ge²p² global

governance, ethics, evidence, policy, practice

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

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

17 June 2024 - Issue 19

GE2P2 Global is a non-profit foundation with a public benefit corporation affiliate formed to advance scientific rigor, ethical resilience, and integrity in research and evidence generation informing governance, policy, and practice.

In the context of this mission, GE2P2 Global is refining a monitoring approach to identify public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education, heritage, climate/environment, peace, and sustainable development.

Monitoring this span of sectors yields a broad variety of public comment opportunities, even though this modality is not employed in any uniform way across the UN system, multilateral agencies, INGOs, or member states and their ministerial/regulatory bodies. As we are still exploring this monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

In parallel, GE2P2 Global is striving to respond to such opportunities where the experience and expertise of members of our growing community of practice suggest that a meaningful contribution can be developed. The GE2P2 Global Foundation also functions as the secretariat for the Global Forum for Research Ethics and Integrity – a global group of individuals from over 30 countries who collaborate on analysis and action including response to selected public consultations.

We welcome information about calls for public consultation – at global or country level – to help enrich this digest. Equally, individuals and organizations/institutions interested in collaborating on joint responses to any of the opportunities listed below are welcome to contact us [David R Curry, GE2P2 Global Foundation, david.r.curry@ge2p2global.org].

Acknowledgements: We appreciate the support of Foundation Senior Fellow Gerald Schatz, JD for his continuing support in helping identify calls included in this digest, and Associate Fellow Sedem Adiabu, MPH, for her critical role in the secretariat function which supports development of submissions to selected calls.

Digest content is organized in three sections:

We expect to add thematic areas as our digest evolves and becomes more comprehensive..

Call for Public Consultation: Title/Source/Sorted by Due Date

Agency Information Collection Revision 60-Day Public Comment Request
Health and Human Services Department 04/25/2024 **Comments due June 24, 2024.**
Reporting of specific human subject protection incidents to OHRP

NIH and FDA Seek Comment on Draft Glossary of Clinical Research Terms Related to Innovative Clinical Trial Design
NIH, FDA [USA] 06 May 2024 **Comments due June 24, 2024.**

Call for input for the report on Artificial Intelligence and international solidarity
call for input | Special Procedures
Issued by Independent Expert on human rights and international solidarity **Deadline: 30 June 2024**

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry
A Notice by the Food and Drug Administration on 05/06/2024 **Written comments due by July 5, 2024**

NEW - **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry**
A Notice by the Food and Drug Administration on 05/06/2024
Written comments on the draft guidance by July 5, 2024

NEW - **Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers**
Health and Human Services Department on 06/12/2024 **Comment period ends 07/11/2024.**

NEW - **Notice of Availability and Request for Information; Federal Evidence Agenda on Disability Equity**
U.S Science and Technology Policy Office on 05/30/2024 **Comment period ends 07/15/2024.**

NEW - **Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity in Access Planning**
Posted on May 21, 2024 **Comments must be received by July 22, 2024.**

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1); Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 05/23/2024 **Comments due by July 22, 2024**

Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing

A Notice by the U>S> Patent and Trademark Office on 04/30/2024
Written comments must be received on or before July 29, 2024

NEW - **Agency Information Collection Request; 60-Day Public Comment Request**
Health and Human Services Department on 06/03/2024 **Comment period ends 08/02/2024.**
Recordkeeping/Informed Consent/Consent Documentation

Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 05/07/2024
Written comments on the draft guidance by August 5, 2024

NEW - **Request for Information: Strategies for Maximizing Public Engagement in NIH Supported Clinical Research**

NEW - **Request for Information on the National Institutes of Health Draft Public Access Policy**
Institutes of Health, HHS. **Comment due 16 August 2024**

Call for submissions on draft general comment No. 27 on children's rights to access to justice and effective remedies
call for input | Treaty bodies Issued by CRC **Deadline: 23 August 2024**

Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence
EMA Reference Number: EMA/CHMP/150527/2024
Consultation dates: 03/05/2024 to 31/08/2024

NEW - **Call for Public Comment: General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of Medicines.**
ICH *Varying deadlines depending on regulatory authority*

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

Contribute a tool - Catalogue of Tools & Metrics for Trustworthy AI
OECD-AI Policy Observatory
Contribute your tools and metrics to our catalogue. No deadline date identified.
This catalogue is a platform where AI practitioners from all over the world can share and compare tools and metrics to help make AI trustworthy, build upon each other's efforts to create global good practices, and speed up the process of implementing the OECD AI Principles. This catalogue can only exist with your contributions and those of AI practitioners from all sectors. You can also share your experience using a tool or metric by submitting a use case.
:: Contribute a tool
:: Share your experience using a tool

Call for Technological, Legal, and Social Solutions to Counter Disinformation on Social Media

NASEM, USA.

No submission deadline date identified.

The National Academies of Sciences, Engineering, and Medicine's *Committee on Evolving Technological, Legal and Social Solutions to Counter Disinformation on Social Media* is seeking creative ideas to detect, measure, and mitigate disinformation on social media and related platforms. If the Committee finds your submission particularly compelling, it will be discussed (or you could be asked to present and discuss it) at an April 10-11, 2024 National Academies' virtual workshop, which will feature two days of interactive brainstorming to foster new research and collaborations and build implementable solutions for a whole-of-society approach to mitigating disinformation and its detrimental effects.

A framework for evaluating rapidly developing digital and related technologies: AI, large language models and beyond - International Science Council Discussion Paper: Invitation to Comment

International Science Council [ISC]

No submission deadline date identified.

Global consultation on the Copenhagen Framework on Citizen Data

Collaborative on Citizen Data - 2 February 2024

Year-long global consultation spanning over 2024.

The Collaborative will aim to finalize the "Copenhagen Framework on Citizen Data" based on this global consultation and other country piloting studies, and submit to the 56th session of the United Nations Statistical Commission in March 2025.

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

Biomedical Research/Regulation/Governance

Agency Information Collection Revision 60-Day Public Comment Request

A Notice by the Health and Human Services Department on 04/25/2024

Comments on the ICR must be received on or before June 24, 2024.

Abstract:

The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting reinstatement of the OMB No. 0990-0477, Incident Report Form, with two new information elements on the Incident Report form: IORG # for Reviewing IRB; and, Revising research policies and procedures as a corrective action plan category, if it applies. **The purpose of the Incident Report form is to facilitate organizations or institutions prompt reporting of specific human subject protection incidents to OHRP,** in a simplified standardized format, as required by HHS protection of human subjects regulations at 45 CFR part 46.

SUMMARY:

In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

NIH and FDA Seek Comment on Draft Glossary of Clinical Research Terms Related to Innovative Clinical Trial Design

NIH, FDA [USA] 06 May 2024 **Comments due June 24, 2024.**

The National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) have released for public comment a draft glossary of clinical research terms related to innovative clinical trial design, including studies using real world data to generate real world evidence. The draft glossary is intended to facilitate communication within the clinical research community by helping establish a common vocabulary to characterize clinical research more uniformly.

For additional context on this NIH-FDA collaboration, please see the latest Under the Poliscope blog by Dr. Lyric Jorgenson. Questions about this draft glossary can be sent to SciencePolicy@od.nih.gov

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry

A Notice by the Food and Drug Administration on 05/06/2024

Written comments on the draft guidance by July 5, 2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #290 (VICH GL61) entitled "Pharmaceutical Development." This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance describes the suggested contents for the Pharmaceutical Development section, which provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management to the development of a product and its manufacturing process.

NEW - Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers

Health and Human Services Department on 06/12/2024 **Comment period ends 07/11/2024.**

SUMMARY:

The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) seeks input on involving community health workers (CHWs) to increase "cultural competency in educational campaigns on public health vaccines and prevention, including but not limited to influenza and COVID-19."

Request for Information

Through this RFI, OMH seeks to obtain information from CHWs, recipients of CHW services, and organizations representing and/or communities using CHWs to guide the development of an educational campaign focused on increasing the cultural and linguistic competency efforts related to public health vaccines (e.g., influenza and COVID-19) and other prevention strategies.

Please Note: This request for information (RFI) is for planning purposes only

NEW - Call for public consultation - Health technology assessment for medical devices, second edition

WHO - 16 June 2024 Call for consultation **Deadline July, 17 2024, 11PM CEST**

The World Health Organization (WHO) is seeking feedback on the first draft of the attached document. Kindly note that chapter nine is in an early stage of development; WHO is particularly interested in global and regional input for this section. The call will be open from June 17 to July 17, 2024. The purpose of the document is to provide technical guidance on health technology assessment for medical device.

:: Read the draft - Health technology assessment for medical devices

NEW - Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity in Access Planning

Posted on May 21, 2024 **Comments must be received by July 22, 2024.**

NIH is proposing to develop and implement a new policy within the NIH's Intramural Research Program, the internal research arm of the agency. The policy would require organizations partnering with NIH through a patent licensing agreement that succeed in bringing certain products to market to submit a plan outlining steps they intend to take to promote patient access to any resulting drug, biologic, vaccine, or device. NIH seeks input on this draft policy and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions.

NIH will use the responses to this request for information to develop a final policy. Comments on the proposed policy must be submitted at: https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning.

In addition, NIH will be hosting an informational webinar on the proposed policy on June 11, 2024. More information on the agenda and how to register will be provided shortly.

For additional context on the benefits of access planning, please see NIH's 2023 Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. Questions may be sent to SciencePolicy@od.nih.gov. Also, please consider following us on Twitter @NIH_OSP

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1); Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 05/23/2024 **Comments due by July 22, 2024**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #115 (VICH GL22) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1)." This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In order to establish the safety of veterinary drug residues in human food, a number of toxicological evaluations are required, including the assessment of any effects on reproduction. The objective of this guidance is to ensure international harmonization of reproduction testing that is appropriate for the evaluation of effects on reproduction from long-term, low-dose exposures; these effects may be encountered from the presence of veterinary drug residues in food.

NEW - Agency Information Collection Request; 60-Day Public Comment Request

Health and Human Services Department on 06/03/2024 **Comment period ends 08/02/2024.**

SUPPLEMENTARY INFORMATION:

Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Assurance of Compliance with Federal Policy/IRB Review/IRB ***Recordkeeping/Informed Consent/Consent Documentation.***

Type of Collection: 3-year extension of a currently approved collection.

OMB No. 0990-0260

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990-0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 05/07/2024

Written comments on the draft guidance by August 5, 2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "REMS Logic Model: A Framework to Link Program Design With Assessment." The guidance describes FDA's risk evaluation and mitigation strategy (REMS) logic model. The REMS logic model is a framework that FDA recommends, which provides applicants with a systematic, structured approach to the design, implementation, and evaluation of a REMS. The aim of applying the REMS logic model is to develop clear goals, objectives, and strategies that align with the intended outcomes and to help applicants of new drug applications (NDAs), biologics license applications (BLAs), and abbreviated new drug applications (ANDAs) incorporate REMS assessment planning into the design of a REMS. The principles in this guidance apply to designing a REMS, developing a REMS assessment, and modifying a REMS.

NEW - Request for Information: Strategies for Maximizing Public Engagement in NIH Supported Clinical Research

NIH [USA} Responses must be received by **no later than August 14, 2024.**

NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research studies.

This request for information (RFI) is part of a larger NIH effort to develop a vision and framework for incorporating public voices in all phases and types of clinical research. To accomplish this, NIH asked the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) to form the ENGAGE Working Group. This Working Group includes patients, advocates, researchers, clinicians, non-profit representatives, and more.

NEW - Request for Information on the National Institutes of Health Draft Public Access Policy

Institutes of Health, HHS. **Comment due 16 August 2024**

SUMMARY:

The National Institutes of Health (NIH) is soliciting comm ents from the public on the NIH Draft Public Access Policy and two supplemental draft guidance documents regarding government use license and rights and costs for publications. The NIH Draft Public Access Policy builds upon NIH's long history of providing public access to scholarly publications resulting from the research it supports and proposes additional steps to accelerate access.

Background

Increasing access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care providers in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances. Importantly, these goals also reflect NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence

EMA Reference Number: EMA/CHMP/150527/2024

Consultation dates: 03/05/2024 to 31/08/2024

Summary

The European Medicines Agency has published a draft reflection paper focusing on methodological principles that are considered critical for the conduct and assessment of non-interventional studies using real-world data (RWD) and used for regulatory decision-making throughout a medicine's lifecycle.

A large variety of real-world data can be used in non-interventional studies. A critical aspect when assessing the suitability of RWD for a regulatory purpose is the data quality, including data reliability and relevance, and, depending on the research question, the extent to which RWD truly reflects routine clinical practice.

NEW - Call for Public Comment: General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of Medicines.

ICH *Varying deadlines depending on regulatory authority*

The guideline will focus on non-interventional pharmacoepidemiological studies using Real-World Data (RWD) and will include basic principles that may apply to these studies when real-world data elements are included.

Guideline Draft:

https://database.ich.org/sites/default/files/ICH_M14_Step3_DraftGuideline_2024_0521.pdf

Public consultation dates [announced to date]:

MFDS, Republic of Korea - Deadline for comments by 15 July 2024

MHLW/PMDA, Japan - Deadline for comments by 28 July 2024

TFDA, Chinese Taipei - Deadline for comments by 30 September 2024

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

Call for input for the report on Artificial Intelligence and international solidarity

call for input | Special Procedures
Issued by Independent Expert on human rights and international solidarity **Deadline: 30 June 2024**
Purpose:
To inform the Independent Expert's report on AI and international solidarity to be presented to the 3rd Committee of the UN General Assembly in October 2024.
Background and objectives
Given the current challenge of increased global inequality there is an interest in exploring whether the incorporation of an international solidarity approach to AI would provide a framework to elucidate the duties of States, corporations, and civil society to strengthen equal access to technology, non-discrimination of groups and individuals in vulnerable situations, as well as generate support for both online diversity and social cohesion. It is proposed that International Solidarity can be a valuable part of AI governance and connect to the corporate due diligence mechanisms for engaging direct and indirect stakeholders by supporting the creation of transparent procedures to address participatory inclusion, compliance and remedies. The report can help map civil society stakeholders, identify corporate mechanisms to communicate with stakeholders, and explore how these mechanisms are monitored and by whom.

The Independent Expert welcomes as much information as possible including concrete examples relating to the issues highlighted in the questionnaire with the link below in English, French and Spanish

Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing

A Notice by the U>S> Patent and Trademark Office on 04/30/2024
Written comments must be received on or before July 29, 2024
SUMMARY:
The United States Patent and Trademark Office (USPTO or Office) seeks public comments regarding the impact of the proliferation of artificial intelligence (AI) on prior art, the knowledge of a person having ordinary skill in the art (PHOSITA), and determinations of patentability made in view of the foregoing. The increasing power and deployment of AI has the potential to provide tremendous societal and economic benefits and foster a new wave of innovation and creativity while also posing novel challenges and opportunities for intellectual property (IP) policy. Through the AI and Emerging Technologies Partnership (AI/ET Partnership), the USPTO has been actively engaging with the innovation community and AI experts on IP policy in view of AI. To build on these efforts, the USPTO is requesting written public comments on how the proliferation of AI could affect certain evaluations made by the Office, including what qualifies as prior art, the assessment of the level of skill of a PHOSITA, and determinations of patentability made in view of these evaluations. The USPTO expects that the responses received will help the Office evaluate the need for further guidance on these matters, aid in the development of any such guidance, and help inform the USPTO's work in the courts and in providing technical advice to Congress.

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

No new digest content identified.

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Human Rights

NEW - Notice of Availability and Request for Information; Federal Evidence Agenda on Disability Equity

U.S Science and Technology Policy Office on 05/30/2024 **Comment period ends 07/15/2024.**

SUMMARY:
Through this Request for information (RFI), the White House Office of Science and Technology Policy (OSTP) seeks input from the public to help inform the development of the Federal Evidence Agenda on Disability Equity. Executive Order 14091 on Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (February 16, 2023) directed the OSTP National Science and Technology Council Subcommittee on Equitable Data (SED) to coordinate implementation of recommendations of the Equitable Data Working Group. To address the recommendations relevant to disability, the SED established the Disability Data Interagency Working Group (DDIWG). The DDIWG is tasked with the development and release of a Federal Evidence Agenda on Disability Equity, in order to improve the Federal government's ability to make data-informed policy decisions that advance equity for the disability community.

Call for submissions on draft general comment No. 27 on children's rights to access to justice and effective remedies

call for input | Treaty bodies Issued by CRC **Deadline: 23 August 2024**

The Committee on the Rights of the Child is currently drafting general comment No. 27 on children's rights to access to justice and effective remedies. The concept note can be found here.

The Committee now seeks contributions from all interested stakeholders to clarify terms, approaches and actions States should take in order to implement the right of all children to access justice and effective remedies. The call for submissions with guiding questions and instructions is available here.

Next Steps
The deadline for submissions is 23 August 2024. No submissions received after this deadline will be considered or posted on the webpage.

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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

NEW - Real-world data and real-world evidence in regulatory decision making

CIOMS – Working Group XIII Year of publication: 2024; Number of pages: 118
SKU: 59906 https://doi.org/10.56759/kfxh6213

In recent years, many medicines regulatory agencies have expressed increased willingness to consider real-world evidence (RWE), that derives from the review and/or analysis of real-world data (RWD), to support claims of efficacy or effectiveness as well as of safety. This increased willingness is changing the regulatory environment in which RWE is generated and used. This consensus report aims to describe the potential use of RWE for decision making; RWD and data sources; key scientific considerations in the generation of RWE; and ethical and governance issues in using RWD.

The intended audience for this report includes medicinal product regulators, healthcare payers, health care and medicinal products industries, researchers, bioethicists, patients and health care professionals. This report was developed to inform discussions about the use of RWD and RWE for regulatory and health care decision making, including decisions to make a product available for use (authorisation), to cover the costs of its use (reimbursement), and to use a product for a particular patient (clinical use).

This report reflects the opinions of the Council for International Organizations of Medical Sciences (CIOMS) Working Group XIII on Real-world data and real-world evidence in regulatory decision making, and it was finalised after considering comments received during a public consultation.

Informed Consent for Research Using Digital Health Technologies: Points to Consider & Sample Language.

NIH Office of Science Policy, USA May 2024

KEY POINTS

- This resource provides points to consider and sample language for informed consent of research studies which plan to use digital health technologies. The use of this resource is completely voluntary.
- The considerations and sample language provided in this resource may not apply to all studies or cover all potential contexts of use. Users of this resource should apply relevant considerations/sample language as applicable to their study. Points to consider and sample language below are included in the most relevant sections, although they may be relevant to multiple sections.
- This resource does not take the place of an informed consent document. The considerations and sample language included in this resource are specific to the inclusion of digital health technologies in a study; other general and population-specific informed consent considerations and language still apply. The sample language provided in this resource should be tailored for individual studies and may need further revision or clarification when used in an informed consent.
- The sample language provided in this resource does not alone satisfy the regulatory requirements for informed consent as described in the 2018 revised Common Rule at 45 CFR46.116 or the FDA's regulations governing the protection of human participants (i.e., 21 CFR parts 50 and 56).
- Within this resource, the term digital health technology refers to wearable devices, sensor technologies, and mobile software applications (“apps”) most often used with tablets, watches, or phones. The resource does not address considerations for implantable devices, artificial intelligence, or other types of digital health technologies.
- This consent resource does not address future use of data collected from digital health technologies, which may have additional considerations when developing or reviewing informed consent.

US Government Releases Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

On May 6, 2024, the White House Office of Science and Technology Policy (OSTP) released an expanded and unified Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

This new U.S. Government-wide policy, which combines the current dual use research of concern and enhanced potential pandemic pathogen oversight frameworks, expands the scope of research requiring additional scrutiny and strengthens our partnership with institutions to ensure robust review and oversight.

NIH will work closely with the biomedical research community as we move towards the policy’s year effective date. We encourage the biomedical research community to review OSTP’s extensive guidance developed to assist with implementation (https://www.whitehouse.gov/ostp/news-

updates/2024/05/06/united-states-government-policy-for-oversight-of-dual-use-research-of-concern-and-pathogens-with-enhanced-pandemic-potential/.
Dr. Monica Bertagnolli, NIH Director, issued a statement upon the Policy's release which can viewed at: https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-release-usg-policy-oversight-dual-use-research-concern-pathogens-enhanced-pandemic-potential

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

A Notice by the Food and Drug Administration on 04/23/2024
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments." Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of post-marketing requirements (PMRs) and post-marketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on the FDA's website entitled "Postmarketing Requirements and Commitments: Reports" (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064436.htm).

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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

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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