

see http://privacyruleandresearch.nih.gov/pr_08.asp.

⁹ An Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to the NIH.

¹⁰ 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. See <http://www.nih.gov/about/mission.htm>.

¹¹ Final NIH Statement on Sharing Research Data. February 26, 2003. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

¹² NIH Intramural Policy on Large Database Sharing. April 5, 2002. See <http://sourcebook.od.nih.gov/ethic-conduct/large-db-sharing.htm>.

¹³ GWAS has the same definition in this policy as in the 2007 GWAS Policy: a study in which the density of genetic markers and the extent of linkage disequilibrium should be sufficient to capture (by the r^2 parameter) a large proportion of the common variation in the genome of the population under study, and the number of samples (in a case-control or trio design) should provide sufficient power to detect variants of modest effect.

¹⁴ Competing grant applications encompass all activities with a research component, including but not limited to the following: Research Grants (Rs), Program Projects (Ps), Cooperative Research Mechanisms (Us), Career Development Awards (Ks), and SCORs and other S grants with a research component.

¹⁵ Investigators should refer to funding announcements or IC Web sites for contact information.

¹⁶ NIH Policy on Sharing of Model Organisms for Biomedical Research. Release Date May 7, 2004. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>.

¹⁷ Gene Expression Omnibus at <http://www.ncbi.nlm.nih.gov/geo/>.

¹⁸ Sequence Read Archive at <http://www.ncbi.nlm.nih.gov/Traces/sra/sra.cgi?>

¹⁹ Trace Archive at <http://www.ncbi.nlm.nih.gov/Traces/trace.cgi>.

²⁰ Array Express at <http://www.ebi.ac.uk/arrayexpress/>.

²¹ Mouse Genome Informatics at <http://www.informatics.jax.org/>.

²² WormBase at <http://www.wormbase.org>.

²³ The Zebrafish Model Organism Database at <http://zfin.org/>.

²⁴ GenBank at <http://www.ncbi.nlm.nih.gov/genbank/>.

²⁵ European Nucleotide Archive at <http://www.ebi.ac.uk/ena/>.

²⁶ DNA Data Bank of Japan at <http://www.ddbj.nig.ac.jp/>.

²⁷ A period for data preparation is anticipated prior to data submission to the NIH, and the appropriate time intervals for that data preparation (or data cleaning) will be subject to the particular data type and project plans (see Appendix A). Investigators

should work with NIH Program or Project Officials for specific guidance.

²⁸ See 45 CFR 46.102(f) at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>.

²⁹ See 45 CFR 164.514(b)(2). The list of HIPAA identifiers that must be removed is available at: <http://www.gpo.gov/fdsys/pkg/CFR-2002-title45-vol1/pdf/CFR-2002-title45-vol1-sec164-514.pdf>.

³⁰ For additional information about Certificates of Confidentiality, see <http://grants.nih.gov/grants/policy/coc/>.

³¹ Confidentiality Certificate. HG-2009-01. Issued to the National Center for Biotechnology Information, National Library of Medicine, NIH. See http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=ConfidentialityCertificate.pdf.

³² Database of Genotypes and Phenotypes at <http://www.ncbi.nlm.nih.gov/gap>.

³³ Cancer Genomics Hub at <https://cghub.ucsc.edu/>.

³⁴ The 1000 Genomes Project at <http://www.1000genomes.org/>.

³⁵ Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications. See http://gwas.nih.gov/pdf/PTC_for_IRBs_and_Institutions_revised5-31-11.pdf.

³⁶ Clinical specimens are specimens that have been obtained through clinical practice.

³⁷ For the submission of data derived from cell lines or clinical specimens lacking research consent that were created or collected before the effective date of this Policy, the Institutional Certification needs to address only this item.

³⁸ For guidance on clearly communicating inappropriate data uses, see NIH Points to Consider in Drafting Effective Data Use Limitation Statements, http://gwas.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf.

³⁹ "Equivalent body" is used here to acknowledge that some primary studies may be conducted abroad and in such cases the expectation is that an analogous review committee to an IRB or Privacy Board (e.g., Research Ethics Committees) may be asked to participate in the presubmission review of proposed genomic projects.

⁴⁰ As noted earlier, for studies using data or specimens collected before the effective date of this Policy, the IRB or Privacy Board should review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.

⁴¹ Compilation of Aggregate Genomic Data. dbGaP study accession: phs000501.v1.p1. See http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study501.cgi?study_id=phs000501.v1.p1&pha=&phaf=.

⁴² dbGaP Authorized Access. See <https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?page=login>.

⁴³ For a list of NIH Data Access Committees, see http://gwas.nih.gov/04po2_1DAC.html.

⁴⁴ User Code of Conduct. See https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html.

⁴⁵ Model Data Use Certification Agreement. See http://gwas.nih.gov/pdf/Model_DUC_7-26-13.pdf.

⁴⁶ Security Best Practices. See http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=dbgap_2b_security_procedures.pdf.

⁴⁷ In Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al. 569 U.S. ____ 2013. See http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf.

⁴⁸ NIH Best Practices for the Licensing of Genomic Inventions. See http://www.ott.nih.gov/policy/genomic_invention.html.

⁴⁹ Research Tools Policy. See http://www.ott.nih.gov/policy/research_tool.aspx.

Dated: September 16, 2013.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

[FR Doc. 2013-22941 Filed 9-19-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to discuss committee business, updates and issues related to autism spectrum disorder (ASD) research and services activities. The meeting will be open to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting.

Date: October 9, 2013.

Time: 9:00 a.m. to 5:00 p.m. * Eastern Time * Approximate end time.

Agenda: To discuss committee business, updates and issues related to ASD research and services activities.

Place: Fishers Lane Conference Center, 5635 Fisher Lane, Terrace Level, Rockville, MD 20852, (Parking on site.)

Web cast Live: <http://videocast.nih.gov/>.

Conference Call: Dial: 888-989-4620.

Access: Access code: 2327818.

Cost: The meeting is free and open to the public.

Registration: Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. To register, please visit www.iacc.hhs.gov.

Deadlines: Notification of intent to present oral comments: Friday, September 27, 2013 by 5:00 p.m. e.t.

Submission of written/electronic statement for oral comments: Wednesday, October 2, 2013 by 5:00 p.m. e.t.

Final Deadline for Submission of written comments: Wednesday, October 2, 2013 by 5:00 p.m. e.t.

Please note: The NIMH Office of Autism Research Coordination (OARC) anticipates that written public comments received by the deadline of 5:00 p.m. e.t., Wednesday, October 2, 2013 will be presented to the Committee prior to the October 9th meeting for the Committee's consideration. Any written comments received after the October 2, 2013 deadline (between October 3, 2013 and October 8, 2013) will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the staff time required to process them in accordance with privacy regulations and other applicable Federal policies.

Access: Twinbrook Metro (Red Line).

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892-9669, Phone: 301-443-6040, Email: IACCPublicInquiries@mail.nih.gov.

Public Comments

Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Friday, September 27, 2013, with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral presentation/statement including a brief description of the organization represented by 5:00 p.m. E.T. on Wednesday, October 2, 2013. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on the number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. ET on Wednesday, October 2, 2013. The comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. E.T., Wednesday, October 2, 2013 will be presented to the Committee prior to the meeting for the Committee's consideration. Any written comments received after the October 2, 2013 deadline (between October 3, 2013 and October 8, 2013) will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the staff time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both

oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

Core Values

In the 2009 IACC Strategic Plan, the IACC listed the "Spirit of Collaboration" as one of its core values, stating that, "We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions." In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

Remote Access

The meeting will be open to the public through a conference call phone number and webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the web cast or conference call, please send an email to helpdeskiacc@gmail.com or by phone at 415-652-8023.

Special Accommodations

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

Security

As a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: September 12, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-22867 Filed 9-19-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 section 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Sample Biorepository and Laboratory Center for Myeloid Dysplasia Diseases.

Date: October 10, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael P Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301-496-9659, reillymp@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Data Center for Myeloid Dysplasia Diseases.

Date: October 10, 2013.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael P Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301-496-9659, reillymp@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 13, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-22866 Filed 9-19-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as