Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0648 Exp., date: 05/2021)

TITLE OF INFORMATION COLLECTION: Data and Safety Monitoring Meeting Evaluation (NIAMS)

PURPOSE: Navitas Clinical Research, Inc. (NCR), as a contractor to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), proposes to use a web-based survey solutions system to gauge client's satisfaction with our services. This evaluation system will allow NCR to continually improve upon the high-quality standards set.

DESCRIPTION OF RESPONDENTS: For the NIAMS contract, NCR will administer a brief survey (6 items) to meeting participants following a Data and Safety Monitoring Board (DSMB) meeting for each study annually. For Safety Officer (SO) studies, this survey will be conducted following the introductory meeting. This method will provide continuous feedback from the monitoring bodies, the NIAMS Program Directors, and the Principal Investigators and research team members NCR interacts with under the scope of this contract.

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 <u>not</u> raise issues of concern to other federal agencies.
4. The results are <u>not</u> intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> 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: Celeste Crouse_____

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
Individuals	200	1	10/60	33
Totals		200		**33**

COST TO RESPONDENT

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Physicians	33	$97.81	$3,227.73
Totals			**$3,227.73**

*the Hourly Wage Rate in table above is cited from https://www.bls.gov/oes/current/oes291228.htm

FEDERAL COST: The estimated annual cost to the Federal government is $16,398.89

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Clinical Research Manager	GS-14-9	$153,665	1%		$1,536.65
Contractor Cost		$56,440	24%	$5,486	$14,862.24
Travel					
Other Cost					
Total					$16,398.89

*the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/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?

[**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?

NCR has a list of names and email addresses of all investigators, study team members, DSMB members, Safety Officers, and NIAMS Program Directors we presently service. NCR will create a web-based survey and the hyperlink to the assessment will be sent immediately following a DSMB or SO meeting. This questionnaire will be sent to all meeting participants including the NIAMS Program Director, the DSMB members, the SO, the Principal Investigator and study team members.

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

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