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

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

**06th February 2023 Meeting, via Zoom**

**Meeting Draft Minutes**

## Participants

Winfred Nazziwa (Uganda National Council of Science and Technology), Anant Bhan (Yenepoya University), Kim Ellefsen-Lavoie (Lausanne University Hospital), Dirk Lanzerath (European Network of Research Ethics Associations), Francine Ntoumi (Congolese Foundation for Medical Research), Roli Mathur (Indian Council of Medical Research), Kotone Matsuyama (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine), Lembit Rago (CIOMS), Raffaella Ravinetto (Antwerp Institute of Tropical Medicine), Andreas Reis (WHO), Aline Sigrist (University of Neuchâtel), Dominique Sprumont (World Medical Association), Vladislava Talanova (University of Neuchâtel), 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

Ames Dhai (University of Witwatersrand), Morenike Folayan (New HIV Vaccine and Microbicide Advocacy Society), Christine Grady (Department of Bioethics NIH Clinical Center), Marie Hirtle (McGill University Health Centre), Rosanna Lagos (Roberto del Río Children's Hospital).

## Objective

This meeting aimed to discuss the internal consultation and the reviewed draft. The WG discusses the finalization of the draft after the internal consultation and before sending it for the public consultation, the continuation of the work and the different parts to be reviewed, the organization of the next full WG meetings and the agenda of the GGPRI WG.

## Discussion

1. Approval of the agenda

* Dominique welcomes all members and thanks them for their work, especially as many of the WG members had professional and personal commitments. He is grateful for the implication and work done by all the WG members.
* The meeting Agenda is approved by all participants.

1. Feedback on the internal consultation

* Dominique reminds that he sent a compiled version of the draft on Saturday, in which he included many remarks of the members. As mentioned in his message, he did not included all remarks. He especially thanks Raffaella for the many comments sent, as they provided key elements regarding the main concerns for the further development of the revised draft. Although the WG is not quite on schedule, it is on track to complete the task by the end of August, as discussed in Geneva in November. The main point shared by many members is that there is still some imbalance between the chapters and that some are not fully reviewed in the way discussed in November in Geneva. Some sections go into too much on details, others are too much based on ICH/GCP or clinical model. The document needs to be more consistent in the message from chapter to chapter.
* Ames was hospitalized last week and could not assists the meeting but she speaks with Dominique and they agreed that we cannot launch the public consultation before having a satisfying document. This does not mean that the document has to be perfect, as the consultation aims to improve the draft. The draft produced is something quite new, there are no guidelines available with such a broad approach and a fundamental shift from individual to institutional ethics. Dominique asks if it is OK to have a document that is not perfect but that all members are comfortable with. After reading the comments, he thinks that it is perfectly achievable in a few weeks. Some of the chapters need to be refined and sex and gender issues need to be added to the guidelines.
* Hans agrees that the WG goes on the right direction but that the document is not ready yet for the public consultation, especially as some chapters are not ready (chapters 6-7-8). The draft could be more consistent. Hans agrees that the document does not need to be perfect.
* Henry also agrees that the draft is not 100 % ready although work is progressing towards the goal. He is concerned with variation in writing style, as many different people produce the document. He wonders how to deal with this and produce a more uniform document. One possibility might be to send the document to an external editor to revise and harmonize it once the content is fixed. Dominique thanks Henry for the remark and invites Lembit to share his experiences of working with other WG. He thinks it is premature to invest in an editor as we are still working on the draft, although the draft could be cleaned up. The use of an English editor should be reserved for the very last step. Lembit agrees that at this stage the final editing is a waste of time because after the public consultation there will be changes. Maybe an editorial group should do it, and then the final language and layout editing should be done. Dominique adds that at the time of the editorial stage, he would like it to be available in French as well. The document should be very understandable and easily translatable into any other language.
* Andreas thanks all the secretariat for their work and acknowledges that the document has progressed since November, some chapters are almost ready to be sent out but a few others chapters need more time to be refined. He agrees that the document needs more time to be reviewed before the public consultation, although it does not need to be perfect. Hopefully there will be lots of feedbacks and the consultation will be meaningful. It should be taken seriously.
* Raffaella also agrees, pointing out that for the consultation, it will be essential to reach out to disciplines that are under-represented in the WG. As she commented, the document may not yet be user-friendly for people working in behavioral or non-clinical research. The public consultation will be the critical time to reach these researchers and professional societies. Dominique invites all members to identify the people and institutions to whom the document should be circulated for public consultation and that it was important to have people who were not yet in the loop and to open the discussion.
* Dirk points out that there is still an imbalance between the chapters, and that regarding the title of the guidelines, we should focus on very general procedural issues. He has problems with the chapters concerning biobanking /biodata /health data. This is a complex issue, and from an ethical point of view, several questions are missing. Perhaps this is not the place to go into detail on these issues, as this is a separate directive. Perhaps the guidelines should be limited to an explanation of how biobanks or data should be integrated into institutions, without going too far into the ethical and legal exchange of data. The reflection should now focus more on the chapters that really need to be included in the guidelines.
* Dominique explained that this should be addressed directly in the introduction. It is difficult to stay at the level of principles in all chapters and to avoid being technical in some. It is also difficult to avoid references to ICH in some chapters. It is extremely useful that all members share with the coordinators their comments on each of the chapters; whether each chapter is sufficiently at the level of principles, too technical or not technical enough, to refer to in the introduction. As mentioned before, it is necessary to have examples and cases to illustrate the chapters. The final task will be to propose different scenarios showing how this document could be used in an institution; in a developing country; in a highly developed clinical center, such as in Hong Kong or in Lausanne.
* Wei is concerned that it the draft deals with a broad definition of research institutions, as there are many different type of research institutions, commercial or not, academic research doing pure research, or pharmaceutical institutions, etc. Although the document aims to reach different types of institutions, how will the guidelines cover all institutions? Dominique reminds that this has been a concern from the beginning and that there is a consensus that the guidelines will cover a very wide range of institutions, commercial and non-commercial. We need to be careful that the pharmaceutical or commercial industries follow the GCP/ICH recommendations and already have documents defining their responsibility, etc.
* Dominique asks Lembit to share his experience of the consultation. Is it acceptable that some parts such as the glossary or the summary are not completely finished, if the process is explained? Lembit says that normally the document should be mature and all parts in place, although there may be exceptions. He adds that the WG must be very clear about how comments/feedback will be handled after the consultation, as transparency is very important. He suggests having an Excel document gathering all the comments to track the process and have a history of the process; like which comments were discussed and taken into account or not, etc. Dominique specifies that the process of the consultation will be discuss in March. He fully agrees with the question of transparency. People should be asked if they agree to have their comments added to the document. For the public consultation, the document will contain the glossary and references for example, and people can add to them.

3. Continuation of the work

* Dominique invites members to make concrete proposals in the text. The chapters “collaboration”, “communication” and “education” will be refined in 3-4 weeks by Koto, Henry, Creany, Winfred and Raffaella. He thanks Winfred for having work with Koto on the education chapter and Koto, Henry and Creany to have already made comments on the communication chapter. The other chapters will be revised based on sex and gender issues and today's discussion by the members. The document will then be updated in a way that is acceptable for consultation.
* Regarding the chapters “collaboration”, “communication” and “education”: Koto thanks and agrees to review the chapters. She adds that she had already work on the three chapters and would review them with Henry, Creany, Winfred and Raffaella. Raffaella asks for practical details about the organization of the subgroup’s work. It is difficult to meet because of everyone's schedule and time difference (it was a problem for several WG). She asks for assistance from the coordinators to organize and schedule the meeting. She proposes that each member works on the draft and then meet to collate the comments. Dominique and Aline will assist them with the administrative and organizational questions. The detail process will be discussed within the subgroup and a meeting will be organize.
* Regarding sex and gender issues: Dominique explains that sex and gender issues must be added to the different chapters. On 2 February, some members of the WG (Andreas, Hans, Raffaella, Lembit, Dominique, Aline) attended a CIOMS / GENDRO meeting in Geneva to discuss how to better include sex and gender issues in the ethical guidelines (cf. documents sent). This is an important topic that is not sufficiently explicit in the document. The idea is not to make new guidelines, but to make readers aware of these issues in our guidelines. There is a paradigm shift and the topic is becoming more important. Dominique invited members to read the SAGER guidelines, which aim to help researchers, ethics committees and journals to ensure that sex and gender issues are included in studies. He stresses that sex and gender issues are not sufficiently recognized and included in research. He points out various domains, like social values, methodology, care for vulnerable population and so on, where these issues should be included. He thinks that in almost all chapters one or two sentences could be added, mentioning sex and/or gender issues. He invites members to add these dimensions where the topic could be addressed. Dominique invites Hans to share his suggestions, as he has already made some in his chapters.
* Hans explains that the best place to add sex and gender issues in his chapters (ch. 2 and 3) is where social values and scientific values (now called “scientific significance”, a term Hans does not find very relevant) are discussed. Attention should be drawn to the importance of responsible population choice and respecting the gender and sex balance in studies. The SAGER guidelines should be added to the document as references. However, he feels that mentioning sex and gender issues in each chapter is disproportionate. He invites members to add them where relevant (e.g. choice of population, consideration of social values when designing the research). He does not think that the SAGER guidelines are relevant for the chapter on biobank for example.

Koto agrees that most, but not all, chapters should include sex and gender issues. She asks for clarification on which chapters need to add these topics. Dominique specifies that we will indeed have to choose which chapters should include these topics. However, the document should include sex and gender issues in a broader way than the SAGER guidelines. In order not to close the door at this stage, we should check where these issues should be added and then choose the chapters that should really include these topics. He invites members to review the whole document with these issues in mind.

* Anant works on this topic with colleague for several years. He suggests that we take these issues as a perspective, as it is not a chapter but an approach. He mentions that we also need to address non-binary, Trans gender people, etc. and not just male/female issues, as they are related to health issues. Issues of equity and inclusion in general should be included. The responsibility of the institutions to include wide range of population and to reflect on which population is included or excluded of research should also be stressed. It is important to raise the awareness of the institutions on these issues without being prescriptive. He will review the documents on that lens. Dominique invites Anant to share references to add to the document and to propose others experts to the WG in order to review all the document concerning these issues. Anant agrees and will ask other experts to review the document and to do a specific consultation on that topic.
* Dominique invites other members to mention their expertise on the topic, like Aline as she is doing postdoctoral research in the health and gender unit at Unisanté, with a team dealing with this kind of issues. He also reminds all members to have in mind sex and gender issues, as well as questions of equity and inclusion in general raised by Anant (e.g. sex, gender, non-binary, vulnerable population etc.) when reviewing the document.
* Dominique specifies that the aim is to have a new refined document by mid-March, with new drafts for the chapters’ “collaboration”, “communication”, and “education”; and refined drafts for the other chapters. He will work on the Introduction. The next full WG meeting will be held on the 20 or 27 March, a doodle will be sent. Wei precises that she is not available on Monday’s evening.

1. Next step:

* A doodle Poll will be sent for the next full WG meeting, on **20 or 27** **March**. The public consultation process will be discussed.
* A doodle Poll will be sent for the next in-person meeting in Neuchâtel, Switzerland, on **17-18; 24-25; 25-26 August; 31 August-1 September; 1-2 September**.
* Koto, Creany, Henry, Winfred and Raffaella will review the three chapters’ “collaboration”, “communication” and “education”. A meeting will be organized to precise the detail process.
* All members are invited to review the chapters they have written to see if it is relevant to **add the sex and gender issues** and to make proposals.
* All members are invited to **review and comment** **all the document**, to **send** **references to add.**
* The public consultation will be launched on **1 April**.

Dominique thanks all the participants for their time and attention.