

Organ Procurement Organization (OPO) Responsibilities

NIH does not propose changes to this category.

Prevention of Inadvertent Transmission of HIV

NIH does not propose changes to this category.

Required Outcome Measures and Data Elements

The 2015 Research Criteria referenced required outcome measures. NIH proposes using the more precise “Required Data Elements and Outcome Measures.” NIH notes that data on these existing and proposed outcome measures is collected by the OPTN as specified by the Secretary. NIH does not intend to propose data collection requirements beyond those collected by the OPTN.

Waitlist Candidates: NIH proposes adding several data elements for waitlist candidates. NIH proposes adding cytomegalovirus (CMV immunoglobulin G [IgG]) as a required outcome measure for co-infection. NIH also proposes adding additional data elements and outcome measures: renal dysfunction, liver dysfunction, indication for transplant, use of mechanical circulatory devices, and use of extracorporeal membrane oxygenation, intra-aortic balloon pump, and ventricular assist device.

Donors (All): First, NIH proposes adding additional elements related to the type of deceased donation: after brain death (DBD) or after circulatory death (DCD) given the increasing use of the latter technique in the U.S. In addition, NIH proposes the following data elements for all donors (if applicable): *ex-vivo* perfusion and normothermic regional perfusion including durations of warm and cold ischemia.

Living Donors: The 2015 NIH Research Criteria included as required outcome measures progression to renal insufficiency in kidney living donors. Because kidney and liver transplants are no longer subject to the research criteria, NIH plans to retain these outcomes only where applicable (e.g., for deceased donor heart-living donor kidney transplants, deceased donor heart-living donor liver transplants, and for other organs subject to the research criteria).

Transplant Recipients: NIH proposes adding several additional data elements and outcome measures to those included for transplant recipients in the 2015 NIH Research Criteria. NIH proposes adding the following outcome measures: type of rejection (antibody-

mediated versus cellular rejection), chronic allograft vasculopathy (heart), chronic lung allograft dysfunction (lung), hospital infections, estimated glomerular filtration rate (heart and lung), HIV superinfection, graft failure (heart and lung), re-transplantation, and simultaneous multiple organ transplants.

While not proposed as a requirement of the Research Criteria, NIH proposes to provide the following recommendation regarding patient management: NIH recommends that transplant programs and healthcare providers follow current and updated practice management guidelines. For specific guidance, transplant programs and healthcare providers should consult vaccination guidance (<https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html>) and expert guidance for the management of patients with HIV pre-, during-, and post-transplant summarized in: Transplantation in people with HIV (<https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new>).

References

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- HIV Organ Policy Equity (HOPE) Act of 2013. Public Law 113–51.
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- Storm, K., & Durand, C.M. (2024). Overcoming barriers and stigma: new frontiers in solid organ transplantation for people with HIV. *Clinical microbiology reviews*, 37(1), e0011122. <https://doi.org/10.1128/cmr.00111-22>.
- Wairimu, F., Ward, N.C., Liu, Y., & Dwivedi, G. (2021). Cardiac Transplantation in HIV-Positive Patients: A Narrative Review. *Journal of acquired immune deficiency syndromes* (1999), 87(2), 763–768. <https://doi.org/10.1097/QAI.0000000000002647>.

Dated: November 21, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 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: National Cancer Institute Special Emphasis Panel; Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE).

Date: January 16, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240–276–6343, schweinfestcw@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Informatics Technologies for Cancer Research.

Date: January 29, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240-276-7975, chufanee@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Review of Research Projects in Physical Sciences Oncology.

Date: January 31, 2025.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240-276-7684, saejeong.kim@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Outstanding Investigator Award (R35).

Date: February 6-7, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: David G. Ransom, Ph.D., Chief, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850, 240-276-6351, david.ransom@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-3: NCI Clinical and Translational Cancer Research.

Date: February 6-7, 2025.

Time: 9:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Prashant Sharma, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850, 240-275-6351, prashant.sharma@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-7: NCI Clinical and Translational Cancer Research.

Date: February 12, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240-276-7684, saejeong.kim@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI IMAT Biospecimen Special Emphasis Panel.

Date: February 13, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, 240-276-5256, shuli.xia@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-11: NCI Clinical and Translational Cancer Research.

Date: February 18, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Bruce Daniel Hissong, Ph.D., Scientific Review Officer, Resource and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850, 240-276-7752, bruce.hissong@nih.gov.

Name of Committee: National Cancer Institute, Initial Review Group; Transition to Independence Study Section (I).

Date: February 26-27, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: *Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Delia Tang, M.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850, 240-276-6456, tangd@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research specialist Award (R50).

Date: February 27, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240-276-6372, zouzhiq@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-2: NCI Clinical and Translational Cancer Research.

Date: March 6, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240-276-6372, zouzhiq@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 22, 2024.

Miguelina Perez,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIEHS Videocast at the following link: <https://www.niehs.nih.gov/news/webcasts/index.cfm>.

The meeting will be closed to the public in accordance with the