

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: Feedback on the 2018 Review Criteria for Evaluating Clinical Trials Applications at the Center for Scientific Reviews (CSR).

PURPOSE: NIH depends on CSRs’ peer review process to ensure that all NIH grant applications receive fair, independent, expert, and timely reviews that are free from inappropriate influences. In 2018, NIH adopted new and more rigorous review criteria for evaluating clinical trials applications. There are some concerns that these new criteria are too numerous and complex, potentially reducing the focus on the scientific merit of applications and increasing reviewer burden. To address these concerns, a working group from the CSR external advisory committee was formed. The working group is currently reviewing the 2018 criteria and making recommendations on how the criteria should be modified to reduce reviewer burden, increase the quality of peer review, and ultimately improve review outcomes. Reviewer input is essential to this process, and CSR proposes conducting a survey with reviewers to hear their opinions about the clinical trials review criteria. Information collected from the survey will help inform the working groups’ recommendations.

DESCRIPTION OF RESPONDENTS: Respondents will be approximately 600 NIH CSR grant reviewers who are regular members of review meetings that review a high number of clinical trials applications. Most of these individuals are research scientists who work at academic universities across the U.S.

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: Hope Cummings _____

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 [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
Individuals	600	1	5/60	50
Totals		600		50

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	50	\$38.15	\$1,907.50
Total			\$1,907.50

*The wage rate was obtained from https://www.bls.gov/oes/2020/may/oes_nat.htm#19-0000

FEDERAL COST: The estimated annual cost to the Federal government is 2,695.64

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health Scientist Administrator	GS-14/4	134,782	2%		2,695.64
Contractor Cost					N/A
Travel					N/A
Other Cost					N/A
Total					2,695.64

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf>

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 customer list will consist of individuals who are regular members of CSR review meetings that review a high percentage of clinical trials applications. The rosters for these review meetings will be used as the participant list. Most of these individuals are research scientists who work at academic universities across the U.S.

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

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