



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Submission for OMB Review; 30-day Comment Request: National Institute of Mental Health (NIMH) Recruitment Milestone Reporting System**

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 1, 2015, page 31053, and allowed 60-days for public comment. Four (4) public comments were received. Comments include concerns about the clarity of the announcement, the utility of the information collected, and the frequency of tri-annual and monthly reporting. NIMH carefully considered all comments received and has changed the language in the supporting statement to confirm that reporting of recruitment milestones in the RMR applies to participants in all extramural NIMH-sponsored clinical trials, regardless of size, as well as other clinical research studies that plan to enroll *150 or more human subjects* in a single study. Investigators who fail to meet their milestones may be requested to submit interim monthly reports. NIMH has determined tri-annual reporting to be the minimum necessary to provide effective recruitment monitoring. When studies fall significantly behind their recruitment goals, monthly reporting is necessary in order to ensure the study can be

completed within the proposed budget and timeframe. Based on current study performance, NIMH expects less than 5% of respondents will require monthly reporting. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**DIRECT COMMENTS TO OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

**COMMENT DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335, or E-mail your request, including your address to: [nimhprapubliccomments@mail.nih.gov](mailto:nimhprapubliccomments@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

## PROPOSED COLLECTION

National Institute of Mental Health (NIMH) Recruitment Milestone Reporting System (OMB control number 0925-0697) – REVISION – National Institute of Mental Health (NIMH), National Institute of Health (NIH).

### Need and Use of Information Collection:

The Recruitment Milestone Reporting (RMR) System allows NIMH staff to monitor more effectively the recruitment of participants in all NIMH-sponsored clinical trials, regardless of size, and other 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. Investigators who fail to meet their milestones may be requested to submit interim monthly reports. The primary use of this information is to ensure that realistic recruitment milestones are established from the onset of a project, and that these milestones 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2295.

| Estimated Annualized Burden Hours                     |                              |                       |                                    |  |                           |
|---|------------------------------|-----------------------|------------------------------------|--|---------------------------|
| Form Name   | Type of Respondent           | Number of Respondents | Number of Responses per Respondent | Average burden per response (in hours) | Total Annual Burden Hours |
| Tri-yearly NIMH Recruitment Milestone Reporting (RMR) | NIMH Principal Investigators | 900                   | 3                                  | 45/60                                  | 2025                      |
| Monthly NIMH Recruitment Milestone Reporting (RMR)    | NIMH Principal Investigators | 40                    | 9                                  | 45/60                                  | 270                       |
| Total   |                              | 940                   | 3,060                              | 45/60                                  | 2295                      |

Dated: October 6, 2015.

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