2nd Meeting of the CIOMS Working Group on
Principles of Good Governance for Research Institutions (PGGRI)

6 October 2021 Meeting, via Zoom

Meeting Minutes

Participants

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), Roli Mathur (Indian Council of Medical Research), Kotone Matsuyama (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine)*, Lembit Rägo (CIOMS), Andreas Reis (WHO), Dominique Sprumont (World Medical Association), Johannes van Delden (University of Utrecht), Annie Volet (University of Neuchâtel), Zhu Wei (Shanghai Ethics Committee for Clinical Research), Creany Wong (The University of Hong Kong), Henry Yau (The International Clinical Trial Center Network).

*New member

Regrets

Winfred Badanga (Uganda National Council of Science and Technology), Anant Bhan (Yenepoya University), Francine Ntoumi (Congolese Foundation for Medical Research), Raffaella Ravinetto (Antwerp Institute of Tropical Medicine).

Introduction

Dominique welcomes the new participants (Kotone Matsuyama and Andreas Reis) in the WG who were invited to introduce themselves. He underlined that the main objective of this meeting was to reach an agreement with the full working group on identified domains requiring resources in research institutions that will be included in the set of Principles of Good Governance for Research Institutions. The domains proposal resulting from the meeting discussions is included at the end of the present document.

Discussion

Minutes of the first working group meeting

- The minutes of the first working group meeting held the 7th July 2021 were approved by all participants and will be made publicly available on CIOMS website.

Main domains in "Good Governance" of "Research Institutions"

- Since the first working group meeting, a subgroup was dedicated to identify the main domains requiring "resources" in "research institutions". After two meetings held the 16th July 2021 and the 6th September 2021, the subgroup has reached a consensus on domains that could be included in the planned guidance document after approval of the full working group during the present meeting.

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Three major fields of "resources" were identified, namely: Human resources, infrastructure and organizational resources.

- The following nine domains requiring "resources" were submitted to the working group:
    - Methodology & Science
    - Ethics
    - Legal
    - IT
    - Biobank & Registries
    - Budget & Financing
    - Communication
    - Collaboration
    - Training

- All participants acknowledged the nine domains submitted by the subgroup and agreed to add the following three domains in the set of principles:
    - **Monitoring**: Including a chapter about research project monitoring and follow-up in the guidance document was found relevant, all the more since little is said about this area in existing guidance documents.
    - **Research Integrity & Conflict of Interest:** This chapter would address for example the question of economic, scientific and academic freedom.
    - **Management**: The broader sense of the term will be considered to include guidance on topics as staff relationship, mismanagement and misconduct.

The resulting proposal of domains is presented at the end of these minutes.

Drafted table of content

- During the second subgroup meeting on identification of domains, Johannes suggested to draft a table of content with main notions and keywords to be addressed per domains to minimize major overlaps between chapters' content.
- A very preliminary draft of general table of content prepared by Annie and Dominique with one chapter per domains and sub-chapters was shared to the working group before the meeting. Subchapters presently drafted were not intended to be implemented, but only served as examples. Each subgroup will have the liability to define subchapters of corresponding notions to address in their assigned domains, regardless of this first visualization of the proposed recommendations.
Later on, the table of content will be completed with the main keywords associated to the domains addressed by each subgroup and will be made available in the dedicated shared folder on the CIOMS' website to allow a quick acknowledgement of the main area addressed by the different subgroups. The objectives are to allow everyone to identify the topics on which other subgroups are working and promote coordination and exchanges.

Creation of subgroups per domains

- Some participants shared their preferences of domains to work on, in preparation of the splitting in subgroups, but since all domains are not yet covered, Annie will organize a poll to gather a rank of domains' preferences of all working group members including those who were not able to join this meeting. A proposition of subgroups composition will be then submitted to all members accordingly and considering that subgroups could also be assigned 2 to 3 domains.

    Thereafter, each subgroup will identify a representative person to lead the process and to be the point of contact and coordinator with the rest of the working group.

Elements to consider

- The planned guidance document will provide recommendations on "resources" needed to work in accordance with the standards in research ethics and regulation. Those recommendations should be simple models of implementation of existing rules and principles, rather than new requirements.
- The question of the stakeholder perspective used to write the principles will have to be define inside subgroups, while considering that the document should remind how can "research institutions" help researchers to conduct their activities in compliance to applicable requirements.
- Dominique will come with a proposition of definition of the terms "Good Governance" and "Research Institutions" for the third working group meeting, that will be plan between December and January.
- Roli suggested that the planned guidance document include a checklist of items that "research institutions" could have for better research governance. Although, this checklist might be one of the final outcomes of the working group, Dominique invited members who would like to already work on this to do so and to share it, since it could also be used as a tool to work with throughout the process.
- Rosanna reminded on the need to stay practical and have in mind the reality of most institutions where research is carried on but which do not consider themselves neither are perceived by others as "research institutions". This is essential that the recommendations encourage those public health and healthcare institutions to promote research by offering better support to researchers. We should not limit ourselves to the traditional "research institutions" which are specifically designed to do research and be careful not to be identified as only addressing those specialized "research institutions".

Communication tool: Shared folder

A protected shared folder dedicated to the working group is accessible through the CIOMS website page on Principles of Good Governance for Research Institutions. Annie presented how to access to the shared folder and its organization. This tool will be used to share and to store documents throughout the working group process. Presented information on the shared folder will be provided to all member by email after the meeting.

Actions

Who	What
Annie	Send shared folder access and organization explanatory document to members
Annie	Send the minutes and the domains' poll to members
All members	Acknowledge the minutes and answer to the domains' poll

Who	What
Dominique & Annie	Constitute subgroups and share proposals to members
Dominique	Provide definition proposal of the terms "Good governance" and "Research institution" for the next WG meeting
All members	Reflect on a checklist for "Good Governance" of "Research Institutions" (On a voluntary basis)

Proposal 3.0 – 14.10.2021

Main domains in «Good Governance» of «Research Institutions»
CIOMS WG on PGGRI
Version 3.0 - 14.10.2021

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