ge²p² global

governance, ethics, evidence, policy, practice

human rights action :: humanitarian response :: health ::
education :: heritage stewardship :: sustainable development

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

14 January 2025 - Issue 27

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, or member states and 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.

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

Call for inputs for the comprehensive report, incl. new developments, in ensuring access to medicines, vaccines and other health products
Issued by OHCHR
Deadline 20 January 2025

Draft of Data Quality Framework for EU medicines regulation application to real-world data
EMA **Consultation dates: 29/11/2024 to 31/01/2025**

Human Studies Review Board (HSRB) Meetings for 2025
A Notice by the Environmental Protection Agency on 11/29/2024
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.

Call for inputs: Reflections on the "super election" year and its global impact on the protection of the rights to freedom of peaceful assembly and association and for ensuring effective and inclusive public participation
UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of peaceful assembly and of association
Deadline: 31 January 2025

Call for Inputs: Study on "Indigenous Peoples right to data, including data collection and disaggregation"
UNHCHR - Issued by Expert Mechanism on the Rights of Indigenous Peoples
Deadline: 31 January 2025

Call for inputs for a research by the Working Group on Enforced or Involuntary Disappearances on the use of universal criminal jurisdiction in cases of enforced disappearance
UNHCHR Issued by Working Group on Disappearances **Deadline: 03 February 2025**

Proposed Data Collection Submitted for Public Comment and Recommendations – Marburg virus
A Notice by the Centers for Disease Control and Prevention on 12/03/2024
Comment period ends 02/03/2025.

Expedited Program for Serious Conditions-Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 12/06/2024 **Comment period ends 02/04/2025**

Patient-Focused Drug Development: Workshop To Discuss Methodologic and Other Challenges Related to Patient Experience Data; Public Workshop; Request for Comments
A Notice by the Food and Drug Administration on 11/14/2024 **Comment period ends 02/11/2025.**

NEW - **Notice of Request for Information (RFI) on Frontiers in AI for Science, Security, and Technology (FASST) Initiative; Reopening of Comment Period**
U.S. Energy Department on 12/13/2024. **Comments to be submitted until February 17, 2025**

NEW - **Request for Public Comment: NIH Plan to Increase Findability and Transparency of Research Results Through the Use of Metadata and Persistent Identifiers (PIDs)**
NIH (NOT-OD-25-050) **Response date: February 21, 2025**

ICC Office of the Prosecutor launches second public consultation on a policy initiative to advance accountability for environmental crimes under the Rome Statute – Call for Comments
International Criminal Court – Office of the Prosecutor 18 December 2024 **Comments by 21 Feb 2025.**

Frequently Asked Questions-Developing Potential Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 11/19/2024 **Comment period ends 02/18/2025**

NEW - **E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

NEW - **M15 General Principles for Model-Informed Drug Development; International Council for Harmonisation; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 2/28/2025**

NEW - **Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

Call for inputs: The role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.
UNHCHR - Issued by Working Group on the use of mercenaries **Deadline: 28 February 2025**

NEW - **Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft Guidance for Industry; Availability**
FDA - Food and Drug Administration on 01/07/2025 **Comment period that ends 03/10/2025.**

NEW - **Considerations for Including Tissue Biopsies in Clinical Trials**

FDA January 7, 2025 - Draft Guidance – **Comment period that ends 03/10/2025**

Call for Input – 2025 Thematic Reports to the UN Human Rights Council and UN General Assembly – Coercive Measures
UNHCHR - Issued by Special Rapporteur on unilateral coercive measures **Deadline: 14 March 2025**

NEW - **Request for Comments on AISI's Draft Document: Managing Misuse Risk for Dual-Use Foundation Models**
National Institute of Standards and Technology, 14 Jan 2025 **Comments before March 15, 2025**

NEW - **The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible additional modalities of the multilateral mechanism**
CBD Convention on Biological Diversity, Notification 2024-114 2024-12-10 **Comments no later than 21 March 2025**

NEW - **The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible**
CBD Convention on Biological Diversity, Notification 2024-115 2024-12-10 **Comments no later than 4 April 2025**

NEW - **Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products Draft Guidance for Industry and Other Interested Parties**
FDA, January 2025 **Submit Comments by 04/07/2025**

NEW - **Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act**
A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 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.

Global consultation on the Copenhagen Framework on Citizen Data

Collaborative on Citizen Data - 2 February 2024

Year-long global consultation spanning over 2024.

The Collaborative will aim to finalize the "Copenhagen Framework on Citizen Data" based on this global consultation and other country piloting studies, and submit to the 56th session of the United Nations Statistical Commission in March 2025.

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

Biomedical Research/Regulation/Governance

Call for inputs for the comprehensive report, incl. new developments, in ensuring access to medicines, vaccines and other health products

Issued by OHCHR

Deadline 20 January 2025

Purpose:

Consultation as per HRC resolution 50/13 and also to inform the comprehensive report on access to medicines, vaccines and other health products

Background

Human Rights Council resolution 50/13, requested the Office of the High Commissioner to prepare a comprehensive report, incl. new developments, in ensuring access to medicines, vaccines and other health products and to present it to the Council at its fifty-ninth session in June 2025.

Draft of Data Quality Framework for EU medicines regulation application to real-world data

EMA **Consultation dates: 29/11/2024 to 31/01/2025**

Summary:

This document describes the Real-World Data (RWD) specific recommendations as derived from the Data Quality Framework (DQF) for EU Medicines regulation endorsed by the Committee for Medicinal Products for Human Use (CHMP). It sets out the principles, concepts, and definitions as intended to be applied widely across datasets used in medicine regulatory use cases. It also provides examples and in-depth clarifications on the developed framework elements for characterising, assessing, and assuring data quality in the regulatory context. Comments should be provided using this EUSurvey form

Proposed Data Collection Submitted for Public Comment and Recommendations – Marburg virus

A Notice by the Centers for Disease Control and Prevention on 12/03/2024
Comment period ends 02/03/2025.
SUMMARY:
The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled 2024 Marburg Traveler Symptom Monitoring and Feedback. This information collection is designed to conduct post-arrival symptom monitoring of travelers who have been in the outbreak area and evaluate the impact of rerouting and public health entry screening on travelers…

Expedited Program for Serious Conditions - Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/06/2024 **Comment period ends 02/04/2025**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics." Accelerated approval is one of FDA's expedited programs intended to facilitate and expedite development and review of certain drugs and biological products for serious or life-threatening conditions. This guidance provides information on FDA's policies and procedures for the accelerated approval program, including discussions of which products may be candidates for accelerated approval, the standards for granting accelerated approval, and the procedures for withdrawing accelerated approval. When finalized, this draft guidance will replace the accelerated approval-related content in the final guidance for industry entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" issued on May 30, 2014 (the 2014 final guidance). Additional programs to expedite product development are covered in the 2014 final guidance as well as other guidances.

Patient-Focused Drug Development: Workshop To Discuss Methodologic and Other Challenges Related to Patient Experience Data; Public Workshop; Request for Comments

A Notice by the Food and Drug Administration on 11/14/2024 **Comment period ends 02/11/2025.**
SUMMARY:
The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public workshop entitled "Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data." The purpose of the public workshop is to discuss methodological challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.

Frequently Asked Questions-Developing Potential Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 11/19/2024 **Comment period ends 02/18/2025**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Frequently asked Questions—Developing Potential Cellular and Gene Therapy Products." The draft guidance document provides industry with answers to frequently asked questions (FAQs) and commonly faced issues that arise during the development of cellular and gene therapy (CGT) products.

The FAQs represent common questions directed to the Agency and span multiple disciplines, including regulatory review; chemistry, manufacturing, and controls (CMC); pharmacology/toxicology; clinical; and clinical pharmacology.
PDF: https://www.fda.gov/media/183631/download
SUPPLEMENTARY INFORMATION:
I. Background
…The guidance was created as part of FDA's response to the PDUFA VII commitment to increase efficiency and to support development of CGT products by providing a repository of common questions posed to the Office of Therapeutic Products by sponsors and other key stakeholders. The Agency compiled FAQs received from a variety of sources, including FDA interactions with sponsors in development programs.
The guidance covers relevant, current, and timely topics related to the development of CGT products, which may be updated to include additional FAQs as appropriate. Sponsors are encouraged to visit the Cellular and Gene Therapy Guidances web page on the FDA website for a full list of finalized as well as draft guidances relevant to the development of CGT products…

NEW - Request for Public Comment: NIH Plan to Increase Findability and Transparency of Research Results Through the Use of Metadata and Persistent Identifiers (PIDs)

NIH (NOT-OD-25-050) **Response date: February 21, 2025**
Purpose
NIH seeks public input on the NIH Plan to Increase Findability and Transparency of Research Results Through the Use of Metadata and Persistent Identifiers (NIH Metadata and Persistent Identifiers Plan). The NIH Metadata and Persistent Identifiers Plan outlines actions to create and make publicly available information uniquely identifying research outputs and information related to who conducted the research, where the research was conducted, when the research was conducted, and how the research was funded. This plan is an update to section IV, "Mechanisms to Increase Findability and Transparency of Research" of the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research and addresses expectations from the fourth section of the 2022 White House Office of Science and Technology (OSTP) Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.
Request for Information
NIH seeks information regarding the NIH Metadata and Persistent Identifiers Plan from all interested individuals and communities, including, but not limited to, investigators, research institutions, libraries, scholarly publishers, scientific societies, healthcare providers, patients, students, educators, research participants, and other members of the public.

NEW - E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E6(R3) Good Clinical Practice: Annex 2." 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 the second annex to "E6(R3) Good Clinical Practice" published June of 2023. This annex provides additional considerations for the application of good clinical practices to a variety of trial designs and data sources. Specifically, this draft guidance discusses trials with decentralized and pragmatic elements and real-world data sources. This draft guidance highlights the importance of quality by design and focusing efforts and resources on critical aspects of the trials

that might impact the safety of participants and the reliability of results. The draft guidance is intended to encourage innovation in trial design and provides flexible, modern, and clear good clinical practices for conducting trials, while avoiding unnecessary complexities.

NEW - M15 General Principles for Model-Informed Drug Development; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 2/28/2025**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "M15 General Principles for Model-Informed Drug Development." 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 discusses the multidisciplinary principles of model-informed drug development (MIDD). This includes recommendations on MIDD planning, model evaluation, and evidence documentation. The draft guidance also includes a harmonized framework for assessing evidence derived from MIDD. The draft guidance is intended to facilitate multidisciplinary understanding, appropriate use, and harmonized assessment of MIDD and its associated evidence.

NEW - Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices." This draft guidance provides recommendations to assist sponsors, clinical investigators, and institutional review boards (IRBs) in defining, identifying, and reporting protocol deviations. The guidance provides definitions for protocol deviations and important protocol deviations. In addition, the guidance provides a recommended classification system for sponsors to report protocol deviations to FDA in clinical study reports for drugs, biological products, and devices; for investigators to report protocol deviations to sponsors and to IRBs; and for IRBs to evaluate protocol deviations.

NEW - Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft Guidance for Industry; Availability

FDA - Food and Drug Administration on 01/07/2025 **Comment period that ends 03/10/2025.**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway." For drugs granted accelerated approval, sponsors conduct confirmatory studies that must be completed post approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This draft guidance describes FDA's interpretation of the term "underway" and discusses policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to accelerated approval.

NEW - Considerations for Including Tissue Biopsies in Clinical Trials

FDA January 7, 2025 - Draft Guidance – **Comment period that ends 03/10/2025**

SUPPLEMENTARY INFORMATION:

I. Background

FDA and OHRP are announcing the availability of a draft guidance for industry, clinical investigators, institutions, and IRBs entitled "Considerations for Including Tissue Biopsies in Clinical Trials." This guidance is intended to assist industry, clinical investigators, institutions, and IRBs in understanding considerations for tissue biopsies that may be conducted in adults and in children as part of clinical trials that evaluate investigational medical products and/or that are conducted or supported by HHS. For the purposes of this guidance, a biopsy is a procedure that involves acquisition of tissue from a trial participant as part of a clinical trial protocol.

Although biopsies inherently include varying degrees of risk, in some circumstances, biopsied tissue(s) may be the only way to obtain information that is necessary to answer questions of interest in a clinical trial, such as to determine trial eligibility or to evaluate treatment effects. In general, when biopsies are to be conducted for evaluation of non-key secondary endpoint(s) and/or exploratory endpoints or for unspecified future research uses, they should not be required and instead should be optional…

NEW - Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products Draft Guidance for Industry and Other Interested Parties

FDA, January 2025 **Submit Comments by 04/07/2025**
Docket Number: FDA-2024-D-4689
PDF: https://www.fda.gov/media/184830/download
Issued by:

Center for Veterinary Medicine
Office of Inspections and Investigations
Oncology Center of Excellence
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research
Office of the Commissioner, Office of the Chief Medical Officer, Office of Combination Products

Purpose

This guidance provides recommendations to sponsors and other interested parties on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU).

NEW - Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act

A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 2025.**

SUMMARY:

The Food and Drug Administration's (FDA, Agency, or we) Office of Pediatric Therapeutics, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research are announcing a public meeting entitled "Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act." The purpose of the public meeting is to seek input from interested parties, including patient/parent/caregiver groups, consumer groups, regulated industry, academia, and others. This input will enable FDA to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatric drug and biologic development and labeling, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The public meeting will be held on May 15, 2025, from 9 a.m. to 4:30 p.m. Eastern Time. Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket.

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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Genetics/Genomics

NEW - The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible additional modalities of the multilateral mechanism

CBD Convention on Biological Diversity, Notification 2024-114 2024-12-10 **Comments no later than 21 March 2025**

As noted in notification 2024-113, at its sixteenth meeting, by decision 16/2, the Conference of the Parties adopted the modalities for operationalizing the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including the global fund, which are set out in the annex to the decision, and decided that the global fund will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources. By the same decision, Parties also set out some intersessional work.

While the Conference of the Parties, in decision 16/2, adopted the modalities of the multilateral mechanism, it also decided (in paragraph 3 of the decision) to explore possible additional modalities, including, in the context of paragraph 7 of decision 15/9 and the annex to decision 16/2, to take products and services into account.

Parties, other Governments, indigenous peoples and local communities, and relevant organizations are invited to submit their views on this issue as soon as possible …

NEW - **The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible**

CBD Convention on Biological Diversity, Notification 2024-115 2024-12-10 **Comments no later than 4 April 2025**

As noted in notification 2024-113, at its sixteenth meeting, by decision 16/2, the Conference of the Parties adopted the modalities for operationalizing the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including the global fund, which are set out in the annex to the decision, and decided that the global fund will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources. By the same decision, Parties also set out some intersessional work.

In particular, the Conference of the Parties, in decision 16/2, decided to explore possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties.

Parties, other Governments, indigenous peoples and local communities, and relevant organizations are invited to submit their views on this issue as soon as possible…

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Emerging/Disruptive Technologies

NEW - **Notice of Request for Information (RFI) on Frontiers in AI for Science, Security, and Technology (FASST) Initiative; Reopening of Comment Period**

A Notice by the U.S. Energy Department on 12/13/2024 **Comments no later than February 17, 2025.**

SUMMARY:

On September 12, 2024, the U.S. Department of Energy ("DOE") published a request for information ("RFI") to inform how DOE and its 17 national laboratories can provide a national AI capability in the public interest. The RFI provided an opportunity for submitting written comments and public input by November 11, 2024. Due to overwhelming public interest, DOE is reopening the public comment period to allow comments to be submitted until February 17, 2025.

SUPPLEMENTARY INFORMATION:

On September 12, 2024, DOE published a RFI seeking public input to inform our ongoing work and DOE's proposed Frontiers in AI for Science, Security, and Technology (FASST) initiative.[1] FASST is DOE's proposed initiative to build the world's most powerful, integrated scientific AI systems for scientific discovery, applied energy deployment, and national security applications. Due to overwhelming public interest and several requests for extension, DOE is reopening the comment period until February 17, 2025. Note that the Government may use or disclose any information that is not appropriately marked as confidential, proprietary, or privileged information that is exempt from public disclosure, regardless of source. DOE may engage in post-response conversations with interested parties.

NEW - **Request for Comments on AISI's Draft Document: Managing Misuse Risk for Dual-Use Foundation Models**

National Institute of Standards and Technology, 14 Jan 2025 **Comments before March 15, 2025**

AGENCY: U.S. Artificial Intelligence Safety Institute (AISI), National Institute of Standards and Technology (NIST), U.S. Department of Commerce.

[Docket Number: 250108-0011] XRIN: 0693-XC137

SUMMARY:
The U.S. Artificial Intelligence Safety Institute (AISI), housed within NIST at the Department of Commerce, requests comments on an updated draft document responsive to Section 4.1(a)(ii) and Section 4.1(a)(ii)(A) of Executive Order 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (AI) issued on October 30, 2023 (E.O. 14110). This draft document, NIST AI 800-1, Managing Misuse Risk for Dual-Use Foundation Models, can be found at https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.800-1.ipd2.pdf. This document is an update to an initial public draft and includes changes based on the previous round of public comment, as well as two new appendices that apply these guidelines to (1) chemical and biological misuse risk and (2) cyber misuse risk.

NEW - Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

A Notice by the Food and Drug Administration on 01/07/2025 **Comment period ends 04/07/2025**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations." This draft guidance, when finalized, will provide recommendations regarding the contents of marketing submissions for devices that include artificial intelligence (AI)-enabled device software functions including documentation and information that will support FDA's evaluation of safety and effectiveness. To support the development of appropriate documentation for FDA's assessment of the device, this draft guidance also proposes recommendations for the design, development, and implementation of AI-enabled devices that sponsors may wish to consider using throughout the total product lifecycle (TPLC). This draft guidance is not final nor is it for implementation at this time.

Catalogue of Tools & Metrics for Trustworthy AI

OECD AI Policy Observatory
Ongoing
These tools and metrics are designed to help AI actors develop and use trustworthy AI systems and applications that respect human rights and are fair, transparent, explainable, robust, secure and safe…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.

Call for Technological, Legal, and Social Solutions to Counter Disinformation on Social Media

NASEM
No submission deadline date identified.
The National Academies of Sciences, Engineering, and Medicine's *Committee on Evolving Technological, Legal and Social Solutions to Counter Disinformation on Social Media* is seeking creative ideas to detect, measure, and mitigate disinformation on social media and related platforms. If the Committee finds your submission particularly compelling, it will be discussed (or you could be asked to present and discuss it) at an April 10-11, 2024 National Academies' virtual workshop, which will feature two days of interactive brainstorming to foster new research and collaborations and build implementable solutions for a whole-of-society approach to mitigating disinformation and its detrimental effects.

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

No submission deadline date identified.

The International Science Council has invited feedback on its discussion paper, which provides the outline of an initial framework to inform the multiple global and national discussions taking place related to AI.

PDF: https://council.science/wp-content/uploads/2023/10/A-framework-for-evaluating-rapidly-developing-digital-and-related-technologies_ISC_2023.pdf

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Biodiversity/Environment/Climate/Disaster Mitigation

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.

ICC Office of the Prosecutor launches second public consultation on a policy initiative to advance accountability for environmental crimes under the Rome Statute – Call for Comments

International Criminal Court – Office of the Prosecutor Statement 18 December 2024 **Comments by 21 February 2025.**

The current draft of the environmental crimes policy is available to download HERE.

The Prosecutor of the International Criminal Court, Mr. Karim A.A. Khan KC, is pleased to invite a second round of comments on a new policy initiative by the Office of the Prosecutor to advance accountability for environmental crimes under the Rome Statute.

The initiative will culminate in a new comprehensive policy paper that aims to guide the Office in ensuring a systematic approach to dealing with environmental crimes from the outset of the preliminary examination process to investigations and prosecutions.

The new policy will seek to further promote accountability, transparency, and predictability in the work of the Office in this crucial area. Developed on the basis of the Rome Statute, other regulatory instruments of the Court, applicable treaties, and the principles and rules of international law, the policy

will also draw on the jurisprudence of the Court and other relevant jurisdictions in seeking to clarify the existing framework within which the Office may take action in this area. Emphasis will also be placed on how the Office can engage with and support national authorities to ensure a collective, effective approach to environmental crimes within the framework of the Rome Statute.

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Science/Evidence to Policy/ Open Science

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.

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Governance

Call for inputs: Reflections on the "super election" year and its global impact on the protection of the rights to freedom of peaceful assembly and association and for ensuring effective and inclusive public participation

UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of peaceful assembly and of association
Deadline: 31 January 2025
Background
Reflecting on the apparent trends of crackdown on the rights to freedom of peaceful assembly and association, the UN Special Rapporteur Ms. Gina Romero will examine the global impact and emerging challenges on the exercise and protection of these rights in the context of the "super election" year (2024). The report will analyse the threats to exercising these rights in the context of general elections (in the run up to, during, and post-election periods) for the period 2023-2025, through highlighting emblematic case studies from different contexts, while examining the contextual environment and the role of different actors contributing to these threats. The Special Rapporteur will further seek to explore the enabling role played by the rights to freedom of peaceful assembly and association towards ensuring inclusive, participatory and more credible elections, and for the realisation of the right to participate in public affairs of everyone without discrimination, without discrimination, including on grounds of religion, ethnicity, sexual orientation and gender identity.

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Human Rights

Call for Inputs: Study on "Indigenous Peoples right to data, including data collection and disaggregation"

UNHCHR - Issued by Expert Mechanism on the Rights of Indigenous Peoples
Deadline: 31 January 2025
Purpose:
In accordance with Human Rights Council resolution 33/25, the purpose of the annual study is to analyze the status of the rights of Indigenous Peoples worldwide in the achievement of the ends of the Declaration, focusing on one or more interrelated articles of the Declaration.
Background
Pursuant to Human Rights Council resolution 33/25, during its seventeenth session in 2024, the Expert Mechanism confirmed its decision to prepare a study on "Indigenous Peoples right to data, including data collection and disaggregation".
The studies and advice of the Expert Mechanism provide a better understanding of the provisions of the Declaration and propose concrete actions that States, Indigenous Peoples, civil society, national human rights institutions, intergovernmental, international and regional organizations, businesses, and others can take in order to further its implementation.
Objectives
The purpose of this study is to highlight the significant value of data to Indigenous Peoples while analyzing the right to data, including through collection and disaggregation. It draws on the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), in accordance with Articles 3, 4, 5,

15(i), 18, 19, 20(i), 23, 31, 32, 33, 38, and 42, which reaffirm the rights of Indigenous Peoples to control data regarding their peoples, lands, and resources. Indigenous data governance enacts those rights through mechanisms grounded in Indigenous rights and interests that promote Indigenous values and equity, while providing a framework for addressing deeper historical issues associated with barriers for underrepresented communities and knowledge systems. Data on indigenous women requires specific attention.

Call for inputs for a research by the Working Group on Enforced or Involuntary Disappearances on the use of universal criminal jurisdiction in cases of enforced disappearance

UNHCHR Issued by Working Group on Disappearances **Deadline: 03 February 2025**

Purpose:

To inform the research on the use of universal criminal jurisdiction in cases of enforced disappearance

Background:

…Pursuant to the notion of 'universal criminal jurisdiction', any State can apply its criminal law with respect to crimes under international law, including enforced disappearance, even when they are committed abroad, and neither the victim nor the perpetrator is a national of the State concerned. In its 'conditional' interpretation, the presence of the accused on the territory of the State is a condition for the existence and exercise of universal jurisdiction. In the 'absolute' interpretation, jurisdiction can be established even if the accused is not present in the forum State and in the absence of any other link between the alleged offender and the forum State.

Objectives:

The research, whose results are meant to be presented in September 2025, aims at assessing the use of universal criminal jurisdiction in cases of enforced disappearance, analysing the applicable conceptual and legal framework (and, where applicable, the loopholes therein), existing challenges, lessons learned, and good practices…

Call for inputs: The role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.

UNHCHR - Issued by Working Group on the use of mercenaries **Deadline: 28 February 2025**

Purpose:

To inform the Working Group's report to be presented to the 60th Session of the Human Rights Council in September 2025.

Background:

…The Working Group intends to dedicate its next thematic report on the role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.

Control and/or access over natural resources drive most armed conflicts in the contemporary period. To date, numerous actors including State entities, transnational companies, especially those engaged in the exploitation of natural resources, may encourage the presence of mercenaries, mercenary related actors or PMSCs, either to protect their infrastructures, repress local civil populations or support the armed group that best serves the company's interests.

Mercenaries, mercenary related actors and PMSCs play complex roles in exploitation and/or protection of natural resources. As the scope of actors is diverse, their connections to the resources and the focus of activities vary as well. For instance, mercenaries, mercenary-related actors and PMSCs are mainly involved in exploitation and transfer of the natural resources, as a means of payment for their services. They are hired by companies or governments to protect installations, support armed groups, or

suppress local resistance. Their operations often involve other actors, state and non-state, who would help them in transformation of the raw minerals and materials, transportation and distribution…

Call for Input – 2025 Thematic Reports to the UN Human Rights Council and UN General Assembly – Coercive Measures

UNHCHR - Issued by Special Rapporteur on unilateral coercive measures **Deadline: 14 March 2025**

Purpose:

To inform the Special Rapporteur's upcoming thematic reports on "The Impact of Unilateral Coercive Measures on Economic, Labor, and Social Rights", to be presented at the 60th session of the UN Human Rights Council in September 2025 and on "The Impact of Unilateral Coercive Measures on the Right to Education and Other Academic Rights" to be presented at the 80th session of the UN General Assembly in October 2025.

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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 Employing Calls for Public Consultation

NEW - **Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons**

Final Rule by the Justice Department on 01/08/2025 Published Document: 2024-31486 (90 FR 1636) (117 pages)

SUMMARY:

The Department of Justice is issuing a final rule to implement Executive Order 14117 of February 28, 2024 (Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern), by prohibiting and restricting certain data transactions with certain countries or persons.

NEW - **Final Scientific Integrity Policy of the U.S. Department of Health and Human Services**

A Notice by the Health and Human Services Department on 12/30/2024

Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, HHS.

ACTION: Notice of final policy. The effective date of the Policy is October 16, 2024.

SUMMARY:

The Department of Health and Human Services (HHS) is publishing its Scientific Integrity Policy to increase access to and raise awareness of the Policy.

SUPPLEMENTARY INFORMATION:

Scientific integrity plays a vital role in the mission of HHS. Ensuring integrity in science throughout the Department allows HHS to foster and produce high-quality science, communicate effectively with the

public, and base critical policy decisions on trustworthy and rigorous scientific findings. HHS has adopted a Department-wide scientific integrity policy to further strengthen scientific integrity and evidence-based policymaking throughout the Department.

The Scientific Integrity Policy of the U.S. Department of Health and Human Services (Policy) was approved on September 16, 2024. The finalized Policy was announced to the HHS community and posted on the HHS scientific integrity website, at https://www.hhs.gov/programs/research/scientificintegrity/index.html, on September 30, 2024.

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the U.S. Department of Health and Human Services (HHS). This policy aims to ensure the integrity of all aspects of HHS scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Core Values That Support Scientific Integrity at HHS

The success of HHS's mission to enhance the health and well-being of all Americans depends on the development and use of accurate, complete, and timely scientific and technical information. Scientific integrity requires that such information be developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment. HHS agencies work to maximize the quality, accuracy, objectivity, utility, and timeliness of the scientific and technological information they produce, use, and disseminate. In turn, this information enables HHS to employ innovative approaches to effectively address the many public health and human services challenges that our work targets. These efforts allow accurate, complete, and timely scientific and technical information to improve the design, delivery, and impact of HHS policies and programs, and support equity, justice, and trust. Responsibility for upholding scientific integrity lies with the entire scientific ecosystem, including all HHS employees, its contractors and grantees, and those engaged in science and scientific activities outside HHS.

Final Scientific Integrity Policy of the National Institutes of Health

A Notice by the National Institutes of Health on 10/21/2024

ACTION: Notice of final policy. DATES: This Final Policy is effective on December 30, 2024.

SUMMARY:

The National Institutes of Health (NIH) is issuing this Final NIH Scientific Integrity Policy to promote a continuing culture of scientific integrity at NIH. This Policy codifies NIH's long-standing expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms.

SUPPLEMENTARY INFORMATION:

Background

Scientific integrity aims to make sure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence (https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf). In support of our mission, NIH has always sought to incorporate robust scientific integrity principles and practices throughout every level of its scientific enterprise. In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous

and that our workforce maintains the highest standards of integrity. In supporting the NIH mission, all NIH researchers and staff are expected to:

- Foster an organizational culture of scientific integrity,
- Protect the integrity of the research process,
- Communicate science with integrity, and
- Safeguard scientific integrity.

NEW - E11A Pediatric Extrapolation; International Council for Harmonisation; Guidance for Industry; Availability

Final Guidance – A Notice by the Food and Drug Administration on 12/30/2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "E11A Pediatric Extrapolation." The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance provides a comprehensive and systematic approach to pediatric extrapolation during drug development. Notably, the guidance discusses approaches to safety extrapolation and defining extrapolation as a continuum. The guidance also includes approaches to study designs and statistical methodologies, including modeling and simulation, for developing and implementing pediatric extrapolation. The guidance is intended to provide approaches that can increase the efficiency of pediatric drug development and accelerate the availability of safe and effective drugs approved for use in children. The guidance replaces the draft guidance "E11A Pediatric Exploration" issued on August 29, 2022.

Food and Drug Administration Report and Plan on Best Practices for Guidance; Availability

A Notice by the Food and Drug Administration on 12/03/2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Food and Drug Administration Report and Plan on Best Practices for Guidance" (Report and Plan). FDA is publishing this Report and Plan in response to the Consolidated Appropriations Act, 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices.

Background

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for FDA staff, industry, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (21 CFR 10.115(b)). Specifically, FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues, such as: the design, manufacturing, and testing of regulated products; content and evaluation of applications for product approvals; and inspection and enforcement policies…

LOC Biosecurity laws : Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russian Federation, Saudi Arabia, South Africa, South Korea, Turkey, United Kingdom, United States

Library of Congress, September 2024

LL File No. 2024-023388 LRA-D-PUB-002658 (corrected 10/2024)

Introduction

This report explores various approaches to defining "biosafety" and "biosecurity" in legislation and regulations in the following jurisdictions: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, the United Kingdom, and the United States. These jurisdictions have been chosen because they are members of the Group of Twenty (G20).

Individual country reports are included after the comparative analysis. These reports discuss definitions of "biosafety," "biosecurity," and related terms, when available, as well as information about legislation, regulations, guidelines, and secondary sources discussing subjects related to those topics. Additionally, most G20 nations are signatories to multinational treaties addressing matters of biosecurity and biosafety. The table below at page 5 identifies G20 nations and indicates whether each has signed key multilateral treaties connected to biosafety: the Biological Weapons Convention, the Convention on Biological Diversity, the Cartegena Protocol, and the Nagoya Protocol. As indicated in the table, all G20 nations have either ratified or acceded to the Biological Weapons Convention. All listed nations, apart from the United States, participate in the Convention on Biological Diversity. The Cartagena Protocol and the Nagoya Protocol supplement the Convention on Biological Diversity; most G20 countries have ratified one or both of these treaties…

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 10/18/2024
ACTION: Notice of availability.
You may 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 "Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry." This guidance is intended to provide a framework for considering whether and what type of long-term neurologic, sensory, and developmental evaluations could be useful in supporting a determination of safety of an FDA-regulated "medical product" (*i.e.,* drug, biological product, or medical device) for use in neonates. Although short-term safety evaluations may be appropriate for adults or other populations, such evaluations may not identify important adverse events in the neonatal population, as medical treatment during the neonatal period coincides with a time of critical growth and physiologic development and latent effects may not be evident until later in life following early-life exposures. Consideration of the potential for long-term neurologic, sensory, and developmental effects in the neonatal population early in a development program is important for establishing safety of a medical product intended for use in neonates. This guidance finalizes the draft guidance of the same title issued on February 13, 2023.

UNESCO - First Draft of the Recommendation on the Ethics of Neurotechnology

UNESCO - SHS/BIO/AHEG-Neuro/2024/2 :: 26 pages
PDF: https://unesdoc.unesco.org/ark:/48223/pf0000391444
Summary
The first draft of the Recommendation on the Ethics of Neurotechnology was prepared by the 24 international experts of the Ad Hoc Expert Group, who convened in Paris in April and August 2024. This text has been submitted to Member States for their comments and observations, opening the intergovernmental phase that will take place until 2025.

Guidance for best practices for clinical trials – WHO

25 September 2024

Overview [excerpted from WHO announcement and guidance executive summary]

The World Health Organization (WHO) today released guidance to improve the design, conduct and oversight of clinical trials in countries of all income levels. This guidance aims to support stronger country-led research and development (R&D) ecosystems to advance health science so that new, safe and effective health interventions can be made more accessible and affordable globally for people everywhere, faster.

The guidance was developed in response to World Health Assembly resolution WHA 75.8 in an extensive and inclusive process, involving nearly 3000 stakeholders from various sectors across 48 countries. The guidance covers trials for any health intervention, including, but not limited to pharmaceutical medicines; vaccines; diagnostics; nutritional measures; cognitive, behavioural and psychological interventions; preventive care; digital and public health approaches; and traditional or herbal measures.

This document aims to complement other guidance in order to support implementation of universal ethical and scientific standards in the context of clinical trials, with a focus on under-represented populations; it does not represent a legal standard and does not supersede any existing guidance. In particular, this guidance shares many common concepts and principles with guidance produced by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *(5)*, especially the ICH E8(R1) General Considerations for Clinical Studies guideline *(6)*, *(*the draft ICH E6(R3) Good Clinical Practice guideline *(7)*, and the ICH E9 statistical principles guideline *(8)* and its associated addendum *(9)*. In addition, it shares attributes with two further recent guidance documents that were highlighted through WHO's public consultation process in 2022: those of the Council for International Organizations of Medical Sciences (CIOMS) on clinical research in resource-limited settings *(10)* and the Good Clinical Trials Collaborative (GCTC) *(11)*.

Both the CIOMS and GCTC guidance have served as sources, with adaptations as needed, for this document. Additional sources highlighted through the consultation include the World Medical Association's (WMA) Declaration of Helsinki *(12)* on medical research involving human subjects, the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks *(13)* and CIOMS' International Ethical Guidelines on Health-related Research involving Humans (2016) *(14)*.

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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

European Medicines Agency's (EMA) open public consultations
https://www.ema.europ a.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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