ge²p² global
governance, ethics, evidence, policy, practice

Public Consultations Watch :: Global Calls for Input/Public Comment/RFIs

25 July 2025 - Issue 33

GE2P2 Global is an integrated non-profit foundation and public benefit corporation formed to advance scientific rigor, ethical resilience, and integrity in research and evidence generation – informing responsible governance, policy, and practice.

In the context of this mission, GE2P2 Global monitors public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education/literacy, heritage, climate/environment, peace, and sustainable development.

Monitoring this span of sectors yields a broad variety of public comment opportunities, even though this modality is not employed in any uniform way across the UN system, multilateral agencies, INGOs, member states or their ministerial/regulatory bodies. As we are still exploring this monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

In parallel, GE2P2 Global is striving to respond to public consultation opportunities where the experience and expertise of members of our growing community of practice suggest that a meaningful contribution can be developed. The GE2P2 Global Foundation also functions as the secretariat for the Global Forum for Research Ethics and Integrity – a global group of individuals from over 30 countries who collaborate on analysis and action, including response to selected public consultations.

We welcome information about calls for public consultation – at global or country level – to help enrich this digest. Equally, individuals and organizations/institutions interested in collaborating on joint responses to any of the opportunities listed below are welcome to contact us [David R Curry, GE2P2 Global Foundation, david.r.curry@ge2p2global.org].

Acknowledgements: We appreciate the support of Foundation Senior Fellow Gerald Schatz, JD for his continuing support in helping identify calls included in this digest, and Associate Fellow Sedem Adiabu, MPH, for her critical role in the secretariat function which supports development of submissions to selected calls.

Digest content is organized in three sections:

We expect to add thematic areas as our digest evolves and becomes more comprehensive.

Calls for Public Consultation: Title/Source/Sorted by Due Date

NEW **- Supporting Fairness and Originality in NIH Research Applications**
NIH Notice Number: NOT-OD-25-132 **Final Guidance - Release Date: July 17, 2025**
NIH is providing guidance to researchers on the appropriate usage of artificial intelligence (AI) to maintain the fairness and originality of NIH's research application process. NIH is also instituting a new policy limiting the number of applications that NIH will consider per Principal Investigator per calendar year.

NEW **- Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases-Questions and Answers; Guidance for Industry; Availability**
Final Guidance A Notice by the Food and Drug Administration on 06/27/2025 **Submit either electronic or written comments on Agency guidances at any time.**

Proposed Data Collection Submitted for Public Comment and Recommendations – New Project: Traveler Risk Assessment and Management Activities during Disease Outbreaks
A Notice by the Centers for Disease Control and Prevention on 06/16/2025 **Comment period ends 08/15/2025**

Proposed Data Collection Submitted for Public Comment and Recommendations - *Proposed New Project:* Global Action in Healthcare Network Antimicrobial Resistance Module (GAIHN–AR)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). A Notice by the Centers for Disease Control and Prevention on 06/16/2025. **Comment period ends 08/15/2025.**

NEW **- Call for Input – Position Paper on the Human Rights Impacts of Using Artificial Intelligence in Countering Terrorism**
Issued by Special Rapporteur on counter-terrorism and human rights **Deadline: 18 August 2025**

NEW **- Agency Information Collection Activities; Proposed Collection; Comment Request; Emerging Drug Safety Technology Meeting Program**
A Notice by the Food and Drug Administration on 07/03/2025 **Comment period that ends 09/02/2025.**

NEW **- National Institute of Environmental Health Sciences; Notice of Meeting - Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)**
Date: September 11-12, 2025. A Notice by the National Institutes of Health on 07/03/2025 **September 3, 2025 is the deadline** for written public comment submissions and for oral comment registration.

NEW **- Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products**
A Notice by the Food and Drug Administration on 07/14/2025 **Comment period ends 09/12/2025.**

NEW - **Call for written submissions on the draft guidelines on addressing multiple and intersectional forms of discrimination against women and girls with disabilities**
UN - Treaty bodies **Deadline: 15 September 2025**

NEW - **Proposed Data Collection Submitted for Public Comment and Recommendations – Enhancing Data-Driven Disease Detection in Newborns**
A Notice by the Centers for Disease Control and Prevention on 07/18/2025 **Comment period ends 09/16/2025.**

NEW – **ICH - E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 07/21/2025 **Comment period ends 09/19/2025**

NEW - **Solicitation of Nominations for Appointment to the Advisory Council for the Elimination of Tuberculosis**
A Notice by the Centers for Disease Control and Prevention on 07/11/2025. **Nominations must be received no later than September 30, 2025**

Draft guideline on the quality aspects of mRNA vaccines
Draft: consultation open **Consultation dates: 31/03/2025 to 30/09/2025**
Reference Number: EMA/CHMP/BWP/82416/2025

NEW - **Request for Public Comment: National Plan for Arctic Research**
National Science Foundation on 07/21/2025. **Written responses are due by October 15, 2025.**

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product
EMA - Draft: consultation open **Consultation dates: 16/04/2025 to 31/10/2025**

NEW - **Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making**
EMA - Draft: consultation open **Consultation dates: 25/07/2025 to 31/10/2025**

NEW - **Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"**
Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

ISO/AWI 14155 - Biological and clinical evaluation of medical devices
ISO/TC 194 Stage 20.00
Due: Ongoing at national standards bodies level

Contribute a tool - Catalogue of Tools & Metrics for Trustworthy AI

OECD-AI Policy Observatory

Contribute your tools and metrics to our catalogue. No deadline date identified.

This catalogue is a platform where AI practitioners from all over the world can share and compare tools and metrics to help make AI trustworthy, build upon each other's efforts to create global good practices, and speed up the process of implementing the OECD AI Principles. This catalogue can only exist with your contributions and those of AI practitioners from all sectors. You can also share your experience using a tool or metric by submitting a use case.

:: Contribute a tool

:: Share your experience using a tool

A framework for evaluating rapidly developing digital and related technologies: AI, large language models and beyond - International Science Council Discussion Paper: Invitation to Comment

International Science Council [ISC]

No submission deadline date identified.

Public Consultation Calls: Purpose/Objective/Scope/Background Information – Sorted by Thematic Area

Biomedical Research/Regulation/Governance

NEW - **Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases-Questions and Answers; Guidance for Industry; Availability**

Final Guidance A Notice by the Food and Drug Administration on 06/27/2025 **Submit either electronic or written comments on Agency guidances at any time.**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers." This guidance assists in the clinical development of new antibacterial drugs to treat serious bacterial diseases in patients with unmet medical needs, including patients with a serious bacterial disease for which effective antibacterial drugs are limited or lacking.

Proposed Data Collection Submitted for Public Comment and Recommendations – New Project: Traveler Risk Assessment and Management Activities during Disease Outbreaks

A Notice by the Centers for Disease Control and Prevention on 06/16/2025 **Comment period ends 08/15/2025**

SUMMARY:

…This notice invites comment on a proposed information collection project titled Traveler Risk Assessment and Management Activities during Disease Outbreaks. The purpose of this Generic information collection request (ICR) is to aid in CDC's responsibility to ensure the successful implementation of traveler management in an efficient and timely manner during disease outbreaks. CDC intends use this Generic information collection request (ICR) in the event of a disease outbreak overseas that would necessitate the public health assessment and/or monitoring of travelers arriving in the U.S. Section 361 of the Public Health Service (PHS) Act (42 USC 264) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into and within the United States. Under its delegated authority, DGMH works to fulfill this responsibility through a variety of activities (including the operation of port health stations) at U.S. ports of entry and administration of foreign quarantine regulations; 42 Code of Federal Regulation part 71, specifically 42 CFR 71.20 Public health prevention measures to detect communicable disease…

Proposed Data Collection Submitted for Public Comment and Recommendations - *Proposed New Project:* Global Action in Healthcare Network Antimicrobial Resistance Module (GAIHN–AR)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC). A Notice by the Centers for Disease Control and Prevention on 06/16/2025. **Comment period ends 08/15/2025.**

SUMMARY:

…This notice invites comment on a proposed information collection project titled Global Action in Healthcare Network Antimicrobial Resistance Module (GAIHN-AR). This project supports planning and

management of antimicrobial resistance prevention, detection, and response activities associated with the GAIHN-AR network.

Background and Brief Description

…The United States National Action Plan for Combating Antibiotic Resistant Bacteria Sub-Objective 2.5.3 describes the creation of a global network for "detection and containing new and critical antibiotic-resistant threats," to "identify innovative and effective strategies for stopping the spread of antibiotic resistant pathogens in low- and middle-income countries," and to "improve standardization of laboratory methodologies and data collection to improve the quality, reliability, and utility of data to facilitate global comparisons of antibiotic resistance."

CDC has established this network, and it is called the Global Action in Healthcare Network – Antimicrobial Resistance Module (GAIHN-AR). GAIHN-AR aims to help prevent and reduce the spread of AR threats before they reach the United States through coordinated laboratory detection, communication, and infection prevention and control (IPC) actions in healthcare.

…The data collected through GAIHN-AR is used to: (1) monitor progress toward core network activity implementation; (2) measure the impact, inform resource needs, and demonstrate return on investment for those activities over time; (3) provide data to the participating healthcare facilities, laboratories, and Ministries of Health to set priorities and support continuous improvement of prevention, detection, and response activities in the participating sites and at the national level within the country; and (4) facilitate collaboration with CDC on the improvement activities described in (3)…

NEW - Agency Information Collection Activities; Proposed Collection; Comment Request; Emerging Drug Safety Technology Meeting Program

A Notice by the Food and Drug Administration on 07/03/2025 **Comment period that ends 09/02/2025.**

Emerging Drug Safety Technology Meeting Program

The pharmaceutical industry is expanding its use of artificial intelligence (AI) and other emerging technologies across the drug product lifecycle. FDA is interested in accelerating its understanding of the research, development, and use of AI and other emerging technologies in the area of pharmacovigilance, including their performance characteristics. The EDSTM program is a means by which applicants and other relevant parties who meet the eligibility and selection criteria for participation, can meet with the Center for Drug Evaluation and Research (CDER) to share information about their use of AI and other emerging technologies, and its potential application in pharmacovigilance (PV)…

The goal of the EDSTM program is to facilitate mutual learning and discussion on the opportunities and challenges with using emerging technologies in PV. If selected for a meeting, application holders and/or other relevant parties will meet with CDER staff to discuss their research, development, and/or use of AI and other emerging technologies in PV. FDA plans to leverage these learnings to help inform potential regulatory and policy approaches relating to the use of AI and other emerging technologies in PV. EDSTMs will collect information for the following purposes: (1) serve as the central point of contact for dialogue between industry and CDER on the use of AI and other emerging technologies in PV; (2) enable knowledge management and transfer within FDA specific to the context of use for AI or other emerging technologies in PV; and (3) further thinking about policy and application of potential regulatory approaches within the landscape of AI and other emerging technologies…

NEW - National Institute of Environmental Health Sciences; Notice of Meeting - Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

Date: September 11-12, 2025. A Notice by the National Institutes of Health on 07/03/2025

September 3, 2025 is the deadline for written public comment submissions and for oral comment registration.

Agenda: The preliminary agenda, registration, and other meeting materials will be available at https://ntp.niehs.nih.gov/go/32822. Public comment welcome.

SACATM is a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

This meeting will be held as a virtual meeting and open to the public. Registration is required to attend to view the webcast, and/or present oral comments.

NEW - Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products

A Notice by the Food and Drug Administration on 07/14/2025 **Comment period ends 09/12/2025.**
OMB Control Number 0910-0595—Extension
SUPPLEMENTARY INFORMATION:

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b). For more information regarding emergency use authorization (EUA), visit our website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products for humans and animals, or unapproved uses of approved medical products for humans and animals, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb-3(c)).

Also, under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health…

NEW - Proposed Data Collection Submitted for Public Comment and Recommendations – Enhancing Data-Driven Disease Detection in Newborns

A Notice by the Centers for Disease Control and Prevention on 07/18/2025 **Comment period ends 09/16/2025.**
Proposed Project
Enhancing Data-Driven Disease Detection in Newborns (ED3N) (OMB Control No. 0920-1391, Exp. 4/30/2026)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).
Background and Brief Description

The Newborn Screening and Molecular Biology Branch (NSMBB), in the National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS), has the only laboratory in the world devoted to ensuring the accuracy of newborn screening (NBS) tests in every state and more than 78 countries. NSMBB supports NBS programs by conducting research, developing methods, and performing analyses by using complex, state-of-the-art molecular and biochemical techniques for identifying risk factors for diseases of public health importance.

Both NSMBB and state NBS programs are experiencing increased data analytic challenges associated with continued expansion of the number of newborn screening diseases, increased complexity of disease detection, and difficulties in correlating disease markers with disease risk. Further, the addition of late-onset diseases to NBS panels necessitates a better way to routinely capture clinical information and outcomes so that NBS programs can fully appreciate the spectrum of disease they are detecting.

The NSMBB is requesting a three-year Paperwork Reduction Act (PRA) Extension for Enhancing Data-driven Disease Detection in Newborns (ED3N), the NBS data platform, that will address these analytic and post-analytic challenges and promote sharing of molecular, biochemical, and clinical information amongst NBS partners. The information shared will help NSMBB and newborn screening partners be better equipped to assess disease risk and will help harmonize approaches for disease detection in newborns. Given the rarity of newborn screening diseases, it is imperative that data be collected and analyzed at a national level in order to glean useful insights and to analyze trends. The NSMBB is best suited to oversee this work given its role in providing technical assistance to NBS programs nationally…

NEW – ICH - E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 07/21/2025 **Comment period ends 09/19/2025**

SUMMARY:

…The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide general principles on the conduct of clinical trials that include pregnant and breastfeeding women to inform evidence-based decisions on safe and effective use of medicinal products by these populations.

The draft guidance includes approaches to generating data that support informed decision-making on the safety, dosing, and efficacy of medicinal products during pregnancy and breastfeeding. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials, while reducing burden and harm on these participants.

Background

…The recommendations found in this draft guidance are the product of the Efficacy Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines strategies and considerations for developing and implementing clinical studies that include pregnant or breastfeeding women. This draft guidance includes approaches to plan, collect data, evaluate outcomes, and monitor safety of pregnant and breastfeeding women participating in clinical trials safely and ethically. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials. The draft guidance also emphasizes reduction of burden on pregnant and breastfeeding women participating in these trials.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication.

NEW - Solicitation of Nominations for Appointment to the Advisory Council for the Elimination of Tuberculosis

A Notice by the Centers for Disease Control and Prevention on 07/11/2025. **Nominations must be received no later than September 30, 2025**

SUMMARY:

In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations

for membership on the Advisory Council for the Elimination of Tuberculosis (ACET). ACET consists of 10 experts including the Chair in fields associated with public health, epidemiology, immunology, infectious disease, pulmonary disease, pediatrics, tuberculosis, microbiology, and preventive health care delivery.
SUPPLEMENTARY INFORMATION:
The Advisory Council for the Elimination of Tuberculosis (ACET) provides advice and recommendations regarding the elimination of tuberculosis (TB) to the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Health, HHS; and the Director, Centers for Disease Control and Prevention (CDC). ACET (a) makes recommendations on policies, strategies, objectives, and priorities; (b) addresses development and application of new technologies; (c) provides guidance and review of CDC's TB prevention research portfolio and program priorities; and (d) reviews the extent to which progress has been made toward eliminating TB.

Draft guideline on the quality aspects of mRNA vaccines

Draft: consultation open **Consultation dates: 31/03/2025 to 30/09/2025**
Reference Number: EMA/CHMP/BWP/82416/2025
Summary:
This guideline addresses the quality aspects of mRNA vaccines. It addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control of mRNA vaccines, as well as the definition of starting materials, active substance and finished product for mRNA vaccines. Additional regulatory considerations are provided for changes in existing mRNA vaccine strains, bivalent and multivalent vaccines, self-amplifying mRNA vaccines, other delivery systems and use of platform technology/prior knowledge. The scope of this guideline is applicable to mRNA vaccines against infectious diseases. Other mRNA-based medicinal products are out of scope of this guideline, although relevant parts of this guideline may be applicable to those. It is not intended to address specific requirements for mRNA vaccines to be used in clinical trials, however the scientific principles described may also be applicable during pharmaceutical development.

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product

EMA Draft: consultation open **Consultation dates: 16/04/2025 to 31/10/2025**
Reference Number: EMA/CVMP/ERA/75412/2023
Summary:
This concept paper provides background to the intended development of a scientific approach for use in the evaluation of the risk for humans exposed to antimicrobial resistance via the environment, originating from use of veterinary medicinal products. It is intended to provide advice on how relevant dossier requirements outlined in Regulation (EU) 2019/6 (e.g., Article 8(2)) may be fulfilled.

NEW - Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making

EMA - Draft: consultation open **Consultation dates: 25/07/2025 to 31/10/2025**
Reference Number: EMA/CHMP/225255/2025
Summary:
Randomised controlled trials are the gold standard of evidence to support causal conclusions on the benefits and risks of medicines in regulatory decision making along the lifecycle. However, in some situations, causal conclusions may be derived from a setting where the investigational medicinal product data was collected under a clinical trial protocol while the control arm was not a randomized arm in that

same protocol. In these situations, a so-called external control, may be derived from data from other clinical trials, real-world data (RWD) or other data sources.

A reflection paper shall be drafted to describe the main challenges with external controls and further discuss the circumstances and methodological constraints under which the use of external controls could be considered appropriate for generating pivotal or supportive evidence, either for efficacy, safety or other relevant regulatory decision-making objectives.

ISO/AWI 14155 - Biological and clinical evaluation of medical devices

ISO/TC 194 Stage 20.00

Due: Ongoing at level of national standards bodies

Scope

Standardization of the approach to biological and clinical evaluation of medical and dental materials and devices together with standardization of biological test methods applicable to those materials and devices as well as good clinical practice principles to clinical investigations in humans of those devices.

Abstract

This document addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.

For post-market clinical investigations, the principles set forth in this document are intended to be followed as far as relevant, considering the nature of the clinical investigation (see Annex I).

This document specifies general requirements intended to

— protect the rights, safety and well-being of human subjects,
— ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
— define the responsibilities of the sponsor and principal investigator, and
— assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

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Human Rights

NEW - Call for Input – Position Paper on the Human Rights Impacts of Using Artificial Intelligence in Countering Terrorism

Issued by Special Rapporteur on counter-terrorism and human rights **Deadline: 18 August 2025**

Purpose:

To inform the Special Rapporteur's 2025 "Position Paper on the Human Rights Impacts of Using Artificial Intelligence in Countering Terrorism", including guidance on good practices.

Background

The integration of technologies encompassing artificial intelligence (AI) into operations to counter terrorism potentially represents a paradigmatic shift in contemporary security governance. As a significant and genuinely disruptive innovation, the exploitation of the capabilities of AI, even in the pursuit of legitimate security objectives, may render novel, acute or even entirely unanticipated challenges to the protection and promotion of human rights and for the rule of law. Today, governments are increasingly deploying AI in areas such as surveillance, predictive law enforcement, biometric identification, behavioural profiling, and automated threat detection and scenario planning. This

potential for AI to deliver both enhanced security competences, but also to significantly enlarge the scope for potential human rights violations, renders these issues a critical area for examination.

The pace at which AI is developing, coupled with its capacity for processing vast datasets at unprecedented scale, is already amplifying existing concerns that surveillance overreach represents an acute threat to the enjoyment of human rights. Moreover, an evaluation of how advances in AI-driven counter-terrorism capabilities—including in areas as diverse as data fusion, automated filtering and threat detection, counter radicalization and operational resource allocation—is necessary to discern whether they disproportionately impact vulnerable groups and marginalized communities. Further concerns also arise where AI-enabled systems may evidence algorithmic bias, opacity in decision-making, and deficits in both transparency and accountability ...

NEW - Call for written submissions on the draft guidelines on addressing multiple and intersectional forms of discrimination against women and girls with disabilities

UN - Treaty bodies **Deadline: 15 September 2025**

Purpose:

To further guide states parties and other duty bearers to address the implementation gaps and to collect a repository of good practices in addressing multiple and intersecting forms of discrimination against women and girls with disabilities.

Background

Since it was established, in 2009, the Committee has considered more than 150 reports submitted by States parties to the Convention. The Committee has identified the following gaps in the implementation of article 5 (non-discrimination), article 6 (women with disabilities) and article 16 (protection against violence, exploitation and abuse):

- Limited understanding and awareness about the concept of multiple and intersecting forms of discrimination against women and girls with disabilities.
- Anti-discrimination legislative and policy frameworks do not often recognize multiple and intersecting forms of discrimination against women and girls with disabilities.
- Disaggregated data is not collected regularly and systematically, limiting the possibilities for influencing action-oriented policies and strategies on addressing multiple and intersecting forms of discrimination.
- Limited identification of instances of multiple and intersecting forms of discrimination against women, limited availability of redress mechanisms and broad impunity of perpetrators.
- Limited understanding about gender-based violence and disability-based violence as forms of discrimination.

NEW - Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"

Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

Purpose:

To inform the drafting of EMRTD's thematic study on "Artificial Intelligence (AI), Cultural Rights, and the Right to Development." This study is part of the Mechanism's broader mandate to examine emerging global challenges that impact the realization of the right to development.

Background

The Human Rights Council, in its resolution 45/6, welcomed the first report (A/HRC/45/29) of the Expert Mechanism on the Right to Development, and requested it to implement the recommendations contained therein, including the preparation and submission to the Council thematic studies in the discharge of Expert Mechanism's mandate. At its 8th session, the EMRTD outlined the thematic studies that it planned to submit to the Human Rights Council during the 2024-2026 cycle, including a study addressing artificial intelligence, regulation and the right to development.

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Genetics/Genomics

No new calls identified.

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Emerging/Disruptive Technologies

No new calls identified.

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Biodiversity/Environment/Climate/Disaster Mitigation

NEW - Request for Public Comment: National Plan for Arctic Research

by the National Science Foundation on 07/21/2025. **Written responses are due by October 15, 2025.**

SUMMARY:

The Interagency Arctic Research Policy Committee (IARPC), chaired by the National Science Foundation, seeks public input from all interested parties on national needs regarding the Arctic and the research necessary to address those needs. The public input provided in response to this RFI will inform the update of the five-year National Arctic Research Plan for 2027-2031.

Seeking Public Input

As called for in the ARPA, IARPC seeks input from any interested individuals and organizations to ensure that the research interests and needs of all are addressed appropriately in the updated Plan. IARPC is committed to an open engagement process throughout the development of the Plan.

In particular, IARPC is interested in feedback in response to the following questions regarding what updates should be made to the Arctic Research Plan 2027-2031:

1. What are the critical issues and needs where federally-funded science, engineering, and technology research should provide knowledge to promote sound decision-making at all levels related to the Arctic?
2. What are examples of research questions that address these issues.

Human Studies Review Board (HSRB) Meetings for 2025

A Notice by the Environmental Protection Agency on 11/29/2024

Public Participation

The HSRB encourages the public's input. You may participate in these meetings via oral comments or written comments.

SUMMARY:

The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of its public meetings of the Human Studies Review Board (HSRB) for 2025. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects' research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Four three-day virtual public meetings will be held on:

1. January 29-31, 2025;
2. April 2-4, 2025;
3. July 22-24, 2025;
4. October 14-16, 2025.

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Science Integrity/Evidence to Policy/ Open Science

:: Call for Public Consultation

The Right to Participate in and Benefit from Science – *Call for Feedback*

ISC / International Science Council
21 November 2024

The ISC's interpretation of 'the right to participate in and benefit from science' provides a clear framework for understanding the right to science, emphasizing its application in research, policy, and global access to scientific knowledge. It clarifies the obligations, opportunities, and responsibilities in ensuring universal access to science, fostering global dialogue to shape a more inclusive and sustainable future.

ISC – The Right to Participate in and Benefit from Science

The International Science Council believes that there is a universal human right to participate in and enjoy the benefits of science, and that it is a responsibility of governments to create and sustain the opportunities of citizens to use this right.

A right to participate in science

This right presumes a right to basic scientific literacy, and a right to scientific education, training and mentoring.

I. A right to participate in generating diverse forms of knowledge through the study of natural and social phenomena using theoretical, observational, experimental, and analytical approaches to introduce and test existing and new models, conjectures, hypotheses and ideas unconstrained by political agendas or belief systems.
II. A right to challenge established knowledge about natural and social phenomena when generating and communicating new models, conjectures, hypotheses and ideas, and the uses to which this knowledge has been or may be put.
III. A right to collaborate and engage in scientific dialogue and research across national, political, regional and other boundaries.
IV. A right to communicate both positive and negative findings.
V. A right to form professional societies and associations.
VI. A right to advocate for the responsible use of science.

A right to enjoy the benefits of science

I. A right not to be excluded from the benefits of science on the basis of unjust discrimination based on race, nationality, ethnic origin, language, sex, gender identity, reproductive ability, sexual orientation, age, disability, political opinion, or religious belief.
II. A right to equitably access information, data, and other resources necessary to enhance scientific knowledge, teaching and research.
III. A right to apply scientific knowledge for technological developments for the good of humanity and the planet.

:: Resources, Events

No new resources identified.

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Heritage/Cultural Assets

:: Call for Public Consultation

No new calls identified.

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Governance, Trade, Global Finance

:: Call for Public Consultation

No new calls identified.

:: Resources, Events

Information Report: Oversight Observations To Inform Department of State Realignment of U.S. Agency for International Development Functions

AUD-GEER-25-19 May 2025

Summary of Review

On March 28, 2025, the Department of State (Department) notified Congress of its intent to realign selected U.S. Agency for International Development (USAID) functions within the Department. The information report, which was developed as part of an Office of Inspector General (OIG) evaluation of the Department's initial realignment efforts, is designed to highlight OIG observations from its prior work, and the work of other federal oversight bodies, that could help the Department more efficiently and effectively realign USAID functions.

OIG concluded that the Department is undertaking a significant and multi-faceted integration of select USAID functions concurrent with a reorganization of domestic offices and bureaus in the Department. Individually, these tasks would be daunting. But together, these initiatives could be overwhelming to the organization without a well thought out plan of action. During its work, OIG observed that senior Department leaders involved in the realignment are aware of the challenges that they face. Additionally, OIG recognizes that the Department's Assistance Transition Working Group has established workstreams related to many of the topics discussed in the OIG report.

Although OIG did not make formal recommendations in the report, OIG encourages the Department to consider how issues identified by OIG and other oversight organizations might impact the success of the Department's efforts. Considering previously identified issues will allow the Department to implement best practices.

Although the focus of the information report is the realignment of USAID functions within the Department, the information may also be applicable to the Department's efforts to implement its internal reorganization.

Strategic Foresight Toolkit for Resilient Public Policy

A Comprehensive Foresight Methodology to Support Sustainable and Future-Ready Public Policy

OECD Report 21 January 2025

PDF: https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/01/foresight-toolkit-for-resilient-public-policy_9ad1cd60/bcdd9304-en.pdf

Abstract

By exploring 25 evidence-based potential disruptions across environmental, technological, economic, social, and geopolitical domains, the Strategic Foresight Toolkit for Resilient Public Policy helps anticipate challenges and opportunities that could reshape the policy landscape between 2030 and 2050. These disruptions are not predictions, but hypothetical future developments identified through extensive research, expert consultations, and workshops.

The Strategic Foresight Toolkit features a five-step foresight process, guiding users to challenge assumptions, create scenarios, stress-test strategies, and develop actionable plans. It includes facilitation guides and case studies to support effective implementation. Each disruption is accompanied by insights on emerging trends, potential future impacts, and both immediate and long-term policy options to ensure resilience and preparedness.

Designed for policymakers, public administrators, and foresight practitioners, this publication is designed to promote holistic, strategic and evidence-informed decision-making. It aims to support countries and organisations in using strategic foresight to design and prepare robust and adaptable public policies for a range of possible futures. With its practical methodology and forward-looking approach, the Strategic Foresight Toolkit is a vital resource for building sustainable, resilient, and effective public policies.

Public Integrity Indicators

OECD - Datasetdata-explorer.oecd.org
14 February 2025
Interactive Graphic: OECD Public Integrity Indicators

Overview

Following the adoption of the OECD Council Recommendation on Public Integrity in 2017, the Public Governance Committee (PGC), via its Working Party of Senior Public Integrity Officials (SPIO) subsidiary body, developed the OECD Public Integrity Indicators (PII) to measure the implementation of the OECD Council Recommendation on Public Integrity. The PII are complementary to the OECD Public Integrity Handbook and the OECD Public Integrity Maturity Models.

The OECD Public Integrity Indicators (PII) measure the quality and effectiveness of public integrity systems across six areas:

- Quality of Strategic Framework (data available)
- Accountability of Public Policymaking – covering conflict-of-interest, political finance, lobbying, public information, open government, and public consultation (data available)
- Effectiveness of Internal Control and Risk Management (data available)
- Integrity and Effectiveness of the Justice System (to be launched in 2024)
- Strength of External Oversight and Control (to be launched in 2024)
- Meritocracy of the Public Sector (to be launched in 2025)

The OECD Public Integrity Indicators provide cross-country comparative data to help policy makers and practitioners strengthen the resilience of public integrity systems towards corruption risks and prevent the mismanagement and waste of public funds. The PIIs measure the strength of standard regulatory safeguards (*de jure*) and implementation of these safeguards in practice (*de facto*). The OECD Secretariat collaborates closely with national administrations to obtain primary data collected directly from a wide range of actors across the executive, legislative and judiciary branches.

Regulatory governance

OECD Datasetdata-explorer.oecd.org
14 February 2025

Overview

The OECD Dataset on the Indicators of Regulatory Policy and Governance (iREG) presents up-to-date evidence of regulatory policy and governance practices of the OECD member countries, the European Union as well as the five EU Member States that are not OECD member countries. It focuses on practices as described in the 2012 Recommendation of the Council on Regulatory Policy and Governance (Recommendation), the first international instrument to address regulatory policy as a whole-of-government activity. The data covers in detail three principles of the 2012 Recommendation: stakeholder engagement, regulatory impact assessment (RIA) and *ex post* evaluation. For each of these areas, the indicators present information in four categories:

1. Systematic adoption records formal requirements and how often these requirements are conducted in practice;
2. Methodology gathers information on the methods used in each area, e.g. the type of impacts assessed or how frequently different forms of consultation are used;
3. Oversight and quality control records the role of oversight bodies and publically available evaluations; and
4. Transparency records information that relates to the principles of open government, e.g. whether government decisions are made publically available.

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Selected Calls for Public Consultation of Global Interest but Limited to State Parties or Other Designated Entities

No new calls identified.

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Selected Final, Published Guidances, Frameworks, Regulations, Meetings Employing Calls for Public Consultation

NEW - Supporting Fairness and Originality in NIH Research Applications

NIH Notice Number: NOT-OD-25-132
Final Guidance Release Date: July 17, 2025
Purpose

NIH is providing guidance to researchers on the appropriate usage of artificial intelligence (AI) to maintain the fairness and originality of NIH's research application process. NIH is also instituting a new policy limiting the number of applications that NIH will consider per Principal Investigator per calendar year.

Background

NIH has recently observed instances of Principal Investigators submitting large numbers of applications, some of which may have been generated with AI tools. While AI may be a helpful tool in reducing the burden of preparing applications, the rapid submission of large numbers of research applications from a single Principal Investigator may unfairly strain NIH's application review processes. The percentage of applications from Principal Investigators submitting an average of more than six applications per year is relatively low; however, there is evidence that the use of AI tools has enabled Principal Investigators to submit more than 40 distinct applications in a single application submission round.

NIH will continue to employ the latest technology in detection of AI-generated content to identify AI generated applications, but it is imperative that all NIH research applications are consistent with the NIH Grants Policy Statement (GPS) Section 2.1.2's expectation that institutions and affiliated research teams propose original ideas for funding. AI tools may be appropriate to assist in application preparation for limited aspects or in specific circumstances, but researchers should be aware that using AI comes with its own risks. AI use may result in plagiarism, fabricated citations, or other kinds of research misconduct. As a reminder, NIH oversees research misconduct investigations and acts on non-compliance (see GPS Section 4.1.27).

Policy

NIH will not consider applications that are either substantially developed by AI, or contain sections substantially developed by AI, to be original ideas of applicants. If the detection of AI is identified post award, NIH may refer the matter to the Office of Research Integrity to determine whether there is research misconduct while simultaneously taking enforcement actions including but not limited to disallowing costs, withholding future awards, wholly or in part suspending the grant, and possible termination.

NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year. This policy applies to all activity codes except T activity codes and R13 Conference Grant Applications. Based on recent data, this limit will affect a relatively small number of Principal Investigators while enabling the NIH to maintain consistently high-quality grant application review and appropriately steward taxpayer dollars.

NEW - 2024 NIH Public Access Policy

Notice Number: NOT-OD-25-047
Release Date: December 17, 2024
Issued by Office of The Director, National Institutes of Health (OD)

Purpose

Background

Increasing access to publications resulting from National Institutes of Health (NIH) funding offers many benefits to the scientific community and the public who funded the underlying research. When patients, families, and healthcare providers can access published findings resulting from NIH funding, they are able to better understand and address the most critical health concerns facing their communities. It also allows researchers, students, and members of the public in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to follow the latest advances more closely. Importantly, these goals reflect NIH's commitment to the responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research, an essential component of fostering trust in research. NIH is issuing this updated Public Access Policy to further advance these goals by accelerating free public access to research results.

NIH has a long history of providing access to research products resulting from its funded research. The NIH Public Access Policy in effect since 2008, requires that NIH-supported researchers submit their final peer-reviewed manuscripts to the National Library of Medicine's PubMed Central® digital archive of full-text biomedical and life sciences journal literature upon acceptance for publication, to be made freely available to the public after an allowable embargo period of not more than 12 months after the official date of publication. The 2008 Policy implements Public Law 110-161, which was made a legislative mandate for FY 2009 and beyond by Public Law 111-8. The Policy has, to date, resulted in more than 1.5 million articles reporting on NIH-supported research being freely available to the public in PubMed Central.

On August 25, 2022, the White House Office of Science and Technology Policy (OSTP) released updated policy guidance (2022 OSTP Memorandum) to all federal agencies with research and development expenditures to further promote equity, advance trust in science, and continue to advance American scientific leadership. Following the 2022 OSTP Memorandum, NIH released its Plan to Enhance Public Access to the Results of NIH-Supported Research in February 2023 (hereafter, the NIH Public Access Plan) and its Draft Public Access Policy in June 2024. The NIH Public Access Plan and Draft Public Access Policy provided a roadmap for how NIH proposed to accelerate access to scholarly publications, consistent with the government-wide expectation to remove the 12-month embargo period before public availability. This 2024 NIH Public Access Policy is consistent with the expectations of the 2022 OSTP Memorandum regarding scholarly publications and is informed by all public feedback, including comments submitted in response to the NIH Draft Public Access Policy.

Overview of Public Comments

A total of 144 written public comments were received in response to the NIH Draft Public Access Policy. Written comments were received from a variety of constituencies, including those from universities, professional associations, nonprofit organizations, and publishers. In addition, NIH hosted a public listening session on the NIH Public Access Plan in April 2023,and in November 2023, NIH sponsored a workshop held by the National Academies of Sciences, Engineering and Medicine (NASEM) on Enhancing Public Access to the Results of Research Supported by the U.S. Department of Health and Human Services (HHS). Commenters and attendees included academic institutional officials, researchers at various career stages, patient advocates, publishers, and officials from professional associations, many of whom also publish academic journals. NIH reviewed and considered all feedback to inform and develop the 2024 NIH Public Access Policy. Upon the listed effective date, the new Policy replaces the 2008 NIH Public Access Policy…

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Selected Peer-reviewed Journal Literature/Gray Lit Integrating Public Consultation

OECD Guidelines for Citizen Participation Processes

Paris: OECD Publishing. 2022
https://www.oecd-ilibrary.org/governance/oecd-guidelines-for-citizen-participation-processes_f765caf6-en [Accessed 10 Nov 2023]

The *OECD Guidelines for Citizen Participation Processes* are intended for any public official or public institution interested in carrying out a citizen participation process. The guidelines describe ten steps for designing, planning, implementing and evaluating a citizen participation process, and discuss eight different methods for involving citizens: information and data, open meetings, public consultations, open innovation, citizen science, civic monitoring, participatory budgeting and representative deliberative processes. The guidelines are illustrated with examples as well as practical guidance built on evidence gathered by the OECD. Finally, nine guiding principles are presented to help ensure the quality of these processes.

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Selected Resources for Public Consultation Notices, Calls, Processes

UNHCHR UN High Commissioner for Human Rights – Calls for Input

https://www.ohchr.org/en/calls-for-input-listing

UNESCO - Consultations
https://www.unesco.org/en/search?category=UNESCO&text=consultation&category=UNESCO&sort_by=unesco_date#toggle-facets

WHO – Public Consultations
https://www.who.int/home/search?indexCatalogue=genericsearchindex1&searchQuery=public%20consultation&wordsMode=AnyWord

OECD - Consultations and calls for contributions
https://www.oecd.org/about/civil-society/consultations-and-calls-for-contributions.htm

IFAD Public Consultations
https://webapps.ifad.org/members/executive-board-public-consultation

European Medicines Agency's (EMA) open public consultations
https://www.ema.europa.eu/en/news-events/open-consultations

U.S. Federal Register – "Public Comment" or RFI
https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=09%2F13%2F2023&conditions%5Bterm%5D=%22public+comment%22+or+RFI#

U.S. HHS – Open Requests for Comments
https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html

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