## 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 Clinical Trial Networks (NeuroNEXT and NIH StrokeNet) Discussion Groups

**PURPOSE:** The National institute of Neurological Disorders and Stroke (NINDS) proposes to do small discussion group with participants in the National Institute of Neurological Disorders and Stroke (NINDS) Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) and Stroke Trials Network (NIH StrokeNet). The purpose of the discussion groups is to follow up on responses received from the NeuroNEXT and NIH StrokeNet feedback surveys (which were approved under this fast track mechanism, titled; “NINDS Feedback Survey of the StrokeNet” OMB# 0925-0648, exp., date 06/30/2024 and “NINDS Feedback Survey of the NeuroNEXT” OMB# 0925-0648, exp., date: 06/30/2024,) to assess further the networks’ delivery of services, and to better understand survey responses received. The discussion group results will be used to inform improvements to implement in future renewals of the networks.

**DESCRIPTION OF RESPONDENTS**: Small Group Discussants 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 2) researchers who serve as principal investigators or co-investigators on research studies conducted within the network. Only those who previously responded “yes” to the question “Would you be willing to participate in a follow-up interview or group discussion?” in the NINDS NeuroNEXT and StrokeNet feedback surveys will be contacted to participate in this small discussion group.

**TYPE OF COLLECTION:** (Check one)

[ ] Customer Comment Card/Complaint Form [ ] Customer Satisfaction Survey

[ ] Usability Testing (e.g., Website or Software [X] Small Discussion Group

[ ] Focus Group [ ] Other:

**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.

Name: Cristina Nigro, Ph.D., M.S., Health Science Policy Analyst, NINDS OSPP

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

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ ] Yes [X] 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 [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**  |
| Academic Sector (NeuroNEXT and StrokeNet Research Study Investigators and Coordinating/Data Center Investigators) | 24 | 1 | 60/60 | 24 |
| **Totals** | **24** |  |  | **24** |

|  |  |  |  |
| --- | --- | --- | --- |
|  **Category of Respondent** | **Total Burden****Hours** | **Wage Rate\*** | **Total Burden Cost**  |
| Academic Sector (NeuroNEXT and StrokeNet Research Study Investigators and Coordinating/Data Center Investigators) | 24 | $43.22 | $1,037.28 |
| **Totals** | **24** |  | **$1,037.28** |

\*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 $4,359.90.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary** | **% of Effort** | **Fringe (if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight**:  |  |  |  |  |  |
| NINDS Staff 1 | 12/1 | $87,198 | 5% |  | $4,359.90 |
|  |  |  |  |  |  |
| **Total** |  |  |  |  | $4,359.90 |

**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. These individuals will indicate their interest in participating in discussions groups on the networks feedback surveys which have been distributed prior to conducting discussion groups. We will follow-up via email with survey respondents that chose to share their email addresses.

**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

[X] Other, Explain – Videoconferencing software (Zoom)

1. Will interviewers, facilitators, or research coordinators be used? [X] Yes [ ] No

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

Please see the attached documents for the discussion group script (questions and prompts) and text for email messages.