ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279	5,650	2	1	11,300
	350	2	1.5	525
Total				11,825

Terry Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2018–17748 Filed 8–16–18; 8:45 am]

BILLING CODE 4150–36–P

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, 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: September 17–18, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., SUITE 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) Program.

Date: November 14–15, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Elizabeth A. Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–1917, *webbere@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: August 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17780 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information To Solicit Feedback on the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative

AGENCY: National Institutes for Health, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Request for Information (RFI) is to solicit input on how best to accomplish the ambitious vision for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® set forth in BRAIN 2025: A Scientific Vision. NIH is soliciting input from all interested stakeholders, including members of the scientific community, trainees, academic institutions, the private sector, health professionals, professional societies, advocacy groups, and patient communities, as well as other interested members of the public.

DATES: The Request for Information is open for public comment. To assure consideration, your responded must be received by November 15, 2018, 11:59 p.m.

ADDRESSES: Responses to this RFI must be submitted electronically using the web-based form at *https://www.braininitiative.nih.gov/rfi.aspx.*

FOR FURTHER INFORMATION CONTACT: Please direct all inquiries to Samantha White, Ph.D., National Institute of Neurological Disorders and Stroke, 301–496–1675; *BRAINFeedback@nih.gov* with ''BRAIN RFI'' in the subject line.

SUPPLEMENTARY INFORMATION:

Background

The BRAIN Initiative aims to develop new tools and technologies to understand and manipulate networks of cells in the brain. BRAIN 2025: A Scientific Vision serves as the strategic plan for the BRAIN Initiative at NIH and outlines an overarching vision, seven high level scientific priorities, and many specific goals. Designed to be achieved over at least a decade, the first five years of BRAIN 2025 emphasizes development of tools and technology, and the next five years shifts emphasis to using these tools to make fundamental discoveries about how brain circuits work and what goes wrong in disease.

The BRAIN Initiative is well underway (see *http://www.braininitiative.nih.gov*), and we are now approaching the midpoint. At this time, NIH is seeking feedback on the BRAIN Initiative's progress and on opportunities moving forward given the current state of the science. NIH has established a new BRAIN Initiative Advisory Committee of the NIH Director (ACD) Working Group that will provide scientific guidance to the ACD on how best to continue to accelerate the ambitious vision for the BRAIN Initiative.

The ACD–WG will use the responses to this RFI, along with information gathered through a series of public workshops, to help inform their discussions of the BRAIN Initiative's progress and potential updates to the plan moving forward.

Information Requested

Anyone wishing to submit a response is asked to include:

- Ideas for new tools and technologies that have the potential to transform brain circuit research.
- Suggestions for fundamental questions about brain circuit function in

humans or animal models that could be addressed with new technologies.

- Considerations for data sharing infrastructure and policies.
- Areas and topics for research on the ethical implications of BRAIN Initiative-supported emerging neurotechnologies and advancements and their applications.
- Approaches for disseminating new tools and technologies as well as training the broader neuroscience research community.
- Any other topic relevant to the strategic plan of the BRAIN Initiative.

Responses to this RFI are voluntary. Any personal identifiers will be removed when responses are compiled. Individual feedback will not be provided to any responder. Proprietary, classified, confidential, or sensitive information should not be included in your response. This Request for Information (RFI) is for planning purposes only and is not a solicitation for applications or an obligation on the part of the United States (U.S.) Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any comment submitted or for its use of that comment.

Dated: August 10, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–17759 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks public comment on its proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline oversight for human gene transfer clinical research protocols and reduce duplicative reporting requirements already captured within the existing regulatory framework. Specifically, NIH proposes amendments to: Delete the NIH protocol registration submission and reporting requirements under Appendix M of the *NIH Guidelines,* and modify the roles and responsibilities of entities that involve human gene transfer or the Recombinant DNA Advisory Committee (RAC).

DATES: To ensure consideration, comments must be submitted in writing by October 16, 2018.

ADDRESSES: Comments may be submitted electronically by visiting: *https://osp.od.nih.gov/comment-form-nih-guidelines/.* Comments may also be sent via fax to 301–496–9839, or by mail to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892–7985. All written comments received in response to this notice will be available for public inspection at NIH Office of Science Policy (OSP), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted without change, including any personal information, to the NIH OSP website.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about these proposed changes, please contact the NIH by email at *SciencePolicy@od.nih.gov*, or telephone at 301–496–9838. You may also contact Jessica Tucker, Ph.D., Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy, Office of Science Policy, NIH, at 301–451–4431 or *Jessica.Tucker@nih.gov.*

SUPPLEMENTARY INFORMATION: NIH is proposing a series of actions to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline oversight of human gene transfer research (HGT), and to focus the *NIH Guidelines* more specifically on biosafety issues associated with research involving recombinant or synthetic nucleic acid molecules. The field of HGT has recently experienced a series of advances that have resulted in the translation of research into clinical practice, including U.S. Food and Drug Administration (FDA) approvals for licensed products. Additionally, oversight mechanisms for ensuring HGT proceeds safely have sufficiently evolved to keep pace with new discoveries in this field.

At this time, there is duplication in submitting protocols, annual reports, amendments, and serious adverse events for HGT clinical protocols to both NIH and FDA that does not exist for other areas of clinical research. Historically, this duplication was conceived as harmonized reporting, enabling FDA to provide regulatory oversight while NIH provided a forum for open dialogue and transparency. However, since these complementary functions were first envisioned, we have now seen several converging systems emerge that provide some of these functions. For instance, *ClinicalTrials.gov* has been instituted, which provides a transparent and searchable database for clinical trials. In addition, the protection of human research subjects was improved through changes that updated provisions of the Common Rule. In 2018, FDA released a suite of draft guidance documents pertaining to gene therapy that includes new guidance on manufacturing issues, long-term follow-up, and pathways for clinical development in certain areas, including hemophilia, ophthalmologic indications, and rare diseases.

While the science and oversight system have evolved, HGT protocols continue to receive special oversight that is not afforded to other areas of clinical research. This observation was also noted in a 2014 Institute of Medicine of the National Academies report, *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee,* in which it was recommended that NIH begin to limit RAC review to only exceptional HGT protocols that meet certain criteria and that would significantly benefit from RAC review. As very few protocols have been assessed by NIH to merit review under this new system, NIH asserts it is an opportune time to make changes to the *NIH Guidelines* to make oversight of HGT commensurate with oversight afforded to other areas of clinical research given the robust infrastructure in place to oversee this type of research.

Briefly to summarize, NIH proposes amending the *NIH Guidelines* to:

1. Eliminate RAC review and reporting requirements to NIH for HGT protocols.

2. Modify roles and responsibilities of investigators, institutions, IBCs, the RAC, and NIH to be consistent with these goals including:

a. Modifying roles of IBCs in reviewing HGT to be consistent with review of other covered research, and

b. Eliminating references to the RAC, including its roles in HGT and biosafety.

NIH suggests that the series of changes proposed in this Notice is a rational next step in the process of considering appropriate oversight of HGT. Consistent with these proposed changes to the *NIH Guidelines,* Section I–A, the Purpose of the *NIH Guidelines,* is proposed to be amended to clarify that the focus of the policy is biosafety