

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB#: 0925-0648 Expiration Date: 05/2021)

TITLE OF INFORMATION COLLECTION: NIMH Clinical Research Education, Support, and Training (CREST) Program Customer Satisfaction Survey

PURPOSE:

The purpose of this survey is to collect anonymous voluntary feedback on the NIMH CREST program. The CREST program provides ongoing educational and technical support to clinical research study teams selected for phone or email consultation, and/or site visit(s), to insure NIMH funded clinical research is conducted in compliance with all applicable laws and guidelines in place to protect study participants safety and data. The NIMH would like to collect anonymous feedback from these study teams to make sure that we are providing the best value to our customers. We consider this type of survey will allow the study teams an avenue for feedback they currently do not have, and the feedback received will be utilized to enhance the CREST program and correct areas that are not meeting our goals.

DESCRIPTION OF RESPONDENTS:

NIMH-funded researchers who interact with our CREST monitors such as the Principle Investigator, Clinical Research Coordinator, Study Nurses, Pharmacists, and other study team members.

TYPE OF COLLECTION: (Check one)

- | | |
|---|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input checked="" 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 type="checkbox"/> 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: Yancy Bodenstein, NIMH Clinical Trials Operations and Biostatistics Branch (CTOBB)

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

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 |
|---|--------------------|---------------------------------|------------------------------|--------------------|
| Individuals/households - Medical Scientists | 200 | 1 | 10/60 | 33 |
| TOTAL | | 200 | | 33 |

| Category of Respondent | Total Burden Hours | Hourly Wage Rate* | Total Burden Cost |
|---|--------------------|-------------------|-------------------|
| Individuals/households - Medical Scientists | 33 | \$46.36 | \$1,529 |
| TOTAL | | | \$1,529 |

*Cite source per www.bls.gov if applicable - <https://www.bls.gov/oes/current/oes191042.htm>

FEDERAL COST: The estimated annual cost to the Federal government is: \$253

| Staff | Grade/ Step | Salary | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|--------------------------|-------------|-----------|-------------|-------------------------|---------------------|
| Federal Oversight | | | | | |
| CTOBB Branch Chief | 14/5 | \$132,818 | 1 | | \$133 |
| Contractor Cost | | | | | |
| Management Analyst | | \$120,000 | 1 | | \$120 |
| Travel | | | | | |
| Other Cost | | | | | |
| TOTAL | | | | | \$253 |

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? 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?

The study team members will be identified by the email addresses used to coordinate our site visits. We obtain these emails from the NIH data system used during the grant application process.

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
- Other, Explain

2. Will interviewers or facilitators be used? Yes No