Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0648 Exp., date: 06/30/2024)

TITLE OF INFORMATION COLLECTION: NINDS Feedback Survey of NeuroNEXT

PURPOSE: The proposed information collection is a survey of individuals who have participated in the National Institute of Neurological Disorders and Stroke (NINDS) Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) over the last ten years. The purpose of this survey is to collect feedback and assess satisfaction with services delivered and consultation received; to determine the extent to which participants feel the network has facilitated the development and conduct of high-quality, multi-site clinical trials focused on key interventions in stroke prevention, treatment and recovery; and to obtain feedback relevant to program improvement. The survey results will be used to inform improvements to implement in future renewals of the network.

NeuroNEXT develops and conducts exploratory trials evaluate promising therapies for neurological disorders other than stroke. Examples include Phase 2 clinical trials to gather critical information about investigational treatments prior to larger, later-stage trials and clinical studies to validate biomarkers and clinical outcomes in preparation for clinical trials. The network infrastructure delivers services and support for the execution of clinical trials and studies and consists of a Clinical Coordinating Center (CCC), a Data Coordinating Center (DCC), and 25 clinical sites throughout the US. NINDS supports the clinical trials and studies conducted through the network through peer-reviewed funding mechanisms open to investigators from academia, foundations, or industry. In addition, NeuroNEXT emphasizes training and career development for clinical investigators. Investigators for NeuroNEXT protocols and individuals at the CCC, DCC, and clinical sites coordinate to develop and conduct clinical trials and studies in neurological disorders.

NINDS will follow up with respondents who have indicated in the survey their willingness to participate in a follow-up discussion group to provide additional, in depth feedback of the network. NINDS will submit the proposal for conducting these discussion groups to OMB for approval.

DESCRIPTION OF RESPONDENTS: Survey respondents will include 1) researchers who serve as principal investigators or co-investigators on cooperative agreements supporting the networks' infrastructure (coordinating centers and clinical research sites) and research studies conducted within the network; 2) research trainees or early career scientists who have participated in training and career development activities conducted by the network; 3) coordinators and managers of the coordinating centers, research sites, and research studies; and 4) clinical and support staff of the network research sites and research studies.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[ ] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[X] Other: Service Delivery

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

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To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [X] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

ESTIMATED BURDEN HOURS and COSTS

Category of Respondent	**No. of Respondents**	**No. of Responses per Respondent**	**Time per Response (in hours)**	**Total Burden Hours**
Individual: Coordinating Center, Research Site, or Research Study Investigator or Co-Investigator, Research trainees, Coordinator/Manager and Other research and Support staff	230	1	20/60	77
Totals	**230**			**77**

COST TO RESPONDENT

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
Individual: Coordinating Center, Research Site, or Research Study Investigator or Co-Investigator, Research trainees, Coordinator/Manager and Other research and Support staff	77	$43.22	**$3,327.94**
Totals	**77**		**$3,327.94**

*Hourly wage rates for 19-1029 Biologic Scientist is $43.22 (based on http://www.bls.gov/oes/current/oes191029.htm).

FEDERAL COST: The estimated annual cost to the Federal government is $18,455.65.

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight:					
NINDS Staff 1	14/8	151,118	5%		$7,555.90
NINDS Staff 2	12/1	87,198	12.5%		$10,899.75
Contractor Cost (optional):					
Travel (optional)					
Other Cost (optional)					
Total					$18,455.65

The selection of targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

We have complete lists of the principal and co-investigators on cooperative agreements that support the networks' infrastructure and clinical research studies; the research trainees who participated in training and career development activities; the coordinators and managers of the coordinating centers, research sites, and research studies; and the clinical and support staff of the

network research sites and research studies. We do not plan to sample these populations; we will make the survey available to all of these individuals.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [x] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [x] Survey form
   - [ ] Chart Abstraction
   - [ ] Other, Explain

2. Will interviewers, facilitators, or research coordinators be used? [ ] Yes [x] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.