**Fourth meeting of the CIOMS Working Group on**

**Good Governance Practices for Research Institutions (GGPRI)**

**22th August 2022 Meeting, via Zoom**

**Meeting Draft Minutes**

## Participants

Ames Dhai (University of Witwatersrand), Kim Ellefsen-Lavoie (Lausanne University Hospital, Christine Grady (Department of Bioethics NIH Clinical Center), Marie Hirtle (McGill University Health Centre), Morenike Folayan (New HIV Vaccine and Microbicide Advocacy Society), Rosanna Lagos (Roberto del Río Children's Hospital), Kotone Matsuyama (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine), Roli Mathur (Indian Council of Medical Research), Raffaella Ravinetto (Antwerp Institute of Tropical Medicine), Andreas Reis (WHO), Aline Sigrist (University of Neuchâtel), Dominique Sprumont (World Medical Association), Johannes van Delden (University of Utrecht), Zhu Wei (Shanghai Ethics Committee for Clinical Research), Creany Wong (The University of Hong Kong), Henry Yau (The International Clinical Trial Center Network).

## Regrets

Winfred Badanga (Uganda National Council of Science and Technology), Anant Bhan (Yenepoya University), Dirk Lanzerath (European Network of Research Ethics Associations), Francine Ntoumi (Congolese Foundation for Medical Research).

## Objective

This meeting aimed to discuss the subgroups’ draft domain sheets and give an overview on the work in progress. The WG discusses the organization of the next steps, the consolidation of the documents for the internal consultation and for the on-site meeting in Geneva in November (10-11-12) where the documents will be discussed and finalized for the public consultation.

## Discussion

1. Approval of the agenda

* Dominique welcomes all members and thanks them for their participation and the work done in the subgroups. He thanks the subgroups’ leaders for the smooth and efficient organization of their subgroup.
* The meeting Agenda is approved by all participants.

1. Work in progress: overview of our current achievements

* Dominique gives an update of the work in progress. He explains that the Gantt Chart provided in the beginning has been modified to extent the GGPRI WG work until April 2023. The subgroups have encountered some difficulties to start the work and more time is needed. The delay itself is less important than the fact the WG is producing the domain sheets in a coordinated manner. Meetings has been added until April 2023 to allow the necessary time to take into account the results of the external consultation. Dominique is very confident that in April 2023 the documents will be finalized during a last on-site meeting and then published.
* The on-site November (10-11-12) meeting in Geneva is confirmed. In this meeting the documents will be consolidated to launch the public consultation. More than the half of the GGPRI WG members will attended the meeting with a broad participation from most regions. Dominique thanks the WG members for their participation in the November meeting.
* Dominique thanks again the WG members and the subgroups’ leaders to have managed to do the work and draft the domain sheets. He informs that globally all the subdomains’ sheets are done, even if some need to be completed. He is seeking for some additional expertise in the field of biobanking and IT for example, and people are already identified to reinforce the WG. Even if the work is extended until 2023, the GGPRI WG is on target.
* There are no questions about the revised Gantt Chart.
* Meetings with the subgroups‘ leaders has been organized where the domains sheets were discussed to be improved. It was suggested to have some external review to look at the work and to make sure that we are on target with our objective: to ensure that research institutions will be motivated and interested by the work and will not be discouraged. As Rosanna has many times pointed out, many research institutions are not considering themselves as doing research. It is important to meet their needs. Three reviewers have then commented the draft domains sheets, a lawyer, and a medical researcher, both working in small regional hospitals and not in research institutions, and Aline. They all give positive comments.
* The initial rule for the draft domain sheet was to have one sheet per each domain. But this was formally discussed, because the first subgroup has put the three domains together: laws, ethics, and research integrity. The first feedback received from the three reviewers, was that it is obvious that these domains are related and drafted together. If we should keep in mind that the domains are important on their own, they can be drafted together like the three domains: laws, ethics, and research integrity. In November we would discuss and see if we could put one or two other domains together to make more senses for our target audience. This is a work in progress, we should be flexible and accept the idea to revise the documents according to the reviewers’ comments. We could slightly reorganize the domains sheets knowing that the domains themselves needs to be well identified.
* Rosanna says that they have same concern in their subgroup. How to combine the three domains, health data based and biobanks into a single concept or guideline sheet, considering the various types of biobanks and management of healthcare data. She appreciates to have comments from others WG members on that.
* Kim approves that it is difficult to wrap up everything in one document, like biobanks and registry. They are figuring out how to have an identic line for registry biobanks and be on the topic.
* Hans is interested to see the comments of the reviewers. Dominique precises that based on Henry demand, he asked Aline and two others person not in the field to read the drafts and give comments to ensure the clarity. It is basic comments. He waits the comments of one last person and the document will be made available to everyone.
* Hans asks to precise if the former demand to separate the three domains are still of actuality. Dominique reminds that the subgroups were initially created in an opportunistic way, and it was not the perfect match of each domain. Now that the work progresses, some domains need to stay separated. Like Creany who has done a self-sustaining document for the financing. Other domains, like ethic and law could definitely stay together, research integrity could be either drafted with law and ethic or with training and communication. The important point is to cover the domains, in combination or not. The management of health data registers or biobanks are cover in the same documents under the declaration of Taipei, but it is clear than when talking about IT and data protection it is separated. Flexibility is important. Dominique thanks the WG members to cope with the difficulty to put some domains together.

1. Discussion/presentation of the Subgroups’ draft domain sheets

3.1. Subgroup 1\_Ethics-Legal-Research Integrity&Conflict of Interest

* Hans says that the document “Ethics-law-Research Integrity” is in a decent shape but could definitely be improved. He waits for the comments of the reviewers. The most important is to be sure that the document is in line with other chapters and to have a guidance about the level of details needed.
* Dominique explains that the comments received was that the document was on target, some bold letters could be added to improve the document’s visibility. The question of where to put conflict interest remains but is not fundamental and can be solved later on.

3.2. Subgroup 2\_Methodology&Science-Biobank&Registries-IT

* Kim explains that they start working with the IT part. They changed the title to “Data Handling and Information Technology” because it is difficult to talk about IT if you are not talking about the data that will be collected. They decided to have one section on the source data, to be sure that people know the differences in source data and study data based. The data can be on paper but should normally be in electronic form. They explain the data-based lifecycle, and finally propose the minimum requirement dedicated for the institutions researchers information’s systems.
* Kim asks Dominique to have someone to go through this document because they are not experts in IT, they are experts in data generation, data source, study data, but not on what goes beyond. They look for different documents or guideline to draft something.
* Dominique will look for experts. He already identified a person for the IT field, a French who was the chair of the National Digital Ethic Committee, a subgroup of the National Life Science Ethic committee.
* Christine starts a draft on methodology in science. She has the same question about the level of details.
* Dominique reacts on the level of details. The documents are quite on the target and don’t need more details. The idea is to work on the references to be provided in the annex of each domain sheets. When the attention of managers, leaders or the decision makers of institutions is grabbed, if they want to go deeper, they will have those references. At the end we should have a list of 10-20 questions for each domain, like a checklist. The kind of questions that WG members are asking themselves when dealing with this topic.
* Kim, Christine, and Rosanna are working on the biobanks document.
* Ames points out that some part of the world have different requirements and wonders if the documents will be adequate for them. She wonders how the documents will be convenient for all part of the world. For example, concerning the data sharing agreements, would the document include a template for data sharing and to show how a data sharing agreement should look like. Ethical principles need to be involved, even if it is a little legalistic.
* Dominique says that they are many issues because of variations from one country to another. South Africa has much stricter legal principles on data sharing than Switzerland for example. We don’t have the capacity to provide details for each continent and even less country. But the idea is that people address to a local lawyer to be sure to be in accordance with the local law. People need to know that they are legal requirements in their country and to have a basic legal person to refer. The domain sheets only need to provide the references.
* Ames says that this point should be discussed once the document is finalized to be sure that it meets the need of all people and assist them or to take this in consideration. Dominique agrees that this point is important and must be discussed in November.

3.3. Subgroup 3\_Budget&Financing-Monitoring-Management

* Henry says that they worked well and managed to have two productive meetings with Roli, Creany and Dirk. They completed a draft for each three chapters which are on the share drive. After discussing with Dominique, he thinks that some parts are maybe too complicated for institutions not dedicated to research (management and financing chapters). They reworked it. He welcomes comments from other members.
* Creany explains that it is a dilemma to include concepts but not to be lengthy. It was a good lesson on how to write a chapter like financing because it is not a common chapter appearing in institution guidelines.
* Dominique says that the reviewers find the examples positive, even if it makes the document lengthier. It is also livelier and more readable. Likewise, the table and graph clarified the documents. He invites people to add some examples, that are culturally or regionally related.
* Roli says that the monitoring domain was challenging, because there is little understanding about how monitoring of research, for ethics and scientific integrity must be done in the institutions. Institutions often don’t have these policies for ensuring the highest standards. It should be in line with the relevant guideline and law of the land. In the section, the monitoring was defined first then the responsibility of various stakeholders at various levels; the researcher, the institution themselves and also the various bodies such as ethic committee, data safety monitoring board, scientific committees, and sponsors monitoring research, accreditation bodies, regulatory agency, etc. The draft encourages the institution to develop monitoring systems, including internal and external monitoring, that would help to develop the confidence and quality. She invites people to give comments on that point.
  1. Subgroup 4\_Communication-Collaboration-Training
* Koto explains that they wrote a semifinal draft for the training and collaboration domains. The communication domain still needs to be drafted, because it is difficult to know what to put in this domain. They identified key concepts related with communication. They will go with stakeholder communication and postponed internal communication. She thanks all the members for their collaboration.
* Rafaella thanks Koto for her work and for having put all the comments together. The three domains are really crosscutting and could be seen from different perspectives. They agree that the collaborative was the “fil rouge”. The challenge is how to write a short but complete final document. The challenge with communication is that you can approach it from different points of view, internal, external, with different level of stakeholder, from other researchers to policy makers. The next step is the communication for the dissemination of research because it is really an ethical requirement, for different reasons there is often shortcoming both in commercial and non-commercial researches.
* Dominique says that the internal communication is also part of management and could be discussed with Henry. This is an element where we can have this balancing of mixing some of the topics to present them in a more understandable way to the target audience.

4. Next steps: Consolidating and harmonizing the domain sheets; Organizing the internal consultation; Assessing the need for expanding participation in the WG

* The next step is the consolidation of the process. Dominique hopes that the feedbacks and discussion from this meeting will help the WG members to consolidate their draft domain sheets. The WG members have some clue on how to continue the work and improving the drafts based on the global discussion. The subgroups should have a final meeting to consolidated and improved them. Then Dominique and Aline (and any voluntaries) will work to make a more streamed line full copy, with the introduction, the definitions, the contextualization. That will allow organizing the internal consultation to prepare the November meeting. Dominique hopes that they could work rapidly on the consolidation to have a general discussion in November.
* Dominique invites the WG members to expand the participation in their subgroup or in the WG if needed and asks if they want that the CIOMS invites additional experts. At that stage the WG must be inclusive, culturally, geographically and includes various disciplines (like anthropology, sociology, public health, etc..).
* The consolidated drafts will be shared on the Drive.
* Andreas says that it would be helpful to have a joint document with all domains included. Dominique reassures him that such document should be made available for the internal consultation prior the November meeting.

1. Organization of the on-site meeting the 10-11-12 November in Geneva

* Hans asks for a timeslot’s indication of the meeting, and if it is planned to begin in the afternoon the first day and finish in the morning the last day, in order to allow travel these same days. Dominique confirms that we should start on Thursday afternoon to allow participants coming from Europe to travel in the morning and end at lunch on Saturday.

1. Varia

* Some WG members ask if they could have an outlook invitation for the next meeting, to facilitate the question of time zone. Dominique welcomes the proposal that will be implemented and apologizes to the members who have been confused with the invitation.
* Dominique thanks all the participants for their time and attention and looks forward to see them all in November.