Supporting Statement A for

National Institute of Mental Health (NIMH)
Recruitment Milestone Reporting (RMR) System

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Table of contents

A. JUSTIFICATION.....

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....

A.2. PURPOSE AND USE OF THE INFORMATION COLLECTION.....

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY.....

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS.....

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS.....

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.....

LIST OF ATTACHMENTS:

- Attachment 1: Screenshot of Recruitment Milestone Reporting (RMR) Database
- Attachment 2: NIMH RMR Privacy Impact Assessment

A.1 Circumstances Making the Collection of Information Necessary

The mission of NIMH is to transform the understanding and treatment of mental illness through basic and clinical research, paving the way for prevention, recovery, and cure. In order for NIMH clinical research to meet it is objectives (including sufficient power to test hypotheses and generalizability to the appropriate target population) it is critical that studies meet their recruitment goals. NIMH developed the Recruitment Milestone Reporting (RMR) System to ensure NIMH investigators develop realistic recruitment targets and that these targets are met throughout the course of the clinical research. The RMR system monitors the recruitment of participants in NIMH-sponsored clinical research studies that plan to enroll *150 or more human subjects* in a single study.

A.2 Purpose and Use of the Information Collection

Recruitment Milestone Reporting (RMR) System allows NIMH staff to monitor more effectively the recruitment of participants in NIMH-sponsored clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure recruitment goals are met within the expected timeframe. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research.

By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, potentially increasing efficiency in the funding process and expediting the availability of treatments for mental illness.

NIMH program staff will use the information collected by the Recruitment Milestone Reporting application to evaluate the feasibility of the recruitment targets and timeline, the appropriateness of the distribution of subjects to the research question, and the acceptability of actual recruitment progress. Staff in the Grants Management Branch or the Contracts Management Branch will ensure the information is included in official files and work with program staff to determine the terms and conditions of the award. Staff in the NIMH Office of the Director and its respective offices will use the information to identify studies or research areas in which recruitment is a potential concern, and monitor the effectiveness of Recruitment Milestone Reporting.

A.3 Use of Information Technology and Burden Reduction

All information is submitted via the internet and collected in the electronic Recruitment Milestone Reporting (RMR) software application. This method of collection is considered to be the least burden to the investigator. A Privacy Impact Assessment was completed for the database (Attachment 2).

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

NIMH staff examined NIH and NIMH data sources to determine if existing information was available. NIH investigators currently provide an overall recruitment target, along with a breakdown by sex/gender, race, and ethnicity, as part of the application/proposal for a grant, cooperative agreement, or contract. This information is provided using the

SF 424 or PHS 398 Targeted/Planned Enrollment Table. In addition, investigators report their actual recruitment, including the sex/gender, race, and ethnicity of subjects, in annual progress reports (PHS 2590).

NIMH staff determined that currently collected information is insufficient to meet recruitment monitoring needs, due to the lack of a stated timeline for recruitment and the infrequency of reporting. In order to identify recruitment challenges and recommend early corrective action, NIMH staff must know the proposed timeline for recruitment and receive frequent reports on progress towards recruitment milestones.

A.5 Impact on Small Businesses or Other Small Entities

Principal Investigators of NIMH studies planning to recruit 150 or more subjects will be required to submit recruitment milestones and tri-annual recruitment milestone progress reports. While most of these investigators are at universities and large research organizations, a small number of these investigators are at small businesses or other small entities. To minimize burden on investigators, including those at small businesses and other small entities, the information requested is the minimum required for the purpose of monitoring recruitment.

A.6 Consequences of Collecting the Information Less Frequently

Recruitment Milestone Reporting requires NIMH investigators to submit planned recruitment milestones prior to funding, as well as tri-annual reports of actual recruitment progress for the duration of recruitment. NIMH staff determined that tri-annual reporting is the minimum required to ensure effective recruitment monitoring. Less frequent reporting would delay identification of studies with recruitment challenges, thus potentially delaying technical assistance and corrective action. Delaying corrective

action could result in the inability of the study to meet its objectives within the expected timeframe, including lack of statistical power to answer the research question, and lack of generalizability of the results to the target population.

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

There are no special circumstances.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. Comments in Response to the Federal Register Notice

A Federal Register Notice was published on August 2, 2013, Vol 78 FR 46994 (https://www.federalregister.gov/articles/2013/08/02/2013-18600/proposed-collection-60-day-comment-request-national-institute-of-mental-health-recruitment-and). One public comment was received from Mr. Gerald S. Schatz, J.D., Affiliated Scholar, Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center.

“Under the law, 42 U.S.C. sec. 289, biomedical and behavioral research conducted or supported by Federal agencies is regulated "in order to protect the rights of human subjects of such research." The regulations, 45 C.F.R. part 46, in turn require the subject's informed consent, in circumstances conducive to voluntariness. In other words, agreement to become a research subject must be fully voluntary.

The Paperwork Reduction Act, under which approval is sought for this proposed information collection, prohibits collections that would have an agency violating the law. As drafted, this proposed information collection could have the apparently unintended but obviously predictable effect of encouraging investigators to pressure patients and others into becoming research subjects. Indeed, the stated purpose is to encourage more

enthusiastic recruitment effort. Such policy or practice contravenes the law and ethics of human subjects research.

This proposed information collection ought to be rescinded or revised in a way that makes clear that investigators must not pressure individuals into becoming research subjects."

The recruitment and enrollment procedures proposed by a NIMH-funded clinical trial are reviewed and approved by an IRB of record, which has agreed to review human subject research projects in accordance with 45 CFR Part 46 and its Federal-wide Assurance. The IRB of record ensures that the possibility of coercion or undue influence is minimized, that an investigator seeks consent only under circumstances that provide the prospective subject/ representative sufficient opportunity to consider whether or not to participate, and approves only oral and written informed consent that do not contain any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights (per 45 CFR Part 46.116).

NIMH has also developed "Points to Consider in Clinical Trial Recruitment and Retention" to assist principal investigators in adopting strategies that promote ethical recruitment and retention of trial participants. http://www.nimh.nih.gov/funding/grant-writing-and-application-process/recruitment-points-to-consider-6-1-05.pdf

To address these concerns, we changed the letter to PIs to include information regarding human subject protections to the RMR policy statement and human subjects training.

B. Efforts to Consult Outside Agency

The RMR was a policy change internal to NIMH; therefore, there was no consultation.

A.9 Explanation of Any Payment of Gift to Respondents

No payment or gifts will be made to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The legal authority to collect this information is granted under 42 U.S.C Sections 232, 281 and 285 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0036, (http://oma.od.nih.gov/public/ms/privacy/pafiles/0036.htm) covering "Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH." The NIH System of Record Notice was previously published in the Federal register on September 26, 2002, Volume 67, No 187, page 60742.

A.11 Justification for Sensitive Questions

No sensitive questions will be asked and no Personally Identifiable Information (PII) will be collected.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The program is using the OPM.gov site for basic Rates of Pay for Employees in Senior-Level and Scientific or Professional Positions to determine the average wage rate for this project. The Principal Investigators complete the RMR reporting form for their respective projects. Based on the above referenced pays scale we are using the average amount of $72 for the wage rate for this study. See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/SLST.pdf for more information.

A. Estimates Annual Burden Hours				
Form	**Number of Respondents**	**Frequency of Response**	**Average time per response (in hours)**	**Estimated Total Annual Burden Hour**

				Requested
NIMH Recruitment Milestone Reporting (RMR)	675	3	75/60	2,531
Total	675			2,531
B. Estimates of Total Annual Cost Burden				
Form	**Estimate Total Annual Burden Hours**	**Wage rate**	**Total Costs**	
NIMH RMR	2,531	$ 72	$182,232	

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 A12.

A.14 Annualized Cost to the Federal Government

Staff	Grade/Salary (Percent FTE or effort)	NIMH RMR Hourly Rate	RMR Operations Cost*
RMR Operations Staff			
RMR Administrator	GS-11 (20%)	$35.27	$14,630.72
RMR Support	GS- 9 (10%)	$29.15	$ 6063.20
RMR IT Project Manager	GS-13 (0.5%)	$73.13	$ 687.41
RMR IT Requirements Analyst	$ 87,307 (2%)	$46.44	$ 1746.14
RMR IT Developer	$ 163,240 (2%)	$86.83	$ 3264.80
RMR Technical Writer	$ 175,531 (1%)	$93.37	$ 1755.31
Total Annualized Cost			**$ 28,147.58**

A.15 Explanation for Program Changes or Adjustments

This is an existing collection in use without OMB control number.

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

There is no specific plan to publish the data collected from this form. These data are for internal monitoring purposes.

NIMH Recruitment Milestone Reporting Timeline	
Activity	**Time Schedule**
Program Officer requests submission of recruitment milestones as part of just-in-time requests of grant, cooperative agreement, or contract	2-3 months prior to award
Deadline for submission of recruitment milestones of grant, cooperative agreement, or contract	Prior to award date
Investigator submits tri-annual recruitment progress reports for the duration of recruitment cycle	April 1, August 1, and December 1
Tri-annual recruitment milestone reports provided to NIMH Director and NIMH Division Directors	Mid-April, mid-August, and mid-December

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

Not applicable.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.