February 25, 2021

Recommended Guidelines on the Principles of Good Governance for Research Institutions

I. INTRODUCTION

Over the last 50 years, the Declaration of Helsinki has been revised 10 times (12 if one counts the notes of clarification on the placebo rule from 2002 and 2004). The CIOMS International ethical guidelines for health-related research involving humans have also been reshaped three times, not mentioning their merging with the 2009 Guidelines for epidemiological studies, which had been revised once since the original version in 1991. During the same period, many guiding documents, regulations and laws have been adopted at the national, regional and international levels. Concerning this inflation of rules, Jay Katz, wrote as early as 1969:

> "Taking as a point of departure the ten "basic principles" set forth by the Nuremberg judges, numerous attempts have been made to propose "improved" codes of ethics to guide medical research. The proliferation of such codes testifies to the difficulty of promulgating a set of rules that does not immediately raise more questions than it answers. At this stage of our confusion, it is unlikely that codes will resolve many of the problems, though they may serve a useful function later. Even the much endorsed Declaration of Helsinki— praised, perhaps, because it is the newest and therefore the least examined— will create problems for those who wish to implement it" (Katz, J. (1969), "The Education of Physician- Investigators," in DAEDALUS, Journal of the American Academy of Arts and Sciences, Spring, pp. 295).

Fifty years later, it is questionable whether researchers are better equipped to face the challenges raised by their activities. They often lack the necessary resources to respond to the increasingly complex ethical and regulatory framework of research. Most 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 defining the context in which research involving human participants is conducted. Instead of adding more rules or revising existing ones, it seems a priority today to improve the research environment.

II. THE ISSUES

Most ethical guidelines and laws focus on individual researchers and sponsors to protect the dignity, integrity and safety of research participants - Research Ethics Committees (REC) acting as gatekeepers. Yet, it is rarely assessed to what extent researchers and sponsors have the necessary resources to fulfil their responsibilities. More precisely, this assessment is done separately for each protocol. It does not provide a broad picture of the research activities and available resources in a given company, hospital or university to guarantee the protection of research participants in the end.

Resources means here 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. In other words, what services and supports are available for the researchers to meet their responsibilities as imposed by research ethics and regulation? Adding more rules does not guarantee that the researchers are able to fulfil them unless they are provided with the necessary means to do it.

In 2016, the World Medical Association included a section on governance in the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. This demonstrates the need for a different approach to research ethics that addresses the responsibilities of the institutions in which researchers are working. COVID-19 has shown a necessity at the world level of more coordination and collaboration within the research community, both objectives that can hardly be achieved by researchers individually. This requires an institutional commitment at all levels.

III. NEED FOR A CIOMS WORKING GROUP

III.1 Background

Taking into consideration that:

- 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.

CIOMS is well positioned as a unique global and scientific organization to develop a multi-stakeholder consensus report on the good governance and ethical practice for research institutions.

The CIOMS guideline would serve as a worldwide reference for research institutions aiming to offer the appropriate environment for their researchers to conduct their activities according to the highest standards in research ethics and regulation.

III.2 Aim of the Working Group (WG)

The main objective of this Working Group would be to discuss and develop a consensus report giving recommendations on the principles of good governance for research institutions.

In order to support this, the CIOMS WG would propose standard guidelines promoting the minimal resources needed for researchers to work in accordance with the highest standards in research ethics and regulation.

III.3 Composition of the WG

Senior experts and research managers with relevant scientific, professional and research backgrounds will be invited from international, regional and national researchers/medical associations, university hospitals associations, research ethics associations, drug agencies, patient organizations, World Medical Association, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and pharmaceutical industry associations.
A balanced approach will be used for selection of experts such that no constituency would have a preponderance of influence within the WG.

III.4 Deliverables

The below list gives some of the possible deliverables:

- harmonized guidelines on the principles of good governance for research institutions.
- structured list of the minimal resources needed for researchers to work in accordance with the highest standards in research ethics and regulation.
- a syllabus and an online course on the principles of good governance for research institutions.

It will be the first task of the WG to agree a final list.

IV. CONCLUSION

There is a strong need to launch this Working Group to develop harmonized guidelines on the principles of good governance for research institutions. Furthermore, the collaborative efforts brought together to accomplish this task could raise the awareness of research institutions to better support their researchers in their activities by evaluating their needs and how best to respond to them. This could 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.