

Supporting Statement A for

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

Date: April 17, 2018

Check off which applies:

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

Federal Government Employee Information:

Name: Sarah Morris, Ph.D.

Address: 6001 Executive Blvd, Rockville MD 20852

Telephone: 301-443-9233

Email: sarah.morris@nih.gov

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Attachment 2 - HHS Privacy Impact Assessment (NIH NIMH Headquarters Network)

Attachment 3 - HHS Privacy Impact Assessment (NIH NIMH Internet and Intranet Websites)

Attachment 4 - Sample RDoC Survey Questions

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 develop 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. In 2012 NIMH issued a series of Funding Opportunity Announcements (FOAs) to encourage the field to start using dimensional approaches to psychopathological research (<https://www.nimh.nih.gov/research-priorities/rdoc/rdoc-funding-opportunities.shtml>) . The initial FOA called for new, innovative research proposals that would study mechanisms that may cut across multiple traditional diagnostic categories, based upon RDoC criteria laid out in the RDoC matrix. A second FOA called for applications which propose secondary analyses of existing clinical research datasets to investigate constructs identified in the RDoC initiative and to test novel hypotheses using the RDoC framework. And, most recently, NIMH published a FOA calling for applications which propose research studies that will use the RDoC framework to advance scientific understanding of neurobehavioral mechanisms related to psychotic symptoms (hallucinations, delusions, disorganized behavior, and thought disorder). The intent was to generate research projects that could help advance the RDoC framework, and further our understanding of the neurobiological basis of psychiatric disorders. A list of grants funded under RDoC FOAs is available on the NIH RePORTER website at https://projectreporter.nih.gov/reporter_searchresults.cfm?redir=sh&sl=13EECE0F4785C6D17598B8961CAA4A01A2FFCEB861BF&icde=27749806&hsid=18236788&shQID=0.

Since its inception, the RDoC initiative has progressed as 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, a working group that guide and advise on larger conceptual matters, as well as several National Advisory Mental Health Council (NAMHC) Workgroups. These groups work together to keep the ideals of the RDoC initiative moving forward, interfacing with the scientific community, and overall helping to move research into a more groundbreaking arena with the hopes of affecting change in identification, prevention and treatment of mental illness. 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, technology companies, and so on. However, there is no formal way to collect information from stakeholders about their perceptions of the RDoC framework, or whether its goals and aims are being communicated and disseminated accurately, and achieved. To date, many academic articles reveal several inaccuracies when reporting about the initiative, thus there is a critical need to monitor how RDoC is perceived by stakeholders, collect information from them, and modify communications and programmatic priorities, as necessary. Additionally, the first set of grants issued under the original RDoC Funding Opportunity Announcement are reaching their end dates. Data and advances from these studies will be coming out over the next year, and it will be crucial to gain further insight and information from the field as to how we may use these findings to help advance the RDoC initiative.

The RDoC Unit has developed several social media platforms and tools for the RDoC initiative, including a dedicated RDoC twitter account (https://twitter.com/nimh_rdoc), the RDoC forum (<https://rdocforum.nimh.nih.gov/portal/>), and the RDoC website

(<https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml>), which also houses the RDoC matrix. RDoCdb (<https://data-archive.nimh.nih.gov/rdocdb/>) provides an infrastructure for sharing subject-level data from NIMH funded grants, and serves as a resource for hypothesis testing and exploration. The NIMH encourages the use of these resources by stakeholders to achieve rapid scientific progress as sharing data, associated tools, and methodologies, rather than just summaries or interpretations of them, accelerates research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. Additionally, NIMH has produced several educational and training resources (to include webinars, monthly office hours and FAQs) as an attempt 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, which has not been formally done since its inception in 2008. The information to be 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. 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 (see Attachment 4 for sample survey questions). Survey instruments 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, while workshops, focus groups, and interviews will be conducted both in person (e.g., at conferences) or through electronic means (e.g., video conference, email, or via phone).

Since RDoC is still in its infancy, information will likely need to be collected for at least 3 years and until the perception of RDoC is more stabilized in the field.

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* (see Attachment 1). 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, workshops, 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 2 and 3).

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. 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 from RDoC grantees. For example, the first round of grants that were funded under the RDoC funding opportunity announcements will be finishing up their project periods within the next year. It will be very useful to solicit the opinions of the principal investigators of those grants to understand more about the impact and ease of using the RDoC framework as results from those studies are published.

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 January 29, 2018, Vol 83 FR 4062.

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. 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 (<https://oma.od.nih.gov/DMS/Pages/Privacy-Program.aspx>).

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. As appropriate, the Privacy Act applies to these information collections per the NIH Privacy Act System of Records Notice (SORN) #09-25-0156 (<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0156.htm>) 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.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	Average Burden Per Response (in hours)	Total Annual Burden Hours
Workshops	50	1	8	400
Interviews	10	1	30/60	5
Surveys	100	1	30/60	50
Focus Groups	10	1	1	10
Evaluation 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

Instrument Type	Type of Respondents	Annual Burden Hours	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Total Wage
Workshop	General Public	40	400	\$23.86	\$954.40
	Researchers	280		\$38.72	\$10,841.60
	Clinicians	80		\$52.58	\$4,206.40
Interviews	General Public	1	5	\$23.86	\$23.86
	Researchers	2.5		\$38.72	\$96.80
	Clinicians	1.5		\$52.58	\$78.87
Surveys	General Public	5	50	\$23.86	\$119.30
	Researchers	30		\$38.72	\$1,161.60
	Clinicians	15		\$52.58	\$788.70
Focus Groups	General Public	2	10	\$23.86	\$47.72
	Researchers	5		\$38.72	\$193.60
	Clinicians	3		\$52.58	\$157.74
Evaluation Forms	General Public	2.5	25	\$23.86	\$59.65
	Researchers	15		\$38.72	\$580.80
	Clinicians	7.5		\$52.58	\$394.35
Total		490	490		\$19,705.39

*Bureau of Labor Statistics: *May 2016 National Occupational Employment and Wage Estimates*
https://www.bls.gov/oes/2016/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 \$14,450.

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
i.e. Health Scientist Administrator and/or Program Officer	GS-15/3	\$141,000	5%		\$7,050
Contractor Cost		\$74,000	10%		\$7,400
i.e. Management Analyst and/or Scientific Program Manager					
Travel					n/a
Other Cost					n/a
Total					\$14,450

* <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf>

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.

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

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 NAMHC council 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.