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

20 April 2023 – Issue 02

GE2P2 Global is developing a formal monitoring approach to identify public consultations/calls for input/RFIs and similar opportunities across its focus areas of health, human rights, humanitarian action, education, heritage, and sustainable development. This span of sectors yields a broad variety of opportunities, even though public consultation is not employed in any uniform way across the UN system, multilateral agencies, INGOs or UN member states and their ministerial/regulatory bodies. As we are still refining our monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

The GE2P2 Global Foundation is striving to respond to these opportunities where the experience and prior analytical/advisory work of members of its community of practice suggest that a meaningful contribution can be developed. The 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 public consultation opportunities primarily focused on biomedical research.

Individuals and organizations/institutions interested in collaborating on responses to any of the opportunities listed below are welcome to contact David R Curry, GE2P2 Global Foundation, at david.r.curry@ge2p2global.org.

Opportunities are organized by due date of inputs/submissions. The initial list below presents title/ source due date. This is followed by the same call with their respective "abstracts" including selective information around purpose, objective, and background. Most opportunities have relatively short time horizons for response, typically 60-90 days from the date of posting.

NIH [USA] - Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research
Deadline: April 24, 2023.

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment
UNHCHR call for input | Special Procedures Issued by Special Procedures
Deadline 01 May 2023

FDA [USA] - Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments
A Notice by the Food and Drug Administration on 03/01/2023
https://www.regulations.gov/docket/FDA-2023-N-0487
Due: May 1, 2023

Call for comments and textual suggestions: Second revised text of the draft convention on the right to development
Issued by Intergovernmental Working Group on the right to development
UN UNHCHR - call for input | HRC subsidiary body
Deadline: 12 May 2023

Call for input to the report of the Special Rapporteur on human rights defenders to the General Assembly on the challenges faced by woman human rights defenders working in conflict, post-conflict or crisis-affected settings
Issued by Special Rapporteur on human rights defenders
Deadline 22 May 2023

Call for inputs: Report on colonialism and sexual orientation and gender identity
Call for Input | Special Procedures
Issued by Independent Expert on sexual orientation and gender identity
Deadline 26 May 2023

Research Involving Children as Subjects and Not Otherwise Approvable by an Institutional Review Board: Process for Referrals to Food and Drug Administration and Office for Human Research Protections, Guidance for Institutional Review Boards, Investigators, and Sponsors;
Public Comment Due: May 30, 2023

ICC - The Office of the Prosecutor launches public consultation to renew the policy paper on crimes against or affecting children
Statement 9 March 2023 Office of the Prosecutor, International Criminal Court
Due: 31 May 2023

Good Governance Practice for Research Institutions
CIOMS – COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES https://cioms.ch/
PUBLIC CONSULTATION IS NOW OPEN 7 June 2023

AI Accountability Policy Request for Comment
U.S. National Telecommunications and Information Administration, U.S. Department of Commerce.
Comment period ends 06/12/2023

Stakeholder Listening Session on Amendments to the International Health Regulations (2005)
A Notice by the U.S. Health and Human Services Department on 04/13/2023
Written Comment Re: Stakeholder Listening Session 2 for the IHR " by
Friday, June 30, 2023.

Call for inputs for the study of the Human Rights Council Advisory Committee on neurotechnology and human rights (HRC resolution 51/3)
Issued by Advisory Committee, UNHCHR
Deadline 02 July 2023

Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response
A Notice by the U.S. Health and Human Services Department
"Written Comment Re: Stakeholder Listening Session 2 for the INB " by
Friday, July 7, 2023

Call for inputs for the study of the Human Rights Council Advisory Committee on neurotechnology and human rights (HRC resolution 51/3)
Issued by Advisory Committee, UNHCHR
Deadline 02 July 2023

ISO/AWI 14155 - Biological and clinical evaluation of medical devices
ISO/TC 194 Stage 20.00
Due: Ongoing at national standards bodies level

Call Abstract Information: Selected Purpose/Objective/Background Information

NIH [USA] - Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research
The comment period will close on April 24, 2023.
NIH seeks public input on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research (NIH Public Access Plan). In 2022, the White House Office of Science and Technology Policy (OSTP) released a memo on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research that establishes new guidance for improving public access to scholarly publications and data resulting from Federally supported research. The NIH Public Access Plan outlines the proposed approach NIH will take to implement the new guidance, consistent with its longstanding commitment to public access. The Public Access Plan can be viewed at: NOT-OD-23-091.

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment
UNHCHR call for input | Special Procedures Issued by Special Procedures
Deadline 01 May 2023
Purpose
To inform the entity's report on "Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment" to be presented at the General Assembly in October 2023.
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. His next thematic report will address 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. In light of the Framework Principles on Human Rights and the Environment, the report will also address related topics including the rights to environmental education, freedom of expression and association, and safe spaces for environmental human rights defenders. The Special Rapporteur is seeking inputs on the topic from States, rightsholders and stakeholders through responses to the questions below.

Your replies will inform the Special Rapporteur's analysis and contribute to his report, which will be presented to the UN General Assembly in October 2023.

FDA [USA] - Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments

A Notice by the Food and Drug Administration on 03/01/2023
https://www.regulations.gov/docket/FDA-2023-N-0487

Due: May 1, 2023

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing publication of a discussion paper providing information for stakeholders and soliciting public comments on a specific area of emerging and advanced manufacturing technologies. The discussion paper presents areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER) scientific and policy experts associated with application of artificial intelligence (AI) to pharmaceutical manufacturing. The discussion paper includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research (CBER) stakeholders.

Call for comments and textual suggestions: Second revised text of the draft convention on the right to development

Issued by Intergovernmental Working Group on the right to development
UN UNHCHR - call for input | HRC subsidiary body

Deadline: 12 May 2023

Background

In its resolution 51/7, the Human Rights Council requested the Chair-Rapporteur of the Working Group to submit a second revised draft convention to the Working Group at its 24th session for intergovernmental negotiation and, following that process, to submit the final draft text of the convention to the Council.

This second revised text of the draft convention on the right to development (A/HRC/WG.2/24/2) and corresponding commentaries (A/HRC/WG.2/24/2/Add.1) are available on the webpage of the 24th session of the Working Group on the Right to Development.

With the view to facilitating the continuation of the negotiations of the draft convention, the OHCHR kindly invites all United Nations Member and Observer States, specialized agencies and other intergovernmental organizations with observer status, national human rights institutions with "A status" and NGOs with ECOSOC consultative status to further submit comments and textual suggestions on the second revised draft convention.

Call for input to the report of the Special Rapporteur on human rights defenders to the General Assembly on the challenges faced by woman human rights defenders working in conflict, post-conflict or crisis-affected settings

Issued by Special Rapporteur on human rights defenders

Deadline 22 May 2023

Background

By women human rights defenders, the Special Rapporteur means all women and girls working on any human rights issue ("women defenders" and "girl defenders"), and any person who works to promote women's rights and rights related to gender equality.[1] This includes lesbian, gay, transgender and intersex (LGBTI) activists, as issues related to sexual orientation and gender identity are part of achieving gender equality. It also includes civil society actors working on the above who may not self-identify as human rights defenders, which could include, for example, journalists, health workers, environmental activists, peacebuilders, private actors, development and humanitarian actors, etc.

The report will build on the report of her predecessor to the Human Rights Council in 2020 (A/HRC/43/51) on the situation of human rights defenders in conflict and post-conflict settings, and will also draw on the work done by the Secretary General in his annual reports on Women, Peace and Security (most recently S/2022/740) presented to the Security Council.

Objectives

The Special Rapporteur is seeking to identify the specific and intersectional risks faced by WHRDs in these contexts, barriers they face in working freely, protection strategies they use to mitigate risk and recommendations for how international actors, including the UN, can make their work safer.

Call for inputs: Report on colonialism and sexual orientation and gender identity

Call for Input | Special Procedures

Issued by Independent Expert on sexual orientation and gender identity

Deadline 26 May 2023

Purpose:

Report to be presented to the 78th session of General Assembly in October 2023

The Independent Expert on protection against violence and discrimination based on sexual orientation and gender identity (IE SOGI), Mr. Victor Madrigal-Borloz, will dedicate his report to the 78th session of the United Nations General Assembly to the issue of the historic and ongoing impacts of colonialism on the enjoyment of human rights by lesbian, gay, bisexual, trans and gender diverse (LGBT) persons.

The report will examine the past and present colonial regulation of sexual orientation and gender identity through laws, policies and practices, and how such regulation continues to impact the lives of LGBT persons, including through layers of cultural influence and social mores on concepts of gender and sexuality. This report will also explore the legal grounds and means available to reckon with the legacies of colonialism in the enjoyment of human rights by all people, including LGBT persons and communities. Finally, the report will account for the different legal or policy measures that have been adopted to recognize and provide reparation and redress for the impacts of colonialism on regulation of sexual orientation and gender identity at the regional or national levels.

Call for Inputs

The Independent Expert invites all interested States, civil society organizations, academics, international organizations, national human rights institutions, activists, corporations, and others, to provide written inputs to the following questions for his thematic report. Inputs are welcome in relation to particular practices in States or territories, as well as more general inputs concerning regions or the international community as a whole.

Research Involving Children as Subjects and Not Otherwise Approvable by an Institutional Review Board: Process for Referrals to Food and Drug Administration and Office for Human Research Protections, Guidance for Institutional Review Boards, Investigators, and Sponsors;

Public Comment Due: May 30, 2023

Today, the FDA announced the draft guidance, This guidance is intended to assist institutional review boards (IRBs), institutions, investigators and sponsors in understanding the processes used for review of research involving children that is not otherwise approvable by an IRB and has been referred to the FDA and/or the Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) for review.

When final, this guidance will replace the final guidance issued by the FDA in December 2006 entitled, "Guidance for Clinical Investigators, Institutional Review Boards and Sponsors: Process for Handing Referrals to FDA Under 21 CFR 50.54: Additional Safeguards for Children in Clinical Investigations" and the guidance issued by the OHRP entitled "Children as Research Subjects and the HHS "407" Process," issued on May 26, 2005.

See the announcement for more information.

ICC - The Office of the Prosecutor launches public consultation to renew the policy paper on crimes against or affecting children

Statement 9 March 2023 Office of the Prosecutor, International Criminal Court

Due: 31 May 2023

The Prosecutor of the International Criminal Court, Mr Karim A.A. Khan KC is pleased to announce a call for public submissions for suggested changes to build upon, and renew, the 2016 OTP Policy on Children.

In launching this policy renewal process the Office will seek to develop new and innovative approaches to its work so as to make children more visible in all of its work, and further improve effectiveness in the investigation and prosecution of crimes against or affecting children.

… In this first round of external consultations, the Office welcomes comments on the substance of the policy and encourages proposals as to how it may be enhanced. The Prosecutor is of the view that external consultations on its policies and working methods are important for maintaining and furthering transparency and predictability, and generating the most comprehensive policies.

Comments can be sent to OTP.Policies@icc-cpi.int by Wednesday,, midnight, CEST. All input received by the deadline will be carefully considered in the internal review and revision process. 31 May 2023

Good Governance Practice for Research Institutions

CIOMS – COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES https://cioms.ch/

PUBLIC CONSULTATION IS NOW OPEN 7 June 2023

You are invited to comment on the below report by sending comments to ggpri@cioms.ch before 7 June 2023 Only comments on this form will be considered: download here

Background

Over the last 50 years, the Declaration of Helsinki has been revised 6 times (8 if one counts the notes of clarification on the placebo rule from 2002 and 2004). The CIOMS International ethical guidelines for health-related research involving humans have also been reshaped three times, not mentioning their merging with the 2009 Guidelines for epidemiological studies, which had been revised once since the original version in 1991. During the same period, many guiding documents, regulations and laws have been adopted at the national, regional and international levels.

Fifty years later, it is questionable whether researchers are better equipped to face the challenges raised by their activities. They often lack the necessary resources to respond to the increasingly complex ethical and regulatory framework of research. Most regulations focus on the responsibilities of researchers and the sponsors, but provide little or even no details on means to achieve them. In particular, there is limited guidance on the governance of research institutions even if it is central to defining the context in which research involving human participants is conducted. Instead of adding more rules or revising existing ones, it seems a priority today to improve the research environment.

The issues

Most ethical guidelines and laws focus on individual researchers and sponsors to protect the dignity, integrity and safety of research participants – Research Ethics Committees (REC) acting as gatekeepers. Yet, it is rarely assessed to what extent researchers and sponsors have the necessary resources to fulfil their responsibilities. More precisely, this assessment is done separately for each protocol. It does not provide a broad picture of the research activities and available resources in a given company, hospital or university to guarantee the protection of research participants in the end.

Stakeholder Listening Session on Amendments to the International Health Regulations (2005)

A Notice by the U.S. Health and Human Services Department on 04/13/2023

Written Comment Re: Stakeholder Listening Session 2 for the IHR ” by

Friday, June 30, 2023.

Purpose:

The U.S. Department of Health and Human Services (HHS) is charged with leading U.S. participation in the Working Group on the Amendments to the International Health Regulations (2005) and will convene a Stakeholder Listening Session.

The World Health Assembly (WHA) originally adopted the International Health Regulations (IHR) in 1969. The regulations were amended multiple times, resulting in the current IHR (2005). The purpose of IHR (2005) is to prevent, protect against, control, and provide public health response to the international spread of disease. In May 2021, Member States set up a Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) with the intent of strengthening WHO's capacities and ability to support Member States in the prevention and response of public health emergencies. The WGPR produced a report with key findings and recommendations that included amending the IHR. The United States submitted a package of targeted amendments to the IHR for consideration. These amendments seek to improve early warnings and alerts, transparency, and accountability in a manner that does not compromise national security or sovereignty.

Other countries have also submitted proposals that the United States seek feedback from stakeholders on the proposed amendments. The Stakeholder Listening Session is designed to seek input from stakeholders and subject-matter experts on these proposals and to help inform and prepare the U.S. government for engagement with the Working Group on the Amendments to the International Health Regulations (2005).

AI Accountability Policy Request for Comment

U.S. National Telecommunications and Information Administration, U.S. Department of Commerce.

Comment period ends 06/12/2023

SUMMARY:

The National Telecommunications and Information Administration (NTIA) hereby requests comments on Artificial Intelligence ("AI") system accountability measures and policies. This request focuses on self-regulatory, regulatory, and other measures and policies that are designed to provide reliable evidence to external stakeholders—that is, to provide assurance—that AI systems are legal, effective, ethical, safe, and otherwise trustworthy. NTIA will rely on these comments, along with other public engagements on this topic, to draft and issue a report on AI accountability policy development, focusing especially on the AI assurance ecosystem.

…The objective of this engagement is to solicit input from stakeholders in the policy, legal, business, academic, technical, and advocacy arenas on how to develop a productive AI accountability ecosystem. Specifically, NTIA hopes to identify the state of play, gaps, and barriers to creating adequate accountability for AI systems, any trustworthy AI goals that might not be amenable to requirements or standards, how supposed accountability measures might mask or minimize AI risks, the value of accountability mechanisms to compliance efforts, and ways governmental and non-governmental actions might support and enforce AI accountability practices.

Call for inputs for the study of the Human Rights Council Advisory Committee on neurotechnology and human rights (HRC resolution 51/3)

Issued by Advisory Committee, UNHCHR

Deadline 02 July 2023

Purpose:

The Human Rights Council Advisory Committee seeks the views and inputs from stakeholders, including Member States, international and regional organizations, the Office of the United Nations High Commissioner for Human Rights, the special procedures of the Human Rights Council, the treaty bodies, other relevant United Nations agencies, funds and programmes within their respective mandates, national human rights institutions, civil society, the private sector, medical and technical communities, academic institutions and other relevant stakeholders, in order to prepare a study on the impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights, including recommendations on how human rights opportunities, challenges and gaps arising from neurotechnology could be addressed by the Human Rights Council and its special procedures and subsidiary bodies in a coherent, holistic, inclusive and action-oriented manner, and to present the study to the Council at its fifty-seventh session (September 2024).

Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

A Notice by the U.S. Health and Human Services Department

"Written Comment Re: Stakeholder Listening Session 2 for the INB " by

Friday, July 7, 2023

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

ISO/TC 194 Stage 20.00

Due: Ongoing at national standards bodies level

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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