Supporting Statement A for

Generic Clearance for the Research Domain Criteria (RDoC) Initiative, National Institute of Mental Health (NIMH)

OMB # 0925-0756, Expiration 07/31/2021

Date: July 6, 2021

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- ✓ Extension
- Emergency
- Existing

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A. Justification

As the lead Federal agency for research on mental illnesses, NIMH's mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Under 42 U.S.C. 285(p) and Section 401(a) of the Public Health Service Act, NIMH is charged with the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness. In 2009, NIMH launched the Research Domain Criteria (RDoC) Initiative to implement Strategy 1.4 of the 2008 NIMH Strategic Plan: "Develop new ways of classifying disorders based on dimensions of observable behaviors and brain functions." To this end, NIMH developed a research framework for new ways of studying mental disorders known as RDoC through a series of workshops (https://www.nimh.nih.gov/research-priorities/rdoc/development-of-the-rdoc-framework.shtml). The framework integrates many levels of information (from genomics to self-report) to better understand basic dimensions of functioning underlying the full range of human behavior from normal to abnormal. This effort resulted in the creation of a matrix of units of analysis (from molecules to self-report) for several domains (cognitive, positive valence, negative valence, social processes, arousal and regulatory systems)—all examined in a context emphasizing developmental trajectories and individual's interactions with their environment. The RDoC matrix has become a framework for organizing our research efforts, with the aim to guide research that begins with disruptions in neurobiological and behavioral mechanisms, and then works across systems to clarify connections among such disruptions and clinical symptoms; it is a flexible entity that can be updated as new research emerges that could influence the understanding of psychopathology.

NIMH is requesting OMB approval of this generic plan to continue using various types of information collection instruments in order to achieve our mission and meet our goal of interfacing with the scientific community and promoting the RDoC Initiative.

A.1. Circumstances Making the Collection of Information Necessary

The authority to collect this information is afforded under 42 U.S.C. 285(p) and Section 401(a) of the Public Health Service Act. Since 2012, NIMH has issued thirteen Funding Opportunity Announcements (FOAs) to encourage the field to use dimensional approaches to psychopathological research (https://www.nimh.nih.gov/research-priorities/rdoc/rdoc-funding-opportunities.shtml). The FOAs call for new, innovative research proposals to study mechanisms that may cut across multiple traditional diagnostic categories, based upon RDoC criteria laid out in the RDoC matrix. A list of grants funded under RDoC FOAs is available on the NIH RePORTER website at https://reporter.nih.gov/search/vTa4NYZqMUOwNnjm2TGcVg/projects.

The RDoC initiative continues to be a significant effort for NIMH. The Institute has a dedicated RDoC Unit within the Office of the Director with full time staff that oversee its daily activities and a working group that provides advice on RDoC activities and projects. Members of the workgroup and the Unit frequently present at scientific conferences, organize webinars, and communicate with a variety of stakeholders in the mental health field including academic researchers, clinicians, other agencies within NIH and HHS, technology companies, and others. NIMH is seeking to extend approval to collect information from stakeholders about their perceptions of the RDoC initiative and whether its goals and aims are being achieved. To maintain momentum of the initiative, it is critical to monitor how RDoC is perceived by stakeholders, collect information from them, and modify communications and programmatic priorities, as necessary. It is crucial to gain further

insight and information from the field as to how we may use findings from studies funded under RDoC FOAs to help advance the RDoC initiative. We plan to conduct web-based surveys to inquire about events we've hosted and get feedback about the future of RDoC. These information collections will help tailor our focus and more adequately target our audience.

There have been social media platforms and tools developed for the RDoC initiative, including a dedicated RDoC twitter account ((https://twitter.com/nimh_rdoc) and the RDoC website (https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml), which also houses the RDoC matrix. The NIMH data archive provides an infrastructure for sharing subject-level data from NIMH funded grants – including those that incorporate the RDoC approach – and serves as a resource for hypothesis testing and exploration. Additionally, NIMH has produced several educational and training resources (including webinars) to educate the field and interface with scientists who may have questions about RDoC (https://www.nimh.nih.gov/research-priorities/rdoc/rdoc-educational-and-training-resources.shtml). In addition to collecting information from stakeholders, NIMH and the RDoC Unit are interested in pursuing evaluation of these, and other RDoC initiatives, to improve the program's utility.

A.2. Purpose and Use of the Information Collection

The proposed information collection serves as an opportunity for NIMH to assess the strengths and weaknesses of the RDoC initiative. The information collected as part of this generic clearance will be used by the RDoC Unit, the RDoC workgroup, and ultimately, senior NIMH leadership in to determine success of the RDoC initiative, develop future directions and endeavors, and to help guide programmatic priorities for the RDoC initiative and the Institute. The focus will be two-fold; both on the web-presence of RDoC information, as well as on the scientific directions and needs

that the initiative should consider. For example, while NIMH has data on how many participants attend RDoC related webinars and how many clicks the RDoC webpages receive, stakeholder perceptions of them are unclear. It would be extremely helpful to collect stakeholder ideas on whether the content was useful, if they liked the format, and gather suggestions for future topics. A similar case can be made for the RDoC website and Twitter feed, which reach even larger audiences. Another example involves considering the scientific organization of the RDoC framework, and as new data are discovered and published it will be imperative to solict feedback and suggestions from the field about the impact this should have on the design and future iterations of the RDoC matrix. We anticipate utilizing various types of information collection methodologies to undertake market research and gather feedback on both the scientific principles and organization of the RDoC framework, as well as the outreach content (i.e., website, twitter, office hours, and webinars) we have undertaken to date. Methods will include surveys, evaluation forms, focus groups, interviews, workshops, and other related forms of data collection. Surveys and evaluation forms will be distributed by several means, including existing mailing lists, registered participants to our webinars, RDoC-relevant funded grantees, and other mechanisms for reaching the intended stakeholders. Workshops, focus groups, and interviews will be conducted both in person (e.g., at conferences) and through electronic means (e.g., video conference, email, or phone). Stakeholder feedback will likely need to be collected for at least three years.

In the past three years, NIMH has collected extremely useful information under this generic clearance. In 2018, NIMH received OMB approval for a survey (NIMH Research Domain Criteria (RDoC) Environment and Development Pre-Workshop Survey) that enabled NIMH to distribute a

post-event online survey to collect information from participants on whether they felt the meeting achieved its intended goal to further develop the RDoC research platform. The survey served as an opportunity for NIMH to assess the strengths and weaknesses of the RDoC Training Meeting. In 2019, NIMH received OMB approval for a survey (NIMH Research Domain Criteria (RDoC) Training Meeting Survey) that enabled the NIMH RDoC Unit to garner opinions and ideas from experts on potential topics to be discussed at the RDoC Environment and Development workshop. Feedback from the survey was crucial in developing the workshop agenda. These surveys can be found in Attachment 1 of the current application.

A.3. Use of Information Technology and Burden Reduction

To the extent possible, data collection will employ automated or electronic methods to reduce the burden on the respondent and federal government costs. These collections may utilize electronic platforms and/or tools with a signed *HHS Terms of Service Agreement*. When using electronic platforms and/or web-based technologies not exclusively operated or controlled by a government entity, NIMH will ensure compliance with the *NIH Social and New Media Policy*, and with OMB Memorandum M-10-23, *Guidance for Agency Use of Third Party Websites and Applications*. Online surveys represent an especially convenient option for eliciting feedback from stakeholders. With online surveys, respondents can easily submit feedback during or immediately after participating in an RDoC Unit sponsored web-based event. They also allow participation from international respondents with virtually no additional costs. Exceptions will include data collection methodologies which may not always lend themselves easily to electronic data capture, such as focus groups, workships, interviews, and surveys and evaluation forms.

All information collected will be stored on the NIMH Headquarters Network, which is covered by a Privacy Impact Assessment (PIA) that includes all NIMH hosted Web applications (see Attachments 3 and 4).

A.4 Efforts to Identify Duplication and Use of Similar Information

This data collection is unique in that no other agencies, organizations or entities seek stakeholder feedback for the RDoC initiative. Hence, there will not be any duplication of efforts.

A.5 Impact on Small Businesses or Other Small Entities

The impact on small businesses will be minimal, as participation in requests for feedback will be voluntary. The length of the data collection instruments will be minimal, and often, in electronic format.

A.6 Consequences of Collecting the Information Less Frequently

NIMH must have timely information to ensure it is reaching the appropriate audiences and providing them with necessary materials, information, and products. Information will be collected as required, in anticipation of or immediately following RDoC Unit sponsored events or activities (e.g., conference talks, webinars, etc.). These will be done to assess the need for, or response to, such activities and events in the targeted stakeholder demographic. Information will also be collected on regular features (e.g. RDoC website, RDoC twitter feed, RDoC matrix, etc.) to provide insight as to our presence in the stakeholder community. Additionally, it will be necessary to collect information as new data emerge.

Less frequent collections would decrease the efficacy of resources, tools, and interventions. Research has illustrated that formative input is crucial to the acceptance of materials and the

delivery of services. In addition, this would decrease the chance that federal efforts are spent on approaches that stakeholders are not responsive to or cannot benefit from.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances are anticipated. This project fully complies with the guidelines of 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

A Federal Register Notice for this new request was published on May 5, 2021, pages 23974–23975 (Vol. 86, No. 85). No public comments were received.

A.8.2 Efforts to Consult Outside Agency

We are not aware of any other agency that is collecting stakeholder feedback on the RDoC initiative. As such, we will not be consulting with any outside entities.

A.9 Explanation of Any Payment of Gift to Respondents

Respondents will not receive any payments or gifts for providing information.

A.10 Assurance of Confidentiality Provided to Respondents

Respondents participation is voluntary, and they retain the right to skip any question(s) they would prefer not to answer, and to quit the survey at any time. No personally identifiable information will be collected. We anticipate collecting basic demographic information from stakeholders that may help us develop and titrate program initiatives towards various groups in the field. Information collected will be private to the extent permitted by law, and will follow the Privacy Act guidelines as set out by the NIH Office of Management Assessment. As appropriate,

the Privacy Act applies to these information collections per the NIH Privacy Act System of Records Notice (SORN) #09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD," which covers evaluation of the policies, programs, organization, methods, materials, activities or services used by PHS in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2) support for training of research investigators; and (3) communication of biomedical information.

A.11 Justification for Sensitive Questions

NIMH does not anticipate asking any sensitive questions of respondents. However, as the RDoC initiative centers around mental health disorders, information related to medical history either in the context of research or clinical work may be collected (i.e., respondents may be asked to identify themselves as a researcher, clinician, patient or family member of a patient). Providing such medical information, however voluntary, may be considered sensitive. Whenever potentially sensitive information is solicited, NIMH will prominently post a Privacy Notice that is conspicuous, salient, clearly labeled, written in plain language and prominently displayed at all locations where sensitive information is requested. NIMH will ensure this information will be non-identifiable, and will work with the NIH Privacy Program to ensure that appropriate disclaimers and/or consents are incorporated.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

A variety of instruments and platforms will be used to collect information from respondents. The estimated annual burden hours are 490 total hours.

Table 12-1: Estimated Annualized Burden Hours

Instrument Type	Number of Respondents	Number of Responses per Respondent	Time Per Response (in hours)	Total Hours
Workshops	50	1	8	400
Interviews	10	1	30/60	5
Surveys	100	1	30/60	50
Focus Groups	10	1	1	10
Assessment Forms	100	1	15/60	25
Total	**270**	**270**		**490**

A.12-2 Annual Cost to Respondent

No costs are anticipated except for the respondents' time to participate in these activities. Estimates are based on projections of collections to be conducted on an annual basis.

Table 12-2: Annualized Cost to Respondents

Type of Respondents	Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
General Public	51	$27.07	$1,381
Researchers	333	$48.94	$16,297
Clinicians	107	$57.12	$6,112
Total	**490**		**$23,752**

Bureau of Labor Statistics:* ***May 2020 National Occupational Employment and Wage Estimates* *(https://www.bls.gov/oes/2020/may/oes_nat.htm)*

*General Public wage rate reflects the mean hourly wage for all occupations (Occupation Code: 00-0000).

*Researchers wage rate reflects the mean hourly wage for Medical Scientists, Except Epidemiologists (Occupation Code: 19-1042).

*Clinicians wage rate reflects the mean hourly wage for Medical and Health Services Managers (Occupation Code: 11-9111).

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs other than the respondents' burden given in section A12. We do not anticipate any other costs for record keepers in terms of equipment or specialized analysis software, as existing NIH and NIMH headquarters equipment and software will be utilized to examine the information collected.

A.14 Annualized Cost to the Federal Government

The total cost to the Federal Government is estimated to be $17,687.

The federal oversight costs were obtained via public records for a standard GS-15 ranked employee in the Washington DC metropolitan area. Contractor cost was obtained by averaging the salaries of contract employees who work in the RDoC Unit who would be conducting the data analysis. There are no other additional operational expenses or expenses which would not normally have been incurred. Most of the data analysis will be conducted electronically and will not require any printing or special equipment.

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health Scientist Administrator	GS-15/S 3	$ 153,737	5%		$7,687
Contractor Cost		$100,000	10%		$10,000
Travel					n/a
Other Cost					n/a
Total					**$17,687**

* https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf

A.15 Explanation for Program Changes or Adjustments

NIMH is requesting extension of approval to continue use of the collection activities described above, with no substantive changes or adjustments to the information collections.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Responses to all information collections will be analyzed internally to help the RDoC Unit tailor and customize new events, web-based information, and potential updates to funding announcements and programmatic direction. The responses may be used to provide insight and advice to NIMH Leadership or National Advisory Mental Health Council (NAMHC) workgroups, however any outward facing publications would not include these results.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be appropriately displayed on all information collection instruments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These exceptions do not apply to this request.