Revised: April 26, 2024

Clarification made to 2.1 Eligibility regarding Federally Funded Research and Development Centers (FFRDCs) and University Affiliated Research Centers (UARC)

Previous Revision: April 24, 2024

***Correction made to NOTICE NUMBER**: Updated the notice number from OTA-24-095 to **OTA-24-015** to match the Notice Number in ASSIST.*
Clarifications made to 2.3 Applications regarding page limits and format guidance.
Clarifications made to 2.3.1 Cover page regarding the use of human subjects or vertebrate animals.
Clarifications made to 2.3.6 Budget Details regarding budget guidance.
Clarifications made to 2.3.7 Milestones and Deliverables regarding potential IRB or other policy requirements.
Addition of 2.3.8 Status of Certification and Verification of Policy Requirements (Optional) as a section for the Application.

Release Date: April 3, 2024

Research Opportunity Announcement

Research Opportunity Title: Advancing Health Research through Ethical, Multimodal AI

NOTICE NUMBER: OTA-24-015

Participating Organization(s): National Institutes of Health (NIH)

Components: This Other Transaction Research Opportunity Announcement (ROA) is part of the NIH's Multimodal AI initiative. The research opportunity will be administered by the Office of Data Science Strategy (ODSS).

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

This funding opportunity will use the Other Transactions Authority (OTA) governed by 42 U.S. Code § 282 (n)(1)(b).

OT awards are not grants, cooperative agreements or contracts and use an OTA, provided by law. Policies and terms for individual OTs may vary between awards. Each award is therefore issued with a specific agreement, which is negotiated with the recipient and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape, performance and or availability of funds.

Objective Review: NIH will convene an appropriate review group to evaluate proposals. 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 effort is planned for $20 million over a two-year period. 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. NIH expects to support up to 10 projects with annual budgets around $1-2M total cost per project.

Award Project Duration: Initial Project duration is anticipated to be two years, but individual projects may be shortened or extended based on programmatic needs, funding availability, and recipient performance.

Key Dates

Release Date of this Research Opportunity Announcement: April 3, 2024

Informational Webinar (optional): April 19, 2024, 2:00-3:00 PM EDT

Letters of Intent (Optional) Due Date: April 29, 2024, by 5:00 PM local time of applicant organization

Proposal Due Date: May 16, 2024, by 5:00 PM local time of applicant organization

Earliest Start Date: August 30, 2024

Kick-off Meeting: To be determined.

Agency Contacts:

Scientific Research Contact(s):
Laura Biven, Rui Pereira De Sa, Lori Scott-Sheldon, Emily Greenspan, Juli Klemm
ODMultimodalAI@od.nih.gov

Financial / Agreements Officer:
DJ Milliken
ODMultimodalAI@od.nih.gov

Related Announcements: N/A

Issued by
Office of Data Science Strategy (ODSS)

Contents

1. Overview

1.1 Purpose

The Advancing Health Research through Ethical, Multimodal Artificial Intelligence (AI) Initiative aims to develop ethically focused and data-driven multimodal AI approaches to more closely model, interpret, and predict complex biological, behavioral, and health systems and enhance our understanding of health and the ability to detect and treat human diseases.

1.2 Background

Multimodal AI (MAI) has emerged as a technique for analyses that can combine multiple types of data (e.g., text, images, videos) simultaneously, rather than relying solely on one modality (e.g., text or image), to generate outputs or predictions. New innovations in data fusion, model training, and model assessment and application are needed to fulfill the promise of MAI in biomedical and health research. New innovations are also needed to ensure ethical approaches and consideration for stakeholder needs drive the design at all stages of development: data selection and preparation, model training, model assessment and application. This initiative is an opportunity for biomedical researchers to collaborate with expert researchers in AI (computer science and applied mathematics) and ethics and to engage with stakeholders to ensure MAI capabilities meet their needs.

A key challenge in building an effective multimodal AI system is to develop a unified representation of data from different modalities that can be used for various downstream tasks. To accomplish this, complex relationships and imbalances between multiple data modalities gathered from a wide range of use cases and scenarios need to be managed. In the biomedical domain, MAI seeks to integrate diverse, complex data from multiple sources such as electronic health records (EHRs), images, wearables, genetic information, and more. It can help in early detection of disease based on the analysis of medical images alongside other clinical information such as medical history and symptoms from EHRs or wearable devices. Furthermore, it can assist in precision medicine approaches that predict treatment outcomes by combining data about the person's genetic profile, lifestyle factors, environmental exposures, and so forth. Insights derived from MAI can also be used to guide research studies of novel biomarkers and therapeutic targets. MAI has the potential to transform healthcare by improving diagnostics, treatment, and the delivery of care, while increasing efficiency and reducing cost.

New methods for multimodal data fusion may help MAI systems discover associations across modalities while accounting for potential biases or other social implications. Automated and objective methods need to be devised to incorporate complementary as well as conflicting information from different modalities into model outputs. The findings of one modality may have different interpretations when combined with another modality; therefore, MAI can help determine the contribution of each modality toward model outputs. It is also important to conduct comparative analyses between unimodal and multimodal models to understand the impact of the multimodal approach.

Another challenge in MAI is the relative paucity of data with all modalities (or a sufficient number of modalities) present, which may introduce biases or imbalances in the data. Furthermore, data alignment may be another challenge because different modalities may represent data of varying scales, time points, and measurements.

Ethical considerations such as privacy, fairness, accountability, and transparency are of utmost importance to minimize algorithmic bias, harm to underrepresented groups, unintended exposure of personal identifiable information (PII), loss of privacy, and risks of re-identification in MAI systems. As a result, a wide variety of stakeholders such as researchers, patients, policy and science communities, and end users need to work together to co-create MAI systems that are more aligned with their values, preferences, and requirements.

1.3 Research Objectives

This initiative supports efforts to create ethics-driven and data-driven multimodal AI models for use in the biomedical, behavioral, and/or clinical fields. NIH envisions a portfolio of innovative projects that address systems level biomedical challenges using collaborative and anticipatory approaches for MAI that will elucidate unique opportunities, risks, and challenges. Collaborative, co-design approaches should be used in which there is continual and iterative feedback between different components of the project (i.e. model development, data preparation and collection, etc). Additionally, ethical considerations should be integral to all phases of development, as should engagement with appropriate stakeholders. Projects are expected to inform considerations for the appropriate use of MAI, relative to other methodologies, and take significant steps towards incorporation of ethical frameworks and co-design approaches in the multimodal AI lifecycle.

1.3.1 Target Biomedical Domain / Systems Level Challenge

Proposals should use multimodal AI approaches to advance knowledge, interpretation and/or prediction of complex biological, behavioural, or health systems. Examples of appropriate systems challenges include but are not limited to:

- Multi-scale biological system modelling spanning molecular, cellular, organismal and population levels
- Pandemic surveillance
- Disease progression modelling and prediction
- Healthcare optimization and clinical decision support
    - Systems level studies such as metabolic, immune, nervous, or endocrine system modelling
- Communication processes spanning molecular, cellular, and organ scales

1.3.2 Ethics and Engagement

AI models are increasingly complex and expensive to train so that retrofitting performance characteristics, or post-hoc ethical design are not feasible. Instead, ethical considerations such as privacy, fairness, accountability, transparency, inclusivity, and stakeholder needs and preferences, need to be part of the data, model, testing and assessment, and application co-design effort. Awareness of ethical implications of AI in biomedical and health research as well as ethics expertise is expected in proposals. Plans for stakeholder engagement to inform data selection and preparation, model development, and assessment are expected to be substantive components of the proposed research plan.

1.3.3 Co-design

Data: How data are prepared for AI can have substantive effects on the performance and suitability of AI models. Data preparation and selection, which may include feature engineering, data fusion, embedding spaces, data representations, FAIRification, the curse of dimensionality and bias mitigations, etc are expected to be a substantial component of the proposed research plan and iteratively developed (i.e. co-designed) with the model development.

Assessment and Applications: Continual assessment of the MAI model and its ethical implications are important throughout the development process. Applications should propose appropriate metrics and/or translational or end use applications for testing and evaluation. Such efforts may consider, for example, model alignment and ethics principles; explainability; model deployment and out-of-sample performance; cross-validation, testing and feedback; generalizability; privacy and identification challenges; long-term auditing; and transfer learning and bias testing. It is expected that assessment, testing and refinement through inclusion of end users, impacted groups, and/or key stakeholders will be a substantial component of the proposed research plan. A co-design approach, through iterative development with rapid feedback from users and stakeholders to model development, data preparation, human-machine hand-off, etc is encouraged.

Proposals should include plans for engaging stakeholders and creating a framework that would evaluate and identify ethical, legal, and social implications throughout the lifecycle of the model, as well as plans for risk management, such as through the NIST Risk Management Framework.

1.3.4 Agility, Risk Management, and Responsiveness to Change

AI technologies are advancing and changing at unprecedented speeds. Proposals should include multi-disciplinary teaming arrangements and change management structures to manage risk and opportunities in this space.

In addition, proposals should manage potential risks from AI including risks to safety and rights. Proposals are encouraged to follow risk management practices as outlined in the OMB Memorandum on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence (M-24-10).

Proposed research plans should identify potential risks and evolving opportunities and potential strategies for addressing these.

1.3.5 Open Science, Transparency, and Data Protection

The reuse of data and models are hallmarks of open science and federally sponsored research and are encouraged for this announcement. In addition, NIH seeks to enable responsible and ethical reuse of data, models, and other research artifacts through appropriate transparency practices and measures. Awardees are encouraged to follow best practices in open science and data stewardship by, for example, sharing data and models with accompanying datasheets, health sheets, model cards (or equivalent documentation) that include information about the motivation, composition, collection process and pre-processing, anticipated use cases, and other information relevant for ethical reuse. NIH also encourages sharing and citing data, models, and other research products using persistent unique identifiers (PUIDs) such as Digital Object Identifiers (DOIs) so that models and the associated training and test data can be linked and tracked. Proposals are encouraged to follow the AI sharing and collaboration guidance outlined in OMB Memorandum on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence (M-24-10).

NIH encourages the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies. CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records. NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g., genome-wide association studies [GWAS]), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository). NIH has established a “Common Data Element (CDE) Resource Portal" (http://cde.nih.gov/) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research. Investigators are encouraged to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.

Awardees are also expected to protect the privacy of individuals and security of data and models through appropriate stewardship, data and model management and sharing, and cybersecurity practices.

Proposals should demonstrate the ability of the research teams and awarded institutions to assess and address challenges with respect to openness, transparency, and data protection.

Intellectual property rights asserted by proposers should be aligned with the open-source regimes used to distribute software made under the award. Exceptions to open-source technology will be considered only in compelling cases. See also 5.5 Intellectual Property.

The proposed 2.2.5 Data Management and Sharing Plans addressing Open Science, Transparency, and Data Protection, which is part of the application, will be reviewed as part of the full proposal. This section should explain whether and how datasets, models, and software will be shared and documented; the timelines for sharing and the anticipated location (repository or other platform); and plans for protecting controlled access or other sensitive data and models. See NIH's Data Management and Sharing Policy for further guidance.

1.3.6 Expected Outcomes:

Research proposals should aim to demonstrate proof of concept for the MAI approaches undertaken by the end of the two-year period. Translational or end-use applications should be identified with stakeholders as test cases for continued testing and evaluation. Research proposals should outline potential measures for assessing success/impact, but final measures, for example, Key Performance Parameters, Key System Attributes, Level of Stakeholder Engagement, use case demonstrations, research findings, or other metrics will be determined in collaboration with NIH. Goals for this two-year period include- demonstration of the feasibility of training an MAI model in terms of computational cost and performance; potential translational applications; potential to enhance the understanding of complex biomedical systems; and management of bias, misinformation, ethics considerations, and other societal impacts.

1.4 Scope

Proposals for this ROA can support MAI for biomedical, behavioural, and/or clinical research or applications. This is an opportunity for experts from ethics, biomedical research, and quantitative research, such as computer sciences, statistics, applied mathematics, and AI to collaboratively innovate new capabilities in MAI. Applications appropriate for this opportunity must address:

- Generation, testing, and demonstration of new models using multimodal AI technologies using two or more different modalities of data (for example, text, images, videos, -omics data,) that have the potential for significant impact on the targeted biomedical research domain/systems level challenge. This could be achieved through the reuse, tuning, fine-tuning, and/or adaptation of pre-trained models. It's expected that new methods for multi-modal data fusion and integration will be generated as needed.

- Use of collaborative multi-disciplinary collaborative approaches that will include stakeholders impacted by or potential users of the anticipated AI solution that could include researchers, research subjects, clinical users, and/or patients as appropriate and relevant to the proposal.
- Creation of a framework that would evaluate/identify ethical, legal, social implications throughout the lifecycle of model development, such as increased risk of reidentification by linkage of multimodal data, and auditing the representations learned based on ethical concerns.

Non-Responsive Applications

Applications that will be considered non-responsive and out of scope include:

- Applications for which the **primary** focus is:
  - data generation or processing without a significant effort toward model development;
  - organization of challenges, competitions, or scientific conferences;
  - workforce development and training;
  - prompt engineering and application of existing models to different use cases;
  - methods for post-hoc interpretation of existing models;
  - collections of samples or other biological materials;
  - model testing without significant efforts toward model enhancement and data preparation.
- Applications that do not result in the development of a multi-modal AI model.
- Applications proposing the use of a single data modality, or use of one modality as input and a second modality as ground truth.
- Applications that do not use or leverage artificial intelligence methods.
- Applications that do not clearly articulate how appropriate ethical, legal, and/or social stakeholders of the AI outcome will be incorporated into the development of AI capabilities.

2. Application and Submission Information

2.1 Eligibility

Successful applicants may or may not have received NIH funding in the past. All entities public and private, small or large, for-profit or not-for-profit, are eligible to apply.

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, as defined in the NIH Grants Policy Statement, **are** allowed.

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.

Federally Funded Research and Development Centers (FFRDCs) and University Affiliated Research Centers (UARC) may not propose to this Research Opportunity Announcement as a prime performer/lead institution; however, subject to any restrictions (i.e., direct competition limitations as determined by the entity or potential limiting organizational conflicts of interest, agency sponsor related requirements and policies, etc.), FFRDCs and UARCs may be included as part the prime performer's proposal, as a sub-awardee. As with all prime/sub-awardee teaming arrangements, the Government will only have privity of contract with the prime performer, and all payments will be made through the prime awardee.

2.2 Letter of Intent

Applicants are strongly encouraged to submit a Letter of Intent (LOI). Although a LOI is not required, is not binding, and does not enter into the review of a subsequent application, it provides an opportunity for NIH scientific staff to estimate the potential review workload and plan the review. NIH may, but are not required to, provide feedback on the scope and appropriateness of the proposed research based on the LOI.

By the date listed in the overview information, prospective applicants are asked to submit a Letter of Intent of no more than 2 pages that includes the following information:

- Number and title of this funding opportunity
- Descriptive title of proposed activity
- First and last name, title, institution, department, mailing address, email address, phone number, and email address for the Lead / Contact PI and Authorized Organizational Representative.
- Names of all key personnel, institutional affiliation, title
- Brief summary of how the project plans to address the key elements listed as part of the scope of this opportunity.
- Estimated budget for the total effort, broken down by year and institution.

Letters of Intent must be submitted by email to ODMultimodalAI@od.nih.gov. Letters of Intent submitted by other means will not be reviewed.

2.3 Applications

Submitted applications will undergo administrative review for scientific scope and relevance. The most meritorious applications will be evaluated by an NIH data science panel.

Each research team should submit one application from the lead PI institution. The single proposal should cover all participating institutions, personnel, and activities.

Applications must be prepared and submitted using NIH's eRA ASSIST **and** by email to ODMultimodalAI@od.nih.gov. The NIH will not review applications submitted from organizations not included in the Eligibility section. Complete applications must be submitted by the Authorized Business Official. The organization must be registered in eRA Commons with one person designated as the contact principal investigator (PI) and one person designated as the Signing Official (SO). The SO'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.

A note about eRA Registration
NIH uses the eRA Commons system to administer OT awards. If you are selected to participate you may need to submit additional information in eRA ASSIST, and 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 a proposal 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/commonsplus/public/registration/initRegistration.era

Applications must be submitted by the due date listed above and include the sections below. All application materials should use size 11 font, 1-inch margins, and single spacing.

- Cover page (max 1 page)
- Abstract (max 250 words)
- Research Narrative (up to 15 pages including any figures and images. The reference list is not included in this page limit.)
- A proposed management structure and teaming arrangements (up to 2 pages)
- A Data Management and Sharing Plan addressing Open Science, Transparency, and Data Protection (up to 3 pages)
- Key personnel and bio sketches (up to 3 pages per individual. No overall page limit)
- Budget Request and justification (no page limit)
- Milestones and deliverables (up to 3 pages)
- Status of Certification and Verification of Policy Requirements (Optional) (no page limit)

2.3.1 Cover page

The cover page should be no more than one page and should contain the following information:

- Number and title of this Research Opportunity Announcement
- Project Title
- First and last name, title, institution, department, mailing address, email address, phone number, and email address for the Lead / Contact PI and Authorized Organizational Representative
- Names of all key personnel, institutional affiliation, title
- Confirmation about whether the work involves human subjects[1] or vertebrate animals[2]
- Agreement that any or all parts of the application can be shared among other applicants
- Summary Budget Table showing requested budget per year for 2 years by institution and by year

Example summary budget table:

Institution Name	**Year 1**	**Year 2**
Organization A	$100	$150
Organization B	$100	$100
…		
TOTAL	**$200**	**$250**

2.3.2 Abstract

The abstract should summarize the application and should not exceed 250 words.

2.3.2 Research Narrative

Proposals should describe a research agenda that describes the biomedical systems level challenge and why multimodal AI approaches are needed to advance the field, including the new AI capabilities that will be created through the intended research. It should also discuss the team's approaches to co-design and how ethical considerations will influence the research design.

Proposals should address each area outlined in *Section 1.3 Research Objectives* of this ROA. Applicants are also encouraged to consult *Section 3. Objective Review* when writing the Research Narrative.

2.3.3 Management structure and teaming arrangements

Submissions should describe the multi-disciplinary approach and how expertise of the team are appropriate for the proposed work. Proposals should also describe a management structure and teaming arrangement that will allow for agile and timely responses to new

[1] Further information about NIH requirements for Human Subjects Research can be found here: https://grants.nih.gov/policy/humansubjects.htm

[2] Further information about NIH requirements for research involving vertebrate animals can be found here: https://olaw.nih.gov/guidance/vertebrate-animal-section.htm

advances in AI and related fields. Teams are expected to be aligned with the Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

Teams should include expertise and knowledge of relevant data protection policies and mechanisms e.g. HIPAA, NIH Controlled Access policies, NIST Cybersecurity framework, FISMA, etc. as appropriate for the proposed work.

NIH expects proposals to include all personnel and institutions needed to carry out the proposed work. NIH intends to make a single award to the lead PI institution for each project. Other institutions will be supported through sub-OTA.

2.3.4 Key Personnel and Biosketches

Proposals should include a list of PI(s), Program Manager, Key Personnel, other significant contributors and their proposed level of effort, as well as the biosketch of each named individual. At a minimum, the information in the biosketch should include the name and position title, education and/or other training, 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 the role. The biosketch should be no more than three (3) pages in length per individual. The format used for an NIH grant application (https://grants.nih.gov/grants/forms/biosketch.htm) is acceptable, but not a required format, as Other Transactions are not grants.

2.3.5 Data Management and Sharing Plans addressing Open Science, Transparency, and Data Protection

Teams are expected to follow best practices for data, model, and software sharing and open science. Applications should include information on how the applicants intend to share any data, tools, technologies, and models developed through the program. Along with complying with the NIH Policy for Data Management and Sharing. This section should describe plans and principles for data and model sharing including metadata and documentation to facilitate informed, responsible, and ethical re-use of data and models.

Applications should describe how any data will be used and plans for ensuring security and privacy of the data. Applicants should also indicate if they already have access, permissions, and consent to proposed data sets or how they plan to obtain these. Applicants are encouraged to use already curated and harmonized data whenever possible; if additional data harmonization and curation is needed, applications should include information on how they plan to do so.

Intellectual Property rights asserted by applicants are strongly encouraged to be aligned with open-source regimes and licensing. It is desired that all non-commercial software and AI models (including source code), documentation, and technical data generated by the projects is provided as deliverables to the Government with open-source or unlimited rights.

Permissive, business-friendly open-source licenses such as CC-BY, BSD, MIT, Apache 2.0 or similar are highly encouraged.

A plan and timeline for sharing research products such as software, data, and models developed through the award must be provided that addresses the following requirements:

- The applicant should indicate which licenses will be used. Applicants are encouraged to use a fully-permissive, Open-Source Initiative-approved license, https://opensource.org/licenses/.
- The research products should be freely available to researchers and educators in the non-profit sector, such as institutions of education, research institutions, and government laboratories.
- The terms of availability should permit the dissemination and commercialization of enhanced or customized versions.
- The research products should be transferable such that another individual or team can continue development in the event that the original investigators are unwilling or unable to do so.
- The terms of software availability should include the ability of researchers to modify the source code and to share modifications with other colleagues.

Further information can be found here: https://datascience.nih.gov/tools-and-analytics/best-practices-for-sharing-research-software-faq

2.3.6 Budget Details

The NIH may elect to negotiate any or all of the elements of the proposed budget. NIH expects to support up to 10 projects with annual total budgets around $1-2 million per project.

Budget

- The level of funding for awards made under this solicitation has not been predetermined and will depend on: 1) the objectives proposed by the applicants and how well they fit with the goals of the initiative; 2) the quality of applications received; 3) the availability of funds; and 4) programmatic priorities.
- The Budget section must provide a realistic, fully justified annual budget and cost proposal for performing the work for up to two (2) years of the initiative. The budget should address costs associated with the community organization, community partners, the research partner(s), consultants, subcontracts, and any collaborators.
- The budget should also include costs for the Principal Investigator(s) and the research partner(s) to attend an in-person annual Multimodal AI consortium meeting to be held in Bethesda, Maryland.
- The budget must include a proposed Milestone-based Payment Schedule (see 2.2.7 Milestones and Deliverables)

- Budgets must adhere to latest NIH salary limitation notice (See NOT-OD-24-057, Guidance on Salary Limitation for Grants and Cooperative Agreements). Applicants may use the SF424 budget form. All the categories listed below must be reflected in all submitted budgets.

The Budget should provide the overall expected cost for each of the following categories:

- Direct Costs
  - Personnel (Salary and Fringe benefits)
    - If fully loaded hourly rates are provided the Applicant must provide a detailed breakdown of the rates (hourly rate must be compliant with the NIH salary limitations).
  - Travel: All travel must be compliant with U.S. General Services Administration (GSA) Travel Regulations (see GSA Travel Resources for assistance)
  - Subrecipients: Subawards/subcontracts (For research partners and community partners)
    - Applicant is responsible for inclusion of all subrecipient budgets and budget justifications.
    - Subrecipient budget justifications should have the same level of details as the Applicant.
    - Agreement between Applicant and Subrecipient is not required at the time of application.
    - Supporting documents are recommended to be included in the application (e.g., Letter of Commitment)
  - Other direct costs, if applicable
    - Consultants: hourly rate, number of hours, total costs, brief statement of work or deliverables.
    - Equipment
    - Cloud Computing/Data Specific Costs
    - Project Related Materials & Supplies, etc.
- Indirect Costs, if requested
  - Indirect Cost Rate = Total Indirect Costs/Modified Total Direct Costs (MTDC)
  - If the Applicant has a federally Negotiated Indirect Cost Rate Agreement (NICRA), the negotiated indirect cost rates may be applied (e.g., F&A Rate Agreement)
  - If an Applicant does not have a NICRA, a ten (10) percent de minimis rate may be applied or an eight (8) percent fixed rate for foreign and international organizations may be applied on MTDC.
  - Submission of the NICRA is required for the Applicant and any Subrecipients.

Applicants must provide a budget justification for all budget items. Subawards need to provide details of cost breakdown.

Computational and storage resources:

Budget justifications should describe the computational and data storage resources needed and how these will be supported. Cloud resources should take advantage of the NIH STRIDES pricing arrangements when appropriate, and data and model sharing should preferentially leverage existing NIH or other existing data repositories.

Cost Sharing and In-Kind Contributions

Cost Sharing and In-Kind Contributions are not required. Applicants 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 or in-kind contribution must be supported in the application by including a letter of support from the providing organization(s)/individual(s). Inclusion of cost sharing will not be considered during the application selection process.

Sample Budget Justification Narratives:

Personnel:

A. Senior/Key Person

- John Smith, PhD, PI (10% Effort, 1.20 Cal. Month, Years 1-10): Dr. Smith has the expertise in social science research. He will lead the administrative, financial, and research aspects of the project.

B. Other Personnel

- Research Assistant-To-Be-Named (TBN): (100% Level of Effort, 12 Cal. Month, Years 1-5). This position requires the candidate to have social science research knowledge and skills. This person will work under the supervision of Dr. Smith.

Travel:

Travel budget for the PI to attend in-person annual Multimodal AI Consortium meeting at Bethesda, MD each year. 2-day meeting cost breakdown is based on GSA per diem rates:

Lodging: $258 per night for 2 nights=$516
Per diem: $79+$59.25*2=197.5
Airfare: $500
Local transportation: $100

Total=$1,314

2.3.7 Milestones and Deliverables

The expected initial project duration is up to two (2) years. Applicants must provide a description of the goals and milestones of the proposed project, including completion criteria, due dates, how success is defined for a given milestone, and payment/funding

schedule (example provided below). Milestones may include, for example: demonstration of data availability, data processing and the ability to fuse data; demonstration of model training; demonstration of stakeholder engagement; demonstration of assessment feedback and co-design. In addition, during the first six months of the project, NIH and the awardees will develop a set of performance metrics for the data sets and multimodal AI model at the "proof-of-concept" level.

Proposed timelines should be commensurate with the pace of technology development.

Milestones that are dependent on, for example, IRB approval, Data Use Agreements or other policy requirements should mention this in the Milestone Definition and include a statement about the status or timeline for the requirements being met e.g. IRB request submitted on DATE and approval expected on DATE.

Example table of milestones and deliverables:

Milestone	Anticipated completion dates (Months after award)	Milestone Definition	Estimate for non-personnel task related expenses

1	End: 6 months from award	Milestone Name/Description Exit Criteria:
		
		• Bulleted list of tasks completed
		
		Deliverables:
		
		• Bulleted list (including data sharing)
			For example:
			
			$ Infrastructure (computing, etc.)
			
			$ travel
			
			$ sub-contracts for this task
			
			$ … applicants should include relevant summary categories as appropriate

2	3	Milestone Name/Description Exit Criteria: • Bulleted list of tasks completed Deliverables: • Bulleted list (including data sharing)	$ …
…			

2.3.8 Status of Certification And Verification of Policy Requirements (Optional)

As part of the negotiations process, NIH will request the submission of certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's

proposed use of live vertebrate animals; and verification of Data Use Agreements or other policy requirements, as applicable.

At the time of proposal submission, applications are encouraged to use this section to provide evidence or attestations regarding the status of IRB approval, IACUC approval, or other processes. This section should ONLY be used for providing information related to the status of IRB approval, IACUC approval, Data Use Agreements, and/or other policy requirements as applicable.

Details on NIH policies for Human Subjects Research can be found here: https://grants.nih.gov/policy/humansubjects/research.htm.

Details on NIH policies for vertebrate animal research can be found here: https://olaw.nih.gov/guidance/vertebrate-animal-section.htm.

3. Objective Review

The intent of the objective review of these applications is to determine the extent to which the proposed activities meet the goal of the Initiative.

Full proposals will undergo objective review by NIH federal employees, federal employees of other agencies, and outside experts, as needed.

Applicants may be invited for a second stage, presentation-based interview.

Components of the full applications may be accepted into the final plan in whole, in part, or may be omitted. The outcome of each review could result in a modified work plan for each proposal based on reviewers' comments and recommendations. 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.

NIH will not provide feedback on proposals, except as a part of follow up on an as needed basis.

3.1 Review of Full Applications

The criteria described below will be considered in the objective evaluation process:

Scientific Merit: Multimodal Approaches:

1. To what extent does the proposal advance the state of the art in multimodal AI for biomedical, behavioral, and/or clinical research or applications? To what extent is the multimodal approach innovative?
2. To what extent is the proposal likely to have significant impact on the targeted research domain and fill a current gap or need in the field?
3. In what ways does the proposed approach(es) clearly demonstrate the advantage of using multi-modal AI over other methods?
4. How suitable and sufficient are the data being used to the proposed work?

Scientific Merit: Ethics Driven Approaches:

1. To what extent does the proposal advance the state of the art in ethics-driven AI for biomedical, behavioural, and/or clinical research or applications? To what extent is the approach innovative?
2. How well does the proposal describe how ethical considerations will influence the research design and what new AI capabilities will be developed?
3. To what extent to does the applicant demonstrate appropriate engagement of relevant stakeholders (which may include researchers, data subjects, end users, and/or patients among others) in AI model design and testing?
4. Are the target applications appropriate to assess performance and ethical considerations?

Scientific Merit: Co-Design Approach:

1. To what extent does the project leverage iterative, co-design approaches for data, models, and assessments with feedback mechanisms that enhance the developed MAI?
2. How well does the application describe how co-design approaches will influence an agile approach to data preparation, model development, and assessment?
3. Is the balance of work in data collection and preparation, model development and training, and testing and validation appropriate? What changes could be made for better alignment?

Data, model, and software sharing: Open Science and Data Protection

1. Are the plans and methods for privacy protection and stewardship of controlled access data and models throughout the project and across the data and model lifecycle appropriate? Which measures, if any, are missing?
2. Does the proposal appropriately address policy, compliance, and legal issues with appropriate safeguards to ensure privacy is protected and biases are managed throughout the lifecycle of model development? Does the proposal recognize risks of re-identification, mosaic effects, and data leakage and appropriately mitigate and manage these risks?
3. To what extent does the proposed work align with best practices in open science and transparency? To what extent will research products generated by this project (e.g. data, models, workflows, tools, etc.) be shared in ways that enable responsible and ethical re-use?
4. To what extent does the proposal align with goals for transparent AI that enhance the responsible and ethical reuse of data, models, and other research products? Does the proposal demonstrate appropriate knowledge and use of Persistent Unique Identifiers (PUIDs) such as DOIs and documentation such as datasheets, health sheets, and model cards? What aspects are the most critical, what components could be improved?

Appropriateness of Team and Ability to Adapt to Change

1. How appropriate are the expertise of the PI(s) and key personnel and investigative team for the proposed activities, including the ethics-driven and co-design approaches and stakeholder engagements?
2. How appropriate is the management structure and teaming arrangements and to what extent do these allow for agile responses to technology developments?

Appropriateness of the Budget and Research Plan

1. How technically feasible and realistic are the proposed timelines?
2. How reasonable and commensurate with the proposed work is the budget and resources requested?
3. Are the computing and storage costs appropriate and realistic?

4. Post-award expectations

Awardees are expected to host an in-person kick-off meeting with NIH and key personnel. Awardees will meet regularly (weekly or as needed) with NIH program staff. NIH also anticipates holding an annual in-person meeting in Bethesda, MD of all project teams to foster crosstalk and build a cross-disciplinary community of practice.

5. Special Award Terms and Information

The administrative and funding instrument used for this program will be the Other Transaction (OT), OTA mechanism, in which active oversight and management by the NIH is expected during the performance of the activities. Under an OT, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients. OTs offer considerable flexibility to renegotiate or terminate agreements when necessary to promote the overall objectives of the program. The award and post-award negotiations will reinforce program objectives and, if necessary, adjust conditions by which progress is assessed.

For this award, NIH staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- NIH Program Officer – The Program Officer (PO) from the Office of Data Science Strategy (ODSS) is responsible for the normal scientific and programmatic stewardship, including monitoring progress and compliance with general statutory, regulatory, or policy requirements; discussing and approving milestones and significant changes to the project; and technical assistance to correct performance and facilitate interactions. The PO must approve in advance and in writing annual milestones and any significant changes to the award. The PO also has the option to recommend restricting an award based on progress towards milestones, to incentivize rapid development and implementation of policies or collaboration between members of the consortium, or generation of data or resources for use by

consortium members or the wider community. The Program Officer will not co-author publications with the PIs. The Program Officer will be responsible for making funding recommendations and otherwise providing programmatic approvals and recommendations. POs will have programmatic authority, including fiscal oversight and will closely monitor progress of all the awards made in their initiative.

5.1 NIH Discretion

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and provides the NIH the flexibility to alter the course of awarded activity in real-time to meet the overarching program goals. This may mean that an awarded activity could be expanded, modified, 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 proposals) 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.

Proposals selected for award negotiation may or may not result in the issuance of an OT award, dependent on the outcome of negotiations, the nature of the work proposed, changing external conditions, 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 proposal lifecycle.

5.2 Award Governance

The NIH will actively engage with award recipients to establish a vision and capabilities for the Advancing Health Research through Ethical, Multimodal AI Initiative and to oversee the effort of individual awards to achieve the vision.

5.3 NIH Roles and Responsibilities:

1. 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 Agreements Officer (AO) 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. Agreement Specialist: A designee of the AO for administrative and financial aspects of the award.
3. Program Official: Individual within NIH who provides day-to-day programmatic oversight of individual awards, working closely with the AO.

5.4 OT Agreement Governance

OT awards are not grants, cooperative agreements, or contracts. They are used by NIH for particular purposes as authorized by Congress. They provide considerable flexibility in establishing policies for the 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. Policies and terms for individual OT awards may vary between awards, which may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape and or availability of funds. 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 Transactions-authorizing legislation cited in the Notice of Award (NoA), as well as all terms and conditions cited in the NoA, Bilateral Agreement, and its attachments, and 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.

5.5 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 (18U.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.

5.6 Budget

The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon work. 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.

5.7 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.

5.8 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 Program Officer 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 but will likely be monthly. Reports will include, as a minimum, financial status reports that will establish the burn rate for the project and a bi-annual status report and research status reports to assess the progress toward agreed milestones and overall project objectives.
    - 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.

In addition to formal reports, awardees should expect weekly meetings with NIH program staff as part of effective oversight of complex, fast-paced research.

Reporting should also adhere to requirements in the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.

5.9 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.

5.10 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.

5.11 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.

5.12 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

proposals 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.

5.13 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 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.

5.14 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.

5.15 Audit

NIH OT recipients for the Multimodal AI Initiative 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.

5.16 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.

5.17 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.

5.18 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.

5.19 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.

5.20 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

6.Inquiries

Please direct all inquiries to:

Scientific Research Contact(s)
Laura Biven, Rui Pereira De Sa, Lori Scott-Sheldon, Emily Greenspan, Juli Klemm
ODMultimodalAI@od.nih.gov

Financial / Agreements Officer
DJ Milliken
ODMultimodalAI@od.nih.gov