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

17 April 2024 - Issue 16

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.

Digest content is organized into 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

NEW **- POLICY BRIEF: Data Ethics and Research Integrity**
Description: This is a draft Policy Brief on Data Ethics and Research Integrity produced by the CODATA Data Ethics Working Group.
We welcome feedback or discussion by 25/04/2024

NEW **- POLICY BRIEF: Data Ethics & Privacy**
Description: This is a draft Policy Brief on Data Ethics and Research Integrity produced by the CODATA Data Ethics Working Group.
We welcome feedback or discussion by 25/04/2024

NEW **- POLICY BRIEF: Data Ethics and Structural Inequities in Science**
Description: This is a draft Policy Brief on Data Ethics and Structural Inequities in Science produced by the CODATA Data Ethics Working Group.
We welcome feedback or discussion by 25/04/2024

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for Food and Drug Administration-Regulated Medical Products; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 01/30/2024 **Comments Close: 04/29/2024**

Request for Information: Responsible Procurement of Artificial Intelligence in Government
An unpublished Notice by the U.S. Management and Budget Office on 03/29/2024
Submission deadline: 4/29/2024

Call for Input – Guiding Principles on Sanctions, Compliance (Over-Compliance) and Human Rights
Issued by Special Rapporteur on unilateral coercive measures, UNHCHR **Deadline 30 April 2024**

NEW **- Model Law on Health Data Governance**
Transform Health and partners, April 11, 2024
The draft Model Law is **open for public consultation until 30 April 2024.**

NEW **- Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft**
National Academy of Medicine April 8 2024
The public comment period will be open until May 1, 2024

NEW **- Invitation for Public Comment: WHO principles for human genome access, use and sharing**
8 April 2024 **Consultation Period: 8th April 2024 – 3 May 2024**

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.

ICC Office of the Prosecutor launches public consultation on Policy on Slavery Crimes
International Criminal Court - Office of the Prosecutor 19 March 2024
Comments can be sent to OTP.Policies@icc-cpi.int by midnight on Tuesday, **30 April 2024**

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards
FDA - 21 CFR Part 50 [Docket No. FDA-2022-D-2997] **Comments due: 04/30/2024**

NEW - **Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft**
National Academy of Medicine April 8 2024
The public comment period will be open until May 1, 2024

Stakeholder Listening Session in Preparation for the 77th World Health Assembly
A Notice by the U.S. Health and Human Services Department on 03/05/2024
The listening session will be held Thursday, May 2, 2024. **Written comments by Friday, May 3, 2023**

NEW - **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

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.

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 - **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

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

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

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for Food and Drug Administration-Regulated Medical Products; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 01/30/2024 **Comments Close: 04/29/2024**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products." The purpose of this guidance is to provide FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data in submissions including information collected and reported from clinical studies and clinical trials for FDA-regulated medical products. Using standard terminology for race and ethnicity helps ensure that data are collected and reported consistently in submissions to FDA. This draft guidance revises the final guidance for industry and FDA staff entitled "Collection of Race and Ethnicity Data in Clinical Trials" issued on October 26, 2016.

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards

FDA - 21 CFR Part 50 [Docket No. FDA-2022-D-2997] **Comments due: 04/30/2024**

SUMMARY:

This draft guidance provides recommendations related to two provisions of the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule) by the U.S. Department of Health and Human Services (HHS) and identical provisions in FDA's proposed rule "Protection of Human Subjects and Institutional Review Boards." FDA's proposed rule, if finalized, would harmonize certain sections of FDA's regulations on human subject protections and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Common Rule, in accordance with the 21st Century Cures Act (Cures Act). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA's proposed rule.

NEW

Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft

National Academy of Medicine April 8 2024

The public comment period will be open until May 1, 2024

Overview

The draft AI Code of Conduct framework is comprised of a set of principles (the Code Principles) grounded in related antecedent work, along with a set of application commitments (Code Commitments) for broad adoption by the key stakeholders of the AI life cycle: developers, researchers,

health systems, payers, patients, and federal agencies. The Code Principles provide touchstones around which health AI governance—facilitative and precautionary—can be shaped, tested, validated, and continually improved as technology, governance capability, and insights advance. The Code Commitments are intended to direct the application of these Principles in practice and are oriented to decisions and actions.

In "Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft," the paper's editors explore strategies to responsibly implement AI advancements to achieve profound benefits in health and health care throughout the United States. Based on an extensive review of existing literature surrounding AI guidelines, frameworks, and principles, the editors identify a series of ten Code Principles and six Code Commitments to ensure that best practices maximize AI's benefits to maximize human health and well-being while minimizing potential risks. The Code Principles promote responsible behavior in AI development, use, and ongoing assessment; they are based on the Leadership Consortium's Learning Health System Core Principles. The Code Commitments support the careful application of these Principles in practice, serving as guidelines when dealing with complex systems.

The NAM Leadership Consortium is seeking input from stakeholders on the Code Principles and Commitments to ensure responsible and equitable use of AI in health, health care, and biomedical science. Share your experiences and feedback to help identify opportunities for improvement and innovation. Participate in the survey.

NEW

Invitation for Public Comment: WHO principles for human genome access, use and sharing

8 April 2024 **Consultation Period: 8th April 2024 – 3 May 2024**

Background:

For the potential of genomics to be realized, access to, use, and the sharing of human genome data is critical. Following the WHO's Science Council 2022 Report on Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social issues, WHO is implementing a programme of activities to promote equitable and fair access to genomics technologies for the benefit of people worldwide. As part of this, WHO is developing guiding principles for human genome data access, use and sharing. To develop these principles, a virtual consultation was held in January 2024 with an interdisciplinary group of participants. This consultation discussed the diverse perspectives on issues related to human genome data access, use and sharing; how a global set of principles from WHO may enable data access, use and sharing; and proposed initial principles. This was followed by an in-person meeting in March 2024 that considered in detail the proposed principles. Following this meeting, a draft document was developed and comments on this document and the principles are now invited.

Feedback on the WHO Principles for human genome data access, use, and sharing

Public feedback on this document is being solicited through this public consultation using the comment form.

Stakeholder Listening Session in Preparation for the 77th World Health Assembly

A Notice by the U.S. Health and Human Services Department on 03/05/2024

The listening session will be held Thursday, May 2, 2024, from 10 a.m. to 12 p.m. eastern daylight time. This session is open to the public but requires RSVP to oga.rsvp1@hhs.gov by Friday, April 26, 2024.

Written comments are welcome by Friday, May 3, 2023 and should be emailed to oga.rsvp1@hhs.gov with the subject line " Written Comment Re: Stakeholder Listening Session for WHA77 "

Purpose:

The U.S. Department of Health and Human Services (HHS) leads the U.S. delegation to the 77th World Health Assembly and will convene an informal Stakeholder Listening Session. The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help the HHS Office of Global Affairs inform and prepare for U.S. Government engagement at the World Health Assembly.

The World Health Assembly is the decision-making body of the World Health Organization (WHO). It is attended by delegations from all 194 WHO Member States. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed program budget. The Health Assembly is held annually in Geneva, Switzerland. Additional information about the World Health Assembly can be found at this website: https://www.who.int/about/governance/world-health-assembly.

Matters to be Discussed:

The listening session will cover items on the provisional agenda of the 77th World Health Assembly. The provisional agenda can be found at this website: https://apps.who.int/gb/ebwha/pdf_files/EB154/B154_39-en.pdf.

Registrants must include their full name, email address, and organization, if any, and indicate whether they are registering as a listen-only attendee or as a speaker participant to oga.rsvp1@hhs.gov. Requests to participate as a speaker must include all of the following information:

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents
3. The primary agenda item(s) of interest, listed in order of the speaker's priorities

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.

NEW

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.

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

POLICY BRIEF: Data Ethics and Research Integrity

Description: This is a draft Policy Brief on Data Ethics and Research Integrity produced by the CODATA Data Ethics Working Group.

We welcome feedback or discussion by 25/04/2024 of the draft briefing via this form: https://forms.gle/SmkhP9XzunRLysGL6 or directly to the authors: Leo Lahti <leo.lahti@utu.fi>, Joy Jang <joyjang@umich.edu>, Hu Lianglin <hull@cnic.cn>, Dirk Hommrich, <hommrich@kulturforschung-hd.de>, Sun Kun Oh <sunkun.oh@gmail.com>

Summary and recommendations

The UNESCO Recommendation on Open Science emphasizes creating the scientific data and knowledge openly available, accessible, and reusable for everyone, thereby helping to ensure the well-established values and norms of the academic community and expand their scope. The UNESCO Recommendation stresses that Open Science and research integrity are inseparable. Research integrity and data ethics are deeply intertwined along the full cycle of research and they are highly dependent on the perspective of multiple stakeholders. Therefore, in the context of data ethics, collaborative efforts to support research integrity need to be further strengthened in areas such as transparency, reusability, and overall quality and impact of research in terms of research data collection, management, interpretation, and dissemination.

NEW

POLICY BRIEF: Data Ethics & Privacy

Description: This is a draft Policy Brief on Data Ethics and Research Integrity produced by the CODATA Data Ethics Working Group.

We welcome feedback or discussion by 25/04/2024 of the draft briefing via this form: https://forms.gle/SmkhP9XzunRLysGL6 or directly to the authors: Ashlin Lee <Ashlin.Lee@csiro.au>, Masanori Arita <arita@nig.ac.jp> and Steve McEachern <steven.mceachern@anu.edu.au>

Summary

- Privacy is a fundamental human right, and a requirement for individual and community wellbeing.
- However, privacy is also theoretically and practically contested and paradoxical.
- A critical understanding of privacy emphasises the importance of power and harm, and how this might differentially and contextually impact individuals and communities.
- Technological advance brings new categories of data, such as genomes, with which privacy rules need to be re-conceptualised and updated.
- For open science to maintain its values of quality and integrity, and collective benefit, we need to update how we conceptualise privacy, especially in the face of rapid and disruptive technological advancement.

NEW

POLICY BRIEF: Data Ethics and Structural Inequities in Science

Description: This is a draft Policy Brief on Data Ethics and Structural Inequities in Science produced by the CODATA Data Ethics Working Group.

We welcome feedback or discussion by 25/04/2024 of the draft briefing via this form:: https://forms.gle/SmkhP9XzunRLysGL6 or directly to the authors: Suchith Anand <Suchith.Anand@nottingham.ac.uk>, Louise Bezuidenhout, <l.m.bezuidenhout@cwts.leidenuniv.nl>, Andrew Cox <a.m.cox@sheffield.ac.uk>, Johannes John-Langba, <JohnLangbaJ@ukzn.ac.za>, Sabina Leonelli, <S.Leonelli@exeter.ac.uk>

Summary and recommendations

The gap that we identify in The UNESCO Recommendation on Open Science is in acknowledging the systematic structural conditions creating inequitable participation in science, and the impact that this has on how a push towards open science might play out in practice.

Science as a global system is riven by inequities. This has five interconnected dimensions:

- Identity-based inequities shaping participation in science at an individual level
- International inequities in the strength, visibility and recognition of research systems
- Inequities in the research infrastructure and access to funding
- Inequitable access to an increasingly commercialised publishing system
- Data colonialism

Request for Information: Responsible Procurement of Artificial Intelligence in Government

An unpublished Notice by the U.S. Management and Budget Office on 03/29/2024

Submission deadline: 4/29/2024

SUMMARY:

This request for information on the responsible procurement of artificial intelligence is being issued concurrently with the release of the OMB Memorandum titled Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence (the "AI M-memo"). Executive Order 14110, Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, directed OMB within 180 days of the issuance of the AI M-memo to develop an initial means to ensure that agency contracts for the acquisition of AI systems and services align with the guidance provided in the AI M-memo and advance the other aims identified in the Advancing American AI Act ("AI Act").

NEW

Model Law on Health Data Governance

Transform Health and partners, April 11, 2024

The draft Model Law is **open for public consultation until 30 April 2024.**

More information on the Model Law and consultation https://lnkd.in/eYdpxXxS

Overview

Transform Health and partners have been catalysing and supporting the development of a draft Model Law on Health Data Governance, which articulates core elements, guidance and model legal text, informed by equity and rights-based principles, among other international, regional and national commitments and best practice.

This (draft) model law provides a foundational structure for the ethical management, protection, and use of health data, emphasising the balance between individual privacy rights and the collective benefits of health data utilisation. By setting out core principles and standards, it seeks to foster a harmonised approach to health data governance that respects the diverse legal, cultural, and societal landscapes of different nations. It serves as legislative guidance and sample reference text to assist countries with their efforts to strengthen their national laws and frameworks dealing with health data governance.

Highlighting some interesting elements in this Model Law, some of which we also find in recent EU policies (Data Governance Act, Data Act, European Health Data Space,...):

- Health data equity tribunal
- Portability of electronic medical records
- Communities' rights in their community health data
- Rights and obligations of health data generators
- Prohibition on re-identification
- Using health data in the public interest
- Health pandemics and other health emergencies
- Emerging technologies

NEW

Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft

National Academy of Medicine April 8 2024

The public comment period will be open until May 1, 2024

Overview

The draft AI Code of Conduct framework is comprised of a set of principles (the Code Principles) grounded in related antecedent work, along with a set of application commitments (Code Commitments) for broad adoption by the key stakeholders of the AI life cycle: developers, researchers, health systems, payers, patients, and federal agencies. The Code Principles provide touchstones around which health AI governance—facilitative and precautionary—can be shaped, tested, validated, and continually improved as technology, governance capability, and insights advance. The Code Commitments are intended to direct the application of these Principles in practice and are oriented to decisions and actions.

In "Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft," the paper's editors explore strategies to responsibly implement AI advancements to achieve profound benefits in health and health care throughout the United States. Based on an extensive review of existing literature surrounding AI guidelines, frameworks, and principles, the editors identify a series of ten Code Principles and six Code Commitments to ensure that best practices maximize AI's benefits to maximize human health and well-being while minimizing potential risks. The Code Principles promote responsible behavior in AI development, use, and ongoing assessment; they are based on the Leadership Consortium's Learning Health System Core Principles. The Code Commitments support the careful application of these Principles in practice, serving as guidelines when dealing with complex systems.

The NAM Leadership Consortium is seeking input from stakeholders on the Code Principles and Commitments to ensure responsible and equitable use of AI in health, health care, and biomedical science. Share your experiences and feedback to help identify opportunities for improvement and innovation. Participate in the survey.

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 – Guiding Principles on Sanctions, Compliance (Over-Compliance) and Human Rights

Issued by Special Rapporteur on unilateral coercive measures, UNHCHR **Deadline 30 April 2024**

Purpose:

To develop a comprehensive set of Guiding Principles to be used by states, regional organizations, businesses and other actors with regards to sanctions and compliance, and, by that, to minimize negative impact of all types of sanctions, compliance and over-compliance with sanctions on human rights.

The Guiding Principles are intended to establish the guidelines and benchmarks for States, international organizations, businesses and other actors to avoid and /or minimize over-compliance and to ensure promotion and protection of human rights in accordance with international law, the work done by the International Law Commission on the Law of International Responsibility as well as the United Nations Guiding principles on Business and Human Rights.

The Special Rapporteur underlines the importance of collective joint efforts of all stakeholders, governmental and non-governmental, including States, international and regional organizations, civil society, academia and businesses, among others, to crystallize a mutual consent on the modes of human rights approach to be implemented in situations of sanctions. For this purpose, after receiving and analyzing the responses to this call, the Special Rapporteur intends to organize a multi-stakeholder conference in November 2024 to discuss the draft document of the Guiding Principles and a commentary to this draft.

ICC Office of the Prosecutor launches public consultation on Policy on Slavery Crimes

International Criminal Court - Office of the Prosecutor 19 March 2024

Comments can be sent to OTP.Policies@icc-cpi.int by midnight on Tuesday, **30 April 2024**

The Prosecutor of the International Criminal Court, Mr Karim A.A. Khan KC, is pleased to announce a call for public submissions for his Office's new Policy on Slavery Crimes.

Today's call represents the first time that an international judicial institution has committed to formulating a Policy to specifically address slavery crimes. The Slavery Crimes Policy will heighten the Office's effectiveness in the investigation and prosecution of these crimes under the Rome Statute and will align with the Office's other relevant policies, including the 2022 Policy Paper on Gender Persecution, the 2023 Policy on Gender-Based Crimes and the 2023 Policy on Children.

A rich and transparent consultation process is central to developing OTP Policies. The Office is currently engaging in an external consultation process that, to date, has included the experiences and voices of survivor communities and civil society, as well as the practices of national authorities, international organisations, accountability mechanisms and other justice actors. Further consultations are anticipated later this year.

To gather additional insights, the Office now also welcomes public comment on the potential substance of the Slavery Crimes Policy. External experts are invited to share proposals as to how the ICC Office of the Prosecutor (OTP) can enhance its approach to and pursuit of slavery crimes, including through complementarity efforts.

NEW

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.

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.

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.

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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

Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

A Notice by the National Institutes of Health on 04/05/2024
Final Guidance PDF: https://www.govinfo.gov/content/pkg/FR-2024-04-05/pdf/2024-07082.pdf

NIH is amending the NIH Guidelines to ensure the continued responsible research involving GDMOs in contained research settings. Specifically, the NIH Guidelines will be amended to:

1. clarify minimum containment requirements for research involving GDMOs;
2. provide considerations for risk assessment;
3. define additional institutional responsibilities for IBCs and BSOs.

In addition to the amendments related to contained research involving GDMOs, the NIH Guidelines will also be amended to:

1. replace the term "helper viruses" with the broader term "helper systems"; and
2. reclassify WNV and SLEV as risk group 2 agents for consistency with containment guidance provided in the BMBL.

The revisions apply to GDMO research in contained settings, which is subject to the NIH Guidelines. These revisions are consistent with the recommendations of the Novel and Exceptional Technology Research Advisory Committee report, Gene Drives in Biomedical Research (NExTRAC Report)…

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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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