Supporting Statement A for

Paperwork Reduction Act Generic Information Collection Submissions for

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

National Institute on Drug Abuse

National Institutes of Health

Extension 0925-0655

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, the National Institute on Drug Abuse, National Institutes of Health (hereafter "the Agency") seeks to obtain OMB approval of a generic clearance to collect qualitative information on (a) service delivery to the public, and (b) electronic medication monitoring devices and other treatment and prevention tools and technologies that are being developed in the NIDA Small Business Innovative Research (SBIR) program and that need initial pilot testing for feasibility and/or viability. By qualitative feedback for (a) above, we mean information that provides useful insights on perceptions and opinions, information of program operations to corroborate the opinions, to have evidence-based information to make program improvements changes in operations, and to improve the management and delivery of the programs, but which are not statistical surveys that yield quantitative results that can be generalized to the population of study. By qualitative feedback for (b) above we mean information on prototype health care technologies – providing feedback information from examining the devices, conducting cognitive testing of questionnaires, or pilot testing of devices for usability. The information will be used for developing the technology and testing it for translation into practice – the Phase II of a study. Results from each Phase I will contribute to the correct implementation and conduct of Phase II of the studies.

This collection of information is necessary. For purpose (a) above, it will enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management and strategic planning.
For purpose (b) above, it will contribute to economic efficiency by demonstrating that the devices are, viable and have user satisfaction, before larger-scale testing and development are funded, the 'customer' feedback from test users would show where improvements to the devices are needed before larger-scale testing is implemented, and contribute to success in the conduct of the Phase II of SBIRs.

2. Purpose and Use of the Information Collection

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit

standards, as a means of contributing to the continuous improvement of the program. The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback; and to identify areas for improvement of a medical device or tool, and any corrections of the technology before large-scale testing. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery; and in the case of medical devices and tools - usability, applicability, feasibility of translation, other improvements and reliability reassurances. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary; True for all participants
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government; Five studies of website dissemination and training are anticipated at this time, with the total burden hours for these internal studies expected to be less than 1500. The focus of the studies will be, for example, the NIDAMED program that offers academic training for medical students; other components of the NIDA website that target different population groups; the mentoring program for diversity trainees funded for research training; the Phase I SBIR programs that develop tools and medical devices for treatment, treatment adherence for substance abuse, and substance abuse prevention.
- The collections are non-controversial and do not raise issues of concern to other Federal agencies; There are no controversial issues to other Federal agencies
- Any 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 near future; who would be able to use a tool or device, or who would be able to provide relevant information for cognitive testing of a medical interview or assessment as per an SBIR project. All NIDA website study participants will have experience with the website, all training program participants have had experience with the program. Study participants for the SBIRs will be relevant subjects or controls and respondents who would be able to provide relevant information for cognitive testing of an assessment instrument, a medical interview, a medical tool or device for treatment and prevention.
- Personally identifiable information (PII) is collected only to the extent necessary[1] and is not retained; PII is not being retained, is not being identified that is not already available in NIDA records;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if

[1] For example, collections that collect PII in order to provide renumeration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.,

released, procedures outlined in Question 16 will be followed); True of said evaluation studies, and Phase I SBIR studies;

- Information gathered will not be used for the purpose of substantially informing influential policy decisions [2]; the information is for program improvement in the case of dissemination programs, and improvement and usability and pilot testing for feasibility and large-scale development in the case of the SBIRs; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study. No generalizing to other programs will be made. The information may be informational for other similar NIH programs.

If these conditions are not met, the Agency will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form will be submitted to OMB along with supporting documentation (e.g., a copy of the comment card). The submission will have automatic approval, unless OMB identifies issues within 5 business days.

The types of collections that this generic clearance covers include, but are not limited to:

- Customer comment cards/complaint forms
- Small discussion groups
- Focus Groups of customers, potential customers, delivery partners, or other stakeholders
- Cognitive laboratory studies, such as those used to refine questions or assess usability of a website;
- Qualitative customer satisfaction surveys (e.g., post-transaction surveys; opt-out web surveys)
- In-person observation testing (e.g., website or software usability tests)

The Agency has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

There have been three projects approved under this generic clearance since its approval three years ago, all intended to contribute significantly to the mission of NIDA and the NIH. These projects included web-based surveys of the school population, and focus groups of youth for customer feedback on information available from the NIDA website, and customer feedback on usability testing of information from a site providing neuroscience information for researchers. The information was to improve dissemination and usability.

[2] As defined in OMB and agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”

3. **Consideration Given to Information Technology**

If appropriate, agencies will collect information electronically and/or use online collaboration tools to reduce burden. The studies will collect information electronically or use online collaboration tools to reduce burden, to the extent this is possible.

4. **Duplication of Information**

No similar data are gathered or maintained by the Agency or are available from other sources known to the Agency.

5. **Reducing the Burden on Small Entities**

Small business or other small entities may be involved in these efforts but the Agency will minimize the burden on them of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments.

6. **Consequences of Not Conducting Collection**

Without these types of feedback, the Agency will not have timely information to adjust its services to meet customer needs and to increase the efficacy and value of its programs that are developing medical tools and devices for treatment and prevention of substance abuse.

7. **Special Circumstances**

There are no special circumstances. The information collected will be voluntary and will not be used for statistical purposes.

8. **Consultations with Persons Outside the Agency**

In accordance with 5 CFR 1320.8(d), December 31, 2014 (79, FR 78875), a 60-day notice for public comment was published in the *Federal Register*. No public comments were received.

9. **Payment or Gift**

Small incentives of supplies or learning assists may be offered to schools if their participation is needed for the dissemination programs. The SBIR studies may provide payment or other forms of remuneration in the case of in-person cognitive laboratory and usability studies, focus groups, small groups interviews.

The Agency will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback. Focus groups and cognitive laboratory studies are the exceptions.

In the case of in-person cognitive laboratory and usability studies, the Agency may provide stipends of up to $40. In the case of in-person focus groups, the Agency may provide stipends of up to $75. If respondents participate in these kinds of studies remotely, via phone, or Internet, any proposed stipend needs to be justified to OMB and must be considerably less than that provided to respondents in in-person studies, who have to travel to the agency or other facility to participate. If such information collections include hard-to-reach groups and the agency plans to offer non-standard stipends, the Agency will provide OMB with additional justifications in the request for clearance of these specific activities. If OMB guidance for the stipend level is adjusted upward, the stipends may also increased accordingly.

10. Confidentiality

If a confidentiality pledge is deemed useful and feasible, the Agency will only include a pledge of confidentiality that is supported by authority established in statute or regulation, that is supported by disclosure and data security policies that are consistent with the pledge, and that does not unnecessarily impede sharing of data with other agencies for compatible confidential use.
Personal identifiable information is not anticipated to be collected for the studies of (a) above; it may be necessary for the SBIR studies that are developing medical tools and devices for treatment and prevention. Each study will be reviewed by the NIH Privacy Act office to determine whether or not a confidentiality pledge is necessary.

11. Sensitive Nature

No questions will be asked that are of a sensitive nature.

12. Burden of Information Collection

A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (1,560) are based on the number of collections we expect to conduct over the requested period for this clearance..

Table A.1 Estimates Annual Reporting Burden

Estimated Annual Reporting Burden				

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Type of Collection	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Customer outcomes and usability testing	900	1	40/60	600
Customer Satisfaction and needs assessment survey	600	1	40/60	400
Focus Groups	130	1	1	130
Small Discussion Groups	130	1	1	130
Pilot Testing of instruments for applicability among diverse populations	450	1	40/60	300
Total				1560

13. Costs to Respondents

No costs are anticipated. Examples of costs to respondents might be: Teachers: 10 persons x 30 hours = 300 hours; @ $60 per hour = $18,000
Researchers or Clinicians: 60 Principal Investigators or Clinicians x 20 hours =1200 hours; @ $75/hour = $90,000
Mentees: 100 mentees x 37hours =3700 hours; @$75/hour = $247,500
Mentors: 40 mentors x 20 hours = 800; @$75/hour =$60,000
Diversity Trainees: 150x1hour=150 hours @ $35/hour = $5,250.

14. Costs to Federal Government

The anticipated cost to the Federal Government is approximately $$744,000 annually. These costs are comprised of: Contractors = $380,000; NIDA staff person for 10 percent time each study at annual salary = $90,000 =$9,000 per study.

15. Reason for Change

This is an extension of a currently approved submission. There are no changes to this submission form from the previously approved submission, except an increase in the burden hours is being requested.

16. Tabulation of Results, Schedule, Analysis Plans

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings will be used for general service improvement, for improvement and refining of tools and devices, but are not for publication or other public release.

Although the Agency does not intend to publish its findings, the Agency may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). The Agency will disseminate the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public.", and will include specific discussion of the limitation of the qualitative results discussed above.

17. Display of OMB Approval Date

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These activities comply with the requirements in 5 CFR 1320.9.