***ge²p² global***

governance, ethics, evidence, policy, practice

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

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

**14 February 2024 - Issue 13**

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

**Public Inspection: Guidance: Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices**
Food and Drug Administration, HHS. 12/19/2023
Submit either electronic or **written comments on the draft guidance by February 20, 2024**

**Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Availability**
Food and Drug Administration, HHS, USA.
Pub. Date: 12/22/2023
Submit either electronic or **written comments on the draft guidance by February 20, 2024**

**Prospective Grant of an Exclusive Patent License: Vaccine Augmented Adoptive Cell Therapy for the Treatment of Cancer**
A Notice by the National Institutes of Health on 02/07/2024 **Comments Close: 02/22/2024**

**Scientific Integrity Policy Draft for Public Comment**
A Notice by the U.S. Environmental Protection Agency
Publication Date: 01/24/2024 **Comments Close: 02/23/2024**

**Concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (PDF/208.8 KB)**
EMA/CHMP/CVMP Reference number: 452614/2023
First published: 23/11/2023
Draft: consultation open **Consultation dates: 20/11/2023 to 28/02/2024**

**Request for Information: National Ocean Biodiversity Strategy**
National Science Foundation [USA} 11/09 2023
**Responses are due by February 28, 2024.**

**Call for Papers: Establishing the impact of WHO's normative and standard-setting functions: a call for papers**
WHO - Bull World Health Organ. 2023 Oct 1; 101(10): 618–618A. Published online 2023 Oct 1.
**The deadline for submissions is 1 March 2024**

**Request for Information (RFI): Inviting Comments on the National Institutes of Health's (NIH) Strategic Plan for Data Science 2023-2028**
A Notice by the National Institutes of Health on 01/16/2024 **Comments Close: 03/15/2024**

**Conducting Remote Regulatory Assessments-Questions and Answers; Revised Draft Guidance for Industry; Availability**
A Notice by the Food and Drug Administration on 01/26/2024 **Comments Close: 03/26/2024**

**Potency Assurance for Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability**
Scheduled Pub. Date: 12/28/2023
FR Document: 2023-28596 PDF 6 Pages (104 KB)
Submit either electronic or written comments on the draft guidance by **March 27, 2024**

**Call for submissions on concept paper for the CERD-CMW Joint General Comment/ Recommendation on Obligations of State Parties on public policies for addressing and eradicating xenophobia and its impact on the rights of migrants, their families, and other non-citizens affected by racial discrimination**
UNHCHR Treaty bodies
**Deadline: 31 March 2024**

**Call for inputs: Resettlement as a human rights issue**
UNHCHR Special Procedures
**Deadline: 31 March 2024**

**Request for Information: Privacy Impact Assessments**
A Notice by the U.S. Management and Budget Office on 01/30/2024 Dates: Consideration will be given to written comments **received by April 1, 2024**.

**Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop: Notice of public workshop; request for comments.**
Food and Drug Administration, HHS. PDF
**Comments on this public workshop must be submitted by April 5, 2024.**

**Agency Information Collection Request. 60-Day Public Comment Request [Research Integrity]**
A Notice by the Health and Human Services Department
Publication Date: 02/09/2024 **Comments Close: 04/09/2024**

**Call for Input: Human Rights Council resolution 54/6 on the centrality of care and support from a human rights perspective**
Issued by OHCHR **Deadline: 13 April 2024**

**Use of Data Monitoring Committees in Clinical Trials; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request**
Agencies: Department of Health and Human Services; Food and Drug Administration
Agency/Docket Number: Docket No. FDA-2001-D-0219
Publication Date: 02/13/2024 **Comments Close: 04/15/2024**

**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**

**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**

## 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.**

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

## Biomedical Research/Regulation/Governance

### Public Inspection: Guidance: Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices

Food and Drug Administration, HHS. 12/19/2023
Submit either electronic or written comments on the draft guidance by **February 20, 2024**
*SUMMARY:*
The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices." FDA is issuing this draft guidance to clarify how FDA evaluates real-world data (RWD) to determine whether they are of sufficient quality for generating real-world evidence (RWE) that can be used in FDA regulatory decision-making for medical devices. This draft guidance proposes expanded recommendations to the 2017 guidance entitled "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices." This draft guidance is not final nor is it for implementation at this time.

### Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Availability

Food and Drug Administration, HHS.
Scheduled Pub. Date: 12/22/2023 FR Document: 2023-28210
Submit either electronic or written comments on the draft guidance by **February 20, 2024**
*SUMMARY:*
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Master Protocols for Drug and Biological Product Development." The draft guidance addresses the design and analysis of trials conducted under a master protocol as well as the submission of documentation to support regulatory review. The primary focus is on randomized umbrella and platform trials that are intended to contribute to a demonstration of safety and substantial evidence of effectiveness. The considerations in this guidance apply to a range of therapeutic areas. The draft guidance is intended to clarify the Agency's thinking on the use of master protocols in drug and biological product development, which was previously addressed in FDA's guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention." FDA is also announcing the withdrawal of the guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention.
PDF: https://downloads.regulations.gov/FDA-2023-D-5259-0002/attachment_1.pdf 8 Pages (109 KB)

### Prospective Grant of an Exclusive Patent License: Vaccine Augmented Adoptive Cell Therapy for the Treatment of Cancer

A Notice by the National Institutes of Health on 02/07/2024 **Comments Close: 02/22/2024**
*SUPPLEMENTARY INFORMATION:*
Intellectual Property

1. United States Provisional Patent Application No. 63/295,762 filed December 31, 2021, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E–046–2022–0–US–01]; and
2. International Patent Application No. PCT/US2022/082579 filed December 29, 2022, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E–046–2022–0–PCT–02].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:
“Development, manufacture, and commercialization of combination immunotherapies for the treatment of cancer in humans, comprising at least the following elements:
1. An autologous T cell product, where the T cells are tumor infiltrating lymphocytes (TIL) or chimeric antigen receptor-expressing T cells (CAR–T); and
2. A neoantigen cancer vaccine.”…

## Concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches

EMA/CHMP/CVMP Reference number: 452614/2023
First published: 23/11/2023
**Consultation dates: 20/11/2023 to 28/02/2024**
*Summary*
This guideline aims to encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches with the aim to replace, reduce and refine in vivo animal studies for human and veterinary medicinal products.

Comments should be provided using this EUSurvey form.

## Call for Papers: Establishing the impact of WHO’s normative and standard-setting functions: a call for papers

WHO - Bull World Health Organ. 2023 Oct 1; 101(10): 618–618A. Published online 2023 Oct 1.
**The deadline for submissions is 1 March 2024**
*Editorial*
Lisa M Askie[a], Rebekah AL Thomas[a], Rok Ho Kim[a], Mubashar Sheikh[a], Jeremy Farrar[b]
doi: 10.2471/BLT.23.290829 PMCID: PMC10523809

Normative leadership is a core function of the World Health Organization’s (WHO) mandate, as outlined in its founding principles.[1] This leadership role is realized by developing evidence-based and ethically sound guidelines as well as other normative products that guide Member States in their public health decisions and actions, and by ensuring their recommendations are implemented.[2] WHO exercises its capacity for normative leadership to influence the development of legal norms and health policy and practice within its Member States…

… In the past five years, WHO has initiated a major change process, driven by its current Thirteenth Global Programme of Work,[6] the transformation agenda, and the need to respond to major global events including the coronavirus disease 2019 (COVID-19) pandemic and other crises. More recently, WHO has developed a comprehensive strategy to enhance its capacities and capabilities at country level, to ensure that its normative work drives measurable impact for all people more effectively.

Despite these initiatives, to date it is unclear whether these changes have improved WHO's credibility and impact as a normative organization. Questions remain as to how successful WHO's normative leadership role has been, how it can be further strengthened and how the impact of WHO's work in countries should be measured and rated in the future. The recent COVID-19 pandemic exposed both the strengths of and the challenges to WHO's normative leadership and global reach. While realizing the crucial role of WHO as a key directing and coordinating authority, the global health community has also witnessed the unprecedented rise of misinformation and mistrust in science.

Considering the spotlight on WHO's global normative leadership role during the pandemic,7 and looking to prepare for future threats such as the health effects of climate change and ongoing conflict situations, the Bulletin of the World Health Organization calls for papers to help shape and inform WHO's mandate going forward. Topics of interest include: where has WHO succeeded in its normative leadership role? In what specific areas has it successfully shaped global health, and why were these initiatives successful? Where has WHO normative guidance been less impactful? If so, why was this the case, and what lessons can be learnt to improve impact in the future? What does the future of WHO's normative function look like, particularly in the context of digital technology and artificial intelligence? What aspects of the Organization's mandate, structure, function and administration need to be further strengthened or changed?

The Bulletin welcomes contributions from all stakeholders including public health decision-makers, researchers, and civil society and community representatives. Articles that propose innovative but feasible ways by which WHO can further strengthen its normative leadership and guidance role, are encouraged.

## Request for Information (RFI): Inviting Comments on the National Institutes of Health's (NIH) Strategic Plan for Data Science 2023-2028

A Notice by the National Institutes of Health on 01/16/2024 **Comments Close: 03/15/2024**

*SUMMARY:*

The purpose of this Request for Information (RFI) is to solicit public comments on the updated NIH Strategic Plan for Data Science, 2023–2028, including members of the scientific community, academic institutions, the private sector, health professionals, professional societies, advocacy groups, and patient communities, as well as other interested members of the public.

*Background*

The updated Strategic Plan for Data Science ( https://datascience.nih.gov/sites/default/files/NIH-STRATEGIC-PLAN-FOR-DATA-SCIENCE-2023-2028-final-draft.pdf) sets a bold vision for the future, one in which data generated in the course of care of individuals and data generated from biomedical and basic research become powerful inputs that enhance our understanding of fundamental biology and enables the development of new clinical treatments and diagnostic technologies. This updated plan builds on accomplishments from the initial NIH Strategic Plan for Data Science ( https://datascience.nih.gov/nih-strategic-plan-data-science) and will prepare NIH to face the acceleration of sophisticated new technologies and address the rapid rise in the quantity and diversity of data. The updated Strategic Plan supports the NIH Policy for Data Management and Sharing ( https://sharing.nih.gov/data-management-and-sharing-policy) and embraces data- driven discovery as a powerful tool to elucidate biological processes and better characterize the health and health consequences of all people. This plan also fosters ethical use of new methodologies arising from artificial intelligence and machine learning.

The updated Strategic Plan will accomplish five overarching goals:

:: Goal 1: Improve Capabilities to Sustain the NIH Policy for Data Management and Sharing
:: Goal 2: Develop Programs to Enhance Human Derived Data for Research
:: Goal 3: Provide New Opportunities in Software, Computational Methods, and Artificial Intelligence
:: Goal 4: Support for a Federated Biomedical Research Data Infrastructure

:: Goal 5: Strengthen a Broad Community in Data Science

The complete draft plan is available at: https://datascience.nih.gov/sites/default/files/NIH-STRATEGIC-PLAN-FOR-DATA-SCIENCE-2023-2028-final-draft.pdf.

## Conducting Remote Regulatory Assessments-Questions and Answers; Revised Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 01/26/2024 **Comments Close: 03/26/2024**

*SUMMARY:*

The Food and Drug Administration (FDA or Agency) is announcing the availability for comment of a revised draft guidance for industry entitled "Conducting Remote Regulatory Assessments—Question and Answers." FDA has revised and is reissuing the draft guidance in response to public comments and recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). When finalized, this guidance will describe FDA's current thinking regarding its use of remote regulatory assessments (RRAs). FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help maximize compliance of FDA-regulated products. This revised draft guidance provides answers to frequently asked questions regarding RRAs.

## Potency Assurance for Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability

Scheduled Pub. Date: 12/28/2023

FR Document: 2023-28596 PDF 6 Pages (104 KB)

Submit either electronic or written comments on the draft guidance by **March 27, 2024**

*I. Background*

FDA is announcing the availability of a draft document entitled "Potency Assurance for Cellular and Gene Therapy Products." FDA is issuing this draft guidance to provide recommendations to help assure the potency of human CGT products that are regulated as biological products under section 351 of the Public Health Service Act (42 U.S.C. 262).

In this draft guidance, we provide recommendations for developing a science- and risk-based strategy to help assure the potency of human CGT products. A potency assurance strategy is a multifaceted approach that reduces risks to the potency of a product through: (1) manufacturing process design, (2) manufacturing process control, (3) material control, (4) in-process testing, and (5) potency lot release assays. The goal of a potency assurance strategy is to ensure that every lot of a product released will have the specific ability or capacity to achieve the intended therapeutic effect.

In this draft guidance, we emphasize that potency assays and their corresponding acceptance criteria should be designed to make meaningful contributions to potency assurance by reducing risks to product potency. We provide illustrative examples of approaches to potency assay development that are grounded in quality risk management. Due to the diversity of CGT products and the product-specific nature of potency assays, the recommendations in this draft guidance regarding the selection and design of potency assays are necessarily general.

This draft guidance, when finalized, is intended to supersede the document entitled "Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products," dated January 2011…

## Request for Information: Privacy Impact Assessments

A Notice by the U.S. Management and Budget Office on 01/30/2024 Dates: Consideration will be given to written comments **received by April 1, 2024**.

*SUMMARY:*
Pursuant to the Executive order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, the Office of Management and Budget (OMB) is requesting public input on how privacy impact assessments (PIAs) may be more effective at mitigating privacy risks, including those that are further exacerbated by artificial intelligence (AI) and other advances in technology and data capabilities

## Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop: Notice of public workshop; request for comments.

Food and Drug Administration, HHS. PDF
Comments on this public workshop must be submitted by **April 5, 2024.**
*SUMMARY*
The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled "Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice." The purpose of the public workshop is to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs. This workshop is being conducted to meet the performance goal of convening a public workshop on complex innovative design (CID) included in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The workshop may also inform a draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products. In conjunction with the workshop, FDA is seeking comments on the use of CID to inform regulatory decision making, including high-level case examples of CIDs and approaches that can advance the use of these designs. The public workshop will be held on March 5, 2024.

## Agency Information Collection Request. 60-Day Public Comment Request [Research Integrity]

A Notice by the Health and Human Services Department
Publication Date: 02/09/2024 **Comments Close: 04/09/2024**
*Abstract:*
The Department of Health and Human Services (HHS) Office of Research Integrity (ORI) has partnered with the Office for Human Research Protections (OHRP) to launch this data collection effort to better understand how to serve those who might benefit from additional education and resources to improve research integrity. ORI and OHRP have found that researchers, Institutional Review Board (IRB) Chairs, Research Integrity Officers (RIOs), Human Protections and Compliance Officers, and Human Protections Administrators, who oversee the conduct of research involving human research subjects, may struggle with identifying reportable noncompliance or unanticipated problems, protocol violations, protocol deficiencies, and falsifications and fabrications of data and methods in that research. Failure to recognize these concerns may result in noncompliance, protocol violations and research misconduct not being adequately addressed; falsified and/or fabricated methods, data, and results that may be published or used to obtain federal funding; human research subjects being harmed; and/or Public Health Service (PHS) funds not being protected.
This data collection is a new request and includes an online survey instrument used with stakeholders holding positions at institutions holding a Federal-wide Assurance (FWA) and/or operating an IRB, and is designed to identify barriers in the identification, evaluation, and reporting of potential research misconduct, protocol violations, reportable noncompliance, and unanticipated problems in research that involves human subjects. This data collection is intended to assist ORI and OHRP in developing approaches to improve how to identify and distinguish incidents that are reportable to ORI and OHRP from those that do not require reporting to these offices. This information is also intended to give RIOs, IRBs, human protections administrators, compliance officers, and other institutional officials involved

with human subjects' research insight into how they can strengthen their policies and procedures for identifying, evaluating, and/or communicating potential research misconduct and reportable noncompliance and unanticipated problems by identifying gaps, barriers, and areas in which communication and education may need to be enhanced within their institution.

## Use of Data Monitoring Committees in Clinical Trials; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

Agencies: Department of Health and Human Services; Food and Drug Administration
Agency/Docket Number: Docket No. FDA-2001-D-0219
Publication Date: 02/13/2024 **Comments Close: 04/15/2024**
*SUMMARY:*
The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled "Use of Data Monitoring Committees in Clinical Trials." This guidance is intended to assist sponsors of clinical trials in determining when a data monitoring committee (DMC) (also known as a data and safety monitoring board (DSMB), a data and safety monitoring committee (DSMC), or an independent data monitoring committee (IDMC)) would be useful for trial monitoring and what procedures and practices should be considered to guide their operation. When finalized, this guidance will supersede the final guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees," issued in March 2006. This draft guidance is not final nor is it in effect at this time.

## 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.

## 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

### 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

### Scientific Integrity Policy Draft for Public Comment

A Notice by the U.S. Environmental Protection Agency
Publication Date: 01/24/2024 **Comments Close: 02/23/2024**
*SUMMARY:*
The U.S. Environmental Protection Agency (EPA) is announcing a 30-day public comment period on the draft updates to its Scientific Integrity (SI) Policy. In accordance with the requirements of the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-based Policymaking, EPA is revising our SI Policy. The updated SI Policy will adopt a new Federal definition of scientific integrity and meaningfully strengthen several policy elements that will help ensure a culture of scientific integrity at the Agency. It will incorporate the model scientific integrity policy from the National Science and Technology Council's A Framework for Federal Scientific Integrity Policy and Practice (2023), lessons learned over the years, and the results of previous surveys of EPA staff on scientific integrity.

### Request for Information: National Ocean Biodiversity Strategy

National Science Foundation [USA} 11/09 2023
**Responses are due by February 28, 2024.**
*SUMMARY:*
The National Science Foundation, on behalf of the National Science and Technology Council Subcommittee on Ocean Science and Technology (SOST), requests input from all interested parties to inform the development of a National Ocean Biodiversity Strategy (Strategy), covering the genetic lineages, species, habitats, and ecosystems of United States (U.S.) ocean, coastal, and Great Lakes waters. The Strategy will strengthen the knowledge foundation and coordination on which federal agencies and other parties can align priorities and investments toward more cost-effective and successful solutions to the increasing challenges that require information on biodiversity and living resources. The Strategy will align research and monitoring on ocean life for safe and sustainable management, conservation, development, and climate solutions; and improve delivery of biodiversity information to support wise management and the growing ocean economy. Through this request for information (RFI), SOST seeks input on the foundational elements of a Strategy for delivering needed knowledge and implementing effective stewardship of ocean life. Those elements will include actions federal agencies should take to collect, coordinate, and deliver information for policy, investment, development, and management, to better align ocean biodiversity investments and policy with societal needs for both use and protection of living resources, ensuring benefits to society across sectors and from local to international levels.

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## Human Rights

### Call for submissions on concept paper for the CERD-CMW Joint General Comment/ Recommendation on Obligations of State Parties on public policies for addressing and eradicating xenophobia and its impact on the rights of migrants, their families, and other non-citizens affected by racial discrimination

UNHCHR Treaty bodies
**Deadline: 31 March 2024**
Purpose:
To provide guidance to the CERD and CMW Committees for the development of their joint general comment by receiving contributions from all stakeholders, including States, United Nations and regional human rights mechanisms, United Nations entities and specialized agencies, national human rights institutions, civil society and grassroot organizations, research institutions, academia and other relevant stakeholders…The submissions received will be taken into account as key inputs for the elaboration of the first Draft of this Joint General Comment/Recommendation.

### Call for inputs: Resettlement as a human rights issue

UNHCHR Special Procedures
**Deadline: 31 March 2024**
Purpose:
To inform the forthcoming reports of the Special Rapporteur to the Human Rights Council and General Assembly in 2024
Objectives
There is multifold evidence that the right to adequate housing and other human rights are often violated due to eviction and displacement without adequate resettlement and resulting in inadequate housing and living conditions, including livelihoods. Frequently, such poor resettlement outcomes are very different from what has been promised on paper in laws, policies, development and resettlement plans…
*The reports*
- will identify key human rights challenges posed by resettlement and take stock of international and national laws, regulations, policies and practices related to resettlement.
- review the laws, regulations and safeguard policies of States, international organizations, international financial institutions, multilateral, bilateral development agencies, and businesses related to resettlement.
- analyze what is needed to ensure that legal protections and safeguards related to resettlement are not only protected on paper, but also are respected in practice, and will look to compile good practices.

*Note: Inputs received to date are posted at title link*

### Call for Input: Human Rights Council resolution 54/6 on the centrality of care and support from a human rights perspective

Issued by OHCHR **Deadline: 13 April 2024**
*Purpose:*

To inform the expert workshop and High Commissioner's report to the Human Rights Council, pursuant to resolution 54/6.

*Background:*

Human Rights Council adopted resolution 54/6 on the centrality of care and support from a human rights perspective on 12 October 2023. Pursuant to this resolution, the Office of the High Commissioner for Human Rights (OHCHR) is organizing in 2024 an expert workshop to address the human rights of women, persons with disabilities, children and older persons as caregivers, as well as receivers of care and support, and for their self-care from a gender equality and human rights perspective, with the objective of evaluating experiences, good practices and main challenges regarding the effective recognition of the rights of caregivers and those receiving care and support.

Based on the discussion of the above-mentioned expert workshop and in consultation with Member States of the United Nations and other interested parties, OHCHR will also prepare a comprehensive thematic study on the human rights dimension of care and support, summarizing and compiling international standards and good practices and main challenges at the national level in care and support systems, and including recommendations on promoting and ensuring the human rights of caregivers and care and support recipients. The report will be submitted to the Human Rights Council at its fifty-eighth session in 2025.

## 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.

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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 Guidance: Charging for Investigational Drugs under an Investigational New Drug Application

**FINAL Guidance** An unpublished Notice by the Food and Drug Administration on 02/15/2024
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Charging for Investigational Drugs Under an IND: Questions and Answers." This guidance addresses frequently asked questions related to the implementation of FDA's regulation on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use. This guidance finalizes the revised draft guidance of the same title issued on August 23, 2022, and replaces the final guidance issued on June 3, 2016.

### Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry; Availability

**FINAL Guidance** A Notice by the U.S. Food and Drug Administration on 01/30/2024
*SUMMARY:*
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry." The guidance document provides recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an investigational new drug (IND) application to assess the safety and quality of the investigational GE product, including information on product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design. The guidance announced in this notice finalizes the draft guidance of the same title dated March 2022.

### Best Practices for Food and Drug Administration Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products; Final Document; Availability

**FINAL Document** A Notice by the Food and Drug Administration on 01/26/2024
*SUMMARY:*
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final document entitled "Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and

Biological Products." The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, requires that FDA make publicly available on its internet website best practices for certain post marketing drug safety surveillance activities. This final document sets forth risk-based principles for FDA's conduct of ongoing post marketing safety surveillance for human drug products and human biological products, in part, to address the Cures Act requirements. This document finalizes the draft document entitled "Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff" that was issued on November 7, 2019.

### ICMR Consensus Policy Statement for the Ethical Conduct of Controlled Human Infection Studies (CHIS) in India, 2023

December, 2023 **[Final]**
*Published by:* Director-General, Indian Council of Medical Research New Delhi 110 029 www.icmr.nic.in
ISBN Number: 978-81-965854-4-0

… This document will guide researchers, sponsors, institutions and other stakeholders involved in reviewing or conducting CHIS. The unique research design of introducing infection in the human body to study diseases and treatment modalities warrants additional safeguards in order to ensure the protection of research participants. The document provides a comprehensive ethical framework, for the conduct of research and an ethics review, covering various aspects of CHIS which includes participant selection, ensuring local and cultural relevance, building public trust, complying with regulations, optimizing research outcomes, emphasizing transparency, accountability and adherence to ethical principles.

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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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