

agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form.

This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

Need and Proposed Use of the Information: The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491(a) of the Public Health Service Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulations, IRBs in the United

States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Burden Statement: The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990-0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

ESTIMATED ANNUALIZED BURDEN TABLE

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|----------------------------------|-----------------------|------------------------------------|--|--------------------|
| IRB Registration 0990-0279 | 5,900 | 2 | 1 | 11,800 |
| New Registration | 500 | 2 | 1 | 1,000 |
| Total | | | | 12,800 |

Darius Taylor,
Information Collection Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Bethesda Campus Chilled Water System Improvements Record of Decision

SUMMARY: The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS, to implement the Proposed Action, referred to as the Proposed Action in the Final EIS. This action is to install a Thermal Energy Storage System and an Industrial Water Storage System to provide sufficient storage capacity to meet two days of chilled water demand and two days of industrial water demand should an outside disturbance interrupt the water supply.

FOR FURTHER INFORMATION CONTACT:
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nihnepa@mail.nih.gov. Responsible Official: Daniel G. Wheeland, Director, Office of Research Facilities (ORF) Development and Operations, NIH.

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the Chilled Water System Improvements, National Institutes of Health, and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

Selected Alternative

The Selected Alternative would implement chilled water system improvements that would enable the NIH to adequately accomplish the project goals. This would include sufficient storage capacity to meet two days of chilled water demand and two days of industrial water demand should an outside disturbance interrupt the normal supply of water by the WSSC.

Elements of the Chilled Water System Improvements project that the NIH would implement under the Proposed Action include the following:

Thermal Energy Storage System

This system would be located at the Building 34 site and would store up to

approximately nine million gallons of chilled water. Components of the system would include a storage tank, at or partially below-grade, with a footprint of approximately 12,000 SF; a pump house building with a footprint of approximately 5,000 SF or less; support equipment, such as pumps, valves, piping, controls, and an emergency generator; and security fencing, lighting, and other site improvements. The NIH would use this system to meet chilled water demands within the Campus.

Industrial Water Storage System

This system would be located at the Parking Lot 41 site and would store up to approximately five million gallons of industrial water. Industrial water is water that the CUP utilizes to generate steam or chilled water. Components of the system would include a storage tank, partially below-grade; a pump house building with a footprint of approximately 5,000 SF; support equipment, such as pumps, valves, variable frequency drivers, electrical equipment, switchgear, piping, controls, instrumentation, and an emergency generator; and security fencing, lighting, and other site improvements. The NIH would use this system to ensure an adequate supply of water to the chillers.

Other Supporting Infrastructure

The Thermal Energy Storage System and the Industrial Water Storage System

would each require new or upgraded utility infrastructure at locations outside the limit of disturbance for each system. Potential locations for many components of this infrastructure have been identified during the planning process. However, precise details including piping locations and sizes are not fully developed. Examples of the types of infrastructure that the NIH may install or upgrade include additional equipment (e.g., pumps, variable frequency drives, electrical equipment, switchgear, emergency generator, control valves, backflow preventers, pressure reducing valves, controls, and instrumentation); other utility buildings; aboveground or buried piping; aboveground or buried utilities; and site improvements (e.g., repairs to existing features, new concrete slabs).

Alternatives Considered

The Proposed Action, Alternative Action and No Action Alternative were the three alternatives analyzed in the Final EIS. The Alternative Action would implement water infrastructure improvements that would enable the NIH to adequately accomplish the project goals. The characteristics, features, and location of the Thermal Energy Storage System would be identical to the Proposed Action. What separates the Alternative Action from the Proposed is the proposal of the Potable Water Storage System. The Potable Water Storage System would store up to nine million gallons of potable water to ensure an adequate supply of industrial water to the chillers and for potable water requirements on the Campus. The proposed location for the Potable Water Storage System would be the same as that described for the Industrial Water Storage System under the Proposed Action. The characteristics and components of the Potable Water Storage System would be similar to the Industrial Water Storage System, except that the storage tank would be larger. The tank would be about 90 feet in height, which is similar to the planned height of MLP-12 once fully built. The pump house, support equipment, and utilities and site improvements would otherwise be identical to the described features of the Industrial Water Storage Tank.

Factors Involved in the Decision

The NIH prefers the Proposed Action over the Alternative Action because the Alternative Action would require the NIH to become a continuous water source, which would incur more upfront and ongoing costs for treatment, maintenance, and monitoring of the campus potable water system.

Additionally, relative to the Alternative Action, the Proposed Action would retain more connections to WSSC water mains (for redundancy), would not require installation and operation of pumps to maintain adequate pressure for fire service, would maintain existing flow dynamics of potable water within the Campus, and would require less construction (and therefore pose less potential for construction-related impacts to campus neighbors).

Resources Impacted

The Final EIS describes potential environmental effects of the Selected Alternative. These potential effects are documented in Chapter 3 of the Final EIS. Any potential adverse environmental effects will be avoided or mitigated through design elements, procedures, and compliance with regulatory and NIH requirements. Potential impacts on air quality are all within government standards (federal, state, and local). NIH does not expect significant negative effects on the environment or on the citizens of Bethesda from construction and operation at NIH.

Summary of Impacts

The following is a summary of potential impacts resulting from the Selected Alternative that the NIH considered when making its decision. No adverse cumulative effects have been identified during the NEPA process. Likewise, no unavoidable or adverse impacts from implementation of the Selected Action have been identified. The Selected Action will be beneficial to the long-term productivity of the national and world health communities. Biomedical research conducted at the NIH facility will have the potential to advance techniques in disease prevention, develop disease immunizations, and prepare defenses against naturally emerging and re-emerging diseases and against bioweapons. Additionally, the local community will benefit from increased employment, income and, government and public finance.

Housing

Implementation of the Selected Alternative would result in temporary minor impacts on the population and the availability of housing, due to construction workers who might temporarily relocate to the area.

Education

Educational resources in the area surrounding the Campus include public schools, the Uniformed Services University of the Health Sciences

(located on NSA Bethesda), and the Foundation for Advanced Education in the Sciences (located at 9109 Old Georgetown Road). Public schools near the Campus include three high schools, five middle schools, and nineteen elementary schools. Implementation of the Selected Alternative will not have a significant impact to education.

Transportation

Implementation of the Selected Alternative would result in minor temporary impacts to off-campus roads, transit, and traffic due to construction activities. This would include additional traffic due to construction vehicles as well as shifts in employee traffic patterns. Implementation of the Selected Alternative would involve the construction of approximately 1–3 parking spaces to accommodate access for operation or maintenance vehicles. The construction of the Industrial Water Storage System would reduce parking capacity at Parking Lot 41 by approximately 90 parking spaces. In total, this will lead to a net decrease of approximately 90 parking spaces.

Security

Implantation of the Selected Alternative may have the NIH install security fencing to prevent unauthorized access to the tanks. There would be no significant impacts to security.

Employment

The Selected Alternative would result in minor benefits to the local economy during construction activities (e.g., meals and incidentals for construction workers). The Proposed Action would not result in a permanent change in job availability at the Campus or associated effects on the local economy.

Environmental Justice

Bethesda as a whole has relatively low proportions of minority, or low-income populations. Although there are areas of higher minority populations (30 to 35 percent) adjacent to the Campus, the percent minority is still low relative to Montgomery County (40.5 percent) and Maryland (37.9 percent). Impacts to social resources such as population and housing would be minor and temporary.

Visual Quality

The Selected Alternative would result in minor adverse impacts to external views. Existing topographical features and vegetation that largely block many potential views from adjacent neighborhoods would not be significantly altered as a result of the Selected Alternative.

The Selected Alternative would result in minor to moderate adverse impacts to internal views. The construction of the Industrial Water Storage System would require removal of a grassy area with trees. This would result in a minor negative impact to the visual character of that area of the Campus. The construction of the Thermal Energy Storage System would have a moderate adverse impact, as the associated tank would be viewable from the central part of the Campus. Also, implementation of the Selected Alternative could result in removal of existing trees and vegetation from the Building 34 site that currently reduces views from the north. The scale of this potential impact is somewhat tempered as the tank would be adjacent to a parking garage and the CUP, so it would not be entirely out of character with surrounding structures.

Under the Selected Alternative, all structures would be constructed to a height that does not exceed the Master Plan building height guidance. Construction of the Industrial Water Storage System into the hillside slope near Parking Lot 41 would be consistent with Master Plan guidance for minimizing the visual impact of new construction.

Noise

Implementation of the Selected Alternative would result in temporary minor noise impacts due to construction activities as well as long-term moderate noise impacts due to operational changes at the CUP.

Air Quality

Implementation of the Selected Alternative would result in minor direct and indirect impacts to air quality.

Greenhouse Gas Emissions

Construction and demolition activities would generate temporary greenhouse gas (GHG) emissions, while periodic emergency generator use, would generate recurring GHG emissions. Current GHG methodologies outlined in the TSD do not describe how to account for construction activities; therefore, they are not included in the current NIH GHG inventory. NIH would strive to minimize GHG emissions by implementing construction, renovation, and demolition best practices.

Stormwater

Temporary Construction Impacts

Implementation of the Selected Alternative would result in minor temporary impacts to stormwater quantity and quality due to earth disturbances during construction

activities. The Limit of Disturbance (LOD) for the Selected Alternative would be approximately 467,000 SF of earth during construction activities.

Potential erosion and sediment runoff impacts would be mitigated through stormwater management, including the development of an erosion and sediment control plan that is approved by MDE. The construction of the Thermal Energy Storage System and Industrial Water Storage System would each disturb more than one acre and therefore would obtain coverage under the MDE 2014 General Permit for Stormwater Associated with Construction Activity. As a result, construction activities under the Proposed Action would have a minor impact on stormwater quality.

Long-Term Stormwater Management

Implementation of the Selected Alternative would result in minor long-term stormwater management impacts. The Selected Alternative would increase impervious surface at the Campus by approximately 153,000 SF, which would increase runoff within the Rock Creek Watershed relative to baseline conditions. However, the construction of the Thermal Energy Storage System and Industrial Water Storage System would each disturb greater than 5,000 SF, and therefore site design would be required to meet The Energy Independence and Security Act of 2007 (EISA 2007) Section 438 requirements to restore each site to predevelopment conditions. This requirement would minimize hydrologic impacts resulting from increased stormwater runoff volumes, such as damage to storm sewer infrastructure, increased likelihood of flooding, and increased erosion.

The Selected Alternative would require permanent site stormwater management to control runoff and provide water quality treatment per federal and Maryland stormwater regulations. Long-term stormwater management facilities would be designed and installed per an MDE approved stormwater management plan. The NIH would incorporate appropriate and feasible Environmental Site Design (ESD) practices into the project designs to restore the predevelopment hydrology to the maximum extent technically feasible. Overall, these ESD practices would reduce runoff volume and rate, disperse flow, remove pollutants, and provide for groundwater recharge by facilitating infiltration into the soil.

Construction of the Industrial Water Storage System and Thermal Energy Storage System would likely incorporate bioretention areas including stormwater

planter boxes. These vegetated areas would infiltrate runoff from impervious surfaces at the site, reducing the quantity of stormwater runoff and improving the water quality.

The Selected Alternative would not impact coverage under the Campus's Municipal Separate Storm Sewer System, MS4 permit.

Historic Resources

Construction of the Thermal Energy Storage System and associated infrastructure would result in temporary construction impacts (e.g., noise) and a permanent change in the appearance of the Building 34 site. These impacts would be perceptible from the rear of the historic Biologics Standards Laboratory and Annex (Buildings 29 and 29A), located north of the project site. The new infrastructure would also result in a minor change in the appearance of the Campus when viewed from the historic National Library of Medicine (NLM) complex (Buildings 38 and 38A). Additionally, construction of the Industrial Water Storage System may result in a minor change in the appearance of the Campus when viewed from the upper levels of Building 38A. Construction of these new facilities, however, would not affect the integrity of setting of these historic properties; would not obscure or compromise their original design intent; and would not otherwise affect the characteristics that qualify these historic properties for listing in the National Register.

Based on this analysis, the NIH has determined that the Selected Alternative would not adversely affect any historic properties or MIHP-listed properties. Pursuant to Section 106 of the NHPA, the NIH initiated consultation with the MD SHPO to obtain their concurrence with this finding. MD SHPO's concurrence of no adverse effect was received on 20 April 2015.

Practicable Means To Avoid or Minimize Potential Environmental Harm From the Selected Alternative

All practicable means to avoid or minimize adverse environmental effects from the Selected Alternative have been identified and incorporated into the action. The proposed Chilled Water System Improvement construction will be subject to the existing NIH pollution prevention, waste management, and safety, security, and emergency response procedures as well as existing environmental permits. Best management practices, spill prevention and control, and stormwater management plans will be followed to appropriately address the construction and operation of the new Chilled Water

System and comply with applicable regulatory and NIH requirements. No additional mitigation measures have been identified.

Pollution Prevention

Air quality permit standards will be met, as will all federal, state, and local requirements to protect the environment and public health.

Conclusion

Based upon review and careful consideration, the NIH has decided to implement the Selected Alternative for a Chilled Water System Improvement System located in Bethesda, Maryland. The decision accounts for a potential outside disturbance interrupting the campus water supply. The system will provide sufficient storage capacity to meet two days of chilled water demand and two days of industrial water demand should an interruption occur.

The decision was based upon review and careful consideration of the impacts identified in the Final EIS and public comments received throughout the NEPA process.

Dated: September 8, 2015.

Daniel G. Wheeland,

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

[FR Doc. 2015-23487 Filed 9-17-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Neurological Sciences Training Initial Review Group, NST-1 Subcommittee.

Date: October 13-14, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Raul A. Saavedra, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, saavedrr@ninds.nih.gov.

Name of Committee: Neurological Sciences Training Initial Review Group, NST-2 Subcommittee.

Date: October 26-27, 2015.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Elizabeth A. Webber Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-1917, webbere@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders A.

Date: October 27-28, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Natalia Strunnikova, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-402-0288, natalia.strunnikova@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders B.

Date: October 29, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-3562, neuhuber@ninds.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C.

Date: November 5-6, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research,

NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, benzingw@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 14, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-23444 Filed 9-17-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Research Education Programs (R25).

Date: October 9, 2015.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, aschulte@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders.

Date: October 14, 2015.

Time: 11:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive