ge²p² global

governance, ethics, evidence, policy, practice

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

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

08 September 2023 - Issue 07

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 these 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 consultation opportunities.

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:

[1] Title and source of all calls identified organized by due date

[2] All calls with more comprehensive information [i.e., objective, scope] organized by due date under broad thematic areas: Biomedical Research; Environment/Climate; Human Rights

[3] Selected Final, Published Guidances/Regulations/Laws Employing Calls for Public Consultation

We expect to add thematic areas as our digest becomes more comprehensive going forward.

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

Public consultation on WHO guidance for best practices for clinical trials
WHO - 19 July 2023
Call for consultation: Deadline 15 Sep 2023

Call for inputs from the mandate of the Working Group on discrimination against women and girls
UNHCHR Issued by Working Group on discrimination against women and girls
Special Procedures **Deadline: 18 September 2023**

ICH Reflection paper on proposed international harmonisation of real-world evidence terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines
30 June 2023
EMA/CHMP/ICH/295401/2023 Committee for Human Medicinal Products
Deadline for comment: 30 September 2023

Consultation on the Global Methodology for Infrastructure Resilience Review
United Nations Office for Disaster Risk Reduction (UNDRR)
23 August 2023
This Global Methodology will be in **consultation from 23 August 2023 to 30 September 2023.**

Investors, ESG and Human Rights
Call for Input - Special Procedures
UNHCHR – Issued by Working Group on Business and Human Rights
Deadline: 30 September 2023

Call for inputs: Resettlement as a human rights issue
UNHCHR - Special Procedures
Issued by Special Rapporteur on the right to adequate housing
Deadline: 30 September 2023

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment
UNHCHR - Issued by Special Rapporteur on human rights and the environment,
Deadline: 02 October 2023

NIH Seeks Input on Proposed Revisions to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
Public comments will be accepted until October 10, 2023

Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework

A Notice by the U.S. Science and Technology Policy Office on 09/01/2023
Responses are due on October 16, 2023 by 11:59 p.m. Eastern Time

Copyright Office Issues Notice of Inquiry on Copyright and Artificial Intelligence

Library of Congress 30 August 2023
The U.S. Copyright Office is seeking information and views on copyright issues raised by recent advances in generative A. The notice of inquiry is an integral next step for the Copyright Office's *AI Initiative.*
Written comments are due by 11:59 p.m. EDT on Wednesday, Oct. 18, 2023. Reply comments are due by 11:59 p.m. EDT on Wednesday, Nov. 15, 2023..

FDA - Meetings: Mitigating Clinical Study Disruptions during Disasters and Public Health Emergencies

The public meeting will be held **virtually on October 18 and 19, 2023**,
Meeting only; No public comment opportunity identified

Call for input: Advocacy of Hatred Based on Religion or Belief - Transformative Responses

UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of religion or belief
Deadline: 29 October 2023

Call for inputs: Human Rights Council resolution 52/8 on promoting human rights and the Sustainable Development Goals through transparent, accountable and efficient public service delivery

Call for input | Office of the High Commissioner for Human Rights
Deadline: 01 November 2023

Request for Information (RFI): Inviting Comments and Suggestions on Updating the NIH Mission Statement

NIH Posted August 28, 2023
To ensure consideration, **responses must be submitted by: 2023-11-24**
As the largest public funder of biomedical and behavioral research in the world, NIH works to turn scientific discoveries into better health for all. This RFI will inform NIH's efforts to update its mission statement to ensure that it reflects the NIH mission as accurately as possible.

EMA – Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft 13 July 2023
Comm. Medicinal Products - Human Use (CHMP); Comm. Medicinal Products -Veterinary Use (CVMP)
End of consultation (deadline for comments): 31 December 2023

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

ISO/TC 194 Stage 20.00
Due: Ongoing at national standards bodies level

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

Biomedical Research/Regulation/Governance

Public Consultation: ICH E6(R3) [GCP] Principles, Annex 1 and Annex 2

The E6(R3) EWG is working on the revision of the E6(R2) Guideline "Good Clinical Practice" (GCP) with a view to addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials. Additional information may also be found in ICH Reflection Paper on "GCP Renovation" on the ICH Reflection Paper page. When complete, E6(R3) will be composed of an overarching principles and objectives document, Annex 1 and Annex 2. E6(R3) Draft Guideline

Status: Step 3

Public consultation dates remaining:

EC, Europe - Deadline for comments by 26 September 2023
Swissmedic, Switzerland - Deadline for comments by 26 September 2023
HSA, Singapore - Deadline for comments by 30 September 2023
Health Canada, Canada - Deadline for comments by 20 October 2023

Public consultation on WHO guidance for best practices for clinical trials

WHO - 19 July 2023

Call for consultation: Deadline 15 Sep 2023

Draft Guidance PDF: https://cdn.who.int/media/docs/default-source/research-for-health/2023-07_who-guidance-for-best-practices-for-clinical-trials_draft-for-public-consultation.pdf?sfvrsn=7a5c9fa5_3

Overview

In May 2022, the Seventy-fifth World Health Assembly adopted a resolution on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination, in which one action requested of the Director-General was to develop WHO guidance on best practices for clinical trials. Please see action 2 under section "Requests the Director-General" at the end of WHA 75.8 resolution here. WHO is launching a public consultation on draft guidance developed in line with this request.

We aim to obtain input from all relevant stakeholders, spanning all diseases and health conditions during this consultation, so that these inputs can be taken into account in revision of this draft, following advice from the WHO Technical Advisory Group established to support this process.

Important stakeholder groups for this technical guidance include, (but are not restricted to): public sector researchers, private sector entities engaged in clinical trials, national health authorities or research councils involved in health research, clinical trial registries, research ethics bodies, national or transnational medicinal product regulatory authorities, decision-making bodies making use of evidence such as guidelines developers, and health technology assessment bodies, healthcare practitioners, patient engagement and community engagement entities, and professional associations in disciplines for whom clinical trials of health interventions are relevant. There may also be some relevance to medical journals.

We would like to receive your overall comments on what the draft guidance does well and less well at the moment, as well as comments on the sections of the document and line by line if desired. Please review the request for guidance development in WHA resolution 75.8 before providing comments….

ICH Reflection paper on proposed international harmonisation of real-world evidence terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines

30 June 2023
EMA/CHMP/ICH/295401/2023 Committee for Human Medicinal Products
Deadline for comment: 30 September 2023

Introduction

The role of real-world data (RWD) and real-world evidence (RWE) in supporting the evaluation of medicines across the different stages of their development and lifecycle is evolving [Framework for FDA, United States' Real-World Evidence Program 2018; Optimizing the Use of Real World Evidence to Inform Regulatory Decision-Making, Health Canada, Canada's 2019; ENCePP Guide on Methodological Standards in Pharmacoepidemiology, EMA 2022].

In July 2022, the International Coalition of Medicines Regulatory Authorities expressed its strong support to strengthening international collaboration on activities to enable the use of RWE in regulatory decision-making [ICMRA, 2022]. This statement emphasises the engagement of regulatory agencies across the globe to address current gaps due to the lack of standardisation of RWD/RWE terminology and formats, the heterogeneity of data quality across RWD sources, and the various study designs used depending on the types of diseases, medicines, and regulatory context. Addressing these challenges should be supported by common definitions and best practices.

This Reflection Paper outlines a strategic approach for ICH to address some of these challenges. The goal is to further enable the integration of RWE into regulatory submissions and timely regulatory decision-making.

Postmarketing Approaches To Obtain Data on Under-Represented Populations in Clinical Trials; Draft Guidance for Industry; Availability

U.S. Food and Drug Administration on Aug 11, 2023
Comments on the draft guidance by October 10, 2023

Summary

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials." The purpose of this draft guidance is to describe FDA requirements and provide recommendations for obtaining safety and effectiveness information on drug and biological products, when appropriate, in the post marketing setting in historically underrepresented patient populations in clinical trials. FDA regulations require sponsors to present information from premarket clinical trials on the safety and effectiveness of drugs in terms of gender, age, and racial subgroups. These clinical trials should include patient populations that are historically underrepresented in clinical research, including but not limited to, populations based on race, ethnicity, sex, age, geographic location, gender identity, socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity.

Obtaining information early in development can be advantageous in that information may help inform subsequent clinical trials and ultimately result in more efficient, informative, and successful drug development. However, if despite the sponsor's best efforts, these populations are not adequately represented in premarket clinical trials or if the data suggests there may be serious safety concerns in these populations, it may be appropriate to collect such data in the post marketing setting. Reviews of clinical trial data indicate that there is often underrepresentation of patient populations, based on race, ethnicity, sex, or age.

The draft guidance discusses mechanisms by which FDA can require or request information on safety and effectiveness be collected in the post marketing setting; design and statistical considerations for subpopulation analyses; and post marketing approaches to obtain information on the benefit-risk profile in underrepresented clinical trial populations.

Underrepresentation in clinical trials remains a significant issue despite the Agency's efforts to encourage sponsors and investigators to improve representation of historically under-represented patient populations. We welcome further dialogue in other settings or collaborative efforts to explore methods to enhance representation in clinical trials…

NIH Seeks Input on Proposed Revisions to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

Public comments will be accepted until October 10, 2023

NIH is seeking public input on a proposal to revise the NIH Guidelines to strengthen biosafety practices research involving gene drive modified organisms (GDMOs) in contained research settings. Part of the proposal seeks to: Clarify the minimum containment requirement for research involving GDMOs; and Articulate considerations for risk assessment and define institutional responsibilities for Institutional Biosafety Committees and Biosafety Officers. These proposed changes are consistent with recommendations contained in the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) report, Gene Drives in Biomedical Research.

The full proposal can be found in the Federal Register. . Comments must be submitted using the electronic comment form. Additional context on the NIH proposal can be found in the latest Under the Poliscope blog at: https://osp.od.nih.gov/turning-listening-into-action-a-proposal-to-strengthen-the-nih-guidelines/

Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework

A Notice by the U.S. Science and Technology Policy Office on 09/01/2023

Responses are due on October 16, 2023 by 11:59 p.m. Eastern Time.

SUMMARY:

Life sciences research is vital for improving health outcomes and protecting the Nation from infectious disease threats, but a small subset of this research could potentially pose risk of accidents or misuse that could harm human health. It is important to regularly evaluate and update biosafety and biosecurity oversight policies to keep pace with new technological developments and the evolving risk landscape.

The Office of Science and Technology Policy (OSTP) invites comments on potential changes to the Policies for Federal and Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) and Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO). These policies establish frameworks for review and oversight requirements for certain categories of life sciences research, namely research with certain pathogens and toxins, including at institutions that accept Federal funding for such research... The public input provided through this Request for Information (RFI) will inform policy evaluations and issuance of a revised policy (Revised Policy).

Copyright Office Issues Notice of Inquiry on Copyright and Artificial Intelligence

Library of Congress 30 August 2023

Written comments are due by 11:59 p.m. EDT on Wednesday, Oct. 18, 2023. Reply comments are due by 11:59 p.m. EDT on Wednesday, Nov. 15, 2023..

The Copyright Office will use the record it assembles to advise Congress; inform its regulatory work; and offer information and resources to the public, courts, and other government entities considering these issues.

The notice of inquiry seeks factual information and views on a number of copyright issues raised by recent advances in generative AI. These issues include the use of copyrighted works to train AI models, the appropriate levels of transparency and disclosure with respect to the use of copyrighted works, the legal status of AI-generated outputs, and the appropriate treatment of AI-generated outputs that mimic personal attributes of human artists.

The notice of inquiry is an integral next step for the Copyright Office's AI initiative, which was launched in early 2023. Instructions for submitting comments are available on the Office's website. Commenters may choose which and how many questions to respond to in the notice of inquiry.

Request for Information (RFI): Inviting Comments and Suggestions on Updating the NIH Mission Statement

NIH Posted August 28, 2023

To ensure consideration, **responses must be submitted by: 2023-11-24 11:59:59 PM ET**

As the largest public funder of biomedical and behavioral research in the world, NIH works to turn scientific discoveries into better health for all. This RFI will inform NIH's efforts to update its mission statement to ensure that it reflects the NIH mission as accurately as possible. See guide notice NOT-OD-23-163 for more information.

Information Requested

This RFI invites input from interest groups throughout the scientific research, advocacy, and clinical practice communities, those employed by NIH or at institutions receiving NIH support, and the public, on a proposed revised mission statement. The bolded language reflects differences between the current and proposed mission statements.

Current mission statement:

"To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

Proposed revised mission statement:

"To seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people."

EMA – Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft 13 July 2023 1

EMA/CHMP/CVMP/83833/2023 2

Committee for Medicinal Products for Human Use (CHMP) 3

Committee for Medicinal Products for Veterinary Use (CVMP)

End of consultation (deadline for comments): 31 December 2023

Comments should be provided using this EUSurvey form).

This reflection paper provides considerations on the use of AI and ML in the lifecycle of medicinal 56 products, including medicinal products development, authorisation, and post-authorisation. Given the rapid development in this field, the aim of this reflection paper is to reflect on the scientific principles that are relevant for regulatory evaluation when these emerging technologies are applied to support safe and effective development and use of medicines.

FDA - Meetings: Mitigating Clinical Study Disruptions during Disasters and Public Health Emergencies

DATES: **The public meeting will be held virtually on October 18 and 19, 2023**, from 10 a.m. to 1:30 p.m. Eastern Time

Meeting only; No public comment opportunity identified

.SUMMARY:

The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled "Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies." This public meeting will satisfy the mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) to convene a public meeting on clinical study flexibilities initiated in response to the COVID–19 pandemic. The public meeting will be convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative (CTTI) to bring the clinical research community together to discuss a variety of topics related to mitigating disruptions of clinical studies of medical products during disasters and public health emergencies (PHEs). The meeting format will include presentations and panel discussions.

Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: www.duke.zoom.us/meeting/register/tJAvcO-oqD4vE9Ov1Vv-A3SoItVhL7Rhg66T. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free, and persons interested in attending this public meeting must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

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.

::::::::::

::::::::::

Environment/Climate/Disaster Mitigation

Call for Public Comment on the Draft Prospectus of the First National Nature Assessment

Posted Aug 4, 2023 Open Notice

The USGCRP Public Contribution System will accept **comments from August 4 – September 18, 2023.**

Overview

In coordination with the U.S. Department of Interior, the U.S. Global Change Research Program (USGCRP) welcomes public comment on the draft prospectus of the First National Nature Assessment (NNA1).

All comments must be made via the USGCRP Public Contribution System if they are to be considered. Reviewers can provide comments via this online mechanism. The NNA1 Draft Prospectus is embedded in the public comment section of the USGCRP Public Contribution System, and you may also access it via the Federal Register Notice.

USGCRP is conducting the First National Nature Assessment to assess changes in nature as an aspect of global change. The scope of NNA1 is to assess the status, observed trends, and future projections of America's lands, waters, wildlife, biodiversity, and ecosystems and the benefits they provide, including connections to the economy, public health, equity, climate mitigation and adaptation, and national security.

In developing NNA1, USGCRP will follow the principles of a use-inspired, knowledge-informed assessment, in which the design is driven both by the potential uses of the final products and by science and other forms of knowledge. USGCRP recognizes the importance of lived experiences and acknowledges Indigenous Knowledge as an important form of evidence. Across all phases of NNA1, USGCRP aims to be inclusive, represent diverse perspectives, and create products that are accessible to the widest possible audience.

All comments must be submitted via the USGCRP Public Contribution System by 11:59 pm EDT, Monday, September 18, 2023.

Consultation on the Global Methodology for Infrastructure Resilience Review

United Nations Office for Disaster Risk Reduction (UNDRR)

23 August 2023

This Global Methodology will be in **consultation from 23 August 2023 to 30 September 2023.**

The United Nations Office for Disaster Risk Reduction invites members of the Disaster Risk Reduction (DRR) community to comment on the Global Methodology for Infrastructure Resilience Review. The Global Methodology, developed by the UNDRR)and the Coalition for Disaster Resilient Infrastructure (CDRI), aims to support countries in assessing the current state of infrastructure resilience so that areas of improvement are identified and actions taken.

The Global Methodology takes into consideration the systemic issues that make infrastructure vulnerable to current shocks and future risks; the expected changes in demand and supply of infrastructure services; and possible improvements in governance and decision-making processes to enhance infrastructure resilience and prepare for future challenges. Please send us your comments through this online form.

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment

Issued by Special Rapporteur on human rights and the environment, UNHCHR

Deadline: 02 October 2023

Purpose:

To inform the entity's report on the implementation of the human right to a clean, healthy and sustainable environment which will be presented at 55th session of the Human Rights Council.

Background:

The Special Rapporteur has completed a series of six thematic reports on the substantive elements of the human right to a clean, healthy and sustainable environment, including clean air, safe and sufficient water, healthy and sustainably produced food, non-toxic environments, healthy ecosystems and biodiversity and a safe, livable climate. He would like to seek inputs on the procedural or participatory elements of the right to a clean, healthy and sustainable environment, including access to information, public participation and access to justice with effective remedies…

How inputs will be used

Your replies will inform the Special Rapporteur's analysis and contribute to a report which will be presented at the 55th session of the Human Rights Council.

Download the questionnaire (WORD): English | Français | Español

::::::::::

::::::::::

Human Rights

Call for inputs from the mandate of the Working Group on discrimination against women and girls

UNHCHR - Special Procedures

Issued by Working Group on discrimination against women and girls

Deadline: 18 September 2023

Purpose:

To inform the Working Group on lessons learned, key challenges and opportunities related to the mandate, and its impact, particularly over the past six years.

Background:

We intend to include stocktaking of the Group's work in its reporting to the Human Rights Council in 2024, as well as an analysis of the global context of escalating backlashes against women's and girls' universal human rights and gender equality.

Objectives:

We hope that this will contribute to strengthening the work of the mandate while reiterating our commitment towards accountability. Such a stocktaking exercise will also be useful for the four new members of the Working Group who will be appointed in September 2023.

Key questions and types of input/comments sought

Download the questionnaire (PDF): English

Investors, ESG and Human Rights

Call for Input - Special Procedures

UNHCHR – Issued by Working Group on Business and Human Rights

Deadline: 30 September 2023

Scope

The report aims to provide practical guidance to States, businesses, especially financial institutions of all types, civil society and other stakeholders on how to align better ESG approaches with the UNGPs in the context of financial products and services. This will be done in relation to the provisions of the UNGPs and related documents. It will build on the work previously undertaken by the Working Group, the Office of the High Commissioner for Human Rights, OECD and other organisations, 8 including the project on Responsible Business Conduct in the Latin American and Caribbean region. 9

Call for inputs: Resettlement as a human rights issue

UNHCHR - Special Procedures
Issued by Special Rapporteur on the right to adequate housing
Deadline: 30 September 2023

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, and 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.

Call for input: Advocacy of Hatred Based on Religion or Belief - Transformative Responses

UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of religion or belief
Deadline: 29 October 2023
Objectives

In this forthcoming report, the Special Rapporteur intends to explore the dimension of hatred and its relationship to intolerance, discrimination, and violence based on religion or belief. She seeks to identify gaps in State and civil society responses to countering advocacy of such hatred, explore their impact, share best practices from the ongoing efforts of different stakeholders, and assess implications for developing transformative responses to counter the advocacy of hatred based on religion or belief.

The Special Rapporteur invites all interested parties (States, UN agencies and international organisations, national human rights institutions, businesses especially media and tech companies, civil society organisations including religious or belief minorities and communities) to provide input for this report in response to the [15] relevant questions noted.

Call for inputs: Human Rights Council resolution 52/8 on promoting human rights and the Sustainable Development Goals through transparent, accountable and efficient public service delivery

Call for input | Office of the High Commissioner for Human Rights
Deadline: 01 November 2023
Purpose:
To inform the report on the role of public service delivery in the promotion and protection of human rights and in the achievement of the Sustainable Development Goals, including in relation to the protection of persons in vulnerable situations, that reflects best practices, challenges and recommendations in assisting national Governments in delivering transparent, accountable and efficient public services.

::::::::::
::::::::::

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

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 08/31/2023
August 31, 2023.
PDF: https://www.govinfo.gov/content/pkg/FR-2023-08-31/pdf/2023-18841.pdf
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products." FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program for drugs and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision making. This guidance discusses the applicability of FDA's investigational new drug application (IND) regulations to various clinical study designs that utilize real-world data (RWD) and clarifies the Agency's expectations regarding clinical studies using RWD submitted to FDA in support of a regulatory decision regarding the effectiveness or safety of a drug that are not subject to the IND regulations. This guidance finalizes the draft guidance of the same title issued on December 9, 2021.

Institutional Review Board Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products; Guidance for Institutional Review Boards and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of availability.
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for institutional review boards (IRBs) and clinical investigators entitled "Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products." FDA is issuing this final guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under FDA regulations. Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek further clarity on this topic.

* * * *