POLICY DEVELOPMENTS IMPACTING ETHICS ASSESSMENT OF R&I AT THE GLOBAL LEVEL

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And the authors of the following reports:
Ethics assessment and guidance at the global level
International differences in ethical standards and in the interpretation of legal frameworks
How globalisation is changing research agendas. Activities and assessment procedures within research & innovation

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GENERAL OVERVIEW OF THE STAKEHOLDERS IN TERMS OF POLICY DEVELOPMENTS AT THE GLOBAL LEVEL (1)

- Global governmental institutions and policies for ethics assessment: WHO, UNESCO, OECD, CIOMS
- Public Research and innovation systems
  - Global research associations and standard-setting bodies: IAU, ICSU, APPE…
  - Research funding organisations: IFS, NIH, EDCTP…

GENERAL OVERVIEW OF THE STAKEHOLDERS IN TERMS OF POLICY DEVELOPMENTS AT THE GLOBAL LEVEL (2)

- Private research and innovation systems
  - Industry associations and accreditation, certification and standard setting organisations: ISO, IAIA…
- Professional groups and associations in the R&I field: ISMPP, CRS, IUPsyS

FOCUS ON GLOBAL GOVERNMENTAL INSTITUTIONS (1)

- The increased presence of **global ethics assessment bodies, discussions, and standards** has facilitated increasing harmonization and debates over proper viable ethics assessment practices.
- **Unesco's Assisting Bioethics Committee programme** creates a model of bioethics committees across different countries with differing social climates grounded in similar ethics principles.
- More recently, **global discussions and actions** within ethics assessment align with the rise of multinational corporations and actors, necessitating even greater global reflection.

FOCUS ON GLOBAL GOVERNMENTAL INSTITUTIONS (2)

- Global governmental and government-funded controlled organs and institutions mainly help provide the conditions for ethics assessments and ethics review to take place.
- To create these conditions, global governmental institutions' activities include:
  - the establishment of internationally recognized standards, codes, declarations and other soft-law instruments,
  - Capacity-building for regional ethics assessment,
  - Providing forums for international collaboration and reflection,
  - Serving in an advisory capacity for governments.

FOCUS ON GLOBAL GOVERNMENTAL INSTITUTIONS (3)

- The **creation process of internationally recognized soft-law and legal provisions** addressing ethics assessments takes various forms. The most prominent role of such organisations is to first create a global platform on which discussion of current and relevant bioethics principles can take place, engaging all parties with vested interest. This leads to the production of international benchmark documents such as the UNESCO Universal Declaration on Bioethics and Human Rights.
- Current exple: UNESCO is currently in the process of revising its 1974 Recommendation on the Status of Scientific Researchers
- The WHO engages in ethics assessment in various capacities. It helps set standards and norms, oversees the ethical review of research being conducted, and capacity building. Notably, it also has a process for ethics committee accreditation.
- Alongside institutions, there has been an accompanying rise in collaborative efforts between ethics committees in different regions. The “Global Summit of National Ethics/Bioethics Committees” is a good example of such efforts.

NEW GLOBAL POLICY INITIATIVES ADOPTING EA OR EIA

- The CIOMS (Council for International Organisations of Medical Sciences) international guidelines for health-related research involving humans which were revised in 2016.
- The Brussels Declaration on ethics and principles for science and society policy-making text was adopted in 2017 during an announcement symposium at the American Association for the Advancement of Science's Annual Meeting.
- The Institute of Electrical and Electronics Engineers , which is the largest professional association of technical professionals, has launched a new project on ethics in system design. The new standards project, IEEE P7000, will "define a process model by which engineers and technologists can address ethical consideration throughout the various stages of system initiation, analysis and design".
- On the other hand, these codes do not include any reference to EA or EIA
  - The European Federation of Academies of Sciences and Humanities, has published the revised edition of the European Code of Conduct for Research Integrity, a document that serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings.
  - In April 2016, ACS International Activities gathered 30 scientists from 18 countries for a workshop to collaboratively draft an actionable Global Chemists' stakeholders Code of Ethics (GCCE), guided by The Hague Ethical Guidelines and the Code of Conduct Toolkit.

GENERAL CONTEXT

- The greater theme of global level ethics assessment is growing **interconnectivity between regional actors**.
- Through policies and soft-laws in ethics do exist on an international platform, **ethics assessment takes place to a greater extent on the national and regional levels**.
- One notable exception is research projects funded by the WHO.
- However, the global dialogue provides the backdrop in which ethics assessment practices occur. **International guidelines are frequently cited by regional level organisations**, from ethics review committees to national level agencies such as the US FDA to EU level Directives.
- **While global standards may exist, the implementation of them varies across countries**. This can be either philosophical or practical reasons. Different priorities by regional actors mean differential commitment to international standards. Exple : the US FDA no longer cites the current WMA Declaration of Helsinki as a reference point to the use of placebos in clinical trials. Instead, it refers to a prior revision.
- There are also **practical barriers**: COHRED and EDCTP both identify lack of capacities to perform ethics reviews due to local deficiencies as practical barriers to international ethics assessment compliance.

POTENTIAL CHALLENGES OR BARRIERS TO OVERCOME IN INTRODUCING THE SATORI ASSESSMENT FRAMEWORK AT THE GLOBAL LEVEL

- EA of Research and Innovation is a complex nexus:
  - ranging from private and public research funding, and
  - performing organizations from civil and non-profit societies and associations
  - all overseen by local, regional, national and international
  - Governmental laws, policies and recommendations
- Research and Innovation is assessed differently according to the type of research that takes place:
  - Certain areas such as biomedical and human subjects' research areas have much stricter global oversight and assessment capacities than others which rely on a more *laissez-faire* approaches, such as:
    - evaluating scientific misconduct or the use of animals of research, both of which the oversight and assessment capacities vary greatly depending upon the region and context

CONCERS TO BE ADRESSED BY GLOBAL POLICIES

- With respect to harmonisation of ethical principles, all interviewees indicated a measure of approval.
- However, each identified issues to consider in the development of a harmonised system:
  - Most frequently cited was the need for adaptability to local conditions.
  - Concerns about an excess of standards without the means for monitoring or implementing were recurrent.
  - The increased attention to the ethical standards by which research and innovation should be evaluated without addressing practical issues that preclude ethics assessment being implemented has also been cited as detrimental to the aims of the development of ethics assessment standards.
  - Other critiques mention the scope of harmonisation across research and innovation practices and whether ethical principles scan the entirety of research and innovation.
  - Another comment was that the focus should be on the future development of standards that may arise as the shift of research performing areas increases from the US, Europe, and Japan, suggesting that new models may emerge to supplant current western dominant ethical systems.

CONCLUSION WITH REGARD TO CONCERNS

Efforts to harmonise ethics assessment across the EU or across the world need to take into account the significant differences in institutions, values, legal frameworks and cultural practices that exist between different countries and regions.

These differences do not automatically imply that no harmonisation is possible, but **they may imply that not every element in ethics assessment can be harmonised, and that there should be flexibility in the formulation and interpretation of international standards.**

SATORI HERITAGE AT THE GLOBAL LEVEL

Some of the suggestions include:

- Contacting associations representing the industry, beginning with the pharmaceutical companies, a sector familiar with ethics assessment: EFPIA at the European level and IFPMA at the global level.
- Contacting the administration of the UN Global Compact.
- Contacting the administration of the OECD Guidelines for Multinational Enterprises
- Liaising with the European Network of Research Ethics Committees – EUREC
- Liaising with the Unesco ABC programme
- Liaising with WHO, the Council of Europe, and of course the European Commission…

To be discussed.