



July 13, 2021

Research Opportunity Announcement

Research Opportunity Title: AIM-AHEAD Coordinating Center: Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity

OTA-21-017

Participating Organization(s): National Institutes of Health

Components: This Other Transactions Research Opportunity Announcement (OT ROA) is part of the *AIM-AHEAD: Artificial Intelligence/Machine Learning (AI/ML) Consortium to Advance Health Equity and Researcher Diversity* Program in institutions with a diversity mission focus. The research opportunity will be administered by the Office of Data Science Strategy on behalf of AIM-AHEAD.

Funding Instrument: The funding instrument is the Other Transactions (OT) Award mechanism.

OT awards are not grants, cooperative agreements, or contracts, and use an Other Transactions Authority, provided by law. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award.

Related Notice:

NOT-OD-21-156 Notice of Intent to Publish a Research Opportunity Announcement for AIM-AHEAD: Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity

Research Opportunity Purpose: The purpose of this announcement is to invite applications from eligible organizations to engage with the NIH, and with other awarded organizations, in the initial phase of *Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD)* program, the goal of which is to establish mutually beneficial, coordinated, and trusted partnerships to enhance the participation and representation of researchers and communities currently underrepresented in the development of artificial intelligence and machine learning (AI/ML) models and improve the capabilities of this emerging technology, beginning with the use of electronic health record (EHR) and extending to other diverse data to address health disparities and inequities. This opportunity is for an initial phase of this program, which focuses on assessment, planning, and capability building for the consortium, and enhancing trust within the communities impacted by this program. This solicitation will establish the AIM-AHEAD Coordinating Center (A-CC), comprised of four cores as detailed below. Applications may address one or more of the cores.

Objective Review: NIH will convene an appropriate review group to evaluate applications. See the Objective Review section of this opportunity for further details.

Eligibility: See the Eligibility section of this opportunity.



Funds Available and Anticipated Number of Awards: The current budget for this award period is planned for up to \$100 million over a 2-year period including the operations and support for the A-CC as well as any proposed activities, projects, infrastructure, or investments for members of the consortium, once established. The OT mechanism allows for significant flexibilities to make adjustments needed to pursue catalytic and transformative initiatives. Award levels may increase or decrease over time based on programmatic needs, funding availability, and recipient performance.

Award Project Duration: Initial Project duration is anticipated to be two years, but individual projects may be shortened or extended needed.

Authority: Other Transactions awards will be made pursuant to current authorizing legislation, including Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n), as amended.

Release Date of this Research Opportunity Announcement: Tuesday July 13, 2021

Informational Webinar (optional): Thursday July 15, 2021

Letters of Intent Due Date: Thursday July 22, 2021 by 5:00 PM local time of applicant organization

Proposal Due Date: Tuesday, August 3, 2021 by 5:00 PM local time of applicant organization

Earliest Start Date: September 8, 2021

Kickoff Meeting: To Be Determined

Agency Contacts

Scientific Research Contact(s): AIM-AHEAD_ROA@od.nih.gov

Financial/Agreements Officer: Dede Rutberg; rutbergd@mail.nih.gov

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Outline of this Opportunity

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Overview of the AIM-AHEAD: Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity Program

Background

NIH's AIM-AHEAD program will establish mutually beneficial, coordinated, and trusted partnerships to enhance the participation and representation of researchers and communities currently underrepresented in the development of AI/ML models and improve the capabilities of this emerging technology, beginning with electronic health record (EHR) and extending to other diverse data to address health disparities and inequities.

The rapid increase in the volume of data generated through electronic health records (EHR) and other biomedical research presents exciting opportunities for developing data science approaches (e.g., AI/ML methods) for biomedical research and improving healthcare. Many challenges hinder more widespread use of AI/ML technologies, such as the cost, capability for widespread application, and access to appropriate infrastructure, resources, and training. Additionally, lack of diversity of both data and researchers in the AI/ML field runs the risk of creating and perpetuating harmful biases in its practice, algorithms, and outcomes, thus fostering continued health disparities and inequities. Many underrepresented and underserved communities, which are often disproportionately affected by diseases and health conditions, have the potential to contribute expertise, data, diverse recruitment strategies, and cutting-edge science, and to inform the field on the most urgent research questions, but may lack financial, infrastructural, and data science training capacity to apply AI/ML approaches to research questions of interest to them. This program will also seek to enhance trust within the communities impacted by this program.

NIH is committed to leveraging the potential of AI/ML to accelerate the pace of biomedical innovation, while prioritizing and addressing health disparities and inequities. Tackling the complex drivers of health disparities and inequities requires an innovative and transdisciplinary framework that transcends scientific and organizational silos. Mutually beneficial and trusted partnerships can be established to enhance the participation and representation of researchers and communities currently underrepresented in AI/ML modelling and application, and improve the capabilities of data curation and this emerging technology.

This solicitation will establish the AIM-AHEAD Coordinating Center (A-CC), which will build a consortium of institutions and organizations that have a core mission to serve minorities and other under-represented or underserved groups impacted by health disparities (e.g., Historically



Black Colleges and Universities, Tribally Controlled Colleges and Universities, health care systems, etc.).

The AIM-AHEAD Coordinating Center

This solicitation will establish the AIM-AHEAD Coordinating Center (A-CC), which will build a consortium of institutions and organizations that have a core mission to serve under-represented or underserved groups (minority populations, low socioeconomic, rural, sexual gender minorities) impacted by health disparities (e.g., Historically Black Colleges and Universities, Tribally Controlled Colleges and Universities, etc.). The A-CC will focus initially on coordination, assessment, planning, and capacity building to enhance the use of artificial intelligence (AI) and machine learning (ML) in research among the consortium institutions and organizations; and to build and sustain trusted relationships between the consortium and groups impacted by health disparities. The A-CC will be comprised of four main cores. This solicitation invites applications that address one or more of these:

- **Leadership/Administrative Core:** Lead the overall A-CC, recruit and coordinate consortium members, project management, partnerships, stakeholder engagement, and outreach to enhance the diversity of researchers in AI/ML related research, with emphasis on health disparities research, and to establish trusted relationships with health disparities groups to enhance the diversity of data used in AI/ML research.
- **Data Science Training Core:** Assess, develop, and implement data science training curriculum to enhance capacity among diverse population groups, specifically underrepresented or underserved groups impacted by health disparities.
- **Data and Research Core:** Determine and address research priorities and needs in linking and preparing linking and preparing multiple sources and types of research data to form an inclusive basis for AI/ML use cases that will illuminate strategies and approaches to ameliorate health disparity. This may include facilitating the extraction and transformation of data from electronic health records (EHR) for research use and consideration of social determinants of health as crucial contributors to health.
- **Infrastructure Core:** Assessment of data, computing, and software infrastructure models, tools, resources, data science policies, and AI/ML computing models that will facilitate AI/ML and health disparities research; and establishment of pilot data and analysis environments to accelerate overall A-CC aims.

Cores:

It's expected that the consortium members and the communities they serve will vary in terms of their research interests, preferences around data sharing and data governance, and training needs. A one-size-fits-all approach to infrastructure, training, research directions, or engagement is unlikely to achieve the overall goals of the AIM-AHEAD program. Dedicated efforts are needed, therefore, in each of these areas. This solicitation invites applications that address one or more of the following Cores:

*Leadership/Administrative Core:*

Broadening the diversity of data for AI/ML applications, as well as the diversity of researchers engaged in AI/ML applications is a cornerstone of the AIM-AHEAD program. The A-CC will establish trusted partnerships with institutions and organizations that have a core mission to serve under-represented or underserved groups impacted by health disparities, as well as trusted relationships among these groups as the foundation for the AIM-AHEAD consortium. It's important that the A-CC take an inclusive approach and not focus on any particular underrepresented or underserved group.

Partnerships with the private sector, for example, with industry or professional societies, will be important for ensuring access to data, computing resources, and for sustaining progress toward the AIM-AHEAD goals.

Applicants to this core are expected to lead and manage the overall A-CC and its partnerships with consortium members and other stakeholders, including sub-awards to enable collaboration. Therefore, the A-CC Leadership/Administrative Core will also require substantial project management capabilities to ensure coordination among the different activities, many of which will be interdependent; to ensure activities stay on time and on budget; and to flexibly meet the needs of potential consortium members as they join the program and as assessments mature. The other cores will provide substantial technical and data science capabilities to integrate data and activities among the consortium participants, which will need to be coordinated and managed by the Leadership/Administrative Core. In doing so, the Leadership/Administrative Core is expected to balance the need for a deliberate and strategic approach to building lasting partnerships and infrastructure with the advantages of quickly seizing opportunities that catalyze rapid advancements in AI/ML capabilities. Throughout the program and as appropriate, activities will leverage existing NIH programs, for example those in data science training, health-related big data resources and platforms, and the [STRIDES](#) (cloud storage and compute) program and its associated training opportunities.

Expectations: At the end of the award period, the A-CC is expected to have:

- Recruited and established a consortium of institutions and organizations that have a core mission to serve under-represented or underserved groups impacted by health disparities to participate in the initiative. The consortium should include multiple underrepresented communities and recruitment of consortium sites should take into account their capacity to establish relationships of mutual trust with health disparity populations and access and analyze data from multiple sources such as EHR, image, and social determinants of health to improve the overall quality, diversity and balance of data used for AI/ML applications and health disparities research.
- Executed sub-awards to consortium institutions and organizations to support capacity building, pilot studies, and collaborative projects that advance the overall goals of the A-CC and leverage strengths and synergies of the consortium.
- Established an organizational and project management structure for the A-CC, including the other three cores, that enables it to meet milestones on schedule and on budget; facilitates trusted partnerships within the A-CC and with external stakeholders; and maintains an agile approach to quickly seize opportunities as needed.



Data Science Training Core:

The AIM-AHEAD consortium members will have a wide range of expertise and skill levels relevant to AI/ML and health disparities research. The A-CC will identify training needs and gaps as well as identify or develop training and workforce development resources to address these.

Training assessments should consider AI/ML and health disparities research as well as related competencies in, for example, cloud computing, distributed computing, data preparation, data science, biostatistics, modelling, epidemiology, clinical/biomedical informatics, data science policy, ethics, and health disparities and community engaged research methods.

Training offerings will be particularly useful for engaging early career investigators and researchers with diverse backgrounds into AI/ML research. The training offerings should consider the skills and competencies needed for the AIM-AHEAD projects as well as the professional development and potential career paths of the trainees. Internships and practical training opportunities with private sector partners may be leveraged.

It's expected that application-based learning opportunities with large scale data will be an important aspect of training and workforce development. The Data Science Training Core therefore will work closely with other A-CC efforts to develop or leverage platforms to access AI/ML-ready data.

Expectations: At the end of the award period, the A-CC is expected to have:

- Established and enhanced trust of the institutions providing data access and groups impacted by health disparities.
- Assessed and enhanced the capacity of consortium members to use AI/ML to conduct health disparities research through, for example, piloting and testing data science training and development modules, as well as developing AI/ML relevant health disparities research questions.
- Built capabilities at consortium institutions through, for example, industry partnerships and in-kind contributions of resources, and the establishment of pilot training activities using platforms for AI/ML-ready data collections and for data analysis.
- Enhanced learning among the consortium members by, for example, establishing trans-disciplinary groups with multiple skill levels around research questions of common interest.
- Leveraged consortium members' strengths to develop and implement innovative training approaches and materials.
- Provided real-time assistance and support through, for example, a technical assistance or mentoring hotline.
- Developed and tested training offerings for the consortium members and determined the near-, medium-, and long-term training needs to be address in future stages of the AIM-AHEAD program.

Data and Research Core:

The interest in AI/ML from underrepresented communities is wide-ranging, and the potential applications of AI/ML in the field of health disparities research is also broad. Through engagement with the consortium members, the A-CC will prioritize and determine the AI/ML and health disparities research use cases that will be enabled by the AIM-AHEAD program. This will be done, for example, through stakeholder engagement, training and education opportunities, and pilot



projects with the consortium members. The resulting use cases will be used to drive the design of the data and computing infrastructure and associated data governance models and training offerings for the AIM-AHEAD program.

Research use cases are anticipated to involve linking and preparing multiple sources and types of research data to form an inclusive basis for AI/ML that will illuminate strategies and approaches to ameliorate health disparity. This may include facilitating the extraction and transformation of data from electronic health records (EHR) for research use and consideration of social determinants of health as crucial contributors to health. This is an opportunity to foster the adoption of standardized data structure such as Fast Healthcare Interoperability Resources (FHIR®) in accessing and exchanging data from EHR.

In this award period, this core focuses on assessment and planning as well as seizing early opportunities to build capabilities that are either necessary for training and/or necessary to address the emerging priority use cases.

Broadening the diversity and representation in of AI/ML data is another essential aspect of the AIM-AHEAD program. The A-CC will work with consortium members in preparing data and making data ready for AI/ML applications.

Expectations: At the end of the award period, the A-CC is expected to have:

- Determined the AI/ML and health disparities research use cases that will drive the design of the data and computing infrastructure and associated data sharing and training offerings.
- Carried out pilot AI/ML projects with consortium members to collect and prepare clinical/biomedical data, including EHR, social determinants of health, and other data from sites within the consortium.
- Prepared and supported the use of existing or purpose-built data resources for AI/ML applications and health disparity research.
- In collaboration with the A-CC training efforts, locally developed the requisite skills, capabilities, and infrastructure for these AI/ML applications.

Infrastructure Core:

There are a wide variety of data and computing infrastructure options to facilitate AI/ML. Cloud platforms, for example, integrate data storage, computing cycles, security, and, often, analysis tools for geographically distributed users and groups. Distributed or federated learning approaches are more appropriate when data cannot be pooled. The A-CC will work with consortium members to assess needs and constraints, and pilot and test different data and computing infrastructure, tools, and governance models including data policy and organizational models.

It's expected that the AIM-AHEAD program will require a variety of, for example, computing platforms depending on the research project, the data needed, and a variety of other factors; and that multiple platforms may be needed in the course of a single project. The Infrastructure Core should therefore consider opportunities to integrate a variety of infrastructure types with portable, scalable, and interoperable environments.

Expectations: At the end of the award period, the A-CC is expected to have:



- Determined options and preferences for data sharing that facilitate AI/ML, including, as appropriate, options for distributed / federated learning, that meet the social and technical needs of the consortium members.
- Prepared the consortium members for AI/ML applications by, for example, carrying out health disparity research pilot projects. These pilots may use existing infrastructure and resources as well as pilots on new datasets made available under this OTA.
- Enhanced the capacity of consortium institutions and organizations to prepare and link data for AI/ML and engage in AI/ML research through, for example, the development of tools and/or local infrastructure investments.
- Established pilot data access and analysis environments to enable AI/ML applications and to better assess the needs, challenge, and opportunities for future infrastructure investments.
- Determined the near-, medium-, and long-term data and computing infrastructure needs and options for the consortium; and options for meeting these needs with integrated platforms and services or cloud computing.

Partnering with other applicants and other teaming arrangements

To ensure the best balance of expertise and capabilities, the Coordinating Center (A-CC) may be comprised of one or more applicants from this solicitation. In addition, individual applications may be submitted by multi-institutional partnerships.

Once established, the A-CC is expected to identify and support engagements, assessment, pilot projects, and capacity building with potential consortium members. The A-CC will manage these relationships and associated contractual arrangements in partnership with NIH as subject to the OTA award. The A-CC will also manage engagement and coordination with existing NIH resources, and private sector stakeholders.

Eligibility

The AIM-AHEAD program expects the A-CC to include experts from diverse social, cultural, economic, academic, and industry backgrounds and communities. This Research Opportunity Announcement invites applications from a broad range of institutions and organizations including non-traditional industry and non-profit organizations. NIH is particularly interested in applications led by institutions and organizations that have a core mission to serve under-represented or underserved groups impacted by health disparities. (See [NIH's Interest in Diversity](#).)

Applications may address one or more of the cores described above, and must meet the corresponding eligibility requirements as follows:

Applications for ***the Leadership/Administrative Core*** from groups with the following characteristics will be considered responsive:

- A strong track record and established connections to a variety of underrepresented or underserved groups impacted by health disparities and institutions and organizations serving these groups.
- Ability and willingness to recruit and build a national scale consortium.



- Expertise in data-intensive, community engaged research or large-scale research efforts that have established long-term relationships with organizations that work with health disparity populations.
- Expertise in the principles of conducting community engaged research.
- Knowledge and expertise in health disparities research, AI/ML applications, and the use of diverse data including EHR for research.
- Willingness to work with other program recipients in a collaborative manner.
- The PI (or contact PI) is from an institution or organization with a core mission to serve underrepresented or underserved groups impacted by health disparities. Demonstration of a core mission may include dedicated program or activities focused on unique needs of these groups.

Applications for **Data Science Training Core** from groups with the following characteristics will be considered responsive:

- Experience and expertise in delivering innovative training and education opportunities to diverse communities with a wide range of skill levels and resources.
- Experience and expertise in identifying workforce development and training gaps and opportunities.
- Willingness to work with other program recipients in a collaborative manner.

Applications for **Data and Research Core** from groups with the following characteristics will be considered responsive

- Expertise and experience preparing and linking a variety of data types from multiple data sources, and developing AI/ML applications using these data.
- Expertise in developing inclusive strategies for developing AI/ML data to mitigate bias and ameliorate health disparities.
- Expertise in preparing and using multi-modal data including electronic health information, other data from clinical settings, and social determinants of health for health disparities research and AI/ML applications.
- Clinical expertise and clinical research expertise. Experience with data models, especially for EHR data.
- Willingness to work with other program recipients in a collaborative manner.

Applications for **Infrastructure Core** from groups with the following characteristics will be considered responsive

- Expertise and experience generating use-case based requirements for software and hardware data infrastructure.
- Expertise and experience building platforms for shared, controlled-access data.
- Experience and expertise in developing data platforms that are compliant with FISMA and related standards; knowledge and understanding of data security solutions, and experience obtaining an ATO.



- Demonstrate proficiency with large scale cloud platforms, multi-modal data including electronic health information and data from clinical settings in health disparities research and AI/ML applications.
- Expertise and ability to provide tools, capabilities, and infrastructure to consortium members to enable or facilitate the preparation and analysis of multiple sources of data, including data from EHR, for AI/ML.
- Understanding and expertise in establishing distributed or federated AI/ML capabilities.
- Willingness to work with other program recipients in a collaborative manner.

Applications nonresponsive to the terms of this ROA will not be considered. The following types of projects would generally not be appropriate and may be deemed non-responsive:

- Proposals that do not meet the eligibility criteria above or that do not explain how these criteria are met.
- Proposals that do not demonstrate an understanding of AI/ML and health disparities research.
- Proposals that do not demonstrate an understanding or ability to engage and collaborate with a diverse researchers and organizations.
- Proposals that do not explicitly address and advance the AIM-AHEAD goals.

Organizations

Non-domestic (non-U.S.) Entities (Foreign applicants) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components **are not** allowed. Foreign consultants are allowed if approved by the NIH official in advance of the full application submission. Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Individuals not affiliated with an organization, or who want to submit an application independently of their current organization, **may not** apply.

The following entities are eligible to apply under this ROA:

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Faith-based or Community-based Organizations



- Regional Organizations

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- American Indian/Native American Tribal Governments (Federally Recognized)
- American Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than Federally recognized tribal governments)

[Multiple Principal Investigators](#)

More than one individual may be named as Principal Investigator in the application. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the applicant organization. If a multiple Principal Investigator proposal is submitted a leadership plan is required.

[Financial and Risk Assessment](#)

Applicants may be subject to financial analysis and risk assessment conducted by NIH staff.

[Cost Sharing](#)

Cost Sharing is not required; however, those proposing to develop commercial applications or who are using other state or government resources may consider identifying a cost share percentage. Applicants may voluntarily choose to propose a financial plan that includes non-federal resources. The budget submission must clearly identify and justify the use of these resources. Any voluntary cost share must be supported in the application by including a letter of support from the providing organization(s)/individual(s).

[Application Submission Instructions and Contact Information](#)

For best consideration, complete applications should be submitted under OTA-21-017 via eRA ASSIST not later than the "Proposal Due Date" shown at the top of this notice, by 5 PM local time of applicant organization. Detailed system instructions for submitting your application will be provided by the NIH Other Transactions Agreements Officer (OTAO).

Financial and administrative questions should be addressed to



Dede Rutberg, OTAO
rutbergd@mail.nih.gov

For further information, please consult the AIM-AHEAD FAQ page:
<https://datascience.nih.gov/artificial-intelligence/aim-ahead/coordinating-center-faqs>

Questions about the scientific scope of the studies should be addressed to AIM-AHEAD_ROA@od.nih.gov

Developing Applications

Letters of Interest (LOIs), due by the “**Letters of Intent Due Date**” shown at the top of this notice, will be used to select individuals or groups who will be invited to submit a full application. Only those who are invited may apply. If invited to submit a full application by NIH staff, the Authorized Organizational Representative and contact PI will be notified and will be provided with guidance on submission of an application. Full applications are due by the “**Proposal Due Date**” shown at the top of this notice. Applicants may also be invited to a virtual, presentation-style review including question and answer time during the week of **August 9, 2021**. Applications and interviews will allow the NIH to: 1) establish a unique review process that will bring together AIM-AHEAD Principal Investigators, the AIM-AHEAD Program Officials, and possibly external experts; and 2) orient or re-orient one or more selected applications into new teaming arrangements to establish the A-CC. NIH may also share, with PI agreement, applications between or among teams to ensure optimal configuration of funding, partnerships, and activities. The applications will be considered during the review. For more details on the review process, see section 6 (Objective Review) below. Partnerships among institutions with complementary skills and expertise to meet the expectations of this ROA are encouraged.

Letter of Intent

Interested applicants should submit a Letter of Intent (LOI) of no more than 2 pages, outlining the following:

- A brief description of the planned activities and approach (see the core-specific guidance below)
- How the proposed activities will meet the needs of the AIM-AHEAD program
- How the team’s prior experience meets the eligibility requirements, stated above.
- A brief description of how the PI’s (or contact PI’s) institutional affiliations meet the core-specific eligibility criteria.
- Anticipated institutional or corporate partners.
- Estimated overall budget per year, for both years of the award.

LOI submissions should include a cover page, as described below for the full application.

LOIs are not binding and will be used only to determine which individuals or groups to invite to submit full proposals. NIH is not responsible for providing feedback on unsuccessful LOIs.



Letters of intent must be submitted by email as a .pdf attachment to AIM-AHEAD_ROA@od.nih.gov. LOIs submitted by other means may not be considered.

Application

Applications will be accepted only from Organizations listed in the Eligibility section of this Announcement that submit a letter of interest, and that are invited to apply. Applications must be prepared and submitted using NIH's [ASSIST](#). The NIH will not review and will return applications submitted from organizations not included in the Eligibility section. Complete applications must be submitted by the Authorized Organizational Representative. The organization must be registered in eRA Commons with one person designated as the primary investigator (PI) and one person designated as the Signing Official (SO). The Signing Official's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application.

Plans must be submitted by the due date, in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins, be single-spaced, may not exceed 12 pages, and the file size must be no greater than 20 MB. The sections of the application should be loaded as separate attachments on field # of the form and should be titled as specified in each section (title included in parentheses following each section).

Cover ("Cover.pdf"; no more than 1 page)

1. Number and title of this Research Opportunity Announcement
2. Project Title
3. Core(s) targeted in the application:
 - a. *Leadership/Administrative Core;*
 - b. *Data Science Training Core;*
 - c. *Data and Research Core; and/or*
 - d. *Infrastructure Core*
4. Names of key personnel, institutional affiliation, title, and percent effort
5. Other involved personnel names, roles, and organizations (multiple Principal Investigators, co-Investigators, collaborators, contractors, authors of letters of support, etc.)
6. Name and address of the submitting organization and department.
7. Authorized Organizational Representative first and last name, title, institution, mailing address, email address and phone number.
8. Approximate budget per year (direct and total)
9. Proposed Project Period Dates
10. Confirmation that the work involves human subjects or data from human subjects.
11. Agreement that any and all parts of the application can be shared among other applicants.

Senior/Key Personnel and Other Significant Contributors ("Senior/Key.pdf"; no more than five pages per individual). At a minimum, the information in the biosketch should include the name and position title, education/training (including institution, degree, date (or expected date), and field; list of positions and employment in chronological order (including dates); and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. The format (<https://grants.nih.gov/grants/forms/biosketch-blankformat.docx>) used for an NIH grant application is acceptable.



Applications may include letters of support from potential partners or organizations and institutions that have existing relationships with the applicant. Letter of support are not included in the application page limit.

Application research plan ("Application.pdf"; no more than 12 pages including any charts or figures.) should be organized into the following sections to facilitate review:

Section 1: Planned activities and approach:

All applications should describe the proposed activities and approaches for each targeted core and how these will meet:

- the overall goals of the AIM-AHEAD program;
- the specific expectations for each core, as described above;
- and the eligibility requirements for each core, as described above.

In addition, applications should address the following core-specific guidance:

Applications for the **Leadership/Administrative Core** should describe:

- Plans for identifying and engaging potential consortium members including efforts to promote diversity and inclusion among the members, avoiding any biases toward particular subgroups, for example, regional outreach, or outreach among ethnic groups (tribal, Latinx,...)
- Plans for outreach and engagement with private sector and other stakeholders that have the potential to add value to the consortium goals.
- Plans for structuring sub-awards to consortium members and capabilities for implementing sub-awards.
- The implementation team that will engage in outreach, their trans-institutional expertise, and experience networking across institutions.
- Approaches for working with other A-CC cores to ensure mutual trust is maintained and strengthened with and among the consortium members as projects and engagements develop.

Applications for **Data Science Training Core** should describe:

- Plans for engaging consortium members and relevant communities to assess the near-, mid-, and long-term training needs and gaps and identify opportunities where training can advance the goals of the AIM-AHEAD program and serve the career development and workforce needs at the consortium sites.
- Plans and approaches for developing and delivering new and existing training offerings to meet the identified needs, including approaches for cross-community or cross-disciplinary training.
- Plans for developing a real-time help center or other resource for consortium members.
- Innovative approaches for enhancing diversity in training programs and workforce.

Applications for the **Data and Research Core** should describe:

- Plans and approaches for working with consortium members to develop and elicit priority research interests and use cases in AI/ML and health disparities research.



- Plans and approaches for working with other A-CC cores to meet the data access, and training needs relevant to enable the priority research interests.
- Plans and approaches for engaging consortium members in pilots and projects.
- Plans and approaches for addressing and remediating potential biases in data and AI/ML models, especially as pertains to health disparities.

Applications for the ***Infrastructure Core*** should describe:

- Plans and approaches for working with consortium members to assess the near-, mid-, and long-term data infrastructure needs, taking in to account, for example, research priorities, preferences around data sharing and management, existing capabilities and opportunities to enhance these through the AIM-AHEAD program.
- Plans and approaches for recruiting and prioritizing pilot projects with consortium members, and how these would be managed.
- Plans and approaches for piloting data infrastructure to enable AI/ML applications, including plans to provide new and existing data resources.
- Plans and approaches for engaging the diverse communities of researchers to explore AI/ML in EHR using existing NIH resources (see section below) or others.

Section 2: Planned coordination with other cores of the A-CC:

All applications should describe how their efforts could be synergistic with other A-CC cores to achieve the overall goals of the AIM-AHEAD program and in ways that maintain and enhance mutual trust between the A-CC and the consortium members and among these groups. In particular, the application should specify what deliverables, expectations, or dependencies there are on other parts of the A-CC. Applications addressing more than one core should describe any advantages from this arrangement.

Section 3: Potential impact and alignment with AIM-AHEAD goals and core-specific expectations:

All applications should describe how the planned efforts will advance the goals of the overall AIM-AHEAD program and the **specific expectations** for each core, as described above.

Section 4: Past performance and expertise of the team members and complementarity with other recipients: At a minimum:

All applications should provide the following details about the teams and personnel involved in the proposed activities:

- Identify key personnel, project leads, and other personnel
- Specify effort levels and specific roles for each person
- Detail partners and specific roles for each partner



- Describe how key personnel and partners will accomplish the objectives(s)
- Describe how the project will leverage existing NIH data and computing resources
- Include relevant past performance for the team and any prior experience working together
- Leadership plan for applications that involve multiple PIs
- How the application meets the specific *eligibility requirements* for each core, as described above.

Section 5: Justification of the budget, resources, data, and resource sharing.

- All applications should provide detailed budget information for planned core activities and partnerships, as described below.
- For applications targeting more than one core, the application should clarify which parts of the budget request correspond to each core.
- Procurement of hardware, data, and the development of software capabilities to support the proposed activities are allowable costs.
- Budgets should include full cost of any potential projects, training, or other collaborations with consortium members or other partners.
 - Explain the total overall cost and the costs per activity and how that is estimated based on the specifics of the proposed activity.

Appendix: PHS Human Subjects and Clinical Trials Information (appendix to study plan; no page limit) When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” you will need to go to the optional forms and select the Human Subjects and Clinical Trials Information form. This will then appear on your forms tab and you can complete as it applies to the study. You must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record located in the optional forms in ASSIST for this OT.

- **Study Record: PHS Human Subjects and Clinical Trials Information**
 - All instructions in the SF424 (R&R) Application Guide must be followed.
- **Delayed Onset Study**
 - Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

Have questions about whether you are conducting a clinical trial? Please reference the following website to learn more: <https://grants.nih.gov/ct-decision/index.htm>

Include any graphs, pictures, or data tables in the body of the text.

Additional information to include in the submission:



- Institutional Letter of Support (“Institutional Support.pdf”): A letter of support from the applicant’s organization indicating institutional commitment for the project, e.g., relaying support for contributions (including, but not limited to, support for training activities or consortium meetings, licenses, and other resources) and preparations to enter into negotiated other transactions agreements
- Letters of support from proposed collaborators (“Letters of Support.pdf”; e.g., school districts, school related organizations or associations, tribal schools or nations, health care partners)
- A bibliography (“Bibliography.pdf”; no more than 1 page)
- Additional Information (“Additional Information.pdf”; no more than 1 page)
- Information on Select Agents
- Plan for Authenticating Key Biological and Chemical Resources

Budget details

The NIH may elect to negotiate any or all elements of the proposed budget and can consider the use of pre-award authority.

Budget (“Budget.pdf”; no page limitations): Applicants can model their budgets on SF424 budget pages for this section of the application which are available as optional forms in ASSIST or a format that best fits their program. All budgets must be readable by ASSIST. Applications must provide a realistic budget and cost estimate for performing the work for the first year. The budget should address costs associated with the Applicant’s group and any collaborators. Budgets for individual awards are expected to vary, depending on the scope of the work proposed, including the number of collaborations involved. Twelve-month budgets are expected not to exceed \$50 million total costs for the overall A-CC, which includes all four cores as well as pilots and projects with the consortium members and other stakeholders. There is no core-specific cap. Second year budget estimates should also be provided, but these budgets will be reassessed as the projects proceed and may be increased or decreased depending on progress, the needs of the program, and funds available. Total budget for a two-year proposal should not exceed \$100 million total costs unless prior approval was granted by the NIH.

Provide the overall expected cost for each of the following categories: personnel, equipment/testing kits, travel, funds for consortium partners or other stakeholders (if applicable), subawards, other direct costs, and total cost (with indirect costs included). Provide a budget justification. Subawards need to provide details of cost breakdown.

Milestones and Deliverables (“Milestones and deliverables.pdf”): Applicants must provide a description of the scientific goals and milestones, completion criteria, due date, how success is defined for a given milestone (e.g., Go/No-Go criteria), and payment/funding schedule (Example provided below). While agreements may be fixed price or expenditure-based, subject to negotiation, the use of fixed price milestones with discrete deliverables and a payment/funding schedule is preferred.

Example table of milestones and deliverables:



Milestone	Task(s)	Due Date (Months after award)	Milestone Definition	Payment
1	1.1	1	Milestone Name/Description Exit Criteria: <ul style="list-style-type: none">Bulleted list of tasks completed Deliverables: <ul style="list-style-type: none">Bulleted list (including data sharing)	\$
1	1.2	3	Milestone Name/Description Exit Criteria: <ul style="list-style-type: none">Bulleted list of tasks completed Deliverables: <ul style="list-style-type: none">Bulleted list (including data sharing)	\$
2	2.2	6	Milestone Name/Description Exit Criteria: <ul style="list-style-type: none">Bulleted list of tasks completed Deliverables: <ul style="list-style-type: none">Bulleted list (including data sharing)	\$

Applicants need to plan to attend a mandatory, 1-day kickoff meeting of the AIM-AHEAD program, to be held virtually on or about October 1, 2021.

Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs.

eRA Registration

Participating organizations must complete and maintain the following registrations to be eligible to receive an award. There should NOT be any cost associated with ANY of these registrations. All registrations must be completed prior to award issuance. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.



NIH will use the eRA Commons system to administer OT awards. If you are selected to participate you may need to submit additional information in eRA ASSIST, you will need to be registered in eRA Commons, which can take some time to complete – as many as several weeks in some cases. Therefore, if you are considering submitting an application and are not yet registered in eRA, it is highly recommended that you begin the process of registering your organization, Program Director/Principal Investigator (PD/PI) and Signing Official (SO) in eRA Commons as soon as possible to avoid possible award processing delays. To register, please follow the instructions via this website: <https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp>.

1. Complete the online Institution Registration Form and click Submit.
2. The NIH database will send you an email with the link to confirm your email address.
3. Once your email address is verified, the NIH will review your request and let you know of the result via email.
4. If your request is denied, you will get an email notifying you of the reason.
5. If your request is approved, you will get an email with your Commons User ID and temporary password.
6. Log into Commons with the temporary password and the system will prompt you to change temporary password to a permanent one. Your SO will be prompted to electronically sign your registration request. (Please review your registration information carefully.)
7. Once your SO has electronically signed the request, your organization will be active in Commons and you may create and maintain additional accounts for your institution staff.

To complete the registration above, you may need to register for the following if you have not done so already:

- Dun and Bradstreet Universal Numbering System (DUNS) – All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application. Registration for DUNS is located here: <https://fedgov.dnb.com/webform/>
- Employer Identification Number (EIN)- <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>
- Small Business Administration (SBA) - <https://www.sbir.gov/registration>
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Registration for SAM is located here: <https://www.sam.gov/SAM/>

Principal Investigators

All Principal Investigators(s) will need an eRA Commons account. If they do not already have one, Principal Investigators should work with their organizational officials to either create a new account or to affiliate their existing account with the proposer organization in eRA Commons. If the Principal Investigator is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.



Objective Review

The intent of the objective review for AIM-AHEAD Coordinating Center is to determine whether the objectives and plans of the proposed activities will contribute to and advance the AIM-AHEAD program goals of enhancing the participation and representation of researchers and communities currently underrepresented in the development of AI/ML models and improving the capabilities of this emerging technology, beginning with electronic health record (EHR) data to address health disparities and inequities.

The review is also intended to facilitate dialogue between applicants and external experts so that applications are improved by the review process. The outcome of each review is therefore intended to be a modified work plan for each proposer. Components of the applications may be accepted into the final plan in whole, in part, or may be omitted. The modified workplan, as shaped by the review process, will serve as a blueprint for the final negotiated terms and milestones for the resulting awards.

Applications may be submitted for one or more cores. Each core will be reviewed separately. NIH does not have a preference for the number of cores addressed in each application.

NIH is not responsible for providing feedback on unsuccessful proposals.

Review of Applications

The review of the applications will be conducted internally, and follow-up negotiations will be held as videoconferences and/or teleconferences.

The Overall Impact will be assessed by an objective review of the applications which will consider four Scored Review Criteria and Additional Review Criteria which include Protections of Human Subjects and the Inclusion of Women, Minorities, and Children:

Scored Review Criteria

Applications may address one or more of the A-CC cores. For applications that address multiple cores, each core will be assessed separately, and any potential benefit from the cores being co-managed will be factored into the score for each, as appropriate. NIH does not have a preference for the number of cores addressed in each application.

1. Reasonableness and merit of the proposed plans and approaches (5 pts)
 - a. All cores: To what extent are the proposed activities reasonable and likely to achieve the core-specific expectations?
 - b. Leadership/Administrative Core: To what extent are the proposed activities likely to result in a balanced and inclusive consortium, founded on relationships of mutual trust?
 - c. Leadership/Administrative Core: To what extent are community and stakeholder engagement plans (including Letters of Support) clearly documented and a history of



- collaboration (e.g., publication, formalized business relationship, etc.) is established.?
- d. Data Science Training Core: To what extent are the approaches to data science training innovative and likely to result in broader diversity of data and researchers for AI/ML applications?
 - e. Data and Research Core: To what extent does the application demonstrate an understanding of AI/ML ready data, missing data techniques, data aggregation strategies to conduct health disparities research?
 - f. Data and Research Core: To what extent does the application demonstrate an understanding of preparing diverse data, including EHR and SDOH data, for AI/ML applications and health disparities research, including considerations around bias and ethical use of data?
 - g. Infrastructure Core: To what extent does the application demonstrate an understanding of data platforms, options for data sharing, and software interoperability likely to be needed to enable the AI/ML applications for the AIM-AHEAD program and its stakeholders?
2. Potential impact of the proposed activities on the overall AIM-AHEAD goals and core-specific aims (5 pts)
- a. All Cores: To what extent are the proposed activities likely to advance the goals of the AIM-AHEAD program?
 - b. Leadership/Administrative Core: To what extent are the proposed activities likely to result in a balanced and inclusive consortium, founded on relationships of mutual trust?
 - c. Data Science Training Core: To what extent does the proposal consider talent retention, career paths, and workforce development at the institutions that will make up the AIM-AHEAD consortium?
3. Appropriateness of the key personnel and potential teaming arrangements (5 pts)
- a. All Cores: Are the expertise and past performance of the PI(s) and key personnel and investigative team appropriate for the proposed activities and successful execution of the proposed program?
 - b. All Cores: Is there an appropriate balance of expertise in AI/ML, health disparities research, EHR data analysis and other relevant expertise?
 - c. All Cores: To what extent do the PI's (or contact PI's) institutional affiliations meet the core-specific eligibility criteria?
4. Appropriateness of the proposed budget (5 pts)
- a. All Cores: Is the proposed budget reasonable and commensurate with the proposed work?
 - b. All Cores: Are there any areas where less funding is needed, or areas where more funding would improve the overall impact?

**Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the objective review committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects. The guidelines are available at the following website: https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research. The guidelines are available at the following website: https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf

Note that past performance and expertise could refer to the applicants' demonstrated track record of particular behaviors (community participation, collaborative efforts, openness to sharing data and resources, etc.), or to traditional measures of scientific productivity such as publication counts, invited presentations, or past funding success.

Funding decisions will be based on the outcome of the review discussion. The number of awards will depend on funds available. The level of funding for awards made under this solicitation has not been predetermined but will depend on (1) the objectives proposed by the applicants and how well they fit with the goals of the AIM-AHEAD program, (2) quality of the applications received; and (3) availability of funds.

Agreements for all awards will be negotiated with eligible organizations whose applications are determined to be the most advantageous and provide the best value to the NIH.

Following the review of applications, NIH may assemble teams from all or parts of applications to establish the A-CC. Individual components from distinct plans may be selectively funded to achieve the goals set forth herein. Additionally, if, over the duration of the project, some of the components



either gain relevance or lose relevance to programmatic goals, the funding for such components may be increased, decreased, or discontinued.

At any relevant point in the process, including the objective review, NIH reserves the right to:

- Invite all, some, one, or none of the Principal Investigators submitting applications in response to this solicitation to present their application in a Web-based videoconference or teleconference;
- Share applications between and among any proposer(s) as necessary for configuring teams, economizing work, and prioritizing activities;
- Select for negotiation all, some, one, or none of the applications received in response to this solicitation;
- Accept applications in their entirety or to select only portions of plans for award.

Appeals of the objective review will not be accepted for plans submitted in response to this ROA.

Application Timeline

Key Events	Receipt Dates	Action needed by Applicants
Research Opportunity Announcement posted for invited applicants	July 13, 2021	
Technical Assistance Webinar	July 15, 2021	Attend webinar and/or submit questions to AIM-AHEAD_ROA@od.nih.gov
Submission Deadline for Letters of Intent	July 22, 2021	Submit to AIM-AHEAD_ROA@od.nih.gov
Last updates to the AIM-AHEAD FAQ page	July 22, 2021	Check https://datascience.nih.gov/artificial-intelligence/aim-ahead/coordinates-center-faqs
Submission Deadline for Applications from invited applicants	August 3, 2021	Submit
Virtual, presentation-style interviews with invited applicants	Week of August 9, 2021	Virtual presentation and Q&A
Review of applications from invited applicants	Week of August 9, 2021	



Award Negotiations begin	August 18, 2021	Attend videoconferences or teleconferences as requested
Awards announced	September 9, 2021	
Kickoff meeting (mandatory)	On or around October 1, 2021	Register and attend

Special Award Terms and Information

NIH Discretion

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and OT Agreements Officer and Agreements Staff and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goals. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made, as necessary. As a result, the NIH reserves the right to:

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.

Applications selected for award negotiation are anticipated to result in the issuance of an OT award based on the nature of the work proposed, the required degree of interaction between parties, and other factors. The NIH reserves the right and sole discretion to engage in negotiation with the selectees applying under this solicitation during all phases of the application lifecycle.

Award Governance

The NIH will actively engage with recipients to establish a vision and capabilities AIM-AHEAD program and to oversee the effort of individual recipients to achieve the vision.

NIH Roles and Responsibilities:

1. Other Transactions Agreements Officer: NIH individual responsible for legally committing the government to an OT award and to the agreement through which terms and conditions are established, and for the administrative and financial aspects of the award. The OTA is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award.



2. Other Transactions Agreements Specialist: A designee of the OT Agreements Officer for administrative and financial aspects of the award.
3. Other Transactions Program Official: Individual within NIH who provides day-to-day programmatic oversight of individual awards, working closely with the OT Agreements Officer.

OT Agreement Governance

Other Transactions (OT) are a special type of legal instruments other than contracts, grants or cooperative agreements. Generally, these awarding instruments are not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of award. They are, however, subject to the OT authorities that govern the initiative and/or programs as well as applicable legislative mandates. They are used by the NIH, including the Common Fund, which have been authorized by Congress to use them. They provide considerable flexibility to the government to establish policies for the awards, so the policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts (including the other transaction legislation cited in the Agreement, as well as all terms and conditions cited in the Agreement and its attachments, conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

For the awards funded under this Research Opportunity Announcement, the NIH will engage in negotiations (before, during, and at the end of award) and all agreed upon terms and conditions will be incorporated into the Agreement. A bilateral agreement will be used as the official Agreement and the Notice of Award (NoA) will be solely used for funding obligations. The signature of the Signing Official on the bilateral agreement will certify that the organization complies, or intends to comply, with all applicable terms and conditions, policies, and certifications and assurances referenced (and, in some cases, included) in the application instructions.

Intellectual Property

Specific terms with respect to intellectual property will be negotiated at the time of award; however, any negotiation will consider other laws (as relevant) that affect the government's issue and handling of intellectual property, such as the Bayh-Dole Act (35 U.S.C. 200-212); the Trade Secrets Act (18 U.S.C. 1905) the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C. 1114 and 1122.

Budget

The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon statement of work, milestones, and deliverables. Subsequent funding periods represent projections of future funding levels contingent on the availability of funds, achievement of agreed-upon activities, and continued alignment with programmatic goals.



Payment

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the Agreement. Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award to minimize the amount of time elapsing between the transfer of funds from the Federal Government and disbursement by the recipient.

Reporting

The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget.

1. Financial and Progress Reports:
 - Recipients will be asked to provide regular progress reports to the OT Program Official and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal Financial Reports) required will be specified in the Agreement document, and will include, as a minimum, financial status reports that will establish the burn rate for the project and a bi-annual status report.
 - A final Federal Financial report is required for all Other Transactions Awards. A final report that summarizes the project and tasks will be required at the end of the Agreement period. The reports shall be prepared and submitted in accordance with the terms and conditions requirements.
2. i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at <https://public.era.nih.gov/iedison>.

Management Systems and Procedures

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage OT award funds and activities as long as they are consistently applied regardless of the source of funds and across their business functions. To ensure that an organization is committed to compliance, recipient organizations are expected to have in use clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

Financial Management System Standards

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of other transaction accounts to ensure that obligations and expenditures are congruent with programmatic needs and are reasonable, allocable, and allowable. A list of unallowable costs will be included in the terms and conditions of the award. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and recipients must notify NIH when problems



are identified. A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award.

Property Management System Standards

Recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds. The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget. Procurement System Standards and Requirements Recipients may acquire a variety of goods or services in connection with an OT award-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. Recipients must acquire goods and services under OT awards in compliance with the organizations established policies and procedures. The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget.

Organizational Conflicts of Interest (OCIs)

Applicants are required to identify and disclose all facts relevant to potential OCIs involving subrecipients, consultants, etc. Under this section, the proposer is responsible for providing this disclosure with each Detailed Plan. The disclosure must include the PI/Collaborators', and as applicable, proposed member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having an unfair competitive advantage.

The government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award issuance and to determine whether it is in the government's interest to grant a waiver. The government will only evaluate OCI mitigation plans for applications that are determined selectable. The government may require applicants to provide additional information to assist the government in evaluating the proposer's OCI mitigation plan. If the government determines that a proposer failed to fully disclose an OCI or failed to reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan, the government may reject the Detailed Plan and withdraw it from consideration for award.

Monitoring

Recipients are responsible for managing the day-to-day operations of OT award-supported activities using their established controls and policies. However, to fulfill their role in regard to the stewardship of federal funds, the NIH program team will monitor their OT awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence, audit reports, site visits and other information, which may be requested of the recipient. The names and contact information of the individuals responsible for monitoring the programmatic and business management aspects of awards will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may



continue for a period of time after the OT award is administratively closed out and NIH is no longer providing active OT award support.

Record Retention and Access

For OT awards, the 3-year record retention period will be calculated from the date of the Federal Financial Report (FFR) for the entire competitive segment is submitted. Therefore, recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper documents, images, and other electronic media.

Audit

NIH OT recipients for the AIM-AHEAD Program are subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F. In general, 45 CFR 75, Subpart F-Audit Requirements requires a state government, local government, or non-profit organization (including institutions of higher education). Please consult the provisions within Subpart F to determine requirements for the program specific audit requirements.

For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one DHHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F-Audit Requirements.

Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award.

NIH may suspend (rather than immediately terminate) an OT award and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision; however, NIH may decide to terminate the award if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An NIH OT award also may be terminated, partially or totally, by the recipient. If the recipient decides to terminate a portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the award was originally made. In any such case, NIH will advise the recipient of the possibility of termination of the entire OT award and allow the



recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

If the NIH decides to terminate an OT award, the termination of the award will be considered a unilateral change and the recipient **will not have the right to appeal**. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access requirements.

Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of an OT award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost-sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances.

Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for DHHS in 45 CFR 30. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

Closeout

The requirement for timely closeout is a recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the recipient or NIH. Terms and conditions of award will outline the specific timeline requirements for submission of the Final Federal Financial Report, the Final Progress Report, Final Invention Statement and Certification, and any other documentation or deliverables negotiated for award.

Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The signature of the Signing Official on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications, and assurances.

The policies, certifications and assurances listed may or may not be applicable to the project, program, or type of applicant organization. This list is not intended to be comprehensive and other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OT.

- Animal Welfare Requirements (PHS Policy on Humane Care and Use of Laboratory Animals)
- ClinicalTrials.gov Requirements
- Comptroller General Access



- Debarment and Suspension
- Dissemination of False or Deliberately Misleading Information
- Federal Information Security Management Act
- Financial Conflict of Interest
- Fly America Act
- Gun Control
- Human Embryo Research and Cloning Ban
- Human Fetal Tissue Research
- Human Subjects Protections
- Human Stem Cell Research (NIH Guidelines)
- Lobbying Prohibition
- Metric System
- National Environmental Policy Act
- Pro-Children Act of 1994
- Prohibition on Promotion or Legalization of Controlled Substances
- Research Involving Recombinant or Synthetic Nucleic Acid Molecule
- Research on Transplantation of Human Fetal Tissue
- Restriction of Abortion Funding
- Restriction on Distribution of Sterile Needles
- Restriction of Pornography on Computer Networks
- NIH Salary Cap/Salary Limitation
- Research Misconduct
- Select Agents
- Trafficking in Persons
- USA Patriot Act

Relevant NIH Resources

NIH supports a number of existing resources and programs that may be leveraged by the AIM-AHEAD program. As needed, the AIM-AHEAD coordinating center may need to establish formal agreements with these resources, or consortium members may take advantage of these as allowed by the resource policies. The relevant NIH resources include, but are not limited to:

- All of Us (<https://allofus.nih.gov/>)
- National COVID Cohort Collaborative (N3C) (<https://ncats.nih.gov/n3c>)
- Other NIH data repositories and knowledgebases (https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html)
- NIH STRIDES (<https://datascience.nih.gov/strides>)

Key Definitions

This ROA is focused on broadening the benefits of AI/ML technologies to underrepresented communities and engaging with underserved institutions:

Artificial Intelligence / Machine Learning: “The term ‘artificial intelligence’ means a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and



human-based inputs to – (A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action.” (National Artificial Intelligence Initiative Act of 2020 (DIVISION E, SEC. 5001) <https://www.congress.gov/116/crpt/hrpt617/CRPT-116hrpt617.pdf#page=1210>)

The term “machine learning” is an area of artificial intelligence that is characterized by providing systems the ability to automatically learn and improve on the basis of data or experience, without being explicitly programmed.

Electronic Health Records (EHR): An electronic health record (EHR) is a digital version of a patient’s medical chart that is maintained by the provider over time and may include all of the key administrative clinical data relevant to that person’s care under a particular provider. <https://nnlm.gov/mcr/training/technology-program/electronic-health-records-ehrs>

Health Disparities: A health disparity (HD) is a health difference that adversely affects disadvantaged populations, based on one or more of the following health outcomes:

- Higher incidence and/or prevalence and earlier onset of disease
- Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a disease outcome
- Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures
- Premature and/or excessive mortality from diseases where population rates differ
- Greater global burden of disease using a standardized metric

<https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html>

Health Disparity Populations: NIH defines health disparity populations as racial and ethnic minority populations, less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM), and any subpopulations that can be characterized by two or more of these descriptions. <https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html>

Social Determinants of Health: Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

<https://health.gov/healthypeople/objectives-and-data/social-determinants-health>

Underrepresented: Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at <http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27>) and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity



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(<https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm>). [NIH's Interest in Diversity [NOT-OD-20-031](#)]

Underserved: NIH-designated health disparity populations (racial/ethnic minorities; low socioeconomic status, rural, sexual gender minorities) and other groups known to experience barriers to accessing needed health care services or have inadequate health care coverage are considered underserved. A full description can be found at <https://www.nimhd.nih.gov/about/overview/>.