Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0925-0668)

TITLE OF INFORMATION COLLECTION: Web based customer satisfaction form for collecting feedback on NIH/NIAID/DAIDS Clinical Quality Assurance Process

PURPOSE:

The Division of AIDS, Office of Clinical Site Oversight (OCSO) of the National Institute of Allergy and Infectious Diseases (NIAID) is committed to ensuring that the rights and safety of participants are protected and that data collection is accurate and complete. The process of Clinical Quality Management (CQM) at DAIDS sponsored and or supported Clinical Trial Units (CTU)s/ Clinical Research Sites (CRS)s provides some assurance of data integrity. CTU and CRS site staff perform ongoing CQM activities, including both quality control and quality assurance activities, in accordance with the International Conference on Harmonization, Guidance for Industry, E6, Good Clinical Practice: Consolidated Guidance. OCSO provides oversight for these CTUs/CRSs and is interested in maintaining a state of audit readiness as well as promote the quality and integrity of the research data. OCSO created this survey tool to gather CQM summary information from CTU/CRSs on a biannual basis.

The information collection will provide DAIDS with critical feedback from the perspective of site staff. This feedback will help improve customer satisfaction during site auditing by streamlining and making the auditing process more efficient for site staff as well as highlighting areas of quality management that may represent challenges to the CRSs.

DESCRIPTION OF RESPONDENTS:

Potential respondents are Clinical Research Coordinators, Quality Controls Managers and designees at CTUs/CRSs who are currently receiving funding or support from DAIDS to conduct network and non-network studies.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form	[X] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software	[ ] 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.

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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 [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

Category of Respondent	**No. of Respondents**	**No. of Responses per Respondent**	**Time per Response (in hours)**	**Total Burden Hours**
Private Sector (Grantees)	160	2	15/60	80 hours
Totals				80 hours

FEDERAL COST: The estimated annual cost to the Federal government is $_932.26_____

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your 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?

Potential respondents are designated staff at CTUs/CRSs who received funding from DAIDS to conduct network and non-network studies. OCSO created this tool for all functioning and operating sites (N=160) to provide improved customer service. The CTUs/CRSs staff will complete this tool on a biannual basis.

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
   - [ ] Other, Explain
2. Will interviewers or facilitators be used? [ ] Yes [X] No