

types to be managed, preserved, and shared, consider:

- Describing data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., exome sequences of 20 to 30 gene variants from an estimated 800 cases and fMRI data from ~100 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be).

- Providing a rationale for decisions about which scientific data are to be preserved and made available for sharing, taking into consideration scientific utility, validation of results, availability of suitable data repositories, privacy and confidentiality, cost, consistency with community practices, and data security.

- Identifying metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) which will be made accessible to facilitate interpretation of the scientific data.

- For scientific data derived from human participants or specimens, outlining plans for providing appropriate protections of privacy and confidentiality (i.e., through de-identification or other protective measures) that are consistent with applicable federal, tribal, state, and local laws, regulations, statutes, guidance, and institutional policies.

2. *Related Tools, Software and/or Code:* An indication of whether specialized tools are needed to access or manipulate shared data to support replication or reuse, and name(s) of the needed tool(s) and software. Consider specifying how needed tools can be accessed, (i.e., open source and freely available, generally available for a fee in the marketplace, or available only from the research team or some other source).

3. *Standards:* An indication of what standards, if any, will be applied to the scientific data and associated metadata to be collected, including data formats, data identifiers, definitions, unique identifiers, and other data documentation. While many scientific fields have developed and adopted common data standards, others have not. In such cases, the Plan may indicate that no appropriate data standards exist for the data to be collected, preserved, and shared. Provide the name of any data standards or metadata standards proposed for use, considering:

- Use of existing, widely adopted standards for scientific data and

associated metadata. Some examples include: Clinical Data Interchange Standards Consortium, Minimum Information About a Microarray Experiment, Minimum Information about a high-throughput SEQuencing Experiment, and the Office of the National Coordinator for Health Information Technology Interoperability Standards Advisory.

- Use of common data elements (CDEs) to facilitate broader and more effective use of scientific data and to advance research across studies. For assistance in identifying NIH-supported CDEs, the NIH has established a Common Data Element (CDE) Resource Portal.

4. *Data Preservation, Access, and Associated Timelines:* An indication of the timelines for data preservation and access, considering:

- Where scientific data will be archived to ensure long-term preservation (i.e., which repository(ies)). If scientific data will be archived in an existing data repository(ies), consider providing the name and URL web address of the repository(ies). If an existing data repository(ies) will not be used, consider indicating why not and how scientific data will be preserved and shared.

- How the scientific data will be findable and whether a persistent unique identifier or other standard indexing tools will be used, and any provisions for maintaining the security and integrity of the scientific data (e.g., encryption and backups).

- Whether additional considerations are needed to implement the Plan, (e.g., whether permission needs to be sought to use a specific data repository, and from whom).

- Whether scientific data generated from humans or human biospecimens will be available through unrestricted (made publicly available to anyone) or restricted access (made available only after the requestor has received approval to use the requested scientific data). If the scientific data will be shared through a restricted access mechanism, consider describing the general terms of access for the data.

- Anticipated timeframes for preserving scientific data, describing if different timelines will apply to different subsets of scientific data, and when the scientific data will be submitted to specified data repositories.

- When the scientific data will be made available to other users (e.g., researchers and the broader public). In general, scientific data should be made available as soon as practicable, independent of award period and publication schedule. If applicable,

consider indicating when scientific data will no longer be available to other users.

5. *Data Sharing Agreements, Licenses, and Other Use Limitations:* NIH encourages the broadest use of scientific data resulting from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. In describing proposed plans for managing data sharing agreements and other types of arrangements, consider indicating:

- A description of any restrictions imposed by existing agreements that would limit the ability to broadly share scientific data, as well as a summarizing what those limitations on sharing or reuse are.

- Whether the applicant anticipates entering into any agreements that could limit the ability to broadly share scientific data and describe those agreements.

- Any other considerations that may result in limitations on the ability to broadly share scientific data.

- How relevant limitations to sharing are consistent with community expectations, and how scientific data will be shared to the maximum extent possible while honoring these limitations.

6. *Oversight of Data Management:* An indication of the individual(s) who will be responsible for executing various components (e.g., data collection, data analysis, data submission) of the Plan over the course of the research project and the roles of the individual(s) in data management, and a description of the appropriate expertise for oversight.

Dated: October 30, 2019.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

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

### **Substance Abuse and Mental Health Services Administration**

#### **Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more

information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

*Comments are invited on:* (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: SAMHSA's Publications and Digital Products Website Registration Survey (OMB No. 0930-0313)—Reinstatement**

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval

for a reinstatement of SAMHSA's Publications and Digital Products website Registration Survey, formerly under the Registration for Behavioral Health website and Resources (OMB No. 0930-0313). SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from mental and substance use disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a website that includes more than 500 free publications from SAMHSA and its component Agencies. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product websites, SAMHSA has developed a voluntary

registration process for its publication website that allows customers to create accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. During the website registration process, SAMHSA will also ask customers to provide optional demographic information that helps SAMHSA to evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a web-based form for information collection to avoid duplication and unnecessary burden on customers who register for an account. Customer information is submitted electronically via web forms on the samhsa.gov domain. Customers can submit the web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process.

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Website Registration Survey .....	21,082	1	21,082	.033 (2 min.)	696

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, Maryland 20857, OR email a copy to [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received by January 7, 2020.

**Summer King,**  
*Statistician.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Docket ID: FEMA-2019-0022; OMB No. 1660-0134]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Preparedness Activity Registration and Feedback**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning FEMA's Individual and Community Preparedness Division's (ICPD) efforts to enable individuals, organizations, or other groups to register with FEMA and to take part in FEMA's preparedness mission by connecting with individuals, organizations, and communities with research and tools to build and sustain capabilities to prepare for any disaster or emergency.

**DATES:** Comments must be submitted on or before January 7, 2020.

**ADDRESSES:** To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at [www.regulations.gov](http://www.regulations.gov) under Docket ID FEMA-2019-0022. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472-3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:** Christi Collins, AICP, Branch Chief, Preparedness Behavior Change, Individual and Community Preparedness Division, National Preparedness Directorate, FEMA, DHS, 400 C Street SW, Washington, DC 20024, 202.615.9865.