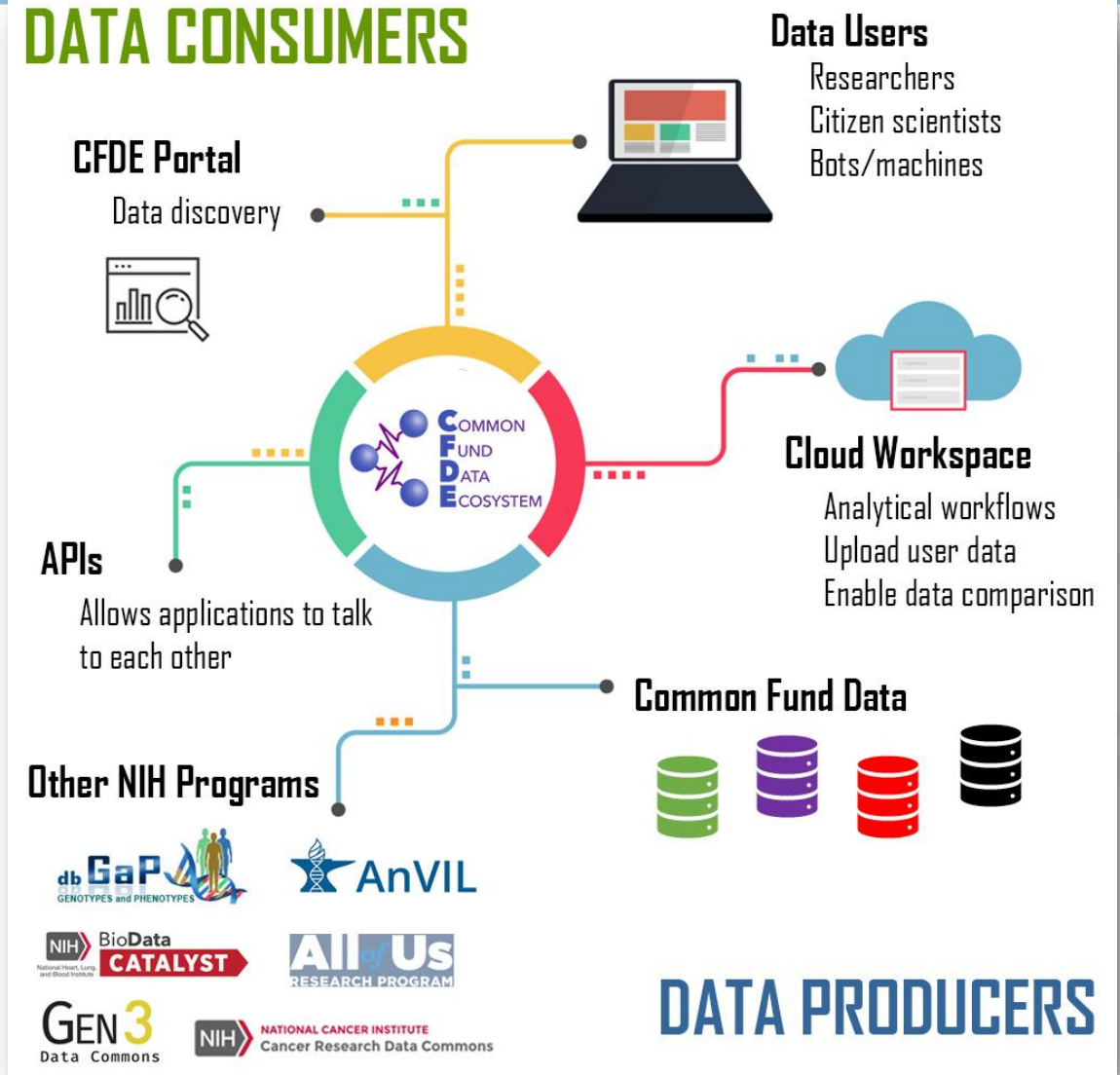
- Transformative** Must have the potential to dramatically benefit biomedical and/or behavioral research
- Catalytic** Must achieve a defined set of goals within 5-10 years
- Synergistic** Outcomes must synergistically advance individual missions of Institutes and Centers
- Cross-cutting** Program areas must cut across missions of multiple Institutes and Centers, requiring a coordinated approach
- Unique** No other entity is likely or able to do



Common Fund Data Ecosystem (CFDE)

Goals

1. **Query** across and use datasets
2. **Sustain** data and tools
3. **Train** researchers to use data and tools



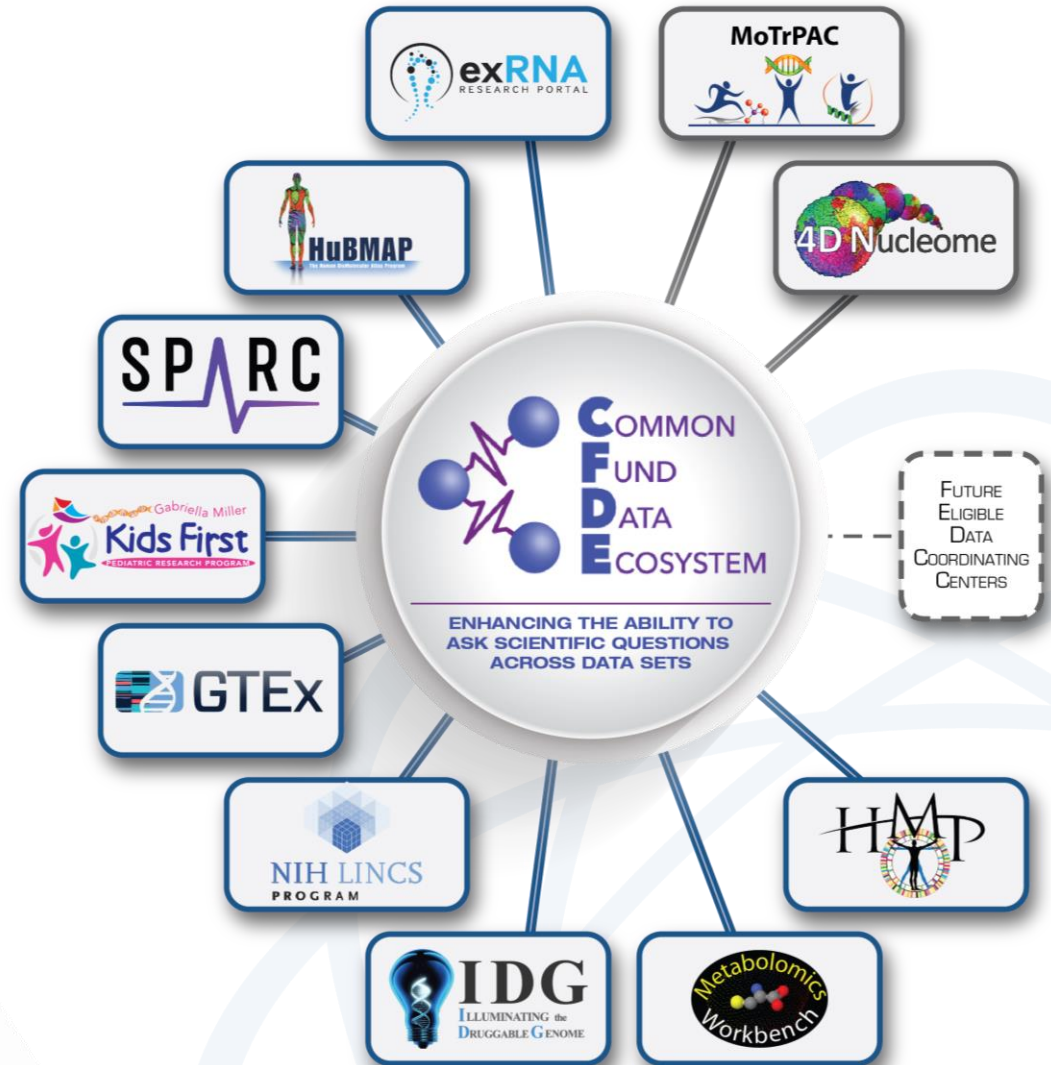
CFDE and Common Fund Data Coordinating Centers (DCCs)

- **CFDE Engagement**

- Construct data infrastructure to ensure FAIRness of data
- Coordinate to ensure data and metadata standards enable interoperability with other Common Fund datasets
- Foster cross-program collaboration

- **Points of Contact**

- Chris Kinsinger: kinsingc@mail.nih.gov
- Haluk Resat: haluk.resat@nih.gov



STRIDES: Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability

- **STRIDES provides:**

- Discounted rates on cloud services
- Access to support & training

- **Common Fund award applicants should:**

- Include cost estimates for cloud computing needs in their application(s)
- NIH will use this cost estimate to provide in-kind services from STRIDES if application is funded
- NIH staff will work with awardees to set up STRIDES accounts



For more information visit:

commonfund.nih.gov/dataecosystem/faqs

<https://grants.nih.gov/grants/guide/notice-files/NOT-RM-20-009.html>



Nutrition for Precision Health Overview



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Nutrition for Precision Health

Powered by the *All of Us* Research Program

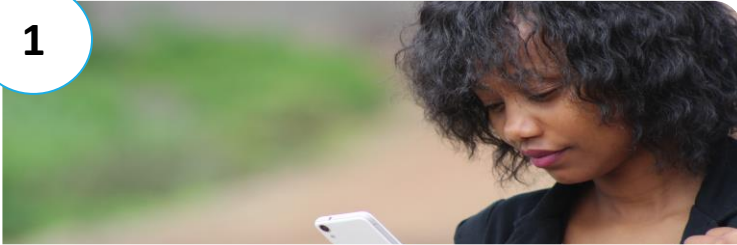


- Primary goal: to develop algorithms to predict individual responses to foods and dietary patterns
 - Using comprehensive set of microbiome, genomic, physiological, metabolic, behavioral, cognitive, contextual, electronic health record, survey, and environmental data
 - In large and diverse population of participants (*All of Us* Research Program)



Proposal overview

1



Examine **baseline diet** in an **observational study** followed by a mixed meal challenge test

10,000 *All of Us* participants

2



Examine responses to 3 short-term intervention diets in free-living **controlled feeding** studies

1,000-2,000 Module 1 participants

3



Examine responses to 3 short-term intervention diets in **domiciled controlled feeding** studies

500-1,000 Module 1 participants

In all 3 modules

- Collect microbiome, physiological, metabolic, behavioral, cognitive, and environmental data, and leverage existing genomic, EHR, and survey data, and conduct mixed meal challenges to model the impact of diet and dietary patterns on physiological responses
- Use machine learning and artificial intelligence to develop predictive algorithms

Program structure



All of Us Research Program



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All of Us Research Program

- ◉ **Diversity at the scale of 1 million people or more**
- ◉ **Focus on participants as partners**
- ◉ **Longitudinal design, ability to recontact**
- ◉ **Multiple data types:** EHR, surveys, baseline physical measurements, biospecimens, genomics
- ◉ **National, open resource for all:** broadly accessible to all researchers with open source software & tools
- ◉ **Security and privacy safeguards** for all participant data

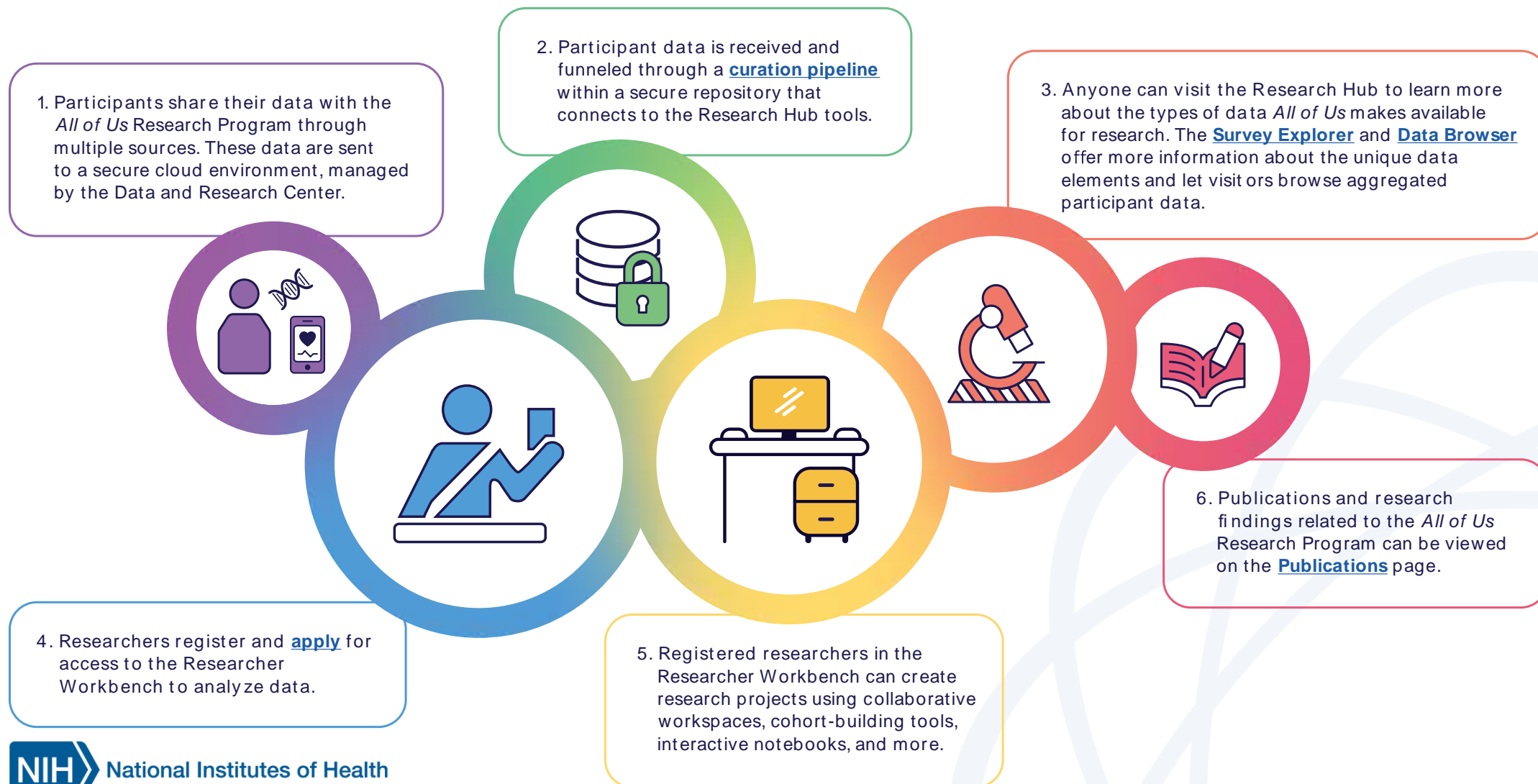


All of Us Core Values

- Participation is **open** to all.
- Participants reflect the rich **diversity** of the U.S.
- Participants are **partners**.
- Trust will be earned through **transparency**.
- Participants have **access** to their information.
- Data will be accessed **broadly** for research purposes.
- **Security and privacy** will be of highest importance.
- The program will be a catalyst for **positive change** in research.



All of Us Researcher Workbench



All of Us Enrollment Sites



<https://allofus.nih.gov/funding-and-program-partners/health-care-provider-organizations>

Key Points for all RFAs



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Important Dates

- Letter of Intent Due Date: March 7, 2021 nutprechealth@nih.gov
- Application Due Date: April 6, 2021
- Peer Review Dates: June 2021
- Advisory Council: October 2021
- Earliest Start Date: December 2021



Administrative Details

- **FAQs** covering many details are available online: <https://commonfund.nih.gov/nutritionforprecisionhealth>
- **NIH Involvement:** There will be substantial NIH programmatic involvement in individual projects and Consortium activities.
- **RFAs:** These are one-off announcements with no revisions or appeals
- **Review:** Reviews will be in Special Emphasis Panels. Please pay attention to review criteria given in the RFAs.



Administrative Details

- **Eligibility:** Foreign institutions are not eligible to apply. Non-domestic components of US organizations are eligible to apply. Foreign components are allowed. For-profit organizations and NIH intramural program are eligible to apply.
 - Exception: RFA-RM-21-004: Non-domestic components are not eligible to apply, and foreign components are not allowed.
- Institutions may apply to one or more RFAs



Budgeting Details

- “NIH Common Fund intends to commit....” refers to total costs, NOT direct costs
- Applicants are encouraged to budget for Consortium activities, travel to annual consortium meetings, resource sharing, outreach, and meeting attendance as part of their proposed budget.
- NIH may modify budgets on award.



Consortium Assurance

- Applicants must submit a Consortium Assurance under “Other Attachments”
- State willingness to participate in consortium activities
 - Sharing scientific portions of applications
 - Participation in regular meetings
 - Abiding by approved consortium policies
 - Following common protocol elements
 - Providing data to RCC in approved formats
 - Providing biospecimens to the Biobank using approved protocols



Data Flow

- Data collection
 - *All of Us* already has some data on participants
 - Clinical Centers will collect new primary data from participants
 - CCs, Biobank, DAC, MMC, MCAC, and RCC may all generate new data from participants' biospecimens, measurements, and survey information
- Data processing and curation
 - DAC, MMC, and MCAC will clean and pre-process data that they generate
 - DAC, MMC, and MCAC may analyze their respective data separately
 - RCC and *All of Us* Data and Research Center (DRC) will curate data
 - DRC will upload data to the *All of Us* Researcher Workbench
- Data analysis and storage
 - All data will be stored in the *All of Us* Researcher Workbench
 - NPH investigators will analyze combined NPH data in the *All of Us* Researcher Workbench
 - No data leaves the Researcher Workbench



Planning Year

- Year 1 of all awards will be a planning year
- Activities:
 - Developing consortium committees, policies, and procedures
 - Finalizing research protocols
 - Planning for data standards, anonymization, assembly, curation, access, analysis, and storage
 - Developing a detailed timeline with concrete milestones for the entire study



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Consortium Governance

- Steering Committee
 - One PD/PI per NPH award plus NIH staff
 - NIH will appoint co-chairs
 - Subcommittees will form in 1st year as appropriate
- Consortium governance rests with Steering Committee
- Subject to oversight by NIH NPH Working Group
- Groups must work collaboratively and interactively




Milestone-Driven

- NPH is a consortium-driven project and relies on specific milestones and timelines accomplished by each component
- Applicants should include a detailed description of a reasonable timeline for proposed activities with achievable milestones as feasible by the capacity and budget
- Awardees will develop a detailed timeline with concrete milestones for the entire study during the planning year

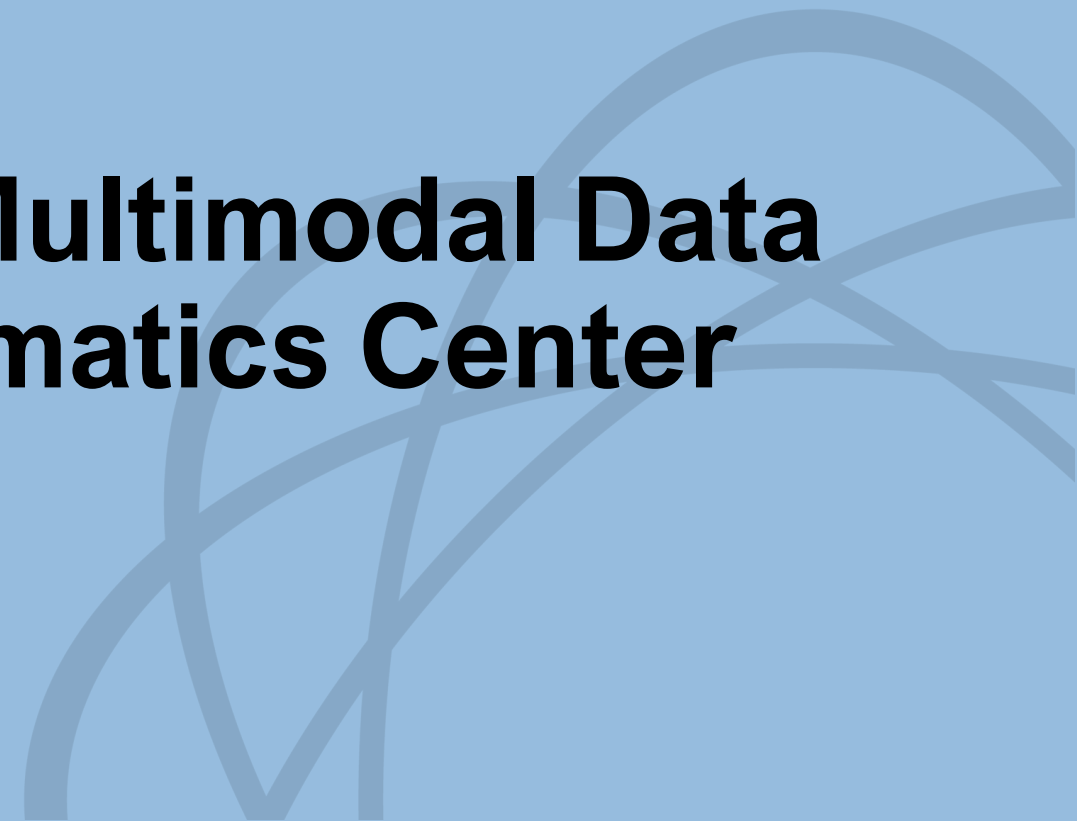


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RFA-RM-21-001

Artificial Intelligence, Multimodal Data Modeling, and Bioinformatics Center



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AIMDMB Center

Goals

- To develop comprehensive dietary intervention algorithms that can predict biological responses to a myriad of input data
- To enable adaptive visualization and interrogation of multimodal data with advanced mathematical and computer modeling tools



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AIMDMB Center

Expertise

- Applicants should assemble a multi-disciplinary team with expertise in biomedical data science, systems biology, artificial intelligence, and nutrition as well as other biological and physical science expertise.



AIMDMB Center

- Activities in the first years should be targeted towards
 - Development of tools with non-study data
 - Collaboration with the consortium
 - Formulation of AI-specific gold standards for all data types
 - Participating in development of the clinical study protocol, in collaboration with Steering Committee, for defining data standards, curation, and provenance needs
 - Development of transparent, ethical protocols and procedures for working with study data within the *All of Us* Researcher Workbench
 - Other aspects specific to the AIMDMB Center project's proposed in the application
 - Identification and leveraging other data sets of value to driving development of their tools, technologies, platforms, or algorithms



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AIMDMB Center

- Pilot projects
 - Administrative and Coordination Core must include pilot projects that have significant potential to address developing needs and opportunities.
 - These will be determined after the awards have been made and will continue through the study.
 - **No pilot needs to be outright defined or developed to be included in the application.**
 - Applicants may suggest example projects that could be undertaken by the AIMDMB Center relative to its structure, proposed projects, or leveraging existing collaborations that will make it unique to other applications.
 - AIMDMB Centers are required to allocate a minimum of \$250K per year direct costs, beginning in Year 2 of the research funding cycle – should be built into Center budget



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RFA-RM-21-002

Metabolomics and Clinical Assays Center (MCAC)



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Metabolomics and Clinical Assays Center

Goals

- To generate targeted and non-targeted metabolite profiles
- To perform or facilitate clinical assays from blood, urine and stool biospecimens




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RFA-RM-21-003

Microbiome and Metagenomics

Center (MCC)



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Microbiome and Metagenomics Center

Goal:

- To perform microbiome, metagenomics and metatranscriptomics analysis of stool specimens collected in the Nutrition for Precision Health study



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MCAC/MMC

Budget

- Applicants should not include costs for specimen collection (e.g., supplies, materials, shipping, courier logistics)



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MCAC/MMC

Sample collection

- Biospecimens listed in the RFA are a guideline
- The final suite of biospecimens to collect, and their timing, will be determined by the Steering Committee in year 1



RFA-RM-21-004

Dietary Assessment Center



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Dietary Assessment Center

Goal:

- To support the side-by-side application of
 - at least one innovative approach to assess dietary intake
 - the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool
 - using free-living and controlled feeding studies
- To improve these methodologies through validation, evaluation, and modeling efforts



RFA-RM-21-005

Clinical Centers



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Clinical Centers

Goal

- To enroll participants and implement complex, modular protocols for dietary interventions studies



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Clinical Centers

Modules

- 1: Follow approximately 10,000 participants for up to 14 days to examine baseline diet and physiological responses to a test meal challenge
 - Two clinic visits approximately two weeks apart, with remote data collection during the study period.
- 2: Free-living controlled feeding study that will examine responses to three short-term (~14 days) intervention diets in approximately 1,500-2,000 Module 1 participants.
 - 3 2-week dietary intervention periods with washouts between
- 3: Domiciled controlled feeding study that will examine responses to the same three short-term (~14 days) intervention diets in approximately 500-1,000 participants from Module 1, but not Module 2.
 - 3 2-week dietary intervention periods with washouts between



Clinical Centers

Sample Size

- Applicants can propose all 3 Modules or Module 1 + one other
 - All participants must do Module 1
 - Some Module 1 participants may then do Module 2 OR Module 3
- Applicants should propose to enroll a feasible number of participants
 - No minimum or maximum requirements



Clinical Centers

Mixed meal challenges

- The same mixed meal challenge will be conducted in modules 1, 2, and 3
- Applicants should propose one type of mixed meal challenge
 - Should be designed to produce different metabolic responses among individual participants in order to provide individual-level dietary response information for precision nutrition algorithm development
- Mixed meal challenge costs should be included in the budget



Clinical Centers

Dietary interventions for modules 2 and 3

- The same 3 dietary patterns will be tested in all module 2 and 3 participants.
- Each participant receives all 3 patterns in randomized order and serves as their own control
- Applicants should propose 3 different dietary patterns
 - Should not be designed to induce weight loss
 - Should be designed to produce differential metabolic responses among individual participants in order to provide individual-level dietary response information for precision nutrition algorithm development.
- Costs to administer controlled diets should be included in the budget



Clinical Centers

Inclusion Criteria

- Adults 18+
- Applicants should propose minimal well-justified inclusion/exclusion criteria
 - Pregnant women, people with chronic diseases/conditions, people without chronic diseases/conditions should all be included
 - Exclusion criteria focused on ability to complete the study ok
- Enrollment of a diverse population is a requirement



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Clinical Centers

Budget

- NIH Common Fund intends to commit approx. \$7M in FY2022 and \$9.5M in FY2023-2026
- 5-6 awards are anticipated
- Budget should reflect actual need, including participant capacity, and modules proposed
- Budget should not include participant incentives



Clinical Centers

Enrolling *All of Us* participants

- Where geographically feasible, work with *All of Us* Health Care Provider Organizations (HPOs) to engage and enroll participants from the *All of Us* cohort to participate in the Nutrition for Precision Health study
 - It is required that an *All of Us* Research Program Investigator be part of the research team
 - No specific requirement for *All of Us* investigator as PI, co-I, etc
 - Can enroll new *All of Us* participants who then enroll in NPH



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Clinical Centers

Enrolling *All of Us* participants

- Where it is not geographically feasible to partner with an existing *All of Us* HPO, CCs will implement the *All of Us* enrollment protocol (<https://allofus.nih.gov/about/all-us-research-program-protocol>) for new *All of Us* participants
 - Will require regulatory onboarding steps including executing a reliance agreement, *All of Us* IRB approval, and an interconnection security agreement to share EHRs and implement the protocol



Enroll, Consent
and Authorize EHR



Answering
Surveys



Physical
Measurements



Provide
Biosamples



Wearables and
Digital Apps



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RFA-RM-21-006

Research Coordinating Center



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Research Coordinating Center

Goals

- To provide administrative management and general coordination across the Nutrition for Precision Health consortium
- To facilitate the development and implementation of dietary intervention and assessment studies across the consortium
- Curate Nutrition for Precision Health data prior to transfer to the *All of Us* Researcher Workbench



Research Coordinating Center

Capitation

- Each year's budget will be limited to a BASE budget
 - \$3.5M in year 1
 - \$2.5M in years 2-5
- RCC will administer a process to provide ~\$2.5M per year in years 2-5 to Clinical Centers for participant incentives
- Applicants should not include the participant incentives in their proposed budget



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Connect with us:

- General mailbox: nutritionresearch@nih.gov
- Website: <https://commonfund.nih.gov/nutritionforprecisionhealth>

Frequently Asked Questions:

<https://commonfund.nih.gov/nutritionforprecisionhealth/faqs>

Interested in applying?

We strongly recommend you discuss any application with us in advance and that you submit a LOI.



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Questions and Answers

Q&A

All (0)

Ask: All Panelists

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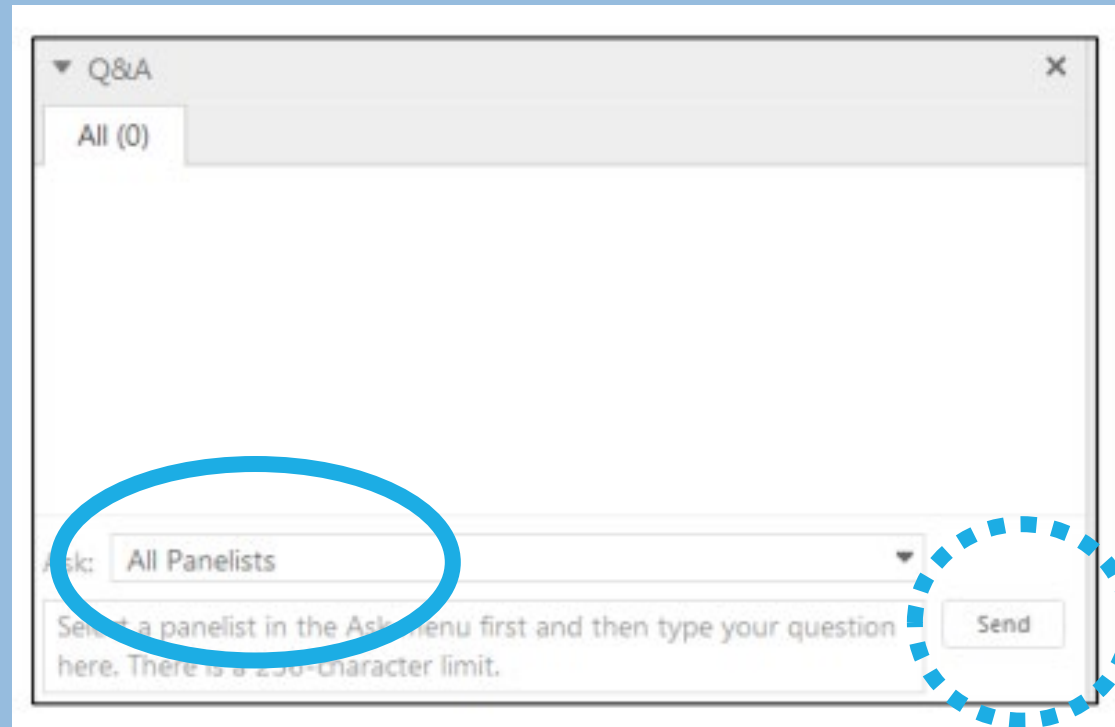
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Questions and Answers





Questions and Answers

A screenshot of a web-based Q&A interface. At the top, there's a header 'Q&A' with a close button. Below it, a tab says 'All (0)'. The main area is a large empty text box. At the bottom, there's a form with a dropdown menu labeled 'Ask: All Panelists' (circled in blue), a text input field, and a 'Send' button (circled with a dashed blue border). Below the form, there's a small instruction: 'Select a panelist in the Ask menu first and then type your question here. There is a 250-character limit.'



Questions and Answers

A screenshot of a web-based Q&A interface. At the top, there is a dropdown menu labeled 'Q&A' with a close button 'x'. Below it is a filter bar showing 'All (0)'. The main area is a large empty text box. At the bottom, there is a form with a label 'Ask:' followed by a dropdown menu currently set to 'All Panelists'. Below the dropdown is a text input field with a placeholder that reads 'Select a panelist in the Ask menu first and then type your question here. There is a 250-character limit.' To the right of the input field is a 'Send' button. A solid blue oval highlights the 'All Panelists' dropdown menu, and a dashed blue circle highlights the 'Send' button.