

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 the NIH StrokeNet

PURPOSE: The proposed information collection is a survey of individuals who have participated in the National Institute of Neurological Disorders and Stroke (NINDS) Stroke Trials Network (NIH StrokeNet) over the last eight 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.

NIH StrokeNet develops and conducts multi-site exploratory Phase 1 and 2 and confirmatory Phase 3 clinical trials focused on promising interventions, as well as validation studies of biomarkers or outcome measures immediately preparatory to trials, in stroke prevention, treatment, and recovery with the objective of having a balanced portfolio between all three approaches. The NIH StrokeNet infrastructure delivers services and support for the execution of clinical trials and studies and consists of a national coordinating center (NCC), a national data management and statistical center (NDMC), and 27 academic regional coordinating centers (RCCs) across the US, each with respective clinical performance and satellite sites representing approximately 500 stroke hospitals. Each RCC is provided funds to annually support a network trainee who can dedicate at least 50% protected time to train and engage in stroke research. NIH StrokeNet trial concepts can be initiated by investigators outside of the network or by NIH StrokeNet investigators. Investigators for NIH StrokeNet protocols and individuals at the NCC, NDMC, RCCs, and clinical performance and satellite sites coordinate to develop and conduct clinical trials and studies in stroke.

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 and data 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)

- | | |
|--|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |
| <input type="checkbox"/> Focus Group | <input checked="" type="checkbox"/> Other: Customer feedback/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? Yes No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? Yes No
3. If Applicable, has a System or Records Notice been published? Yes No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes 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 and Data Centers, Research Site, and Research Study Investigator or Co-Investigator, Research Trainee, Coordinator/ Manager and Other Research and Support Staff	1,090	1	20/60	363
Totals	1,090	1,090		363

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
Individual: Coordinating and Data Centers, Research Site, and Research Study Investigator or Co-Investigator, Research Trainee, Coordinator/Manager and Other Research and Support Staff	363	\$43.22	\$15,689
Totals			\$15,689

*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 and data 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)

Web-based or other forms of Social Media

Telephone

In-person

Mail

Survey form

Chart Abstraction

Other, Explain

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

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

Please see attached screenshots of the survey, which include instructions and all survey questions.