Research Opportunity Announcement

Research Opportunity Title: DS-Connect®: The Down Syndrome Registry (OT2 Clinical Trial Optional)

OTA-24-007

Participating Organization(s): *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Components of Participating Organizations:
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

This initiative also complements the work of the National Institutes of Health (NIH)-wide INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project administered by the NIH Office of the Director.

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

OT awards are not grants, cooperative agreements, or contracts, and use Other Transaction Authority, provided by Congress. 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 Notices:
RFA-OD-20-007 – Development of the INCLUDE (Investigation of Co-occurring Conditions across the Lifespan to Understand Down syndromE) Project Data Coordinating Center

NOT-HD-24-002 -- Notice of Information: Research Opportunity Announcement for DS-Connect®: The Down Syndrome Registry Targeted Solicitation

Research Opportunity Purpose: The purpose of this announcement is to invite proposals from eligible organizations to engage with NICHD to conduct a rapid transition of the online patient registry, DS-Connect: The Down Syndrome Registry, from an NICHD contracted system that will no longer be supported as of February 28, 2024, to a new, secure, sustainable platform. The registry serves as a critical conduit that connects people with Down syndrome with researchers conducting high-impact research that improves the fundamental biological and clinical understanding and treatment of Down syndrome and its associated conditions.

Objective Review: NICHD will convene an appropriate review group to evaluate proposals. Visit the Objective Review section of this opportunity for further details.

Eligibility: Review the Eligibility section of this opportunity.

Funds Available and Anticipated Number of Awards: The current budget for this effort is planned for up to $10 million over a 5-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.

Award Project Duration: Initial Project duration is anticipated to be five years, but the project may be shortened or extended as required to support the mission and capabilities of the NICHD and relevant NIH-wide initiatives in Down Syndrome.

Authority: Other Transaction 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: February 5, 2024

Proposal Due Date: February 20, 2024

Earliest Start Date: April 1, 2024

Kickoff Meeting: To Be Determined During Negotiations of Agreement

Agency Contacts

Scientific Research Contact(s): Sujata Bardhan; Sujata.bardhan@nih.gov

Financial/Agreements Officer: Artisha Wright; Artisha.wright@nih.gov

Outline of this Opportunity

1. Overview of the DS-Connect: The Down Syndrome Registry

Background

In September 2011, the NIH created the Down Syndrome Consortium to foster communication and idea-sharing among the NIH, individuals with Down syndrome and their families, national and international organizations interested in Down syndrome, and other relevant groups. Under the auspices of the Down Syndrome Consortium, NICHD supported development of a family-focused, web-based registry for individuals with Down syndrome, DS-Connect.

NICHD awarded a contract in September 2012 to create and maintain an online registry named DS-Connect®: The Down Syndrome Registry, which was subsequently housed in a system of record known as the Research Data Patient Registry (RDPR) and contained personally identifiable information (PII). This contract was recompeted in 2015 and again in 2018. The RDPR was hosted on the Amazon Web Services

(AWS) cloud using a government-owned URL (https://dsconnect.nih.gov/). The data were owned by the NICHD, but all software was proprietary and not transferrable to the government or another entity.

DS-Connect facilitates contact and information sharing among families, individuals with Down syndrome, researchers, and parent groups. Down Syndrome Consortium members are involved in outreach efforts to the Down syndrome community to encourage families to sign up for DS-Connect. DS-Connect is composed of a demographic survey as well as an Initial Health Survey that collects baseline information about the health status of the person with Down syndrome, with additional specialty surveys based on age, sex, and specific medical issues. Participants can compare their survey answers to the aggregate, de-identified responses of other DS-Connect participants, as well as access resources such as healthcare provider lists, Down syndrome-specific growth charts, a medication tracker, and information about NIH-funded Down syndrome clinical trials.

In 2014, a Professional Portal was incorporated into the registry to allow investigators and others with an interest in Down syndrome to review the aggregate, de-identified data, perform limited search functions on the data, and request recruitment support to invite eligible participants to join specific clinical studies. In this latter situation, when the Research Review Committee (RRC) has approved a study, the registry coordinators serve as trusted intermediaries to inform participants of the research opportunity and invite them to contact the investigator if interested. The registry has been designed to: take advantage of existing Common Data Elements (CDEs) and established platforms; employ unique identifiers to protect confidentiality and facilitate future linkages to other research resources; develop an outreach/marketing strategy that takes advantage of partnerships within the Down syndrome community; work with the RRC on changes related to governance of the Professional Portal; develop a plan for sustainability of such a registry; and determine policies for data access in conjunction with the NIH and RRC.

In 2018, the NIH launched the INCLUDE Project with a renewed interest in supporting research in Down syndrome. The registry supports studies funded under INCLUDE that request recruitment assistance and promotes linkages with other NIH-funded datasets.

Each participant in the online registry is given a Global Unique Identifier (GUID) generated based on PII elements. This allows information to be combined between data sources or biospecimen repositories by matching to the GUID without revealing PII. DS-Connect also includes a Spanish language version of the entire website and surveys.

2. Eligibility

This Research Opportunity Announcement will rapidly transition the online web-based registry, DS-Connect: The Down Syndrome Registry, from an NICHD-contracted system that will no longer be supported by the contractor as of February 28, 2024, to a new, secure, sustainable system. Applicants are required to have:

- a strong working knowledge of the DS-Connect Registry;
- a ready-to-implement system capable of handling participant's PII at an appropriate level of security
- existing registry infrastructure based on widely available or transferrable software;
- the ability to receive existing data from the government and transition it to an operable data infrastructure that meets requirements for usability; and the ability to work with NIH/NICHD staff to develop, implement, enhance, and maintain an online registry, including related responsive-

template websites all of which are Section 508 compliant in accordance with HHS regulations (https://www.hhs.gov/web/section-508/).

Proposals from applicants with the following characteristics are strongly encouraged:

- A strong track record with and current established connection to individuals with Down syndrome and their families and communities
- Expertise in professional interaction needs for use of a patient registry to enable recruitment and retention of individuals with Down syndrome in ongoing clinical studies and trials
- Strategies to ensure rapid implementation of an interactive patient registry (including a Spanish language version) using widely available or transferrable software on a secure platform
- Availability of a research team with appropriate expertise to implement rapidly the project with a strong history of collaborative work
- Demonstrated ability to operate a system with security controls appropriate to protecting PII
- Experience and willingness to share data, software, algorithms, digital objects, tools, and other resources, as needed
- Familiarity with and knowledge of common data elements required by the DS-Connect registry and the process to create GUIDs for data linkage
- A plan for sharing de-identified data, metadata, and project documentation with the INCLUDE Data Coordinating Center Data Hub (https://portal.includedcc.org/login?redirect_path=/dashboard) at regular intervals
- A plan for rapid resumption of registry operations and implementation of a communications and outreach strategy to re-enable contact with and participation by the community
- A plan for ongoing operation and maintenance of the platform
- Experience with and commitment to creating excellent user interfaces with appropriate user experience.

Proposals 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:

- Projects that do not involve a data system and online registry
- Projects without a focus on individuals with Down syndrome
- Projects that do not demonstrate an established relationship with or engagement strategy with the Down syndrome community
- Projects with teams who do not have demonstrable expertise or experience with the Down Syndrome community and relevant science supported by the NIH or other federal agencies
- Projects that do not utilize widely available or transferrable software and/or are not willing to share data, software, algorithms, digital objects, tools, and other resources where possible
- Projects that do not have evidence of or ability to implement a system with security controls appropriate to protecting PII
- Projects that do not have an infrastructure to rapidly transition data from the government and move to a usable format by the community
- Projects that do not include a plan for human subjects review through an Institutional Review Board (IRB) for the registry and inclusion of collection of common data elements to support data linkage.

Applications which propose studies in vertebrate animals will be considered non-responsive to this funding opportunity and will be withdrawn without review.

Organizations

This is a targeted solicitation due to the requirements of the program; only invited entities are eligible to apply. 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.

Multiple Principal Investigators

Multiple Principal Investigators are not allowed for this Proposal. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the proposer organization.

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).

3. Developing Proposals

The Proposal will allow the NIH to establish a unique review process that will bring together NIH personnel with subject matter expertise in Down Syndrome, IT systems (including appropriate security requirements), DS-Connect operations, and platform project management. NIH may also share, with PI agreement, the proposal with other staff at NIH to ensure optimal configuration of funding and activities. The proposal will be considered during the review. For more details on the review process, review the next section, 4: Objective Review.

Proposal

Proposals will be accepted only from Organizations invited to apply to this Announcement and that submit a proposal. NIH will use the eRA Commons system to administer OT awards.

The NIH will not review and will return proposals submitted from organizations not included in the Eligibility section. Complete proposals must be submitted via ASSIST by the Authorized Organizational Representative. The Authorized Organizational Representative's signature certifies that the proposer 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 Proposal.

Plans must be submitted by the due date, in text-recognizable PDF (Adobe) format, use Arial 10-point font with 1" margins, be single-spaced, may not exceed 12 pages, and the file size must be no greater than 20 MB.

Cover Page (up to 1 page)

1. Number and title of this Research Opportunity Announcement
2. Project Title
3. Principal Investigator first and last name, title, institution, mailing address, email address, and phone number.
4. Name and address of the submitting organization and department, if any, with the organizational DUNS number and employment identification number (EIN) provided.
5. Authorized Organizational Representative first and last name, title, institution, mailing address, email address and phone number.
6. Approximate budget per year (direct and total)
7. Proposed Project Period Dates
8. Other involved personnel names, roles, and organizations (Co-Investigators, collaborators, contractors, authors of letters of support, etc.)
9. Confirmation that the work involves human subjects or data from human subjects.

Biosketch of the Principal Investigator (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. Biosketches of Senior/Key Personnel and Other Significant Contributors can be included as desired by the applicant in the initial application; the NIH reserves the right to request these during negotiations.

The proposal should be organized into the following sections to facilitate review (12-page limit):

Section 1 (limit 1 page): The potential impact of the work to be done if it were successfully implemented. At a minimum:

- Describe the scientific importance and resultant impact of the proposed program to foster communication and idea-sharing among the NIH, individuals with Down syndrome and their families, national and international organizations interested in Down syndrome, and other relevant groups.

- Describe the utility and impact of the Professional Portal to enable investigators to request recruitment support to invite eligible participants to join specific studies.

- Describe institutional experience with and capability to support data coordination and registries relevant to the Down syndrome community, the work of the applicant and institution on relevant NIH projects and programs, and the impact of the adoption of "open science" principles to facilitate better integration of the DS-Connect Registry with ongoing scientific initiatives.

Section 2: DS-Connect Registry Development, Operations, and Maintenance.

At a minimum:

- Describe the proposed widely available or newly developed technical solutions that will be used to support registry operations. Include how the system will comport with "open science" principles. To preserve utility to the community, newly developed software should be transferrable such that another entity can continue operations and development. Provide support for sharing newly

created software, algorithms, metadata, data, digital objects, tools, and other resources in the event the registry is transferred to another entity.

- Describe the license(s) that apply to any widely available software used in the registry and that will be applied to newly developed software, algorithms, digital objects, tools, and other resources. Explain how these licenses will ensure DS-Connect can be seamlessly transferred to another entity to continue operations and development without interruption. At any time, NIH may request transfer of the registry and associated resources to NIH or another entity designated by NIH.

- Provide a plan for and agreement to support transition-out/closeout if the award moves to another entity, including transfer and sharing of all existing SOPs, dashboards, metrics, service tickets, active projects and orderly transfer of files, data, documentation detailed instructions for re-deploying the platform in a new environment, and software developed or altered (where possible) in the performance period of the award.

- Describe a system security plan and associated efforts to establish and maintain security controls appropriate to protecting the confidentiality of PII and participant privacy, and provide associated documentation as needed to the NIH. This may include reviews and updates on system control, security incident tracking and root cause analysis, immediate management plan for security incidents, IRB reporting of security incidents, and security audits.

- Describe an operations, maintenance, and enhancement service plan that incorporates feedback and prioritization from NIH, with supporting reportable monthly metrics which generally describes up-time of a minimum viable product and a fully operational system (expectation is 99.9%, excluding planned maintenance periods), day-to-day operations (e.g., system backups, bug fixes, security patches/scans, anti-virus management, review of system emails, management of infrastructure configuration, and tracking of software version levels), expected system reviews and status reports, audit capabilities, planning activities for minor enhancements or technical issues, and continuous monitoring activities.

- Describe the ability to develop, implement, and maintain a responsive web design and related materials for all versions of the registry (i.e., English and Spanish) that are Section 508 compliant *upon delivery*, in accordance with HHS regulations (https://www.hhs.gov/web/section-508/), and that conform to HHS 508 checklists.

- Describe methods to support review of provided information for participants and professionals for quality and completeness, methods to create and maintain DS-Connect® Registry resources (e.g., listings of providers, Down-syndrome specific growth charts for participants, medication tracker, health care recommendations, partially pre-populated ClinicalTrials.gov search function), and methods to provide minor system enhancements with technical concerns (e.g., updates to Down Syndrome Consortium membership page, “Need help” and “FAQs” documents, account holder home page, linkages to ClinicalTrials.gov and other pages as needed).

- Describe methods to support set-up and access request processes for professionals, support for upgrades to the Professional Portal, methods to maintain information about investigators and their approved studies on the website.

- Describe coordination plans with the Research Review Committee (RRC) and NICHD staff for activities related to the Professional Portal (e.g., approval process for access request, recruitment support for approved clinical studies).

- Describe the capability of the site to provide registry customization and enhancements which shall include, but not be limited to:
    - system, website, and registry enhancements; development of additional survey modules (including skip logic) from content or requirements provided by NICHD;

    - changes to the consent process and/or addition of consent process functionality to ensure changes at ages 7 years and 18 years;

    - enhanced functions for account holders (e.g., outreach materials);

    - assistance with preparing for de-identified data sharing out of the Registry using NDA GUID to facilitate linkages.

Section 3: Data integrity and sharing services to support the DS-Connect Registry.

At a minimum:

- Describe a data management and sharing plan describing how existing registry data, new data collected from participants, and meta data will be managed, how the de-identified data will be prepared for sharing in regular intervals, including specific considerations related to making de-identified registry data rapidly available, findable, and accessible through the INCLUDE Data Hub, in collaboration with the INCLUDE Data Coordinating Center (DCC), while considering special cases of data protection if applicable.

- Provide a plan for curation processes and procedures to ensure data quality, integrity, and utility and a proposal for a Policy Manual for staff to perform curation functions.

- Provide a commitment to monitor and report summary metrics on DS-Connect database activities at least quarterly using analytic tools for use by the NICHD/NIH, INCLUDE Project, Down Syndrome Consortium, Down syndrome advocacy groups, academic and public sector researchers and industry members. Such tools/metrics may consist of the following: consent process success rates and outcomes, number of registered users (participants and professionals), engagement metrics such as frequency of page/survey updates, number of countries accessing website, user traffic, number of clicks/visits, exit page, average time on site, survey response completion rate; and professional requests for recruitment support and outcomes.

- Provide a process or procedure for administration and management of the participant- and professional-provided information for quality and completeness including reminders and follow-up plans.

Section 4: DS-Connect Project Management Support.

At a minimum:

- Describe the plan for the overall management, integration and coordination of all registry activities including the management and coordination of activities carried out under subcontracts or agreements.
    - For initial milestones, provide a transition-in plan including necessary documents (e.g., project documentation, policy manuals), standard operating procedures (SOPs), metrics/statistics, data dictionaries, DS-Connect Registry surveys, webpages, and participant data, and all master files as available to the government. The government can provide a full listing of available resources transitioned from the previous contract holder upon request.

    - Within 7 days of OT award, provide the date by which the system will be operational (minimum viable product).

- Describe the technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and timely completion of projects carried out under this award and effective communications with the Other Transactions Authority Agreements Officer (OTAO) and Program Official (PO), as well as other NICHD Staff.

- Describe the capability to ensure Human Subjects Protections. This includes support for required submissions to the IRB, as needed. Describe procedures to ensure personnel have IRB-required Human Subjects Protections training and ability to provide certification/re-certification documentation for the IRB, as needed.
    - Describe the ability to collect PII to enable GUID creation for data linkage via the NIMH Data Archive GUID Tool; visit https://nda.nih.gov/s/guid/nda-guid.html for information on registration requirements.

    - Describe the ability to support the enhanced consent process via separate survey based on skip logic principles for participants and provisions of metrics to monitor usage and functionality.

- Describe the methods used to coordinate, support and maintain data linkages to other databases to facilitate data sharing while maintaining confidentiality of PII. Sharing and linkage of de-identified registry data is required with the INCLUDE DCC Data Hub on a regular schedule, to be determined. Additional linkages could be with databases and biospecimen repositories such as those associated with the INCLUDE Project, the NIH NeuroBioBank (https://neurobiobank.nih.gov), the Alzheimer's Disease Research Centers, and other databases or biorepositories that utilize the GUID system.

- Describe the implementation plan for communications, outreach, and user interface and experience development, including plain language explanation of the information on the website for NICHD/NIH stakeholders, Down syndrome community, advocates, academics, industry representatives, and the general public. Ensure this includes informational content for distribution of recruitment notification for clinical studies supported by DS-Connect.

Section 5: Past performance and expertise of the team members, plan for operations and maintenance of the registry, and overall project management.

At a minimum:

- Identify key personnel, project leads, and other personnel; key personnel must include specification of a project manager, systems engineer, and a technical expert.

- Specify effort levels and specific roles for each person.

- Include relevant past performance for the team and any prior experience working together.

Section 6: The adequacy and appropriateness of the budget, resources, data and resource sharing.

- Review budget details in the next section

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

Additional information to include in the submission:

- A letter of support from the proposer's organization indicating institutional commitment for the project, e.g., relaying support for contributions (including, but not limited to, support for activities, licenses, and other resources) and preparations to enter into negotiated other transactions agreements.

- A bibliography (not to exceed 1 page)

Budget details

The NIH may elect to negotiate any or all elements of the proposed budget.

The Budget section is not subject to page limitations. Proposals 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 $1.4 million total costs. Second year budget estimates should also be provided, but these budgets will be reassessed as the project proceeds 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 $2.5 million total costs.

Provide the overall expected cost for each of the following categories: personnel, equipment, servers/cloud-based resources (if applicable), travel for staff to support NIH activities at conferences, funds for community partners (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.

Provide a list of milestones including description of the scientific goals and deployment of testing to meet them, completion criteria, due date, and payment/funding schedule. 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.

Applicants need to plan to attend a mandatory kickoff meeting of the DS-Connect® Registry, to be held virtually likely in April 2024. Applicants should be willing to interact with the NICHD team through regular

virtual meetings at the cadence desired by the NICHD team and to adhere to a schedule of program meetings as needed during the five-year project period.

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

Proposal Submission Instructions and Contact Information

For best consideration, complete applications should be submitted under OTA-24-007 via eRA ASSIST (at https://public.era.nih.gov/assist/public/login.era) not later than February 20, 2024, by 5 PM local time of applicant organization. Detailed system instructions for submitting your proposal will be provided by the NIH Agreements Officer. Please review eRA Training ASSIST, https://www.era.nih.gov/help-tutorials/assist/era-training-assist.htm, for additional guidance about Resource only for Other Transaction Authority (OTA) Users of ASSIST (instruction guide for NIH OT Applications in eRA's ASSIST can be found at https://www.era.nih.gov/files/ASSIST-Instruction-Guide-for-NIH-Other-Transactions.docx).

Financial and administrative questions should be addressed to
Artisha Wright
Artisha.wright@nih.gov

Questions about the scientific scope of the studies should be addressed to
Sujata Bardhan, Ph.D.
sujata.bardhan@nih.gov

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 Investigator

The Principal Investigator should already have an eRA Commons account. If not, the Principal Investigator 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 Authorized Organizational Representative, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

4. Objective Review

The intent of the objective review for the DS-Connect Registry is to determine whether the objectives and plans of the proposed project will contribute to, and enhance the contact-sharing, communication and idea-sharing among NIH staff, individuals with Down syndrome and their families, national and international organizations interested in Down syndrome, and other relevant groups. The review is also intended to facilitate dialogue between applicants, the NICHD, and other program and data experts within NIH so that proposals are improved by the review process. The outcome of each review is therefore intended to be a modified work plan for the NICHD as it works with the proposer. Components of the proposals 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.

Review of Proposals

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

The objective review of the Proposals will consider:

- The potential impact of the proposed activities to address the stated goals of the project if implemented and the ability to implement rapidly;
- Assembly of a team with appropriate expertise to rapidly implement the project;
- Past performance and expertise of the team members;
- Approach for managing and sharing data, and ability to transfer newly developed software, algorithms, digital objects, data, and other resources;
- Adequate system security plan to maintain confidentiality of registered participants' identifying data;
- The adequacy and appropriateness of the project management plan, budget, resources, data and resource sharing
- The appropriateness and clarity of projected milestones and feasibility of achieving interim and final outcomes outlined.

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

Funding decisions will be based on the outcome of the review discussion. NICHD will issue an award to one eligible entity. The level of funding for an award made under this solicitation has not been predetermined but will depend on (1) the objectives proposed by the participant and how well they fit with the goals of DS-Connect (2) quality of the proposal received, and (3) availability of funds.

The agreement for the award will be negotiated with an eligible entity whose application is determined to be the most advantageous and provide the best value to the NIH.

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.

NIH reserves the right to:

- Invite the Principal Investigator submitting the proposal in response to this solicitation to present their application in a Web-based videoconference or teleconference;
- Select for negotiation all, some, one, or none of the proposals received in response to this solicitation;
- Accept a proposal in its 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 RO.

5. Application Timeline

Key Events	**Key Dates**	**Action needed by Applicants**
Research Opportunity posted	February 5, 2024	
Proposal due	February 20, 2024	Submit
Review	February 26, 2024	

Key Events	Key Dates	Action needed by Applicants
Award Negotiations begin	March 1, 2024	Attend videoconferences or teleconferences as requested
Award announced	April 2024	
Kickoff meeting (mandatory)	TBD	Attend

6. Special Award Terms and Information

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 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.

Proposal(s) 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 the recipient to establish a vision and capabilities for the operations and management of DS-Connect: The Down syndrome registry and to oversee the effort of the recipient to achieve the vision.

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 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 Agreements Officer for administrative and financial aspects of the award.
3. Program Officer: Individual within NIH who provides day-to-day programmatic oversight of individual award, working closely with the Agreements Officer.

OT Agreement Governance

OT awards are not grants, cooperative agreements, or contracts. They are used by the NIH which have been authorized by Congress to use them. They provide considerable flexibility to the government to establish policies for the award. 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 Notice of Award (NoA), as well as all terms and conditions cited in the NoA 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 award 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.

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.

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.

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 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, 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 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 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.

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.

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 awardees for DS-Connect: The Down Syndrome Registry 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.

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 Financial Report, the Final Progress Report, and Final Invention Statement and Certification.

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 Authorized Organizational Representative 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
- Salary Cap/Salary Limitation
- Research Misconduct
- Select Agents
- Trafficking in Persons
- USA Patriot Act