***ge²p² global***

governance, ethics, evidence, policy, practice

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

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

**17 March 2023 – Issue 01**

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, 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.

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***Opportunities are organized by due date of inputs/submissions. The list below presents title/source due date> The full abstract for each call is presented further below. Most opportunities have relatively short time horizons for response, typically 60-90 days from the date of issue/posting.***

**Call for inputs: Food, nutrition and the right to health**
UNHCHR call for input | Special Procedures
**Deadline 24 March 2023**

**Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development - Draft Guidance for Industry**
[February 2023 Docket: 2023-02962
**Due: 04/14/2023**

**Call for input on The use of technology in facilitating and preventing contemporary forms of slavery**
UNHCHR call for input | Special Procedures
Issued by Special Rapporteur on contemporary forms of slavery, including its causes and its consequences

**Deadline: 14 April 2023**

**Call for input: Addressing the exploitation and sexual abuse of children in the context of travel and tourism; a closer look at the phenomena of voluntourism**

UNHCHR call for input | Special Procedures

Issued by Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material

**Deadline: 21 April 2023**

**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.**

**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**

**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**

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

ISO/TC 194 Stage 20.00

**Due: Ongoing at national standards bodies level**

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**Call for inputs: Food, nutrition and the right to health**

UNHCHR call for input | Special Procedures

**Deadline 24 March 2023**

Purpose

To inform the Special Rapporteur's forthcoming thematic report on "Food, nutrition and the right to health" to be presented to the General Assembly in October 2023

Background

Within the framework of Human Rights Council resolution 51/21, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, has identified analyzing the progress and challenges to attaining the Sustainable Development Goals (SDGs) as one of the strategic priorities during her tenure, along with analyzing the role of the underlying determinants of health, such as climate change and environment, water and sanitation, education and gender equality (See: A/HRC/47/28 para. 108). In compliance with her mandate and in line with these priorities, she has decided to devote her next thematic report to the General Assembly, to be held in October 2023, to the issue of "Food, nutrition and the right to health".

**Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development - Draft Guidance for Industry**

[February 2023 Docket: 2023-02962

**Due: 04/14/2023**

The purpose of this guidance is to provide a framework for considering whether and what type of long-term neurologic, sensory and developmental evaluations could be useful to support a determination of safety of a drug, biological product, or device (referred to as 'medical product' in this guidance) for use in neonates2, and if so, which domains of neurodevelopment may be most applicable.

This guidance will not specifically address efficacy or effectiveness assessments for products primarily intended to improve neurologic outcomes, e.g., neuroprotective agents. This guidance is focused on long-term evaluations of neurodevelopmental safety. Although assessments of nephrotoxicity, pulmonary toxicity, and toxicity to other tissues and organs may also be warranted in neonatal medical product development, the approach to those assessments is outside the scope of this guidance…

**Call for input on The use of technology in facilitating and preventing contemporary forms of slavery**

UNHCHR call for input | Special Procedures

Issued by Special Rapporteur on contemporary forms of slavery, including its causes and its consequences

**Deadline: 14 April 2023**

Purpose

To inform the report of the Special Rapporteur on contemporary forms of slavery, including its causes and consequences, to the 78th session of the General Assembly

Objectives of the report

The Special Rapporteur on contemporary forms of slavery, including its causes and consequences, wishes to focus his next thematic report to the General Assembly on "the use of technology in facilitating and preventing contemporary forms of slavery". For the purpose of the report, he aims to also assess the experiences of survivors/victims who have been recruited and exploited in conducts within his mandate, particularly forced labour, the worst form of child labour, and forced and early marriage, with the use of modern technology in addition to analysing information from multiple other stakeholders and sources.1

**Call for input: Addressing the exploitation and sexual abuse of children in the context of travel and tourism; a closer look at the phenomena of voluntourism**

UNHCHR call for input | Special Procedures

Issued by Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material

**Deadline: 21 April 2023**

Purpose

To inform the Special Rapporteur's forthcoming report to the 78th session of the UN General Assembly in October 2023.

Background

Global travel and tourism have more than doubled in the past 30 years, and there has been a surge in new travel "products" which have exposed children to exploitation. Such products include volunteer tourism, orphanage tourism and mega-events. This global growth in travel and tourism has outpaced efforts to respond at the international and national levels, leaving child protection regulations lagging behind the unprecedented growth of travel and new forms of tourism.

The socioeconomic crisis caused by the COVID-19 pandemic has exacerbated the existing stark inequalities and vulnerabilities of the most disadvantaged children, and as travel and tourism picks up after the pandemic, our attention is once again fixed on the risks to exploitation and sexual abuse children are exposed to particularly in the context of orphanage tourism and orphanage trafficking.

The Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material has therefore initiated the preparation of her next thematic report to the 78th session of the UN General Assembly, to be presented in October 2023 on this issue.

## 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.

**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

**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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