Office of the Assistant Secretary for Preparedness and Response
Public Access to Federally Funded Research: Publications and Data

Preamble

The sharing and preservation of scientific data through public access to peer-reviewed publications and curated data sets advances science by promoting the scrutiny, validation, and creative reuse of research findings, which in turn promotes innovation and the commercial application of such findings, thereby enhancing U.S. economic development and competitiveness and maximizing the impact of research investments. In developing its Public Access Plan, the Office of the Assistant Secretary for Preparedness and Response (ASPR) has been mindful that coordination and communication with other Federal agencies and U.S. Department of Health and Human Services (HHS) operating divisions is essential to minimize burdens, prevent unnecessary duplication, conserve resources and funding, and facilitate increased access to the results of its investments in research and development.

1. Background & Purpose

The Office of the Assistant Secretary for Preparedness and Response (ASPR) leads the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. ASPR focuses on preparedness planning and response; building federal emergency medical operational capabilities; medical countermeasures research, advance development, and procurement; and administering grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. ASPR is in the process of establishing a science preparedness and response grant portfolio, and has the authority to support research and development programs relevant to its mission using grants, cooperative agreements, contracts, and other transactions.

On February 22, 2013, the White House Office of Science and Technology Policy (OSTP) released the memorandum entitled, "Increasing Access to the Results of Federally Funded Scientific Research." This memorandum requires federal agencies to make the results of federally funded scientific research available to and useful for the public, industry, and the scientific community. This document establishes a governing policy to enable public access to digitally formatted scientific data created with ASPR funds. ASPR intends, to the extent feasible and consistent with law; agency mission; resource constraints; U.S. national, homeland, and economic security; and the objectives specified in section 3 of the OSTP memorandum, to make available to the public all scientific publications and data arising from research and programs funded wholly or in part by ASPR.

The ASPR Public Access Plan will maximize access, by the general public and without charge, to scientific research results created with Federal funds while protecting confidentiality and personal privacy; recognizing proprietary interests, business confidential information, and intellectual property rights and avoiding significant negative impact on intellectual property rights, innovation, and U.S. competitiveness; and, as part of the evaluation of relevant Data Management Plans, taking into account the relative values of long-term preservation and access and the associated cost and administrative burden. The ASPR Public Access Plan will:

- Facilitate easy public search, analysis of, and access to peer-reviewed scholarly publications directly arising from research funded by ASPR via PubMed Central (PMC), as described in the *National Institute of Health Draft Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research* (NIH Plan) and no later than 12 months after publication.
- Ensure full public access, via PMC and the NIH's abstract and metadata service, PubMed, to such publications' metadata without charge, in a data format that ensures interoperability with current and future search technology and to the full text via publisher-supplied links to the publisher site and a link to the PMC version when available, as described in the NIH Plan.
- Ensure that attribution to authors, journals, and original publishers is maintained.
- Ensure effective access to and reliable preservation of ASPR-funded digital scientific data for research, development, and education, in formats consistent with Section 508 of the Rehabilitation Act of 1973.
- Increase the use of research results to enhance scientific discovery and medical countermeasure product development
- Ensure the use of archival methods that provide for long-term preservation and access to publications, research data, and metadata, in formats consistent with Section 508 of the Rehabilitation Act of 1973. The metadata for scientific data will include, at a minimum, the common core metadata schema in use by the Federal government, found at https://project-open-data.cio.gov/.
- Require all researchers receiving ASPR grants, cooperative agreements, contracts, other transactions, intramural funding, or funding via interagency agreements to develop data management plans describing how they will provide for the long-term preservation of, and access to, scientific data in digital format.
- Support training, education, and workforce development, related to scientific data management, analysis, storage, preservation, and stewardship.

Ensuring public access to ASPR-sponsored publications via PMC and to publication metadata via PubMed will leverage the capabilities of and public familiarity with these archives to increase awareness of ASPR-funded scientific research while fostering the archives' longstanding public-private partnership with peer-reviewed academic journals, as described more fully in the NIH Plan.

2. DEFINITIONS

- **Research Data:** Research data is defined in OMB Circular A-110 as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This 'recorded' material excludes physical objects (e.g., laboratory samples). Research data also do not include:

    (A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

- **Digital Scientific Data:** For the purpose of this plan and consistent with OMB Circular A-110,[1] digital scientific data is defined as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings including data sets used to support scholarly publications, but does not include laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens."

  For the purpose of this plan, the definition of digital scientific data does not include software. However, ASPR recognizes that in some cases, software and other tools such as interview protocols, measures, coding guides, or manuals may be necessary to interpret data. In such cases, the Data Management Plan will be expected to include a description of these tools.

  A published data set consists of at least one formal metadata document, the digital scientific data described by that metadata, and supplemental information provided to assist the data user. A published data set can be cited in the scientific literature and, following the practice used by most publishers of scholarly journals, has a persistent and unique identifier associated with it. A published data set is expected to persist over time, just like the scholarly articles that are based on the digital scientific data.

- **Data Sharing Plan:** A data sharing plan outlines whether and how data will be made available to others. It may include the expected timeline for when the data will be available, the format of the final dataset, the documentation and any analytic tools that will be provided, and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). A plan might also specify whether or not a data sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use). If data sharing is not possible, the plan would provide an explanation.

- **Data Management Plan:** Data management plans are more comprehensive than data sharing plans in that they include additional elements such as descriptions of the data to be produced in the proposed study, any standards to be used for collected data and metadata, mechanisms for providing access to and sharing of the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights), provisions for reuse and redistribution, and plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access

[1] http://www.whitehouse.gov/omb/circulars_a110

cannot be justified. (Source: OSTP memo "Increasing Access to the Results of Federally Funded Scientific Research" (February 22, 2013))

3. SCOPE

The ASPR Public Access Plan for Digital Scientific Data applies to any digital scientific data set or publication that arises from

- Any ASPR-sponsored research grant, cooperative agreement, contract or other transaction awarded on or after October 1, 2014.
- Any ASPR-sponsored intramural research project, whether funded directly or via interagency agreement.
- Any ASPR employee

The ASPR Public Access Plan will apply to all research funded by ASPR, except where such research is administered or performed by a partner agency with a comparable Public Access Plan, in which case ASPR will defer to the partner agency's policies on the management of scholarly publications and digital data sets.

Implementation will be prospective and will not apply to any publication or digital data set arising from an ASPR-sponsored grant, cooperative agreement, contract, other transaction, or intramural research project funded prior to publication of the final ASPR Public Access Plan.

Digital scientific data that are covered by this plan include:

- Field data
- Lab data
- Other data (e.g., quality control samples, sample ID data, and instrument calibration data)

Digital scientific, clinical, or institutional data that can be in scope at the discretion of the program or in an appropriate context:

- Models and model-related content, including parameters and outputs, including models of public health emergencies
- Data from secondary sources (typically referred to as secondary or outside data)
- De-identified Electronic Health Record (EHR) patient treatment records
- Non-proprietary records and data collected as part of the National Hospital Preparedness Program

Digital scientific data that are *not* in scope for this plan include:

- Personally identifiable data
- Proprietary trade data
- Data related to protecting critical infrastructure
- Other data whose release is limited by law, regulation, security requirements, or policy

Per OMB Circular A-110 the following are not research data and therefore not subject to this plan: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens. However,

investigators are encouraged to include relevant content from laboratory or field notebooks in their published data sets if that information provides documentation that would help future users successfully re-use the data. (That is, lab and field notebooks are not themselves scientific data, but may contain relevant metadata to be included in the published data set.)

4. REQUIREMENTS

Publications

ASPR will adapt the National Institutes of Health (NIH) Public Access Policy for eligible ASPR-funded research and require that ASPR-funded investigators submit an electronic version of final peer-reviewed journal manuscripts to the digital archive PubMed Central (PMC) upon acceptance for publication.

Manuscripts resulting from funded work must be submitted directly to the NIH Manuscript Submission System (NIHMS) http://www.nihms.nih.gov/. At the time of submission, the submitting author must specify the date the final manuscript will be publicly accessible through PMC. Authors may own the original copyrights to materials they write and should work with the prospective publisher as necessary before any rights are transferred to ensure that all conditions of the NIH Public Access Policy can be met. Authors should avoid signing any agreements with publishers that do not allow the author to comply with the NIH Public Access Policy.

Digital Data Sets

All ASPR-funded researchers will be required to make the data underlying the conclusions of peer-reviewed scientific research publications freely available in public repositories at the time of initial publication in machine readable formats. ASPR will ensure that data management plans include clear plans for sharing research data. ASPR will also ensure new awards to researchers or institutions are not made unless the researcher has successfully satisfied all terms of completed previous awards from ASPR, including making digital data produced in the course of previous ASPR-funded research freely available in compliance with the relevant data management plans for the previous awards.

This plan creates two specific requirements with respect to sharing digital data sets:

1. ASPR-supported researchers must publish digital scientific data sets resulting from research projects meeting the scope criteria above in a recognized scientific data repository capable of long-term preservation of the data and open access to the public within a proscribed time period of 30 months from the creation of the data set (if the data set has not been used in a peer-reviewed publication) or upon publication of a peer-reviewed publication based on the data set, whichever is sooner, unless this requirement has been waived in the approved data management plan. ASPR will recognize intellectual property rights as appropriate, consistent with regulations and program policies, including considerations for intellectual property based on the type of data subject to those policies (e.g., varied embargo dates, conditions for delaying data release). For the purpose of this plan, proprietary interests include receiving appropriate credit for

scientific work. If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

2. Affected investigators must submit to the ASPR program staff a conforming metadata document that references the ASPR funding source(s), describes the data set, and provides a URL for the location of the published data set; the metadata document is subject to review and approval by ASPR before the author's responsibilities will be considered to be satisfied. This metadata document will be publicly available on data.gov, and other appropriate sharing locations such as phe.gov. The metadata for scientific data will include, at a minimum, the common core metadata schema in use by the Federal government, found at https://project-open-data.cio.gov/

In all cases, ASPR will promote the deposition of data in publicly accessible databases. To the extent feasible and consistent with applicable law and policy; agency mission; resource constraints; U.S. national, homeland, and economic security; and the objectives listed below, digitally formatted scientific data resulting from unclassified research supported wholly or in part by Federal funding should be stored and publicly accessible to search, retrieve, and analyze. Where appropriate, authors are encouraged to use Federally-sponsored data repositories for publishing their digital scientific data sets and meeting their obligations under this plan. HHS is exploring the development of a research data commons, a federated system of research databases, along with other Departments and Agencies for storage, discoverability, and reuse of data with a particular focus on making the data underlying the conclusions of peer-reviewed scientific publications resulting from federally funded scientific research available for free. ASPR, for its part, will participate in any HHS-wide data commons. Although this plan does not require the publication of secondary source data, ASPR encourages such publication when those data are not generally available or are subject to undocumented change over time and the researcher is authorized to include those data in the published data set.

While investigators will be required to share data sets within the proscribed time periods of up to 30 months, depending on the status of derivative scientific publications (as described above), it should be noted that ASPR encourages that data be made available as soon as possible and for as long as possible. Considerations for planning a dataset sharing timetable can include: the timing of publication of primary results derived from the data set; whether or not data from longitudinal studies could be made available in increments during the study; whether or not data sharing is contingent upon other relevant policies (as specifically noted by the funding announcement, for example); and how data will be maintained after the period of financial support ends.

This plan creates two additional requirements specific to intramural research. First, published data sets authored by ASPR employees shall be accorded the same status as journal articles or internally published research articles authored by ASPR employees for compliance purposes. Second, recognizing that URLs change over time, internally published research articles authored by ASPR employees shall provide a persistent identifier, such as a digital object identifier (DOI), that allows the metadata document associated with a published data set to link to the original article(s) developed from the published data set.

Data Management Plans

All research that meets the Scope criteria above, conducted by ASPR employees or funded wholly or in part by ASPR, must have a reviewed and approved data management plan. Data management plans will require both intramural and extramural scientists seeking funding to describe how and where they will make their data available to the public and explicitly describe how they will make the data that underlies scientific publications available for discovery, retrieval, and analysis. Approval of the data management plan will be conferred in the relevant grant award, contract award, or final interagency agreement governing the work to be performed. Contract or Grant Proposals must include a supplementary document labeled "Data Management Plan". This supplement should describe how the proposal will conform to ASPR policy on the dissemination and sharing of research results and may include:

- The types of data, samples, metadata associated with physical collections, software, curriculum materials, and other materials to be produced in the course of the project
- The standards to be used for data and metadata format and content
- Policies for access and sharing including provisions for appropriate protection of privacy, confidentiality, security, intellectual property, or other rights or requirements
- Policies and provisions for re-use, re-distribution, and the production of derivatives; and
- Plans for archiving data, samples, and other research products, and for preservation of access to them

5. APPLICABILITY

The ASPR Public Access Plan will be applicable to all research funded by ASPR, regardless of the funding mechanism used (e.g., grant, cooperative agreement, contract, other transaction) under terms and conditions of award as well as all peer-reviewed publications authored or co-authored by ASPR employees.

6. LEGAL AUTHORITIES

The Secretary has delegated to ASPR the following authorities under the Public Health Service (PHS) Act that relate to research and dissemination of research information:

- Section 301, 42 U.S.C. § 241 - conduct and support of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment control, and prevention of physical and mental diseases and impairments of man, and collecting and making available though publications and other appropriate means, information as to, and the practical application of, such research and other activities.
- Section 307, 42 U.S.C. § 242l - participation with other countries in cooperative endeavors in biomedical research.
- Section 319F, 42 U.S.C. § 247d-6 - public health systems research and accelerated research and development of priority pathogens and countermeasures.
- Section 319F-2(c), 42 U.S.C. § 247d-6b(c) - procurement of security countermeasures.
- Section 319L, 42 U.S.C. § 247d-7e - advanced biomedical research and development of medical countermeasures.

- Section 1702, 42 U.S.C. § 300u-1 -research in health information and health promotion.

In addition, section 2811 of the PHS Act, 42 U.S.C. § 300hh-10, authorizes ASPR to oversee advanced research, development, and procurement of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products.

The following HHS and government-wide statutes, regulations and policies are also relevant to this plan:

- OMB Memorandum M-13-13 – Open Data Policy–Managing Information as an Asset
- Section 319C-2 of the PHS Act, 42 U.S.C. § 247d-3b – Hospital Preparedness Program
- Section 2812 of the PHS Act, 42 U.S.C. § 300hh-11 – National Disaster Medical System
- Section 465 of the Public Health Service Act, 42 U.S.C. § 286 – National Library of Medicine
- Section 103 of The America COMPETES Reauthorization Act of 2010 Pub. L. No. 111-358, 42 U.S.C. 6623 – Office of Science and Technology Policy to establish the interagency public access committee.
- 45 C.F.R. Part 74 and OMB Circular A-110 - administrative requirements for grants and cooperative agreements to institutions of higher education, hospitals, other nonprofit organizations, and other commercial organizations
- 45 C.F.R. Part 92 – administrative requirements for grants and cooperative agreements to state, local, and tribal governments.
- 42 C.F.R. Part 52 – grants for research projects
- Federal Acquisition Regulations and HHS Acquisition Regulations

7. ROLES AND RESPONSIBILITIES

Assistant Secretary for Preparedness and Response

- Establishes, manages, implements, and evaluates the ASPR public access policy, i.e., public access to scholarly publications and data in digital format funded by ASPR.

Biomedical Advanced Research and Development Authority (BARDA)

- Manages the implementation of this plan as it applies to BARDA grants, cooperative agreements, contracts, interagency agreements, and other transactions.
- Coordinates with ASPR's Office of Acquisition Management, Contracts, and Grants (AMCG) to ensure the requirements of this plan are included as terms and conditions of funding for grants, contracts, and cooperative agreements established after June 1, 2014.
- In collaboration with the Office of Acquisitions Management, Contracts, and Grants and the Office of Policy and Planning, develops practical strategies to ensure the successful implementation of this plan.
- Monitors compliance of BARDA research funding recipients with this plan.

Office of Acquisitions Management, Contracts, and Grants (AMCG):

- Ensures that funding opportunity announcements and solicitations include appropriate language and requirements to assure submission of comprehensive publication and data sharing and management plans as outlined in this plan.
- Ensures the integrity of the technical evaluation and/or peer review process by ensuring that data management plans receive objective review.
- Ensures appropriate language is included in all awards.
- Monitors awardees' performance to ensure they are in compliance with all terms and conditions of award.

Office of Emergency Management[2]

- Ensures that all information related to the National Disaster Medical System (NDMS) Electronic Health Records (EMR/EHR) adhere to the provisions noted for information sharing and routine use in the NDMS System of Record Notice (SORN).
- Maintains Electronic Health Records (EHR)) in accordance with Health Information Technology for Economic and Clinical Health (HITECH) Act
- Oversees data collection related to healthcare system preparedness through the National Hospital Preparedness Program (NHPP)

Office of Policy and Planning

- Evaluates the effectiveness and potential impact of the plan after it has been in place for 18 months (see implementation section below, requiring an iterative process of plan impact, evaluation, and redesign).
- Convenes all stakeholders in the event that the plan requires further refinement, alterations, redesign, etc., based on the results of the 18-month evaluation.
- Ensures that the Public Access Plan is aligned with other ASPR policies and strategies for maximum effectiveness.
- Coordinates collaboration and cooperation with other federal agencies of public access and data sharing

Grant, Cooperative Agreement, and Contract Awardees

- Ensure that authors are aware of and comply with the ASPR Public Access Plan.
- Ensure all terms and conditions of awards are met.

[2] The Office of Emergency Management oversees two programs, the National Disaster Medical System (NDMS) and the National Hospital Preparedness Program (NHPP), that routinely collect patient care, hospital, and other data that may be of interest to emergency preparedness researchers but that are not research data per se and to which access is limited due to privacy concerns and other considerations. Currently, no mechanism exists to integrate and leverage these disparate data sources for analytical purposes or modeling efforts. In the long-term, ASPR aspires to maximize the data derived from a wide variety of sources (e.g., de-identified patient care data, grant applications, technical assistance, end of year reports, performance measures, exercises, and after action reports) that can be released to qualified researchers and scientists to help evaluate and improve NDMS and NHPP. NHPP program staff intend to develop an IT system with meta-data set descriptors and text mining capabilities which will be designed to enhance the creative analysis of accumulated NHPP data and discovery of relevant new patterns with speed and flexibility. An OEM Data Use Agreement (DUA) is under development that will facilitate:

- sharing data that has been collected from or is related to NHPP
- releasing NHPP data to external parties for research purposes
- responding to requests under the Freedom of Information Act and GAO

- Submit data management plan with grant, cooperative agreement and contract applications.
- Include reasonable cost projections for public access to publications and data in digital format as a component of grant, cooperative agreements, and contract applications.

Authors

- Work with the publisher before any publication rights are transferred to ensure that all conditions of the ASPR Public Access Plan can be met.

8. IMPLEMENTATION

This Public Access Plan includes the following implementation steps.

Planning

The ASPR Public Access Plan development process will:

- Establish an iterative process of policy design, planning, implementation, evaluation/impact assessment, and policy redesign.
- Work in full and open consultation with all stakeholders, including federally funded researchers and universities, libraries, publishers, users of Federally-funded research results, civil society groups, and other federal organizing bodies, to develop, maintain, and improve the Public Access Plan.
- Explore new approaches and partnerships with publishers and other stakeholders to obtain final peer-reviewed manuscripts or published articles.
- Maintain attribution to authors, journals, and original publishers.
- Establish a mechanism for monitoring compliance with the plan.
- Ensure the public can search, read, and download the final peer-reviewed manuscripts or published articles without charge no later than 12 months following publication.

ASPR will post the draft Public Access Plan in the *Federal Register* and solicit public comment. After reviewing and adjudicating any comments received, ASPR will post the final ASPR Public Access Plan on the ASPR website and in the Federal Register. ASPR will partner with the NIH to use PMC as the repository of publications resulting from ASPR-funded grants, contracts, cooperative agreements, other transactions, and intramural research.

Submission of Manuscripts/Publications

ASPR-supported investigators will be required to submit an electronic version of their final, peer-reviewed manuscripts to PMC upon the acceptance of such manuscripts for publication, with the understanding that these manuscripts (or the final scholarly publication, if available) will be made publicly available no later than 12 months after the official date of publication

PubMed Central provides public access to final peer-reviewed manuscripts or final published articles and includes the following functionalities:

- Allows users to submit and manage manuscripts directly

- Allows submission by the author, the publisher, or the manager of the funding agreement
- Accepts manuscripts in a range of common electronic formats
- Accepts any additional files of figures, tables, or supplementary information included with the manuscript
- Provides flexible and multiple approaches to manuscript submission
- Provides a common XML format in which publishers and archives can exchange journal content by preserving the intellectual content of journals independent of the form in which that content was originally delivered
- Via eRA Commons, provides interoperability and integration with Federal grants management systems used by NIH, other HHS operating divisions, and several U.S. Government agencies.

ASPR-supported investigators will be required to report the submission of materials subject to the ASPR Public Access Policy in periodic updates to program managers.

Management

ASPR will maximize access, by the general public and without charge, to digitally formatted scientific data created with Federal funds by designing, implementing and maintaining a sustainable network of data management capabilities to enable discovery, appropriate use, and long term management of digitally formatted scientific data. This includes but is not limited to:

- Establishment of a standard set of attributes for metadata to enable discovery and identification
- Development of policies to ensure the appropriate cataloguing of data sets resulting from ASPR-funded research to make them findable, accessible, and citable
- Development of approaches for identifying and providing appropriate attribution to scientific data sets that are made available under the plan
- Development of procedures to ensure data integrity over time

ASPR will provide guidance to awardees and training, education, and workforce development for its employees about the new requirements related to scientific data management, analysis, storage, preservation, and stewardship in advance of the implementation date. This guidance and training will describe any required changes to the conditions of awards and a publicly available timeline for the implementation of the plan. ASPR will also use public web sites and internal mechanisms to disseminate information and solicit feedback before and after the implementation date. The capability for ASPR and the science communities it supports to help one another through on-going dialogue is expected to be a key part of a successful plan implementation.

ASPR will modify existing policies or create new policies as necessary to establish the expectation that data management plans will be developed by all researchers whether they are funded by a grant, cooperative agreement, contract, other transaction, or intramural funds. ASPR will include requirements to comply with the ASPR Public Access Plan in contract solicitations and grant Funding Opportunity Announcements. In order to ensure public access to data in digital format resulting from ASPR-funded grants, contracts, cooperative agreements, and other transactions, ASPR will require all research applicants to include a data management and sharing

plan as a component of their grant applications or contract proposals. Intramural researchers will also be required to submit a data management plan, where applicable.

ASPR will allow the inclusion of appropriate costs for data management and access in applications and proposals for ASPR funding. The appropriateness of requested funding levels for data management plans will be assessed on a case-by-case basis through technical evaluation, and by program and grants management staff. Comparable assessments will need to be explored for intramural researchers. ASPR will confer with interagency partners to estimate the costs of current data management activities in order to determine how to support future data management.

Submitted data management plans will be expected to include descriptions of the data to be produced in the proposed study, any community-based standards to be used for collected data and metadata, mechanisms for providing access to and sharing of the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights), provisions for reuse and redistribution, and plans for archiving and long-term preservation and access to the data, with an estimate of the associated costs, or explanation of why data sharing is not possible.

The data management plan will undergo objective review and approval by ASPR grant and cooperative agreement peer review groups and contract proposal technical evaluation panels. The data management plan will become part of the terms and conditions of award for all appropriate research grants and cooperative agreements and a requirement of appropriate contracts and other transactions. ASPR will require periodic reporting on compliance with the approved data management plans as part of the terms and conditions of award and will develop mechanisms to monitor such compliance.

ASPR encourages grantees and contractors to register all clinical trials with ClinicalTrials.gov (whether or not they are subject to Title VIII of Food and Drug Administration Amendments Act (FDAAA)) and is in the process of developing a policy for intramural researchers to extend the registration requirement to all clinical trials. ASPR will give further consideration to taking steps to expand submission of results to encompass all ASPR-funded clinical trials, not only those subject to FDAAA.

Access and Discoverability

PubMed Central will ensure easy search, analysis and download of peer-reviewed scholarly publications arising from research funded by ASPR without charge no later than 12 months following publication. PubMed Central also provides long term stewardship of the published results of federally funded research, as described in the NIH Plan. The ASPR Public Access Plan will allow for the embargo of published work for up to 12 months and digital scientific data sets for up to 30 months.[3] Data that is not approved for public release shall not be included under this plan. HHS is developing a common approach to the issue of alternative embargo periods and ASPR will comply with the departmental policy in this regard.

[3] The ASPR Public Access Plan allows an embargo period for data sets that derive from federally funded research of up to 30 months depending on the status of derivative scientific publications, as described on page 5.

ASPR's responsibilities to ensure public access include:

- Working with NIH to ensure that publications are reliably available through the Internet.
- Conforming with PMC policies governing bulk downloads for research and restrictions on unauthorized bulk downloads, as described in the NIH Plan.
- Managing exposure to third party services
- Ensuring the system is accessible to people with disabilities and compliant with Section 508a of the Rehabilitation Act (29 USC 794d). ASPR will provide an accommodation for final publisher PDF versions that are not 508 compliant but cannot be remediated due to copyright constraints.

Preservation

ASPR will ensure the permanent preservation and long term accessibility of peer-reviewed scholarly publications and data in digital format by:

- Adopting sound, non-proprietary preservation standards and archival formats for publications and associated content, as described in the NIH Plan.
- Developing practical backup, migration, and technology refreshing strategies.
- Partnering with PMC, PubMed, and other appropriate scholarly data and metadata archives across the federal, academic, non-profit, and business communities.
- Ensuring data and metadata are securely stored and safeguarded.

9. METRICS, COMPLIANCE, AND EVALUATION

All ASPR-funded researchers will be required to make the data underlying the conclusions of peer-reviewed scientific research publications freely available in public repositories at the time of initial publication in machine readable formats. ASPR will ensure that data management plans include clear plans for sharing research data. ASPR will also ensure new awards to researchers or institutions are not made unless the researcher has successfully satisfied all terms making digital data produced in the course previous ASPR-funded research freely available in compliance with the relevant data management plans

ASPR will ensure compliance with and evaluate the success of its Public Access Plan by:

- Utilizing HHS-wide metrics of compliance with ASPR's Public Access Plan and disseminating compliance information to ASPR grant, cooperative agreement, and contract program officials by July 1, 2015
- Establishing meaningful compliance terms and conditions in contracts, grants, cooperative agreements, and other transaction awards deriving from Funding Opportunity Announcements (including Broad Agency Announcements) and Requests for Proposals issued after October 1, 2015
- Establishing meaningful compliance terms and conditions for interagency agreements involving funding of intramural research established after October 1, 2015, where such research is not already governed by an OSTP-approved Public Access Plan
- Utilizing data from PubMed Central, other reference sources, and grant, cooperative agreement, and contract reports to determine compliance for all research subject to the ASPR Public Access Plan that is funded after October 1, 2015

- Requiring submission of a metadata summary of data sets for compliance approval by ASPR program staff, which is subsequently catalogued and shared once approved
- Requiring extramural investigators to report the PubMed Central Identification Number (PMCID) or equivalent tag to their project or grant officers for any publication associated with their grant, cooperative agreement, contract, or other transaction
- Manually checking applications, proposals, and reports for compliance with the Public Access Plan (ASPR will explore mechanisms for automating this process) and delaying processing for all non-competing continuation awards with a start date of October 1, 2016, and beyond that are not compliant
- Utilizing ASPR intramural research databases to assess and monitor compliance by intramural researchers Measuring and reporting compliance publicly on an annual basis

10. PUBLIC NOTIFICATION

ASPR will invite public comment by posting the Public Access Plan in the *Federal Register*. ASPR will post the final ASPR Public Access Plan on the ASPR website and in the *Federal Register*.

11. INTERAGENCY COORDINATION

To ensure consistency as well as reduce development costs ASPR will work with NIH to utilize the NIH Manuscript Submission (NIHMS) system and PubMed Central infrastructure. This will alleviate the need for ASPR to develop its own submission system. Utilizing NIHMS also ensures that ASPR awardees will use the same submission system as NIH grantees.

ASPR interagency coordination will also include:

- Full participation on the HHS interagency public access work group.
- Full participation on the government-wide public access publications and data work groups facilitated by OSTP.
- Coordinating with NIH in the use of PubMed Central and adherence to all established PubMed Central requirements.

12. PUBLIC NOTICE

ASPR will post for public comment a Notice of Intent to Publish a Public Access Plan. ASPR will post the Public Access Plan in the *Federal Register* and solicit public comment. ASPR will post the final Public Access Plan on the ASPR website.

13. UPDATE AND RE-EVALUATION OF THE PLAN

ASPR will conduct periodic updates on the final published Public Access Plan, which will be informed by feedback from all stakeholders. Feedback will be sought periodically through Requests for Information published in the *Federal Register*, and re-evaluation will include analysis of metrics developed for the Plan. ASPR will develop criteria for and conduct periodic

reviews to identify gaps in preservation coverage and respond to changing needs arising from new data types. In order to determine how best to develop and sustain repositories for digital scientific data, ASPR intends to collaborate with HHS operating divisions and other agencies that support research in related areas.

14. TIMELINE FOR IMPLEMENTATION

This is a prospective plan and applies to contracts, grants, cooperative agreements, interagency agreement and other transactions awarded after completion and posting of the plan.

ASPR will establish an interagency agreement with NIH establishing PMC as the depository for peer-reviewed scholarly publications arising from ASPR-funded research in the first half of FY2015 and begin communicating and socializing requirements of the ASPR Public Access Plan to ASPR stakeholders. To this end, the ASPR Public Access Plan will be posted in the *Federal Register* and on the ASPR website (PHE.gov) upon its approval by OSTP. A point of contact within ASPR will be identified to respond to questions, comments, or suggestions.
ASPR will include terms and conditions in contracts, grants, cooperative agreements, and other transaction awards deriving from Funding Opportunity Announcements (including Broad Agency Announcements) and Requests for Proposals issued after October 1, 2015. It is anticipated that model language for use with generic data templates will also be developed and incorporated into any ASPR-sponsored grant, cooperative agreement, contract, other transaction, or intramural funding deriving from Funding Opportunity Announcements or Requests for Proposals issued after October 1, 2015.

It is conceivable that a cost-benefit analysis may determine that given current fiscal or other constraints, ASPR must delay the implementation of some aspects of this plan. ASPR will revisit the status of implementation of this overall policy within 18 months of the start date, as per Section 7.

Timeline

Establish an interagency agreement with NIH establishing PMC as the depository for peer-reviewed scholarly publications	End of Q2 FY2015
Begin communicating and socializing requirements of the ASPR Public Access Plan to ASPR stakeholders	Q2 FY2015
Post ASPR Public Access Plan in the *Federal Register* and on the ASPR website (PHE.gov) and identify point of contact within ASPR to respond to questions, comments, or suggestions	Q2 FY2015
Include model language for use with generic data templates will also be developed and incorporated into any ASPR-sponsored grant, cooperative agreement, contract, other transaction, or intramural funding deriving from Funding Opportunity Announcements or Requests for Proposals	Q1 FY2016
Include terms and conditions in contracts, grants, cooperative agreements, and other transaction awards deriving from	FY2016

Funding Opportunity Announcements (including Broad Agency Announcements) and Requests for Proposals	
Review the status of implementation of ASPR Public Access Plan	Q3 FY2017
Measure and report compliance publicly	Annually

15. RESOURCES

ASPR will leverage existing Departmental capabilities and will identify resources to implement its Public Access Plan within its current operating budget.

16. ADDITIONAL MATERIAL

Additional public access policies and guidance include:

- Memorandum for the Heads of Executive Departments and Agencies – Open Government Directive, Executive Office of the President, Office of Management and Budget, December 8, 2009: http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-06.pdf
- National Digital Information Infrastructure & Preservation Program: A Collaborative Initiative of the Library of Congress: http://www.digitalpreservation.gov/
- NIH Public Access: http://publicaccess.nih.gov/
- Open Government Directive, Memorandum for the Heads of Executive Departments and Agencies, M-10-06 (Dec 8, 2009): http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf
- Planets – Preservation and Long-Term Access through Networked Services. Open Planets Foundation: http://www.planets-project.eu/
- Interagency Public Access Coordination: A report to Congress on the coordination of policies related to the dissemination and long-term stewardship of the results of federal funded scientific research (March 2012): http://www.whitehouse.gov/sites/default/files/microsites/ostp/public_access-final.pdf
- Harnessing the Power of Digital Data for Science and Society (January 2009): http://www.nitrd.gov/About/Harnessing_Power_Web.pdf
- Scholarly Publishing Roundtable, Report and Recommendations from the Scholarly Publishing Roundtable (2009): http://www.aau.edu/policy/scholarly_publishing_roundtable.aspx?id=6894