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COMMISSION CANTONALE
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CIOMS

CIOMS International Guidelines on Good Governance Practice for Research Institutions 2023

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Institute of Health Law, University of Neuchâtel (Switzerland)
Academic Partner of WMA
CIOMS Executive Committee

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BMJ

LONDON, SATURDAY 29 JANUARY 1994

The scandal of poor medical research

We need less research, better research, and research done for the right reasons

DOUGLAS G ALTMAN
Head

Medical Statistics Laboratory,
Imperial Cancer Research Fund,
London WC2A 3PX

Do We Do Better Today ?

"WHO's International Clinical Trials Registry Platform (ICTRP) recorded **more than 18 000 COVID-19-related clinical trials during the pandemic**, but of these the vast majority are thought to have contributed little to the evidence base, owing to failure to complete enrolment or through poor design features. A small proportion, probably **less than 10%,** were well-designed and well-implemented clinical trials (both publicly and non-publicly funded) and **contributed greatly to policy recommendations by WHO and other bodies**".

WHO guidance for best practices for clinical trials DRAFT FOR PUBLIC CONSULTATION, 2023

Research waste

Research that, for instance due to inappropriate design, conduct or dissemination of research, fails to advance scientific knowledge or provide a social return on the resources invested.

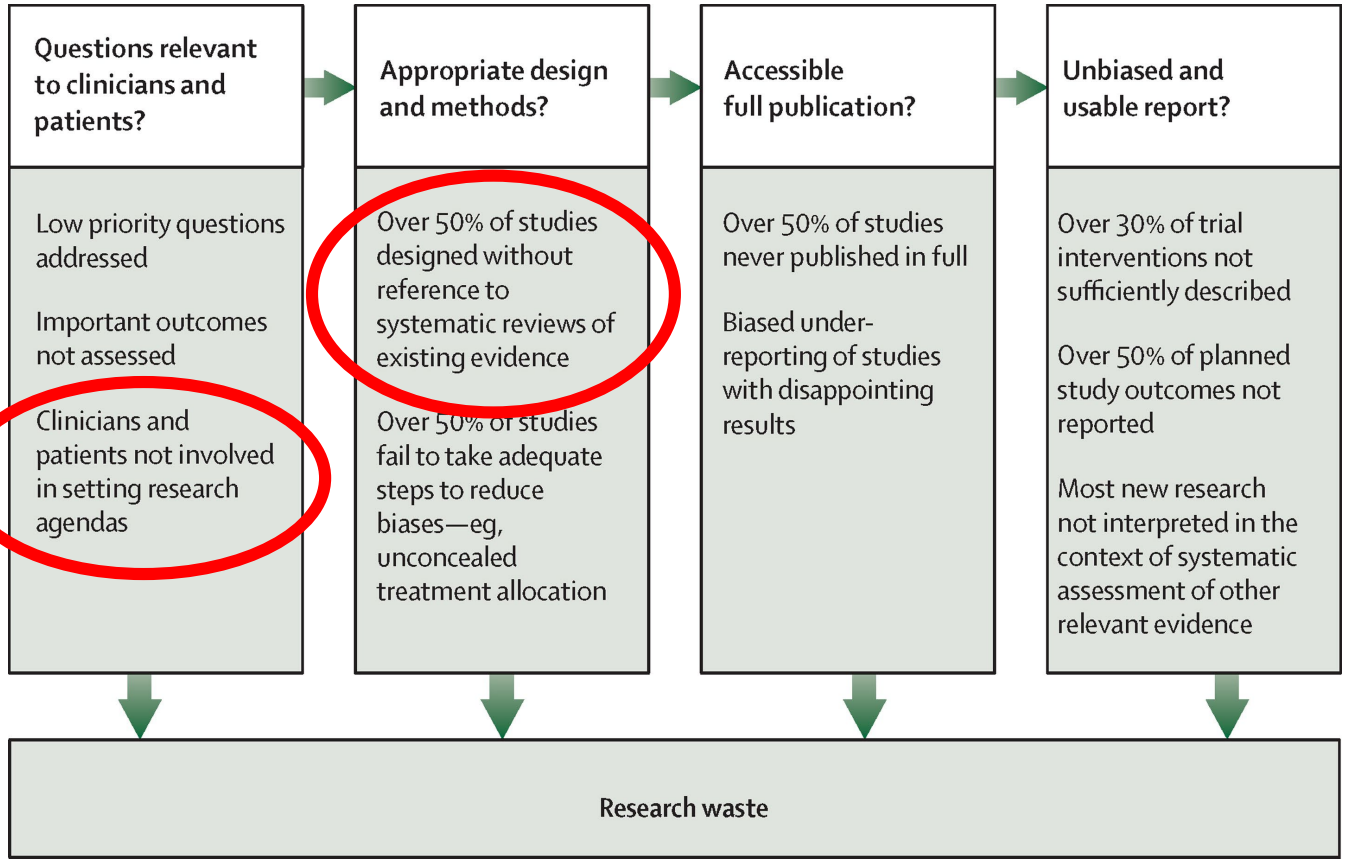
CIOMS International Guidelines on Good Governance Practice for Research Institutions 2023

Research waste

Multiple causes

- Wrong question;
- Lack of priorities;
- Lack of assessment of patients' needs;
- No or limited PPIE;
- Poor design;
- lack of rigor in the conduct of the research;
- Poor representativity of recruited participants (selection bias);
- Weak or inappropriate (statistical) analysis of the results;
- Late, partial or lack of publication/dissemination;
- Poor interpretation and implementation of the results…

Reproduced from: Avoidable waste in the production and reporting of research evidence, Iain Chalmers, DSc, Prof Paul Glasziou, RACGP, The Lancet, Volume 374 Issue 9683 Pages 86-89 (July 2009) DOI: 10.1016/S0140-6736(09)60329-9



Lack of respect for research ethics principles and standards

Origins of health-related research ethics and regulation

- The ethics and regulation of research involving human participants is rooted in a long history of abuses.
- Research ethics and regulation was developed originally by researchers and for the researchers to protect **the participants against research risks** ***and themselves against liability risks***.

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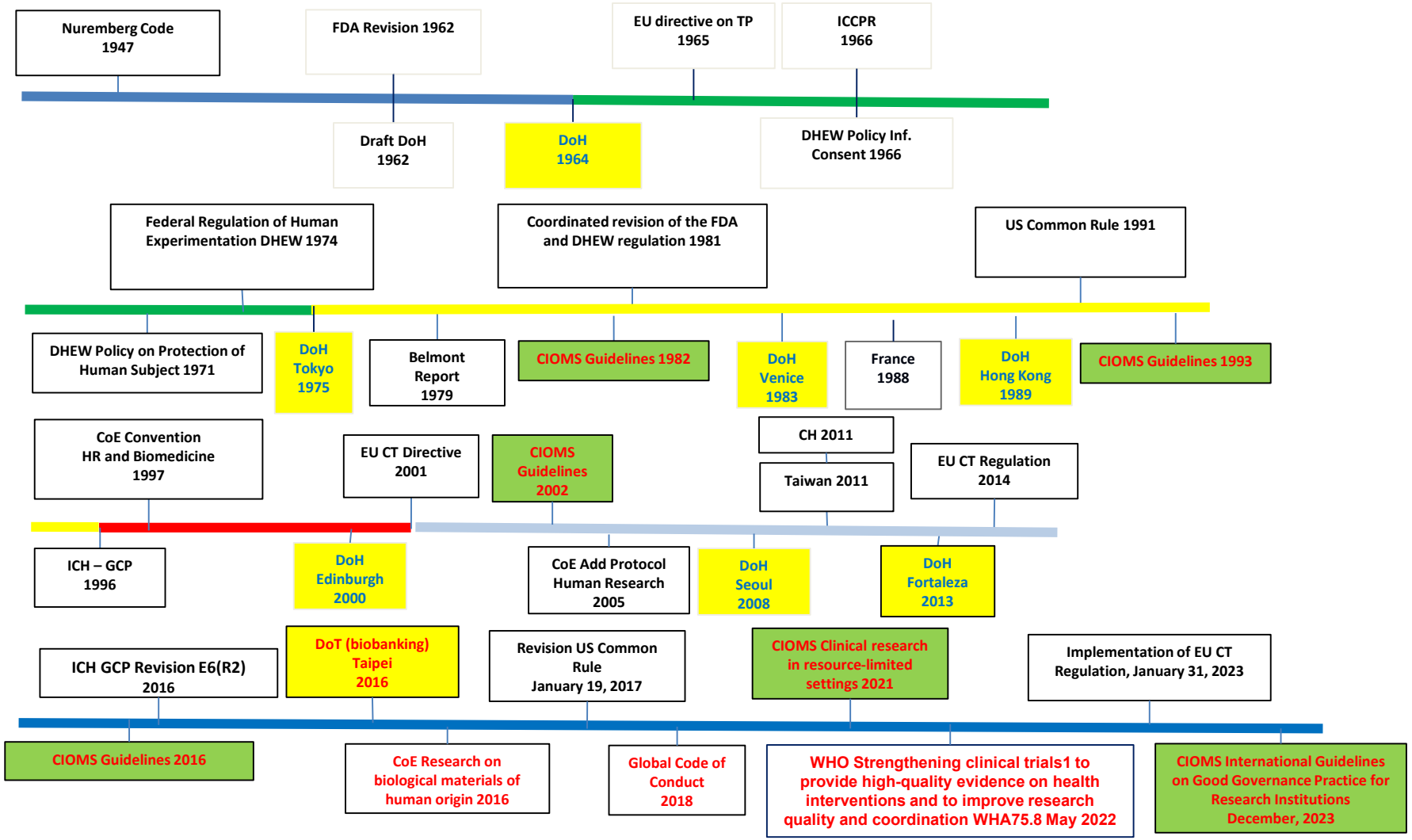
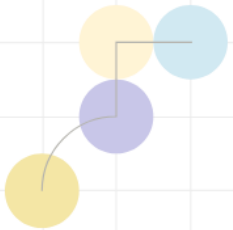
Main documents of reference in health-related research ethics and regulation



Adapted from Dominique Sprumont, Research Ethics Regulation : Rules versus Responsibility, in *Ethical Research: The Declaration of Helsinki, and the Past, Present, and Future of Human Experimentation*, Ulf Schmidt, Andreas Frewer, and Dominique Sprumont (eds); Oxford University Press, April 2020, pp. 243-283, figure 10.2

Recent trends in health-related research ethics and regulation

- Recent research ethics guidelines not only aim at protecting participants and guaranteeing research quality but also at promoting the involvement of patients, participants, communities and population in research from its design to the dissemination of the results (**participation, transparency and accountability**) in a **public health** objective



Introduction

Guidance for Good Randomized Clinical Trials

May 2022

Developed by the Good Clinical Trials Collaborative

On this page:

Explore the full guidance ↓

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 16.2

WHA75.8
27 May 2022

Strengthening clinical trials[1] to provide high-quality evidence on health interventions and to improve research quality and coordination

The Seventy-fifth World Health Assembly,

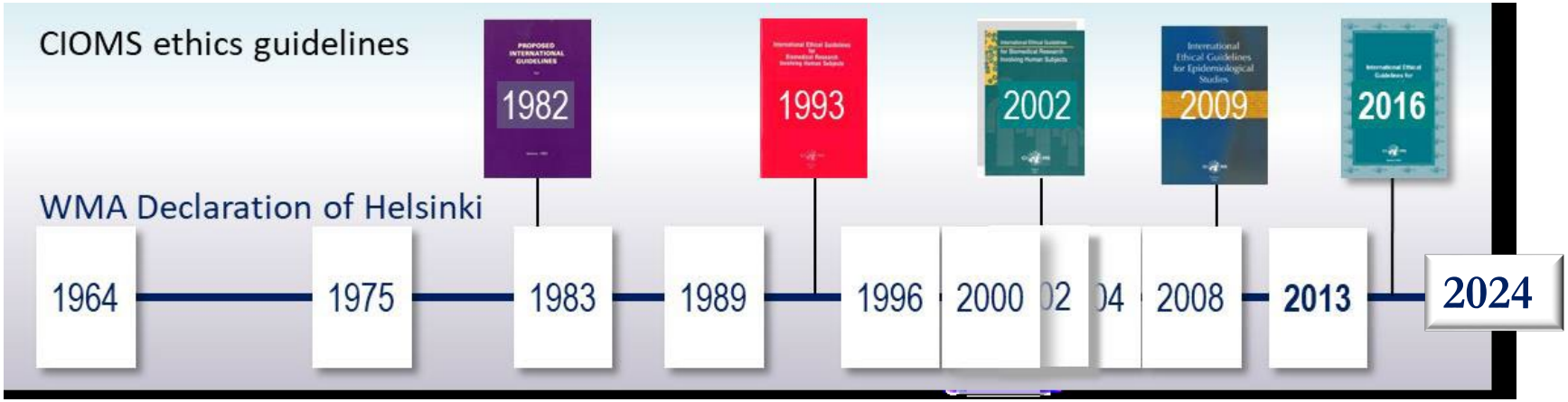
Recalling resolutions WHA58.34 (2005) acknowledging that high-quality, ethical research and the generation and application of knowledge are critical in achieving internationally agreed health-related development goals, WHA63.21 (2010) outlining WHO's role and responsibilities in health research, WHA66.22 (2013) and WHA69.23 (2016) on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, and WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which notes the importance of basic and clinical research and recognizes the critical role of international collaboration in research and development, including in multicountry clinical and vaccine trials, as well as rapid diagnostics test and assay development, while acknowledging the need for further rigorous scientific evidence;

Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review "COVID-19: make it the last pandemic"[2] relating to health research and development, including clinical trials;

[1] "A clinical trial is defined by WHO as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials." Joint statement on public disclosure of results from clinical trials, 2017 (https://www.who.int/news/item/18-05-2017-joint-statement-on-registration, accessed 25 May 2022).

[2] Independent Panel for Pandemic Preparedness and Response. COVID-19: make it the last pandemic, 2021 (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf, accessed 25 May 2022).

Current agenda of WMA and CIOMS in Research Ethics



- Consolidating existing **recognized international standards** based on **universal values**;
- Promoting patients, participants, communities and population involvement in research from its design to the dissemination of the results (**participation, transparency and accountability**) with cleare public health objectives

Moving from strictly individual research ethics (mainly targeting researchers) to institutional or collective ethics (Good Governance Practice).

CIOMS 2016 International Ethical Guidelines for Health-Related Research Involving Humans… and Beyond

- CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety. https://cioms.ch/about/

- CIOMS reports are in-depth guidance documents which serve as worldwide references and guidance for specific subject matters (see for instance CIOMS Clinical research in resource-limited settings, 2021).

- CIOMS is well positioned as a unique global and scientific organization to trigger a new approach in research ethics and regulation moving from individual responsibilities to institutional engagement to guarantee the respect of the highest ethical and quality standards in research.

CIOMS International Guidelines on Good Governance Practice for Research Institutions (2023)

- Most research ethics guidelines and 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 the defining the context in which research involving human participants is conducted.

- Researchers often lack the necessary resources to respond to the increasingly complex ethical and regulatory framework of research. They find themselves lacking support from their institutions and thus are facing difficulties to fulfil their obligations.

- **This requires an institutional commitment at all levels.**

Set up of the CIOMS GGPRI Working Group

Terms of reference:

To develop a consensus report giving recommendations on the good governance practice for research institutions by:

- identifying and defining the essential resources needed for researchers to work in accordance with the ethical, legal and scientific standards in research involving human participants;

- helping research institutions providing/assuring those necessary resources to researchers to fulfil their responsibilities.

Set up of the CIOMS GGPRI Working Group

Name	Affiliation	Country
Dominique Sprumont (chair)	Comité d'éthique de la recherche du canton de Vaud (CER-VD), Institute of Health Law, University of Neuchâtel, WMA academic partner	Switzerland
Aline Sigrist (secretary 2022-23)	Institute of Health Law, University of Neuchâtel, WMA academic partner	Switzerland
Annie Volet (secretary 2021,2023)	Institute of Health Law, University of Neuchâtel, WMA academic partner	Switzerland
Anant Bhan	Department of Community Medicine, Yenepoya Medical College. The Centre for Ethics, Yenepoya University, Mangaluru	India
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Ames Dhai	School of Clinical Medicine, University of the Witwatersrand, South Africa	South Africa
Kim Ellefsen	Director of the Sponsor research Office, Centre Hospitalier Universitaire Vaudois (CHUV) and University of Lausanne.	Switzerland
Morenike Folayan	New HIV Vaccine and Microbicide Advocacy Society (NHVMAS)	Nigeria
Marie Hirtle	Centre for Applied Ethics, REB - McGill University Health Centre (MUHC)	Canada
Rosanna Lagos	Centro para Vacunas en Desarrollo, Santiago, Hospital de Niños de Santiago	Chile
Dirk Lanzerath	European Network of Research Ethics Associations (EUREC)	Germany
Roli Mathur	Dr Roli Matur, ICMR Bioethics Unit, Indian Council of Medical Research, WHO Collaborating Centre for Strengthening Ethics in Biomedical & Health Research	India
Kotone Matsuyama	Department of Health Policy and Management, Nippon Medical School	Japan
Winfred Nazziwa	Uganda National Council for Science and Technology (UNCST) African Vaccine Regulatory Forum (AVAREF)	Uganda
Francine Ntoumi	Fondation Congolaise pour la Recherche Médicale	Congo Brazzaville
Lembit Rägo	Council of International Organizations of Medical Sciences (CIOMS)	Switzerland
Raffaella Ravinetto	Institutional Review Board, Institute of Tropical Medicine, Antwerp	Belgium
Andreas Reis	Global Health Ethics, Health Systems and Innovation Cluster, World Health Organization (WHO)	Switzerland
Vladislava Talanova	Institute of Health Law, University of Neuchâtel, WMA academic partner	Switzerland
Creany Wong	The University of Hong Kong Clinical Trials Centre (HKU-CTC)	Hong Kong/China
Henry Yau	International Clinical Trial Center Network (ICN)	Hong Kong/China
Zhu Wei	Shanghai Ethics Committee for Clinical Research (SECCR)	China

CIOMS WG Meeting 2021-2023

Meeting	Date	Venue
1		
2		
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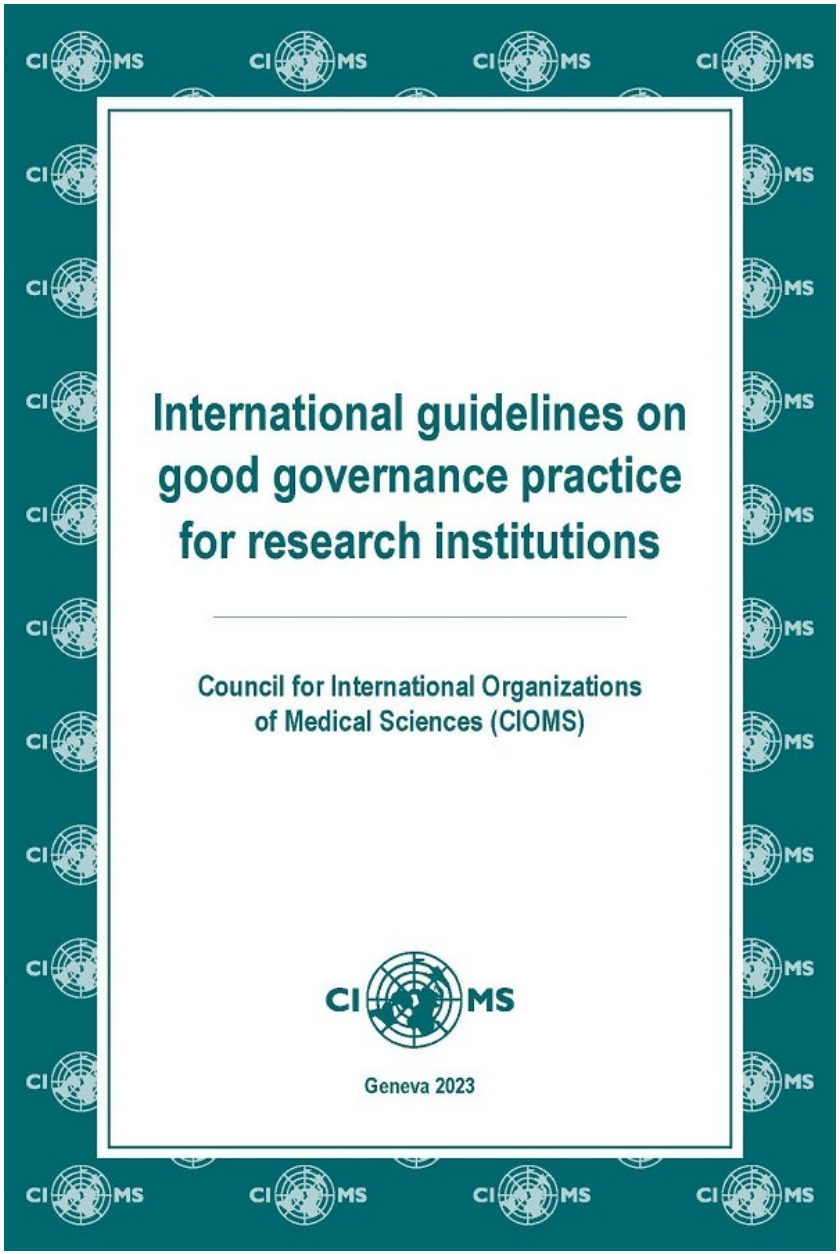

International guidelines on good governance practice for research institutions
Council for International Organizations of Medical Sciences (CIOMS)
CIOMS
Geneva 2023

Definitions

Research institution: Any public or private entity or agency or healthcare or public health facility where health-related research is conducted. For the purpose of the present guidelines, the term "research institution' covers all facilities where—or in relation with which—health-related research activities are carried out, regardless of whether the research is explicitly recognized as part of the institution's mandate or core business, and is not limited to facilities primarily dedicated to health-related research (e.g. clinical trial centers)

The majority of health-related research involving human participants is carried on in, or in relation with, institutions which primary mission is NOT research

(see WHO Health Report: Research for universal health coverage. 2013)

Definitions

Good Governance Practice for Research Institutions : A methodological tool describing good governance with the goal of helping research institutions to assess and improve the way they provide support to research stakeholders depending on their needs and according to their available resources. The purpose of GGPRI is that each research institution is aware both of the research activities carried out within its infrastructures— or in relation with them— and of its responsibilities on that behalf, and adopts the appropriate level of governance of research depending on its needs and resources.

Definitions

- **Resources** means time, training, qualified staff, facilities, clinical and laboratories equipment, hardware and software, communication tools, data protection infrastructure, health databases and biobanks, ethical and legal counselling, etc.

This is not only a matter of financial support but more a question of governance: what services and supports are available for the researchers to meet their responsibilities as imposed by research ethics, NRAs and regulation.

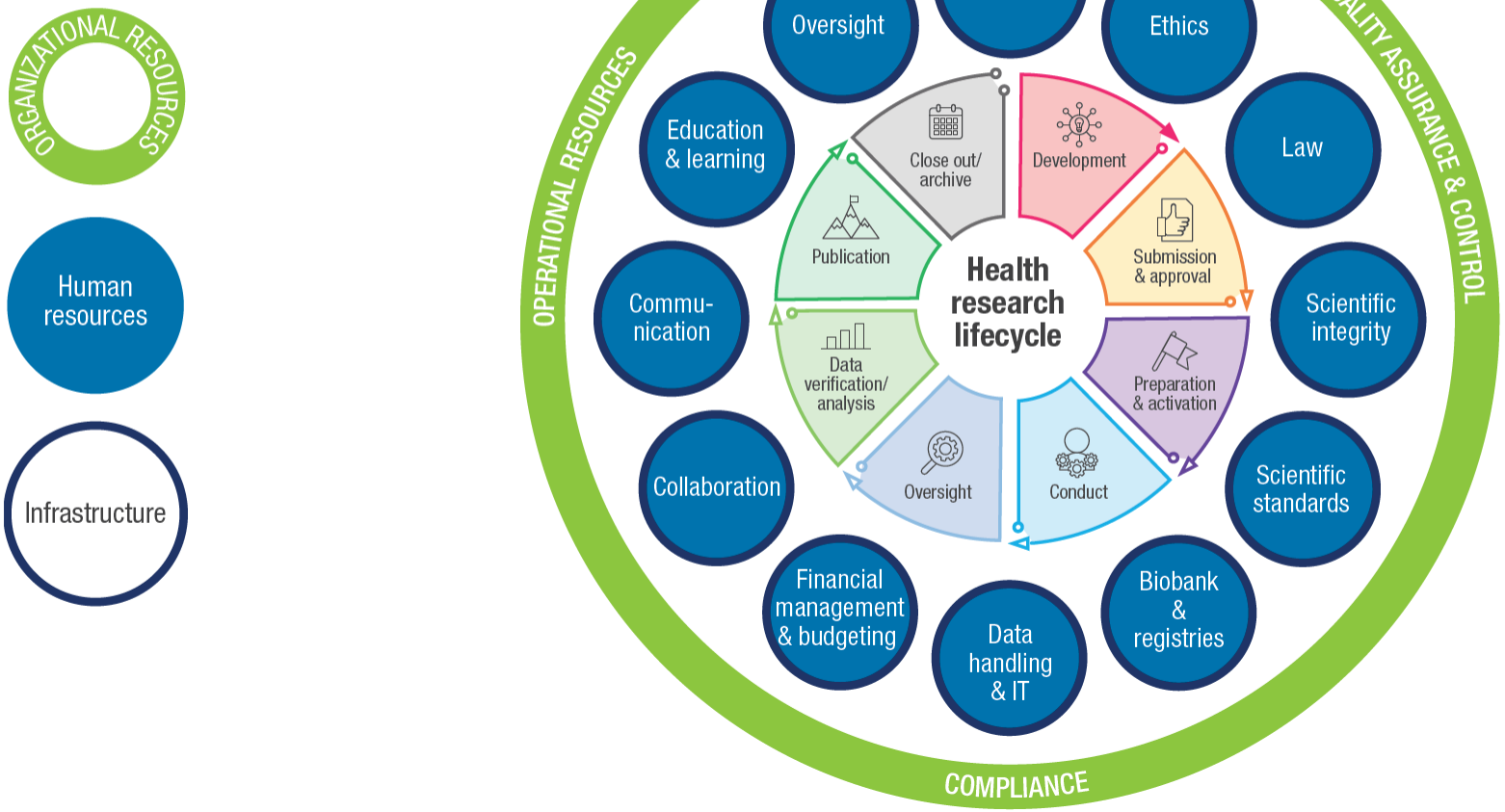
Aims

Introduction p. XIII

"The aim of the present guidelines is to help research institutions better fulfil their responsibilities in terms of protecting human research participants and their communities, involving and engaging them in the research processes, and guaranteeing the pertinence and quality of research while making best use of available resources. The guidelines review the existing international standards and best practices in the field of health-related research and offer research institutions detailed and specific guidance on how to implement them. **The present guidelines are complementary to the provisions on governance that have been introduced in the recent documents of reference listed at the end of this foreword, including the ICH GCP**."

CIOMS International Guidelines on Good Governance Practice for Research Institutions

Main domains to Consider in the Good Governance Practice of Research Institutions



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No need to reinvent the wheel !

https://www.who.int/our-work/science-division/research-for-health/implementation-of-the-resolution-on-clinical-trials

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Home / Our work / Science Division / Research for health / Implementation of the resolution on clinical trials

Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

Implementation of the resolution on clinical trials WHA 75.8

In May 2022, the Seventy-fifth World Health Assembly adopted a resolution (WHA75.8) on "Strengthening clinical trials to provide high-quality evidence on health

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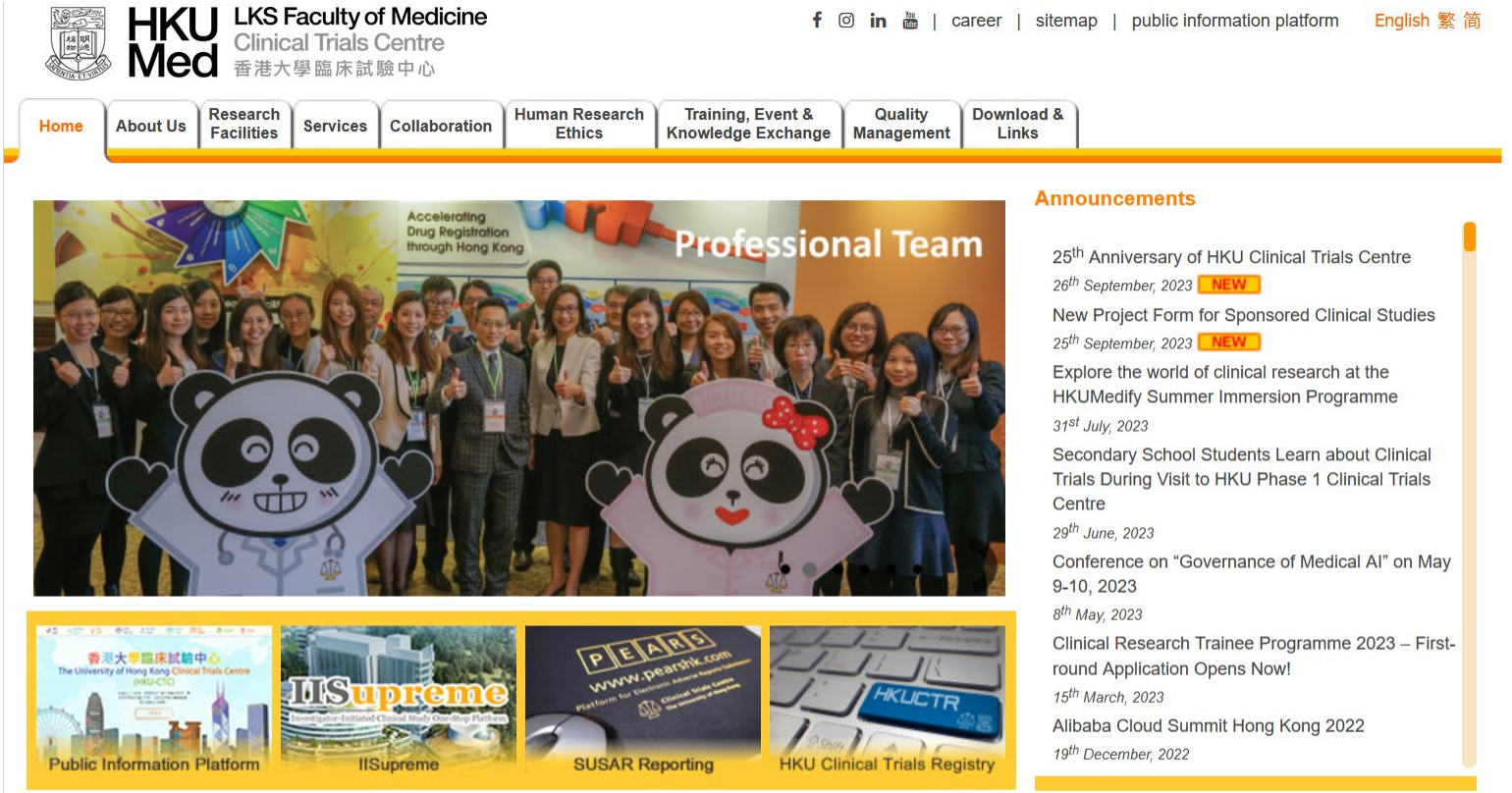
Congratulations and Happy Anniversary !



public.hkuctc.com/en/projects/current

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