First (virtual) meeting of the CIOMS Working Group on Principles of Good Governance for Research Institutions (PGGRI)

7 July 2021 Meeting

Meeting Minutes

Participants

Anant Bhan (Yenepoya University), Ames Dhai (University of Witwatersrand), Kim Ellefsen-Lavoie (Lausanne University Hospital), Morenike Folayan (New HIV Vaccine and Microbicide Advocacy Society), Marie Hirtle (McGill University Health Centre), Rosanna Lagos (Roberto del Río Children's Hospital), Dirk Lanzerath (European Network of Research Ethics Associations), Hervé le Louët (CIOMS), Roli Mathur (Indian Council of Medical Research), Kateriina Rannula (CIOMS), Raffaella Ravinetto (Antwerp Institute of Tropical Medicine), Lembit Rägo (CIOMS), Dominique Sprumont (World Medical Association), Johannes van Delden (University of Utrecht), Annie Volet (University of Neuchâtel), Creany Wong (The University of Hong Kong), Henry Yau (The International Clinical Trial Center Network), and Zhu Wei (Shanghai Ethics Committee for Clinical Research).

Regrets

Winfred Badanga (Uganda National Council of Science and Technology), Carel IJsselmuiden (Council on Health Research for Development, Switzerland) (declined to participate in the WG at this stage), Francine Ntoumi (Congolese Foundation for Medical Research), and Andreas Reis (WHO) (will join the WG in future meetings).

Introduction

- Lembit Rägo, Secretary General, CIOMS, welcomed the members of the new CIOMS Working Group (WG) on Principles of Good Governance for Research Institutions (PGGRI).
- Hervé le Louët, President, CIOMS, welcomed all present and thanked the WG members for their participation. He hoped to be able to meet face-to-face once the circumstances permit and wished all a fruitful meeting.
- Dominique Sprumont was appointed the Chair of the WG.
- The meeting agenda was adopted.
- Kateriina was rapporteur.

Discussion

- Dominique opened the discussion:
    - Research ethics as a discipline is considered to have started with the Nuremberg Code and perhaps with the Declaration of Helsinki in 1964. Regardless of the existence of various documents, researchers find themselves lacking support from their institutions and are thus not able to fulfil their obligations.

  - The feasibility of a project and the ability to maintain control over the usage of resources when conducting research are integral parts of research ethics.
  - One of the aims of the WG is to identify the primary resources that should be made available by research institutions to researchers. Encouraging researchers in this way increases the capacity and quality of research.
  - The WG should create a guideline focusing on a pragmatic set of recommendations and identify various domains where researchers require support to fulfil their responsibilities.
  - The guideline will also help institutions from resource-limited settings to negotiate a stronger position with their funding agencies. Support that is not always connected to a single protocol or a project could also be based on longer-term negotiations, e.g. the European & Developing Country Clinical Trial Partnership (EDCTP), a public-public partnership between countries in Europe and sub-Saharan Africa, supported by the European Union.
  - The strength of the WG lies in its cultural and linguistic diversity and professional competencies. There is value in conveying the important messages of the WG in languages other than English and thus building bridges across nations.
- Dominique was confident that the WG with such vast competencies and experience would achieve its goal and expressed hope that all will work jointly towards developing the guideline.
- Lembit briefly introduced CIOMS and made the following announcements:
  - The CIOMS WG on Severe Cutaneous Adverse Reactions (SCARs) was launched in February;
  - The CIOMS WG on Recommended Standards for Education and Training for Health Professionals Participating in Medicines Development was launched in April;
  - The Version 1.1 of the CIOMS Cumulative Pharmacovigilance Glossary was published in June 2021 and is available on the CIOMS website. The glossary compiles the terms and definitions from published CIOMS pharmacovigilance reports.
- The objective of the WG is to develop a consensus report giving recommendations on the principles of good governance for research institutions and proposing guidelines promoting the resources needed for researchers to work in accordance with the highest standards in research ethics and regulation.
- Lembit continued by explaining a few practical matters about the CIOMS WGs in general:
  - Each CIOMS group finalizes a guideline within approximately two to four years, which will be published both in electronic and print formats. All CIOMS reports are free to be downloaded from the CIOMS website.
  - The draft minutes from meetings will always be provided to the members to review and approve before they are published on the CIOMS website. The members will have an opportunity to specify if the content is considered confidential, and if yes, only redacted minutes will be made available to the public.
  - Where WG members consent to meetings being recorded for the purposes of taking minutes, the recordings will not be used for any other purpose and will be deleted as soon as possible.

  - Each CIOMS WG has its public section on the CIOMS website and a password-protected section available only to the WG members for sharing working documents and necessary publications. The WG webpage will become live soon.
  - The CIOMS Secretariat provides support to the WG, and in addition, Annie Volet from the University of Neuchâtel will act as a primary contact to the WG, and help with setting up virtual meetings, writing minutes, and assisting with general communications.
- "Tour de table" followed for all to introduce themselves.

The scope and target audience of the guideline

- Dominique suggested all members share their opinions on the target audience of the guideline.
- Wei commented that strengthening the capability of researchers at research institutions is vital, and institutions (both commercial and non-commercial) are not confident in how to regulate their actions. Training and research ethics workshops are sometimes held, but institutions require more exact and obvious principles. A project is under way in Shanghai to investigate institutions' needs regarding research ethics, and the results will be used to provide recommendations to the government.
- Anand shared the BMJ opinion blog entry by Richard Smith on the topic of poor research practices and issues vital also for this WG:
  - Eliminating research fraud, strengthening the role of individual researchers and institutions. What kind of governance mechanism and infrastructure could be built?
  - Is peer review an acceptable method? What type of oversight mechanisms are required at the institutional level and beyond?
- Rosanna commented that the definition of research is multifaceted, and researchers and research facilities need to be carefully defined.
- Most of the applied clinical research that implements clinical research and other investigations involving humans is conducted in institutions that are not primary care facilities. Would these be defined as research institutions?
- A classical research institution is an important clinical research centre or network, but in many countries, research is conducted in public health institutions, hospitals, primary care institutions, etc. The investigators are not primarily defined as researchers but wish to be able to participate.
- Dominique commented that large university hospitals with substantial resources can fully staff a sponsor office with a legal department, an IT department, etc., dedicated to conducting research.
- The WG could guide public hospitals where research is carried out towards a more precise understanding of the resources available and aid the institutions in understanding their strengths and weaknesses in conducting research.
- Hans raised several questions:
  - Should the WG consider only the institutions with sufficient resources to create the proper infrastructure for conducting research? Would the bar for research institutions be raised so high that small institutions would not be able to participate in research at all? In remote trials, research is to a certain extent run at the patient's home - are these to be considered as research centres as well?
  - Do we want to focus on research institutions and determine the available resources and structure needed to be a proper place to conduct research? Should we tackle the topic of responsible innovation, open society, and the whole philosophy of science that addresses the system and its faults? How broad should the scope of the guideline be?

- Morenike addressed the scope of the future guideline by bringing the example of COVID-19 and its influence on the domain of research ethics:
    - When we speak of governance, usually we mean fixed systems and structures, but in the case of COVID-19, the world witnessed public health encompassing research, whereas guidance documents have not in the past considered public health and research ethics within that context. There are no references to research ethics in international health regulation documents.
    - Would global research governance be discussed?
- Raffaella suggested considering also research conducted in sub-Saharan Africa, where the research agreements were signed by the representatives of parent research institutions in Europe, as the local institutions in Africa did not have a research office with a legal department with skills in drawing up research contracts.
- The importance of the WG also lies in the empowerment of research institutions and addressing the issues of global health research.
- The created guideline could also guide funders to strengthen the structural capacities of researchers in global health research institutions.
- Lembit noted that the CIOMS WG on Clinical Research in Resource-Limited Settings has published a report addressing specific recommendations to stakeholders, and it serves as a valuable resource for discussions among the current WG members.
- Roli presented challenges from the funding agencies' perspective to be considered when deciding on the scope of the future guideline:
    - Research frameworks are not established in institutions where research is funded, and there is a lack of capacity to manage the research;
    - There are no systems in place for managing conflicts of interest;
    - In university settings, research is conducted as a part of an educational programme, and often there are no research departments;
    - There is a lack of appropriate training in research methodology and/or faulty adherence to existing guidelines;
    - We need a holistic approach to creating a framework, which would provide flexibility to researchers, encourage collaboration, and support the allocation of resources with effective mechanisms for oversight;
    - What kind of priority setting in research ethics is needed for a specific country or institution?
- Ames added that when defining the target audience, the state actors within countries must be considered. Should they be the statutory councils that develop in-country guidelines for research institutions and researchers? The developed guideline could assist the state actors in terms of building into the country guidelines.
- Community organisations constitute an important target audience. The COVID-19 pandemic has demonstrated the need to involve the community through various organisations. We need tangible operational guidelines on how to meaningfully involve the community.
- Lembit commented that the work of CIOMS WG XI on Patient Involvement in the Development and Safe Use of Medicines addresses the community and patients as part of the community. The report of the WG will be made available for public consultation in September and is a beneficial source to consider regarding the discussion of the current WG.
- Dirk is involved in an EU-funded project on Ethics Governance System for Responsible Research and Innovation in Higher Education, Funding and Research Centres (ETHNA System), which systematically involves stakeholders in research institutions. The concept of stakeholders is

broad and could include patient organisations, certain kinds of nongovernmental organisations (NGOs), industry-related groups, etc.

- Dominique suggested for the guideline to focus on research institutions, including those not designed to be research institutions but which still conduct research within their organisation.
- The guideline developed will be an essential tool to communicate with funding agencies about the support provided to research institutions financially and/or in human resources and other tools, whether through research institutions, public or private hospitals or healthcare organisations.
- Dominique suggested defining the guideline's scope, both in terms of the guideline's target and the future communication and dissemination.
- Ames enquired whether the WG should address differences in research and the different types of research institutions where research is being conducted, or further specify the scope of the work?

On the term "governance"

- Henry suggested discussing the interpretation of the term "governance", drawing from his personal experience of working with different stakeholders where the term carries a negative connotation. Governance is often regarded as imposing external rules, thus creating feelings of insecurity.
- Research institutions are the main target of the guideline, but we want to address investigators and industry too. We need to ensure that governance is not only taken to cover limitations and regulations, but that it covers also services, support, and any additional value generated to the investigators and the industry.
- Lembit suggested the possibility of paraphrasing governance into good support practices for clinical research depending on the situation and the context.
- Dominique added that the term "governance" is currently being used more systematically. It was introduced in the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks in 2016 as well as in Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological materials of human origin of the Council of Europe. Through the regulation of biobanks, the term "governance" is slowly appearing in the field of research ethics.
- Governance in terms of research means having reliable data protection, meeting ICH requirements regarding follow-up, etc.
- He suggested addressing the terms later and expressed satisfaction with having reached an agreement on the scope and that the guideline's target is a research institution. Defining the term research institution will need further consideration.
- Lembit questioned whether the issues discussed always refer to actual governance or instead to the availability of resources. An institution may have a governing structure in place but not necessarily possess sufficient resources to support the structure.
- Ames suggested substituting "governance" with "best practice guidelines" or any other similar term. What is meant by governance needs careful consideration. Governance is a system of administration and supervision through which research is managed, participants and staff are protected, and accountability is assured.

On minimum requirements

- Creany added two key points to the discussion:

1. The WG will aim to assist research institutions in creating principles and a governance framework to support investigators in conducting research;
2. The future guideline will assist researchers and research institutions to lower the risks involved, and establish minimum requirements to institutions, e.g. setting up research offices in the institutions.

- Hans agreed that governance, to a certain extent, also provides security. Setting minimum requirements would be a feasible and viable path forward.
- Dominique added that the existing guidelines have set minimum standards and recommendations. The WG would aim to translate the existing standards into practice for those research institutions with less information and experience in conducting research.
- Raffaella agreed with defining the minimum set of requirements and recommended considering creating two levels of requirements: the minimum ones to conduct and steer research and a set of complementary requirements recommended to go further with the research.
- Dominique summarised that identifying the minimal set of essential requirements for which some guidance on implementation can be provided is important. He emphasised that there are enough existing standards, and the WG should aim to select the fundamental requirements in research, ethics and regulation, and translate these into practice at the level of the institution, but not add new standards and requirements.
- Rosanna commented that there is a difference between "research institutions" and "institutions that host biomedical research", and the difference should be noted. In Latin America, 80%-90% of research is conducted in public hospitals and often by external research teams and resources. Clinicians are invited and allowed to participate in international studies by their institution, but all responsibility would lie with the researcher and the sponsor, not the institution.
- Dominique responded that the WG should use appropriate wording and ensure that the definitions are as inclusive as possible. Public hospitals and institutions need to be empowered, especially when conducting international research.
- He suggested all consult the WHO report Research for Universal Health Coverage (2013).
- Hans commented that not all institutions consider themselves research institutions. Would setting guidelines to these institutions result in them not being able to participate in research as they cannot respond to the requirements?
- Previous guidelines do not include minimum requirements for institutions. The WG's task is to address and frame e.g. data storage issues, ensuring and checking quality, training and educating researchers, etc.
- Raffaella emphasised the topic of minimal resources because having practical recommendations on resources needed for research would give added value to the guidance. In the example of Ebola, clinical research was commenced by investigators without the necessary training, resulting in conflicts of interest and non-transparent distribution of research funds.

Next steps

- Morenike enquired whether it would be possible to explore opinions from stakeholders outside the WG.
- CIOMS has several ways of retrieving input from outside the WG: before publishing, reports are made available for public consultations, or if different opinions are needed before, experts from other networks can be invited to join the WG.
- Dominique emphasised the need to operationalise existing standards and not create new ones.

- The first task of the full WG would be to identify the various domains where the minimum requirements for the maximum benefit of the institutions involved should be defined. He suggested forming a small group to identify the domains and dedicate the next full WG meeting to discussing those essential domains in which the requirements are produced.
- Following the next full WG meeting, he proposed to continue with subgroups of four to six people based on the members' experience and discipline and focus on more detailed work with the already identified domains.
- The WG aims to create a guideline of approximately 10-15 pages, including two or three pages per domain.
- The following WG members volunteered to identify the guideline's domains before the next meeting: Ames, Anant, Hans, Henry, Kim, Marie, Morenike, Raffaella, and Roli (subgroup domains, SGD).
- Dominique thanked all for their enthusiasm and suggested creating a smaller sub subgroup from the volunteers for efficient working (with Ames, Henry, Kim and Marie). He will circulate the proposal within the group of volunteers for them to read and reflect, and then create a smaller subgroup. The WG agreed.

Future meetings and closing remarks

- Annie will send a Doodle poll to help schedule the next meeting for September.
- Dominique thanked all for joining the meeting and for their constructive discussions and hoped to reconvene as soon as possible.
- Lembit thanked the WG members for the rich discussions and their time.

Actions

Who?	**What?**
Annie	Circulate the draft meeting minutes.
Annie	Send Doodle polls to schedule a subgroup meeting with half of the volunteers to identify domains for July.
Dominique	Coordinate the sub subgroup to draft a first list of domains
Annie	Circulate the proposed domains of the sub-subgroup to all members of the SGD.
Annie	Send Doodle polls to schedule a SGD meeting with all volunteers in September.
Annie	Send Doodle polls to schedule the next full WG meeting between end of October and November.