

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:** On April 9, 2015, from 8:30 a.m. to 4 p.m. and on April 10, 2015, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 March 20, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. on April 10, 2015. 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 March 12, 2015. 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 March 13, 2015.

**Closed Committee Deliberations:** On April 9, 2015, between 4 p.m. and 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (see 5 U.S.C. 552b(c)(3) and (c)(4)). This portion of the meeting will be closed because the Committee will be discussing trade secret and/or confidential data provided by Swedish Match North America Inc.

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 Caryn Cohen 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: February 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Bethesda Campus Master Plan 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 for a long-range physical Master Plan for National Institutes of Health Bethesda Campus (NIH) located in Bethesda, Maryland. This alternative accounts for potential growth in NIH personnel, new construction, additions, renovations, demolitions, and upgrades in site utilities.

**Responsible Official:** Daniel G. Wheeland, Director, Office of Research Facilities (ORF) Development and Operations, NIH.

**FOR FURTHER INFORMATION CONTACT:** Valerie Nottingham, Deputy Director, DEP, ORF, NIH, Building 13, Room 2S11, 9000 Rockville Pike, Bethesda, MD 20892, Phone 301-496-7775, [nihnepa@mail.nih.gov](mailto:nihnepa@mail.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the Master Plan, National Institutes of Health Bethesda Campus, 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 is intended to be a strategic tool for the efficient allocation of campus resources, the orderly accommodation of future growth, and the creation of an environment that is both functionally and aesthetically conducive to

accomplishing the NIH mission. The Selected Alternative will provide a guide for the reasoned and orderly development of the NIH campus, one that values and builds on existing resources, corrects current deficiencies and meets changing needs through new construction or renovation. The plan sets forth implementation priorities and a logical sequencing of planned development.

The Selected Alternative is for a long-range physical Master Plan for NIH. This alternative covers a 20-year planning period, with reviews every 5 years to ensure that the plan continues to address issues affecting the campus. The alternative addresses the future development of the NIH site, including placement of future construction; vehicular and pedestrian circulation on and off-campus; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. This alternative accounts for potential growth in NIH personnel, and consequent construction of space over the planning period. Future construction on the site could include such facilities as new animal holding, research laboratories, and support facilities.

NIH will continue to develop the Bethesda campus to accommodate NIH's research needs and required programmatic needs consistent with the commitment to maintain the "campus" character of the site. The Selected Alternative advances this objective by programming and locating future NIH growth so that new development would tie into the existing utility services and utilities are available to support growth, and establishing development guidelines for future changes to the site that ensure that as the campus grows new development would be responsive to the context of adjacent neighborhoods or developments. Under the Selected Alternative, the total NIH population on the campus is anticipated to grow in the next twenty years to a total of approximately 23,594, which is an increase of approximately 3,000 employees. The primary growth at the campus would be in intramural research personnel and the administrative and facility staff to support them. The majority, if not all, of the employees would be coming from off-site facilities and are already employees, or contractors, of NIH.

##### Alternatives Considered

The Proposed Action Alternative, the Redevelopment Alternative and No Action Alternative were the three alternatives analyzed in the Final EIS.

The Master Plan covers a 20-year planning period, but will be reviewed every 5 years to ensure that the plan continues to remain current and relevant to the key issues affecting the campus. The alternatives addressed the future development of the NIH site, including placement of future construction; vehicular and pedestrian circulation on and off-campus; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. The alternatives account for potential growth in NIH personnel, and consequent construction of space over the planning period. Future construction on the site could include such facilities as new animal holding, research laboratories, and support facilities.

#### **Factors Involved in the Decision**

The Department of Health and Human Services (HHS) requires that NIH facilities have a Master Plan and, the previous Master Plan for the NIH campus was outdated. In addition, factors such as the aging of facilities that were designed only to accommodate temporary use, animal housing facilities that do not provide adequate space for projected increases in animal populations, and research support facilities not being adequate to sustain current and projected programs. The Master Plan contains information, analysis, and recommendations to guide development of individual projects. It also serves as a means of informing city and county officials and utilities of future NIH development plans so they can anticipate and plan for the potential effects of NIH proposals on their systems.

#### **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 Alternative have been identified. The Selected Alternative will be beneficial to the long-term productivity of the national and world health communities. Biomedical research conducted at the NIH facilities on the campus will have the potential to advance techniques in disease prevention and cures, 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**

Under the Selected Alternative, the building program would improve existing laboratory and office spaces. This would allow NIH to attract well-qualified personnel to the campus. The campus building program would be expanded with nominal population increases. These added employees would continue to seek regional housing options and use local community services. This modest expansion would have a modest beneficial economic impact with modest increased demand for housing and community services.

#### **Education**

The expected increases of employees on the NIH campus are from employees already working in the Bethesda area in the agency's off campus, leased facilities. If any new employees were hired, the current public school capacity in Bethesda or Montgomery County and surrounding school districts would be adequate to accommodate the expected minimal growth caused by the Selected Alternative.

#### **Transportation**

The potential increase in vehicular traffic generated by the additional facilities and employees envisioned in the Master Plan would only minimally contribute to the amount of traffic on the roadways in the vicinity of the campus. If the campus houses 3,000 additional staff, the impact on morning and evening rushes is estimated to be approximately 12 percent more NIH vehicles. When taking into account that NIH's contribution to local traffic constitutes only approximately 25% of the traffic, the impact on the community is estimated to be 3%. Furthermore, by the time the capital improvements contemplated under the Selected

Alternative are in place, mass transit developments such as the Purple Line and Bus Rapid Transit might well be in place, thereby offsetting the 3% congestion. The Selected Alternative includes 3,000 additional employees, and would generate approximately an additional 432 a.m. and 439 p.m. trips. The seven proposed Base Realignment and Closure (BRAC) improvements, discussed in the EIS, several of which were facilitated through NIH easements, would result in mitigating this slight increase AM and PM peak traffic, and also help keep the congestion standard below 1,600 Calculated Load Value (CLV). Stated differently, the modest increase in traffic would not change the intersection ratings. Lastly, if NIH increases the campus population, it will increase parking at the ratio of 1 parking spot per 3 additional staff.

#### **Security**

The Selected Alternative would not be expected to have adverse impacts on security on the NIH Campus. No new security measures are proposed in the Master Plan.

#### **Employment**

If the Selected Alternative is fully implemented, an increase of up to 3,000 employees and contractors would increase the current total of 20,594 up to approximately 23,594. The increase draws from employees that are already working in the Bethesda/Montgomery County area.

#### **Environmental Justice**

The Selected Alternative would not be expected to have disproportionately high or adverse impacts on low income or minority populations of the affected area.

#### **Visual Quality**

The Master Plan's land use plan provides a framework to help organize future development at NIH so that similar land use types are consolidated while open space and natural features are preserved. NIH would exhibit the same basic types of land use as it does currently, but in a slightly different configuration. The Master Plan does not propose any land use changes outside NIH. Therefore, the NIH campus is anticipated to remain consistent with the county plan and zoning regulations.

#### **Noise**

To limit impacts to nearby residences, NIH would limit construction activities to normal daytime working hours. Under the Master Plan, the ambient noise levels at NIH would remain within Maryland and Montgomery

County noise thresholds. Furthermore, any minor change in noise levels is not expected to affect the character of the site.

#### *Air Quality*

Traffic is expected to be the primary mobile source of air emissions at or near the campus. Mobile air emissions for the campus at this time are expected to originate from vehicles associated with visitors, commuter transportation, employee parking, commercial delivery, and construction vehicles. Future traffic generated carbon monoxide (CO) concentrations were predicted to be less than 2003 concentrations in the Selected Alternative due to projected vehicle emission rate reductions. Based on predicted values, the one and eight-hour average National Ambient Air Quality Standards (NAAQS) CO concentrations would not be exceeded and no impacts are expected for any of the proposed Alternatives.

#### *Wastewater/Water Supply*

The Selected Alternative would increase the amount of wastewater generated on campus with the proposal of additional development. To facilitate the construction of the improvements under this proposed alternative, the existing wastewater distribution system would need to be relocated and upgraded as necessary. With the increase in demand, NIH will consult with the Washington Suburban Sanitary Commission (WSSC) to ensure adequate sewer capacity is available for the campus. This consultation would also assist WSSC in determining if and when any of the public lines surrounding the campus need to be upgraded. All sanitary sewer design would be in accordance with the NIH Facilities Development Manual, "Section 8-6: Drainage Systems" of the 2008 National Institutes of Health Design Requirements for Biomedical Laboratories and Animal Research Facilities and the WSSC requirements. No significant impacts are expected for wastewater or the NIH campus water supply.

#### *Historic Resources*

NIH would comply with National Historic Preservation Act (NHPA) Section 106 by consulting with Maryland Historical Trust (MHT) on the need for particular archeological studies as individual Master Plan project elements are funded, designed, and executed. In the event that eligible prehistoric resources are identified and adverse effects are anticipated, NIH would continue Section 106 consultation with the appropriate

consulting parties (which would include MHT and may also include Advisory Council on Historic Preservation (ACHP) and Native American tribes) to establish a Memorandum of Agreement (MOA) to resolve adverse effects. Mitigation measures identified through this consultation could include in-place preservation through site avoidance, protection, or easement acquisition; development and implementation of a data recovery plan to retrieve and analyze the site's resources; implementation of innovative, alternative mitigation measures or a combination of these measures.

#### **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 Action have been identified and incorporated into the action. The proposed Master Plan construction will be subject to the existing NIH pollution prevention, waste management, and safety, security, and emergency response policies and 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 envisioned in [or "described in"—the Master Plan itself will not be constructed and operated] of the new Master Plan 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 long-range physical Master Plan for NIH Bethesda Campus located in Bethesda, Maryland. The decision accounts for potential growth of NIH personnel, and consequent construction of space over the planning period. 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.

Separate NEPA reviews, when required, will be done on projects discussed in the Master Plan. Proper

NEPA documentation will be completed based on the outcome of that review.

Dated: February 5, 2015.

**Daniel G. Wheeland, P.E.**

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

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**BILLING CODE 4140-01-P**

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

### **National Institutes of Health**

#### **Announcement of a Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information**

**SUMMARY:** On November 19, 2014, the National Institutes of Health (NIH) published a request for public comments in the NIH Guide for Grants and Contracts on a draft policy to promote broad and responsible dissemination of information on clinical trials funded by the NIH through registration and submission of summary results information to ClinicalTrials.gov. See Guide notice NOT-OD-15-019 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html>. NIH is publishing this notice in order to inform readers of the **Federal Register** about the draft policy and the opportunity to comment.

**DATES:** The deadline for receiving comments on the draft policy is no later than 5:00 p.m. on March 23, 2015.

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Email:*  
[clinicaltrials.disseminationpolicy@mail.nih.gov](mailto:clinicaltrials.disseminationpolicy@mail.nih.gov).
- *Fax:* 301-496-9839.
- *Mail/Hand delivery/Courier:* Office of Clinical Research and Bioethics Policy, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

**FOR FURTHER INFORMATION CONTACT:** Office of Clinical Research and Bioethics Policy, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838, [OCRBP-OSP@od.nih.gov](mailto:OCRBP-OSP@od.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The National Institutes of Health (NIH) is dedicated to improving the health of Americans by conducting and funding biomedical and behavioral