www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm. The link will become active shortly before the open session begins at 9 a.m.

Interested persons can also log on to *https://collaboration.fda.gov/rcac/* to see and hear the proceedings.

Agenda: On November 3 and 4, 2014, the Risk Communication Advisory Committee will discuss methods for effective risk communication with a focus on messages about the importance of eating adequate amounts of fish, while avoiding certain fish with higher amounts of methyl-mercury. These messages are especially important for women who are pregnant or nursing, or for anyone who prepares food for young children.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 20, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 3 and 4, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 10, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 14, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Luis G. Bravo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20481 Filed 8–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting

SUMMARY: In accordance with the National Environmental Policy Act, 42 U.S.C. 4321–4347, the National Institutes of Health (NIH) is issuing this notice to advise the public that an environmental impact statement will be prepared for the Assure/Expand Chilled Water Capacity project located on the National Institutes of Health, Bethesda Campus, Bethesda, Maryland.

DATES: The Scoping Meeting is planned for 6:00 p.m., formal presentation to begin at 7:00 p.m., on Wednesday September 24, 2014. Scoping comments must be postmarked no later than October 18, 2014 to ensure they are considered.

ADDRESSES: The Scoping Meeting will be held on The National Institutes of Health Bethesda Campus, Building 50, Room 1227/1233, Bethesda, Maryland. All comments and questions on the Scoping Meeting and Environmental Impact Statement should be directed to Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email <*nihnepa@mail.nih.gov*>.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email <*nihnepa@mail.nih.gov*>.

SUPPLEMENTARY INFORMATION: The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In order to fulfill and uphold this mission the infrastructure of the NIH Bethesda Campus must be able to support the NIH's biomedical research programs.

Chilled water is a critical utility for the Bethesda Campus. The campus chilled water demand has exceeded the design capacity several times during the previous years. Expansion of the chilled water capacity is necessary.

The NIH has also become increasingly concerned about the vulnerability of the local water utility system, and the risk of reliably delivering water to the NIH Bethesda Campus infrastructure. A reliable water supply is vital to the NIH mission. The NIH proposes to address these concerns by construction of water storage structures to expand the Bethesda Campus chilled water capacity and to assure the availability of chilled water and potable water during a water emergency. In addition, NIH desires to improve sustainability, energy conservation, and to reduce the operating cost on the campus.

In accordance with 40 CFR 1500–1508 and DHHS environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed project. The EIS will evaluate the impacts of the alternatives should development occur as proposed. Among the items the EIS will examine are the implications of the project on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services. To ensure that the public is afforded the greatest opportunity to participate in the planning and environmental review process, NIH is inviting oral and written comments on the proposed project and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas, including recommended alternatives and environmental issues the EIS should consider. All interested parties

are encouraged to attend. NIH has established a 45-day public comment period for the scoping process.

Dated: August 21, 2014.

Daniel G. Wheeland,

Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. 2014–20489 Filed 8–27–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final NIH Genomic Data Sharing Policy

SUMMARY: The National Institutes of Health (NIH) announces the final Genomic Data Sharing (GDS) Policy that promotes sharing, for research purposes, of large-scale human and non-human genomic [1] data generated from NIH-funded research. A summary of public comments on the draft GDS Policy and the NIH responses are also provided.

FOR FURTHER INFORMATION CONTACT: Genomic Data Sharing Policy Team, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892; 301–496–9838; *GDS@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

The NIH announces the final Genomic Data Sharing (GDS) Policy, which sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. The NIH has longstanding policies to make a broad range of research data, in addition to genomic data, publicly available in a timely manner from the research activities that it funds.[2] [3] [4] [5] [6]

The NIH published the *Draft NIH Genomic Data Sharing Policy Request for Public Comments* in the **Federal Register** on September 20, 2013,[7] and in the *NIH Guide for Grants and Contracts* on September 27, 2013,[8] for a 60-day public comment period that ended November 20, 2013. The NIH also used Web sites, listservs, and social media to disseminate the request for comments. On November 6, 2013, during the comment period, the NIH held a public webinar on the draft GDS Policy that was attended by nearly 200 people and included a question and answer session.[9]

The NIH received a total of 107 public comments on the draft GDS Policy. Comments were submitted by individuals, organizations, and entities affiliated with academic institutions, professional and scientific societies, disease and patient advocacy groups, research organizations, industry and commercial organizations, tribal organizations, state public health agencies, and private clinical practices. The public comments have been posted on the NIH GDS Web site.[10] Comments were supportive of the principles of sharing data to advance research. However, there were a number of questions and concerns and calls for clarification about specific aspects of the draft Policy. A summary of comments, organized by corresponding sections of the GDS Policy, is provided below.

Scope and Applicability

Several commenters stated that the draft Policy was unclear with regard to the types of research to which the Policy would apply. Some commenters suggested that the technology used in a research study (i.e., array-based or high-throughput genomic technologies) should not be the focus in determining applicability of the Policy. They suggested instead that the information gained from the research should determine the applicability of the Policy. Many other commenters expressed the concern that the Policy was overly broad and would lead to the submission of large quantities of data with low utility for other investigators. Several other commenters suggested that the scope of the Policy was not broad enough. Additionally, some commenters were uncertain about whether the Policy would apply to research funded by multiple sources.

The NIH has revised the Scope and Applicability section to help clarify the types of research to which the Policy is intended to apply, and the reference to specific technologies has been dropped. The list of examples of the types of research projects that are within the Policy's scope, which appeared in Appendix A of the draft GDS Policy (now referred to as ''Supplemental Information to the NIH Genomic Data Sharing Policy'' [11]), has been revised and expanded, and examples of research that are not within the scope have been added as well. Also, the final GDS Policy now explicitly states that smaller studies (e.g., sequencing the genomes of fewer than 100 human research participants) are generally not subject to this Policy. Smaller studies, however, may be subject to other NIH data sharing policies (e.g., the National Institute of Allergy and Infectious Diseases Data Sharing and Release Guidelines [12]) or program requirements. In addition, definitions of key terms used in the Policy (e.g., aggregate data) have been included and other terms have been clarified.

The statement of scope remains intentionally general enough to accommodate the evolving nature of genomic technologies and the broad range of research that generates genomic data. It also allows for the possibility that individual NIH Institutes or Centers (IC) may choose on a case-by-case basis to apply the Policy to projects generating data on a smaller scale depending on the state of the science, the needs of the research community, and the programmatic priorities of the IC. The Policy applies to research funded in part or in total by the NIH if the NIH funding supports the generation of the genomic data. Investigators with questions about whether the Policy applies to their current or proposed research should consult the relevant Program Official or Program Officer or the IC's Genomic Program Administrator (GPA). Names and contact information for GPAs are available through the NIH GDS Web site.[13]

Some commenters expressed concern about the financial burden on investigators and institutions of validating and sharing large volumes of genomic data and the possibility that resources spent to support data sharing would redirect funds away from research. While the resources needed to support data sharing are not trivial, the NIH maintains that the investments are warranted by the significant discoveries made possible through the secondary use of the data. In addition, the NIH is taking steps to evaluate and monitor the impact of data sharing costs on the conduct of research, both programmatically through the Big Data to Knowledge Initiative [14] and organizationally through the creation of the Scientific Data Council, which will advise the agency on issues related to data science.[15]

Data Sharing Plans

Some commenters pointed out that the Policy was not clear enough about the conditions under which the NIH would grant an exception to the submission of genomic data to the NIH. Some also suggested that the NIH should allow limited sharing of human genomic data when the original consent or national, tribal, or state laws do not permit broad sharing.

While the NIH encourages investigators to seek consent for broad