Section 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Neurological Disorders and Stroke (NINDS)
Research Opportunity Title	**Ultra-rare Gene-based Therapy (URGenT) Clinical Trials Conducted within NeuroNEXT: Stage 2 Protocol Application (OT2)**
Activity Code	OT2: Application for an Other Transaction Agreement
Research Opportunity Number	OTA-24-003
Related Notices	OTA-24-002
Key Dates:	Posted Date: December 4, 2023
	Open Date (Earliest Submission Date): December 28, 2023
	Application Due Date: Rolling submission
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Content by Sections

Section 2. Objectives of this Opportunity

The purpose of this research opportunity announcement (ROA) is to invite Stage 2 Protocol Applications for clinical trials of gene-based and gene-targeted therapies for ultra-rare neurological diseases, to be conducted within the Network of Excellence in Neuroscience Clinical Trials (NeuroNEXT).

Background:

The National Institutes of Health (NIH) reports that nearly 7,000 rare diseases affect more than 25 million Americans. In the United States (US), based on the definition created by Congress in

the Orphan Drug Act of 1983 and adopted by the Food and Drug Administration (FDA), a rare disease is defined as a condition that affects fewer than 200,000 people in the US. Ultra-rare diseases affect substantially fewer people, 6,000 or fewer individuals, this equates to one in 50,000 people or less.

Approximately 95% of rare diseases, including ultra-rare diseases, have no FDA-approved therapeutic available and an estimated 80% of rare diseases have an identified genetic origin. These rare diseases are often due to pathogenic variants in a single gene that alter gene product function. Many rare and ultra-rare diseases are caused by different pathogenic variants, some of which may be unique to a single individual or to a very small number of individuals. Many of these rare diseases are serious or life-threatening conditions, many in children. The overall economic burden of rare diseases is $966 billion, of which 43% ($418 billion) are direct medical costs and 57% ($548 billion) are indirect costs associated with productivity losses ($437 billion) and non-medical costs, ($111 billion). Cumulatively, these diseases represent a large unmet medical need as there are few available effective treatments and limited commercial incentive for therapeutic development. Successful gene-based therapies for some genetic diseases, such as spinal muscular atrophy, have fueled promise for the rarest of diseases and reports of custom-designed treatments for individual patients have gained public attention. Such efforts present challenges for safety and efficacy research, regulatory approval, and business processes built around larger patient populations.

The NINDS supports gene-based therapy research through the Ultra-Rare Gene-based Therapy (URGenT) program. The URGenT program is a major initiative funded by the NINDS to provide bench to bedside resources that remove impediments to gene-based therapy development. Specifically, it is a late-stage pre-clinical therapy development program that aims to address challenges of gene-targeting technologies, de-risk these approaches for industry adoption, and coordinate their entry into clinical trials. URGenT facilitates data standardization and sharing, allocation of resources, and engenders best practices across diseases to make therapy development for rare and ultra-rare diseases more efficient and accessible. It supports Investigational New Drug (IND)-enabling studies and planning activities for First-in-Human clinical testing.

This ROA expands the URGenT program to support conduct of gene-based therapy clinical trials for ultra rare neurological diseases (URGenT clinical trials) following IND acquisition. The addition of clinical trials to the URGenT program will expedite progression of an asset from the pre-clinical to clinical phase, thereby accelerating the time course of gene therapy development. The URGenT clinical trials program will not be limited to assets developed through the URGenT pre-clinical program, which is funded via a separate grant mechanism: applicants who were not part of the URGenT pre-clinical program may apply to this ROA.

URGenT clinical trials may be conducted within the NeuroNEXT clinical trial network. NeuroNEXT provides funded infrastructure to efficiently conduct multiple, scientifically sound, possibly biomarker-informed exploratory clinical trials evaluating the most promising therapies, and to facilitate collaborations between academia, industry, non-profit foundations, government organizations, and other possible stakeholders. The network consists of a Clinical Coordinating Center (CCC), a Data Coordinating Center (DCC), and geographically distributed clinical sites. NeuroNEXT can include ad hoc clinical sites for particular clinical trials, if needed. The network utilizes a central IRB of record and other central resources, including central pharmacy and laboratory facilities. Additionally, NeuroNEXT will establish a Gene Therapy Consortium (GTC) consisting of members with expertise in gene-based and gene-targeted therapies, ultra-rare and rare diseases, industry aspects, and clinical trial planning and execution, with particular emphasis on first-in-human or first-in-disease trials, small clinical trials, and adaptive trial designs. The GTC will provide support and advice as requested for URGenT clinical trials proposed for and/or conducted within NeuroNEXT. Clinical trials conducted in NeuroNEXT undergo rigorous scientific vetting. Awarded projects under this Program will be milestone driven and progress must be demonstrated in order to advance through successive phases of support.

Objectives:

Under this ROA the NINDS will accept Stage 2 Protocol Applications for gene-therapy products that have an active Investigational New Drug (IND) designation and are proposed for URGenT clinical trials to be conducted within NeuroNEXT. URGenT clinical trial applications are accepted and reviewed in a two-stage process. Stage 1 Preliminary Applications, submitted under ROA (insert ROA number) may be submitted by academic investigators, industry applicants, private institutions, or nonprofits. At Stage 2 the NeuroNEXT CCC is the applicant of record. NeuroNEXT CCC will work with the Stage 1 applicants to obtain relevant information. Stage 2 Protocol Applications are accepted by invitation only and involve the submission of more detailed information on the proposed clinical trials and related activities. Please refer to Section 5: Application Information and Submission for detailed information.

Scope:

The URGenT program is focused on the development of gene-based therapeutics for patients with serious, life-threatening ultra-rare neurological diseases. The following therapeutic modalities are amenable to the development of individualized genomic-based medicine approaches:

Oligonucleotide-based approaches
Oligonucleotides offer the potential to treat many monogenic diseases by either ameliorating splicing mutations, promoting exon skipping, or targeting dominantly acting transcripts. Oligonucleotides-based interventions for neurological diseases include but are not limited to antisense oligonucleotides (ASOs) and small interfering RNAs (siRNA).

Viral vector-based approaches
Viral-based therapeutics (e.g., Adeno-Associated Viruses (AAVs)) and other potential vector and/or delivery vehicles, containing the correct gene construct, may be used as an *in vivo* therapeutic approach to replace or knockdown expression of a disease-causing gene. Alternatively, cell therapies involving *ex vivo* gene targeting may offer another therapeutic approach.

Genome editing-based approaches
Several platform technologies such as Zinc Finger Nucleases (ZFNs), Transcription Activator-like Effector-based Nucleases (TALENs), and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)- associated protein systems, have emerged as promising alternative approaches for editing DNA owing to both their versatility and ease of use.

Other gene-based therapeutic approaches
Small-molecule drugs that can selectively bind RNA and modulate pre-mRNA splicing have potential as a treatment strategy for human disease. These nucleic acid–targeted small molecules have therapeutic potential in the treatment of some ultra-rare neurological diseases.

URGenT clinical trial proposals that utilize the modalities described above or related approaches and are to be conducted within the NeuroNEXT are eligible under this ROA.

The proposed asset must have an open IND and be ready for clinical trials. Potential applicants are STRONGLY encouraged to contact NeuroNEXT/URGenT Program Staff to discuss their application and the application process prior to submission.

Section 3. Potential Award Information

NIH funds to conduct the study will be awarded to the NeuroNEXT CCC only after successful completion of both stages of application and review. The NeuroNEXT CCC then administers the funds to other NeuroNEXT research components as appropriate.

Authority: This Research Opportunity Announcement (ROA) is issued with the goal of soliciting IND-ready assets and the conduct of clinical trials for URGenT. An OT Agreement will be used to fund clinical trials conducted within NeuroNEXT, pursuant to OT authority described in section 402(n) of the Public Health Service Act, 42 U. S. C. 282(n).

Section 4. Eligibility

Organizations:

The following entity is eligible to apply under this ROA if selected after the URGenT clinical trials within NeuroNEXT Stage 1 review: The NeuroNEXT CCC.

Eligible Individuals (Program Director/Principal Investigator): Any individual(s) identified by NeuroNEXT CCC as having the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s). Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

Section 5. Application Information and Submission

Application Process Overview:

For URGenT clinical trials conducted within NeuroNEXT there are two stages of application and review.

Stage 1 Preliminary Application: The asset holder will submit a Stage 1 Preliminary Application under ROA (OTA-24-002), including all required documents. This application must include detailed information on the proposed asset, including prior basic, pre-clinical and clinical research completed and rationale as well as brief information on the proposed study population and design. Stage 1 Preliminary Applications are received and reviewed on a rolling basis. The review includes an independent /objective review by a panel of external experts convened by the NINDS. No funding is provided at Stage 1.

Stage 2 Protocol Application: Upon completion of the Stage 1 review process, the applicant may be invited to work with the GTC and NeuroNEXT to develop a full clinical protocol (to include budget and timeline) for submission under this ROA, resulting in a Stage 2 Protocol Application. The NeuroNEXT CCC will be responsible for submission of the Stage 2 application package. The following will be considered in making funding decisions: 1) Scientific and technical merit of the proposed project as determined by scientific peer review, 2) Availability of funds, and 3) Relevance of the proposed project to program priorities. Protocols selected following the review will be presented to the NANDS Council for funding approval. If approved by the NANDS Council, a funding decision will be made by the NINDS Director. If funded, the OTA trial funds will be released to the NeuroNEXT CCC and study implementation may begin within the NeuroNEXT.

URGeNT Clinical Trial Stage 2 Protocol Application Information:

Application Requirements:

Complete applications must be submitted by the Recipient Business Official/Signing Official. The organization must be registered in eRA Commons with one person designated as the 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.

The application must clearly and fully demonstrate the applicant's capabilities, knowledge, and experience and the budget proposed. Full applications must be submitted in text- recognizable PDF (Adobe) format.

1. **Cover Page, Abstracts and Specific Aims:** Applicants for NIH Other Transactions shall include a cover page, an abstract and specific aims in each application. Abstracts are limited to one page, and Specific Aims are limited to three pages.

   The Cover Page should include (no more than 1 page):

   - Number and title of this ROA
   - Project title
   - The Recipient's
     - Legal entity name
     - Address and contact information
     - SAM # and expiration date
     - Unique Entity ID# and expiration date
     - EIN number
   - Principal Investigator(s) first and last name, title, organization, mailing address, email address and phone number (with NIH Commons Account information). If multiple PIs are named, the Contact PI must be clearly identified.
   - The name and contact information for the Recipient's Business Official, the person authorized to negotiate and bind the Recipient as a signatory to the Other Transaction agreement.
   - The total cost proposed.

   Abstract ("Abstract.pdf"; no more than 1 page): The project abstract is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). It should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader. Do not include proprietary, confidential information or trade secrets in the abstract. If the application is funded, the project abstract will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT) and will become public information. The attachment is limited to one page.

   Specific Aims ("SpecificAims.pdf"; no more than 3 pages): State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the research will have on the research field(s) involved. List succinctly the specific objectives of the research. This attachment is limited to three pages.

2. **Clinical Trial Protocol Application (no page limit):** The Clinical Trial Protocol Application should include following information.

   - Clinical Trial Protocol- The NIH-FDA Phase 2 and 3 IND/IDE Clinical Trial Protocol Template) (NOT-OD-17-064) will be used as a guideline for the protocol. This template will be adapted to reflect the asset and population to be studied.
   - A detailed Timeline and Milestones
   - Manuals of Operations for the research procedures
   - Statistical analysis plan
   - Protocol Investigator(s) and key research personnel

- A detailed budget and budget justification as further explained below.

3. **NIH Biosketches:** Biosketches of each key personnel must be included (no more than five (5) pages in length. NIH biosketches must conform to a standardized format (https://grants.nih.gov/grants/forms/biosketch.htm).

4. **Letter of Support:** If collaborations have been established, include letters of collaboration in the application that document the role of each collaborator. Letters should be combined into a single PDF.

5. **Budget Information:** The budget shall contain sufficient information to allow the Government to perform an analysis of the proposed cost of the work. This information shall include the amounts of the line items of the proposed cost. These elements will include the following elements by milestone event and/or proposed period as applicable.

   - Direct Labor – Individual labor category or person, with associated labor hours or effort and unburdened direct labor rates;
   - Indirect Costs – Fringe Benefits, F&A, etc. (Must show base amount and rate). Offerors must submit a copy of their most recent indirect cost rate agreement negotiated with any federal audit agency, if applicable;
   - Travel – Separate by destinations and include rationale for travel, number of trips, durations - number of days, number of travelers, per diem (hotel and meals in accordance with the Federal Travel Regulations), airfare, car rental, if additional miscellaneous expense is included, list description and estimated amount, etc.;
   - Subawardee – A separate detailed budget shall be submitted by each proposed subawardee. The subawardee's proposal shall include on company letterhead the following:
     - Complete company name and mailing address, technical and administrative/business point of contacts, email address, and telephone number.
     - Include the Unique Entity ID.
     - A commitment letter from the proposed subcontractor's business official that includes:
       - Willingness to perform as a subawardee for specific duties (list duties) or a SOW;
       - Proposed period of performance;
       - Supporting documentation for proposed costs (personnel documents to verify salaries, vendor quotes for equipment, negotiated indirect cost rate agreement)
   - Consultants – For proposed consultants, provide draft consulting agreement or other document which verifies the proposed loaded daily/hourly rate and labor category;
     - Written verification from the consultant of their proposed rate, along with a statement that it is their usual and customary rate charged to other customers;
     - Description of the work to be performed by the consultant and direct relevance to the work. Include information on why this expertise is not available in-house

- Materials & Supplies – Must be specifically itemized with costs or estimated costs. Where the total cost is greater than $3,500, indicate pricing method (e.g., competition, historical costs, market survey, etc.). Include supporting documentation, i.e., vendor quotes, catalog price lists, and past invoices of similar purchases.

- Other Direct Costs – Especially any proposed items of equipment. Equipment generally must be furnished by the Offeror. Justifications must be provided when Government funding for such items is sought.

Salary Rate Limitation:

- Pursuant to current and applicable prior NIH appropriations acts, it is anticipated that Offerors submitting applications under this ROA will be subject to a salary rate limitation on funds used to pay the direct salary of individuals.

- Congress has stipulated in the NIH appropriations act that, under applicable extramural awards appropriated funds cannot be used to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II.

- For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary”, in this clause. An individual's direct salary is the annual compensation that the Offeror pays for an individual's direct effort (costs) under the award. Direct salary also excludes fringe benefits, overhead, and G&A expenses (also referred to as indirect costs or facilities and administrative [F&A] costs). Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an NIH award; it merely limits the portion of that salary that may be paid with Federal funds.

- The salary rate limitation also applies to individuals under subawards.

- See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

6. **Data Management and Sharing Plan (no more than 2 pages**): In accordance with NIH Policy for Data Management and Sharing, describe how the proposed data generated from the project will be managed and shared. For elements to include in the Data Management and Sharing Plan, please see Data Management & Sharing Policy Overview, Writing a Data Management & Sharing Plan | Data Sharing (nih.gov) and NOT-OD-21-014: Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan. NIH respects and recognizes Tribal sovereignty and American Indian and Alaska Native (AI/AN) communities’ data sharing concerns. For research teams working with Tribes and AI/AN communities, please refer to NOT-OD-22-064: Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data.

Submission Information:

Applications to the Ultra-rare Gene-based Therapy (URGenT) Clinical Trials Conducted within NeuroNEXT: Stage 2 Protocol Application (OT2) may be submitted after the open date shown under the “Key Dates” section of this announcement. Applications are submitted via eRA ASSIST. Use this ROA number when submitting the application. Detailed instructions for submitting OT Applications can be found at ASSIST-Instruction-Guide-for-NIH-Other-Transactions.docx (live.com).

Upon receipt, applications are evaluated for completeness, compliance with application

requirements and responsiveness by NINDS. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed and the applicant will be so notified.

Applications not responsive to this ROA:

Nonresponsive applications include those that involve any of the following activities:

- Nonclinical studies of disease mechanism or therapeutic mechanism of action studies
- Animal studies
- Development of diagnostics or diagnostic devices
- Research focused entirely on biomarkers and/or clinical endpoint development
- Clinical trials that seek to develop therapeutics (including gene-based therapy) for common neurological disorders
- Clinical trials that seek to develop therapeutics without involving gene modification technique

Section 6. Independent/Objective Review Information

Study proposals will undergo objective, independent review. Independent review is an assessment of scientific or technical merit of applications by individuals with appropriate scientific knowledge and expertise. Conflicts-of-interests of review panel members are appropriately managed during the review process in accordance with standard NIH policies. Independent review provides information essential to ensuring selection of applications that best meet the needs of the program using the criteria delineated below and that application selection is conducted in a fair, objective manner free of prejudices and avoidable biases. The Independent reviewers are instructed to consider only the review criteria below in their individual assessment of scientific merit. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field, or a proposed Clinical Trial may include study design, methods, or an intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or that it might lead to new avenues of scientific investigation.

Independent/Objective Review Criteria:

1. Significance/Innovation
    a. How will successful completion of this clinical trial change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
    b. How compelling is the justification for the development of the proposed intervention in terms of potential advances in clinical practice, public health, and/or patient quality of life?
    c. Does the clinical trial protocol include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?
    d. Is the potential impact of the intervention on the disease and patients clear? Would the project advance the field even if the trial is negative?
2. Approach
    a. Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the

hypothesis being tested? How appropriate are the primary and secondary outcome measures?

b. Are rigorous testing methodologies (e.g. biomarker assays) available and proposed to assess the safety and efficacy outcomes of the therapeutic candidate in the clinical trials?
c. Is the trial appropriately designed to conduct the research efficiently?
d. Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?
e. How appropriate are the eligibility criteria, randomization/blinding methods (if applicable), sample size, and plans for training of site personnel?
f. Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate?
g. Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Is the study design adequately powered to answer the research question and provide interpretable results?
h. Does the protocol identify research-related risks and provide ways to minimize those risks?
i. Are the plans for quality control, quality assurance and quality monitoring adequate? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable?
j. Are potential challenges and corresponding solutions discussed (e.g. strategies that can be implemented in the event of enrollment shortfalls)?
k. Is the study timeline feasible?

3. Expertise and Resources

a. Do the investigators have the relevant experience and expertise in the subject matter and clinical trial execution?
b. How are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
c. Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
d. Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?
e. If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and (4) operate within the proposed organizational structure?
f. Does this project include a partnership with the private sector (e.g. patient groups and/or industry), and if so, have agreements with proposed partners been established?
g. Are substantive letters of support or other documentation provided to assure commitment of subcontractors, consultants, and/or service agreements for personnel and facilities?

Additional Review Criteria:

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the reviewers will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For additional information on review of the Human Subjects section, please refer to the Guidelines for Reviewers: Protections for Human Subjects Review Criterion

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the reviewers will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Additional Review Considerations:

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources (as applicable), are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Composition of Objective Review Panel:

The review of applications is carried out by a panel of experts with complementary knowledge of multiple areas related to the proposed study subject matter and the conduct of clinical trials such as pharmacokinetics, biological mechanisms, pharmaceutical industry development, and other relevant scientific and clinical expertise. NIH program officials attend the review meetings to provide programmatic input. Summary statements of the review panel meetings will not be made available. However, feedback on the Independent/Objective Review and the NINDS decision on the application are provided to applicants. Appeals are not allowed.

Selection Process:

NINDS will select applications based on their scientific and technical merit, including consideration of the issues identified during independent/objective review and relevance of the proposed project to program priorities for presentation to NINDS Advisory Council for approval followed by NINDS Director approval before award of Other Transactions funding and study implementation within the NeuroNEXT.