***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

**08 May 2024 - Issue 17**

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

In the context of this mission, GE2P2 Global is refining a monitoring approach to identify public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education, 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 such 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.

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## *Digest content is organized into three sections:*



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

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

**IESBA Launches Public Consultation on New Ethical Benchmark for Sustainability Reporting and Assurance**
International Ethics Standards Board for Accountants (IESBA) Jan 29, 2024
**Comments on the Using the Work of an External Expert ED are requested by April 30, 2024, and on the Sustainability ED by May 10, 2024.**

***NEW -*** **GPEI: Switch lessons learned project – draft for public consultation [OPV Cessation]**
**Contributions, ideas or suggestions by Friday 10 May 2024**

**Call for input: Existing and Emerging Sexually Exploitative Practices against Children in the Digital Environment**
UN Special Rapporteur on the sale and sexual exploitation of children
**Deadline: 15 May 2024**

***NEW -*** **Interagency Coordinating Committee on the Validation of Alternative Methods; Notice of Public Meeting; Request for Public Input**
National Institutes of Health on 05/08/2024
***DATES:***
Meeting: May 20, 2024, 1 p.m. to approximately 5 p.m. EDT; Tuesday, May 21, 2024, 9 a.m. to approximately 4:30 p.m. EDT.
Registration for Onsite Meeting: Deadline is May 17, 2024.
Registration for Webcast: Deadline is May 21, 2024.
**Registration for Oral Statements: Deadline is May 15, 2024**

**Methods and Leading Practices for Advancing Public Participation and Community Engagement With the Federal Government**
A Notice by the Management and Budget Office on 03/20/2024
**Responses to this RFI should be received by May 17, 2024.**

***NEW -*** **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expedited Programs for Serious Conditions-Drugs and Biologics**
A Notice by the Food and Drug Administration on 04/18/2024
**Written comments (including recommendations) on the collection of information by May 20, 2024.**

***NEW -*** **Call for Inputs on "Best Practices in the Contribution of Development to the Promotion and Protection of Human Rights in the context of recovery from the COVID-19 pandemic"**
Issued by OHCHR
**Deadline 30 May 2024**

**Draft guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials - Second version**

**EMA** Draft: consultation open First published: 25/03/2024 Last updated: 25/03/2024
**Consultation dates:** 25/03/2024 to **31/05/2024**

***NEW -*** **Call for inputs: Access to information on climate change and human rights**
Issued by UN Special Rapporteur on climate change
**Deadline: 02 June 2024**

**Data Integrity for In Vivo Bioavailability and Bioequivalence Studies; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 04/03/2024
**Comments on the draft guidance by June 3, 2024**

***NEW -*** **PUBLIC CONSULTATION OF THE DRAFT SCAR [Severe Cutaneous Adverse Reactions] REPORT**
CIOMS – COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES
**Deadline: Friday 7 June 2024**

**Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 03/21/2024
**Submit comments by June 18, 2024**

***NEW -*** **Agency Information Collection Revision 60-Day Public Comment Request**
A Notice by the Health and Human Services Department on 04/25/2024
**Comments on the ICR must be received on or before June 24, 2024.**

***NEW -*** **NIH and FDA Seek Comment on Draft Glossary of Clinical Research Terms Related to Innovative Clinical Trial Design**
NIH, FDA [USA] 06 May 2024 **Comments due June 24, 2024.**

***NEW -*** **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry**
A Notice by the Food and Drug Administration on 05/06/2024
**Written comments on the draft guidance by July 5, 2024**

***NEW -*** **Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing**
A Notice by the U>S> Patent and Trademark Office on 04/30/2024
**Written comments must be received on or before July 29, 2024**

***NEW -*** **Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 05/07/2024
**Written comments on the draft guidance by August 5, 2024**

***NEW* - Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence**

EMA Reference Number: EMA/CHMP/150527/2024

**Consultation dates: 03/05/2024 to 31/08/2024**

**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

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

NASEM, USA.

**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**

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

### *NEW* - GPEI: Switch lessons learned project – draft for public consultation [OPV Cessation]

**Contributions, ideas or suggestions by Friday 10 May 2024**

*The switch*

In April 2016 a switch was implemented from trivalent OPV to bivalent OPV in routine immunization programmes. Following WPV1 and WPV3 eradication, use of all OPV in routine immunizations will be stopped.

The Strategy Committee of the Global Polio Eradication Initiative (GPEI) in 2023 commissioned an external evaluation of the 2016 global withdrawal of Sabin poliovirus 2 (OPV2) and switch from trivalent oral polio vaccine (tOPV) to bivalent OPV (bOPV). The evaluation aims to generate critical lessons learnt from the OPV2 withdrawal, in order to guide the direction of the GPEI (including future OPV withdrawal efforts) and secure a lasting world free of all polioviruses. The evaluation was designed and implemented by a team of experts, informed by a wide range of stakeholder consultations across all levels, and presented last month to the Strategic Advisory Group of Experts on immunization (SAGE).

To ensure the evaluation is as relevant and useful as possible, and to provide the public health community and other interested stakeholders the opportunity to contribute, the lessons learned team is soliciting thoughts, comments and suggestions on the public draft for consultation. Interested stakeholders and members of the public health community are invited to share any, to: Switch@who.int.

Final publication of the evaluation on www.polioeradication.org is anticipated shortly after this public consultation.

Related Documents:

:: Public draft for consultation

:: Annex A

:: Annex B

### Methods and Leading Practices for Advancing Public Participation and Community Engagement With the Federal Government

A Notice by the Management and Budget Office on 03/20/2024

**Responses to this RFI should be received by May 17, 2024.**

*SUMMARY:*

The Federal Government is committed to making it easier for the American people to engage with their Government, and to harnessing their knowledge, needs, and lived experiences to improve how Government works for them and with them. Federal laws and Executive directives require agencies to frequently consult with the public to inform regulations, policies, program and service design, and other actions. However, these consultation efforts may be perceived as inaccessible, convoluted, or disconnected from the interests and priorities of impacted stakeholders. According to the 2023 Partnership for Public Service (PPS) survey on trust in government, only about 1 in 5 Americans believe that the Federal Government "listens to the public" or "is transparent."

The Office of Management and Budget (OMB), in partnership with Federal agencies and the public, is working to develop a government-wide framework, common guidelines, and leading practices for public participation and community engagement (PPCE or "participation and engagement"). This framework

will enable agencies to more frequently, effectively, broadly, and meaningfully involve the public, including underserved communities, in government decision-making.

Through this Request for Information (RFI), OMB seeks input on the experiences of individuals and organizations, including from underserved communities, with informing Federal Government decision-making and participating in engagement activities with government agencies; examples of leading practices in this space; and other recommendations on available methods, approaches, and tools that could assist in the effort to develop and implement a Federal framework for participation and engagement. OMB welcomes input from a wide and diverse array of stakeholders in the public, private, advocacy, not-for-profit, and philanthropic sectors, including State, local, Tribal, and territorial governments. OMB will review and consider the usability and applicability of responses to this RFI as OMB develops a Federal framework for PPCE and supports.

## *NEW -* Interagency Coordinating Committee on the Validation of Alternative Methods; Notice of Public Meeting; Request for Public Input

National Institutes of Health on 05/08/2024

***DATES:***

Meeting: May 20, 2024, 1 p.m. to approximately 5 p.m. EDT; Tuesday, May 21, 2024, 9 a.m. to approximately 4:30 p.m. EDT.

Registration for Onsite Meeting: Deadline is May 17, 2024.

Registration for Webcast: Deadline is May 21, 2024.

**Registration for Oral Statements: Deadline is May 15, 2024**

*SUMMARY:*

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) will hold a public forum to share information and facilitate direct communication of ideas and suggestions from stakeholders. Interested persons may attend in person or view the meeting remotely by webcast. Time will be set aside for questions and public statements on the topics discussed. Registration is requested for attending in person and required for viewing the webcast. Registration is also required for presenting oral statements, whether in person or online. Information about the meeting and registration are available at https://ntp.niehs.nih.gov/go/iccvamforum-2024.

*Background*

ICCVAM, a congressionally mandated committee, coordinates the development and validation of alternative testing strategies that protect human health and the environment while replacing, reducing, or refining animal use.

ICCVAM's goals include promotion of national and international partnerships between governmental and nongovernmental groups, including academia, industry, advocacy groups, and other key stakeholders. To foster these partnerships ICCVAM initiated annual public forums in 2014 to share information and facilitate direct communication of ideas and suggestions from stakeholders (79 FR 25136).

This year's meeting will be held on May 20 and 21, 2024. NICEATM and ICCVAM members will give presentations on current activities related to the development and validation of alternative test methods and approaches...

## *NEW -* Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expedited Programs for Serious Conditions-Drugs and Biologics

A Notice by the Food and Drug Administration on 04/18/2024

**Written comments (including recommendations) on the collection of information by May 20, 2024.**
*SUMMARY:*
The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.
… This information collection supports regulations governing FDA expedited programs for serious conditions. These provisions are set forth in 21 CFR part 312, subpart E and are intended to speed the availability of new therapies to patients with serious conditions, especially when there are no satisfactory alternative therapies, while preserving appropriate standards for safety and effectiveness. The regulations call for earlier attention to drugs that have promise in treating such conditions, including early consultation with FDA for sponsors of such products. Respondents to the information collection are sponsors of drug or biologic product applications submitted to FDA.

## Draft guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials - Second version

EMA Draft: consultation open First published: 25/03/2024 Last updated: 25/03/2024
**Consultation dates: 25/03/2024 to 31/05/2024**
Reference Number: EMA/CAT/123573/2024Summary:
This guideline provides guidance on the structure and data requirements for a clinical trial application for exploratory and confirmatory trials with advanced therapy investigational medicinal products.
Note: This is a short, second public consultation for the guideline. All comments received during the first public consultation have been reviewed and incorporated, where possible, in this guideline. Stakeholders can consult the 'Overview of comments' document: comments submitted on the first version of this guideline should not be resubmitted.

## Data Integrity for In Vivo Bioavailability and Bioequivalence Studies; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 04/03/2024
**Comments on the draft guidance by June 3, 2024**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Data Integrity for In Vivo Bioavailability and Bioequivalence Studies." The purpose of this guidance is to provide recommendations to applicants and testing site management on achieving and maintaining data integrity for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and the bioanalytical portion of clinical pharmacologic studies supporting Center for Drug Evaluation and Research-regulated biologic license applications (BLAs) as well as amendments and supplements to these applications. In addition, the recommendations in this guidance apply to the bioanalytical portion of nonclinical studies. FDA also encourages applicants and testing sites to consider these recommendations when conducting other studies, including in vitro and pharmacology and toxicology studies.
…This guidance provides recommendations to achieve and maintain data integrity with respect to (1) applicants, (2) testing site management, and (3) implementation and management of a quality management system. This guidance does not include a comprehensive list of all best practices that applicants and testing sites should use to achieve and maintain data integrity. It is each applicant's responsibility to achieve and maintain data integrity for their studies, which includes identifying and

implementing the most effective and efficient risk-based controls. FDA encourages applicants and testing site management to review FDA regulations and all applicable guidance for industry to understand FDA's current thinking on a topic.

## *NEW* - PUBLIC CONSULTATION OF THE DRAFT SCAR [Severe Cutaneous Adverse Reactions] REPORT

CIOMS – COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES
**Deadline: Friday 7 June 2024**
*Working Group objectives*
To establish a balanced, efficient, global perspective on SCAR detection, susceptibility factors, severity, outcome and probability through causality assessment tools, monitoring and management during the drug development and post-marketing phases.
:: Draft report
:: Comment form

## Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 03/21/2024
**Submit comments by June 18, 2024**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products." FDA is issuing this draft guidance as part of a series of guidance documents under its Real-World Evidence (RWE) Program and to satisfy, in part, a mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision-making. The draft guidance provides recommendations to sponsors who are considering submitting a non-interventional study, also referred to as an observational study, to FDA to contribute to a demonstration of substantial evidence of effectiveness and/or evidence of safety of a drug. This draft guidance was developed in response to stakeholders' growing interest in the potential use of non-interventional studies to contribute to a demonstration of the effectiveness or safety of a drug.

## *NEW* - Agency Information Collection Revision 60-Day Public Comment Request

A Notice by the Health and Human Services Department on 04/25/2024
**Comments on the ICR must be received on or before June 24, 2024.**
*Abstract:*
The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting reinstatement of the OMB No. 0990-0477, Incident Report Form, with two new information elements on the Incident Report form: IORG # for Reviewing IRB; and, Revising research policies and procedures as a corrective action plan category, if it applies. **The purpose of the Incident Report form is to facilitate organizations or institutions prompt reporting of specific human subject protection incidents to OHRP,** in a simplified standardized format, as required by HHS protection of human subjects regulations at 45 CFR part 46.
*SUMMARY:*

In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

### *NEW* - NIH and FDA Seek Comment on Draft Glossary of Clinical Research Terms Related to Innovative Clinical Trial Design

NIH, FDA [USA] 06 May 2024 **Comments due June 24, 2024.**

The National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) have released for public comment a draft glossary of clinical research terms related to innovative clinical trial design, including studies using real world data to generate real world evidence. The draft glossary is intended to facilitate communication within the clinical research community by helping establish a common vocabulary to characterize clinical research more uniformly.

For additional context on this NIH-FDA collaboration, please see the latest Under the Poliscope blog by Dr. Lyric Jorgenson. Questions about this draft glossary can be sent to SciencePolicy@od.nih.gov

### *NEW* - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry

A Notice by the Food and Drug Administration on 05/06/2024

**Written comments on the draft guidance by July 5, 2024**

*SUMMARY:*

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #290 (VICH GL61) entitled "Pharmaceutical Development." This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance describes the suggested contents for the Pharmaceutical Development section, which provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management to the development of a product and its manufacturing process.

### *NEW* - Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 05/07/2024

**Written comments on the draft guidance by August 5, 2024**

*SUMMARY:*

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "REMS Logic Model: A Framework to Link Program Design With Assessment." The guidance describes FDA's risk evaluation and mitigation strategy (REMS) logic model. The REMS logic model is a framework that FDA recommends, which provides applicants with a systematic, structured approach to the design, implementation, and evaluation of a REMS. The aim of applying the REMS logic model is to develop clear goals, objectives, and strategies that align with the intended outcomes and to help applicants of new drug applications (NDAs), biologics license applications (BLAs), and abbreviated new drug applications (ANDAs) incorporate REMS assessment planning into the design of a REMS. The principles in this guidance apply to designing a REMS, developing a REMS assessment, and modifying a REMS.

### *NEW* - Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence

EMA Reference Number: EMA/CHMP/150527/2024

**Consultation dates: 03/05/2024 to 31/08/2024**

*Summary*

The European Medicines Agency has published a draft reflection paper focusing on methodological principles that are considered critical for the conduct and assessment of non-interventional studies using real-world data (RWD) and used for regulatory decision-making throughout a medicine's lifecycle.

A large variety of real-world data can be used in non-interventional studies. A critical aspect when assessing the suitability of RWD for a regulatory purpose is the data quality, including data reliability and relevance, and, depending on the research question, the extent to which RWD truly reflects routine clinical practice.

### 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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## Emerging/Disruptive Technologies

### *NEW* - Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing

A Notice by the U>S> Patent and Trademark Office on 04/30/2024

**Written comments must be received on or before July 29, 2024**

*SUMMARY:*

The United States Patent and Trademark Office (USPTO or Office) seeks public comments regarding the impact of the proliferation of artificial intelligence (AI) on prior art, the knowledge of a person having

ordinary skill in the art (PHOSITA), and determinations of patentability made in view of the foregoing. The increasing power and deployment of AI has the potential to provide tremendous societal and economic benefits and foster a new wave of innovation and creativity while also posing novel challenges and opportunities for intellectual property (IP) policy. Through the AI and Emerging Technologies Partnership (AI/ET Partnership), the USPTO has been actively engaging with the innovation community and AI experts on IP policy in view of AI. To build on these efforts, the USPTO is requesting written public comments on how the proliferation of AI could affect certain evaluations made by the Office, including what qualifies as prior art, the assessment of the level of skill of a PHOSITA, and determinations of patentability made in view of these evaluations. The USPTO expects that the responses received will help the Office evaluate the need for further guidance on these matters, aid in the development of any such guidance, and help inform the USPTO's work in the courts and in providing technical advice to Congress.

## 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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## Environment/Climate/Disaster Mitigation

### IESBA Launches Public Consultation on New Ethical Benchmark for Sustainability Reporting and Assurance

International Ethics Standards Board for Accountants (IESBA) Jan 29, 2024

**Comments on the Using the Work of an External Expert ED are requested by April 30, 2024, and on the Sustainability ED by May 10, 2024.**

- Two new exposure drafts set forth the first comprehensive suite of global standards on ethical considerations in sustainability reporting and assurance
- Proposed standards aim to foster greater trust in all publicly communicated sustainability information through the application of a consistent ethical approach
- The IESBA welcomes comments from the entire sustainability community – professional accountants, all other sustainability practitioners, regulators, and investors

The International Ethics Standards Board for Accountants ("IESBA") today announced the launch of two Exposure Drafts (EDs):

:: International Ethics Standards for Sustainability Assurance ED, which includes revisions to the existing Code related to sustainability reporting;

:: Using the Work of an External Expert ED

The Exposure Draft on International Ethics Standards for Sustainability Assurance (including International Independence Standards) (IESSA) and ethics standards for sustainability reporting proposes a clear framework of expected behaviors and ethics provisions for use by all sustainability assurance practitioners regardless of their professional backgrounds, as well as professional accountants involved in sustainability reporting. The goal of these standards is to mitigate greenwashing and elevate the quality of sustainability information, thereby fostering greater public and institutional trust in sustainability reporting and assurance.

The Exposure Draft on Using the Work of an External Expert proposes an ethical framework to guide professional accountants or sustainability assurance practitioners, as applicable, in evaluating whether an external expert has the necessary competence, capabilities and objectivity in order to use that expert's work for the intended purposes. The proposals also include provisions to aid in applying the Code's conceptual framework when using the work of an external expert.

These proposed ethics (including independence) standards are especially relevant in a context where sustainability information is increasingly important for capital markets, consumers, corporations and their employees, governments and society at large, and when new providers outside of the accounting profession play a prominent role in sustainability assurance.

*About the IESBA*

The International Ethics Standards Board for Accountants® (IESBA®) is an independent global standard-setting board. The IESBA's mission is to serve the public interest by setting high-quality, international ethics (including independence) standards as a cornerstone to ethical behavior in business and organizations, and to public trust in financial and non-financial information that is fundamental to the proper functioning and sustainability of organizations, financial markets and economies worldwide.

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## Human Rights

## Call for input: Existing and Emerging Sexually Exploitative Practices against Children in the Digital Environment

UN Special Rapporteur on the sale and sexual exploitation of children

**Deadline: 15 May 2024**

*Purpose:*

To inform the Special Rapporteur's forthcoming report to the 79th session of the UN General Assembly in October 2024.

*Overview*

The Special Rapporteur invites all interested parties including States, international and regional organizations, UN agencies, national human rights institutions, law enforcement, civil society and hotline organizations, academics, lawyers, policy experts, child protection officers, educators, communities and children and other relevant stakeholders to share information, documents, statements, analysis and input for this thematic report.

For the purpose of the report, she aims to explore the existing and emerging sexually exploitative practices and abuse against children in the digital environment, as well as the role Artificial Intelligence plays in facilitating the sexual exploitation and sexual abuse of children and how states and other child protection stakeholders can respond to this problem.

There is an urgent need for States and all stakeholders to scale up efforts and strengthen collaboration through a core global alliance and multilateral instrument dedicated exclusively to eradicating child sexual abuse and exploitation online, addressing the complexity of these phenomena and taking a step forward to protecting children in the digital space and in the field of Artificial Intelligence.

The Special Rapporteur also invites comments and views on how all stakeholders including the technology industry can be mobilised to factor in the best interest of the child in the design of technologies.

## *NEW* - Call for Inputs on "Best Practices in the Contribution of Development to the Promotion and Protection of Human Rights in the context of recovery from the COVID-19 pandemic"

Issued by OHCHR

**Deadline 30 May 2024**

*Purpose*

To invite all interested stakeholders to provide written input for the thematic report to be submitted to the fifty-seventh session of the UN Human Rights Council.

*Background*

In its resolution 53/28[1], the Human Rights Council invited the Office of High Commissioner on Human Rights (OHCHR) to "prepare a compilation of best practices in the contribution of development to the promotion and protection of all human rights in the context of recovery from the COVID-19 pandemic." The resolution also encourages OHCHR "to reinforce its work and initiatives on fighting poverty and addressing inequalities in the context of the implementation of the 2030 Agenda."

The onset of the pandemic worsened several underlying issues. Progress on sustainable development goals 1 on ending poverty and 10 on reducing inequalities within and among countries was particularly affected. In the aftermath of COVID-19 pandemic, the number of people living in severe poverty increased, for the first time in a generation while hunger levels regressed to those not witnessed before 2005.[2] As per the Secretary-General's 2023 report measuring the progress on Sustainable Development Goals, 575 million people will continue to be living in extreme poverty in 2030.[3] The recent crises have also "reversed the decades-long trend of narrowing global income inequality".[4]

### *NEW -* Call for inputs: Access to information on climate change and human rights

Issued by UN Special Rapporteur on climate change

**Deadline: 02 June 2024**

*Purpose*

To inform the thematic report of the Special Rapporteur on the promotion and protection of human rights in the context of climate change to the United Nations General Assembly 79th session.

*Background*

In her upcoming report, the Special Rapporteur seeks to explore the specificities, challenges and good practices related to access to information on climate change and human rights. The report will focus on States' international obligations, individually and as part of international cooperation, as well as business responsibility to respect human rights in this context. The report will identify gaps and shortcomings, in relation to which the Special Rapporteur would seek to make constructive and concrete recommendations to help States strengthen access to information on climate change and human rights, as a view to supporting the exercise of procedural rights in the context of climate change, enhancing the effectiveness of decision-making processes, and better protecting substantive human rights that can be negatively impacted by climate change, including by preventing discrimination.

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

*No new content identified.*

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

### *NEW -* US Government Releases Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

On May 6, 2024, the White House Office of Science and Technology Policy (OSTP) released an expanded and unified Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

This new U.S. Government-wide policy, which combines the current dual use research of concern and enhanced potential pandemic pathogen oversight frameworks, expands the scope of research requiring additional scrutiny and strengthens our partnership with institutions to ensure robust review and oversight.

NIH will work closely with the biomedical research community as we move towards the policy's year effective date. We encourage the biomedical research community to review OSTP's extensive guidance developed to assist with implementation (https://www.whitehouse.gov/ostp/news-updates/2024/05/06/united-states-government-policy-for-oversight-of-dual-use-research-of-concern-and-pathogens-with-enhanced-pandemic-potential/.

Dr. Monica Bertagnolli, NIH Director, issued a statement upon the Policy's release which can viewed at: https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-release-usg-policy-oversight-dual-use-research-concern-pathogens-enhanced-pandemic-potential

***NEW -*** **Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability**

A Notice by the Food and Drug Administration on 04/23/2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments." Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of post-marketing requirements (PMRs) and post-marketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on the FDA's website entitled "Postmarketing Requirements and Commitments: Reports" ( https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064436.htm).

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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

### 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

**ICMR [Indian Council for Medical Research] – Public Consultation**
https://ethics.ncdirindia.org/CHIS_Public_Consultation.aspx

**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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