”Equivalent Protection” Assurance:
a Matter of Principles

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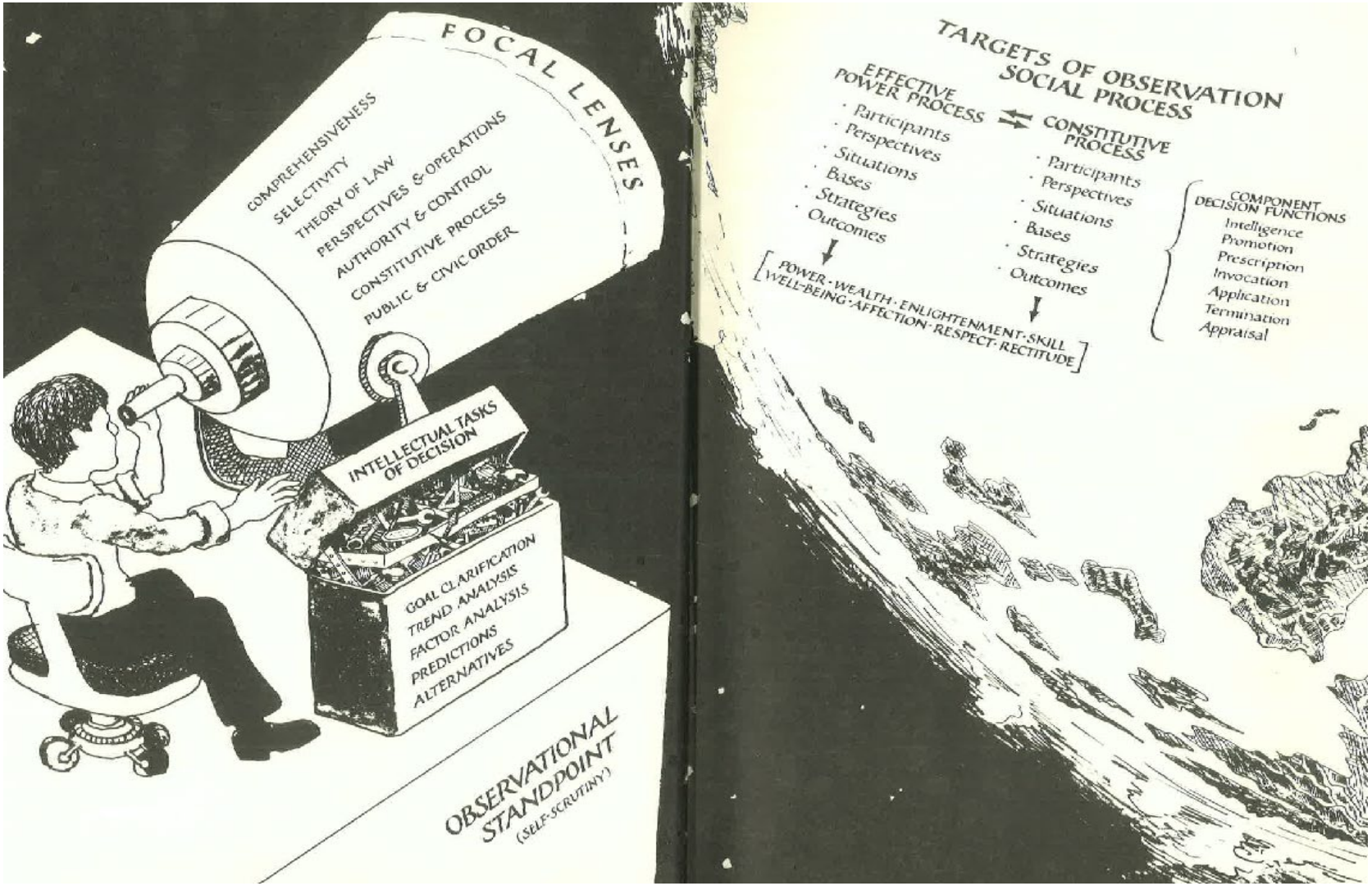
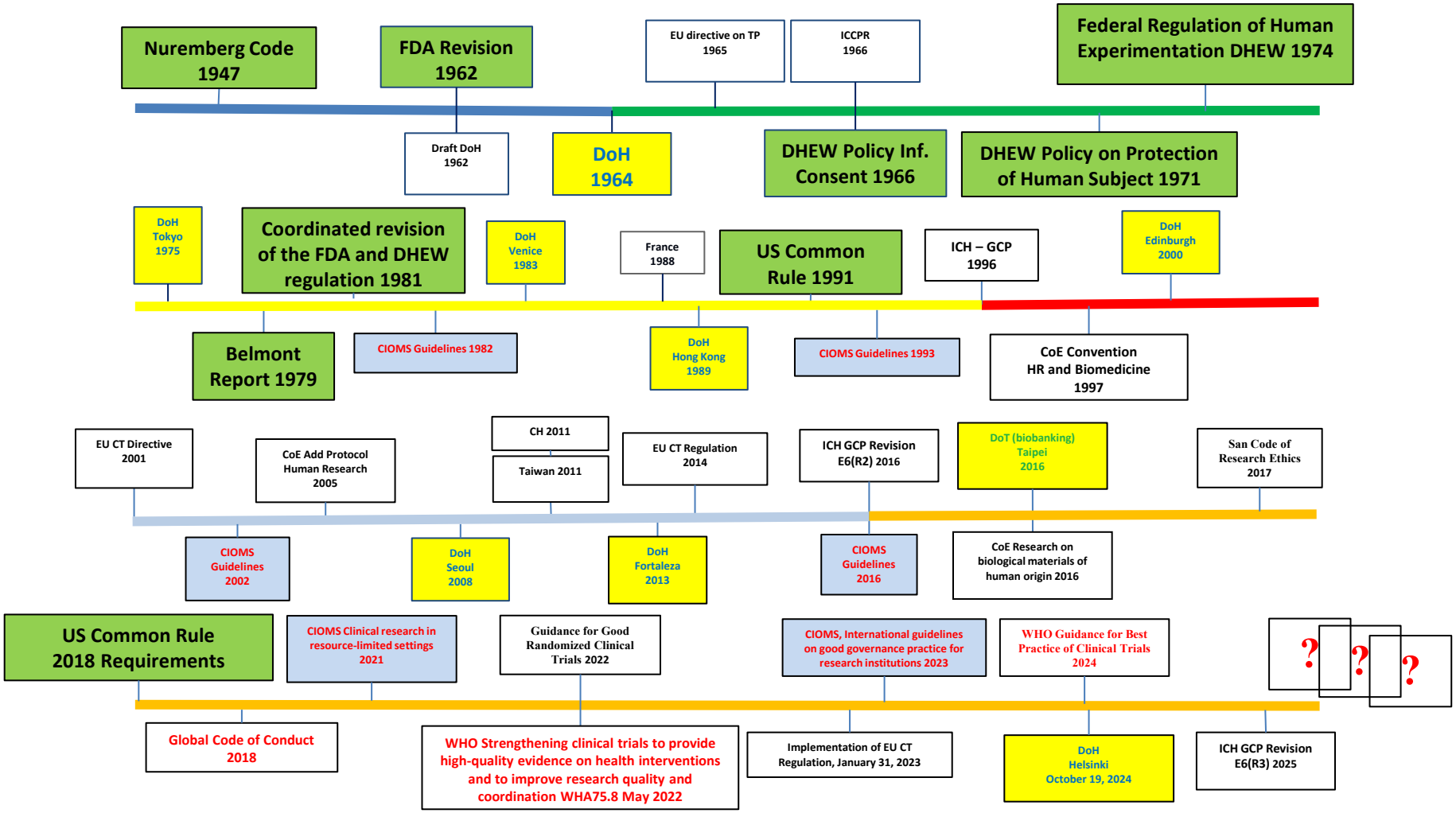
What is your perspective ?



Michael W. Riesman, *Jurisprudence : understanding and shaping law : cases, readings, commentary,* New Haven Press (1987), p. 18s

Evergrowing landscape of health-related research ethics and regulation



Adapted from Dominique Sprumont Research Ethics Regulation : Rules versus Responsibility, in *Ethical Research: The Declaration of Helsinki, and the Past, Present, and Future of Human Experimentation*, Ulf Schmidt, Andreas Frewer, and Dominique Sprumont (eds); Oxford University Press, April 2020, pp. 243-283, figure 10.2

The Belmont Report 1979

US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (8 men/3 women including the only African American)

"The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations." (summary, p. 1).

"The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three **basic principles, among those generally accepted** in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice." (Part B, p. 4)

Western and/or Universal Principles ?

- Although contested by some, especially from the West («Georgetown Mantra»), the four pillars of research ethics have demonstrated their universality, being imbedded in the most widely recognized international ethical guidelines including the DoH and the CIOMS.

Toward Global Research Ethics Principles

- Recognition of research as a **common good** with the duty to conduct it **for the common good** (scientific rigor, social value) (cf. DoH, CIOMS)
- **Respect** as the expression of **solidarity** and **reciprocity**, implying involvement and inclusion of all and not only respect of the individuals' autonomy and protection of vulnerables.

Doing research with human beings is not a right but a privilege only justifiable if aiming at common good (social value)

Latest trends in research ethics and regulation

- Consolidating existing guidelines based on **universal values**;
- Promoting patients, participants, communities and population involvement and engagement in research from its design to the dissemination of the results (**participation, transparency and accountability**);
- Moving from strictly individual research ethics (mainly targeting researchers) to institutional or collective ethics, also for the re-use of data and biospecimens (**Good Governance Practice**)

Some Core Issues Covered by Research Ethics and Regulation

Q. 1/4

- Scientific and social value
- Pre-clinical data
- Proper design of the research
- Free and informed consent of the participants
- Participants and community engagement and involvement (PPIE)
- Participants' register (healthy volunteers)
- Favorable balance benefits/risks
- Respect of privacy / data protection / coding / de-identification/ **anonymisation**
- **Compensation for research induced damages**
- Qualification of the investigator
- Sufficient ressources of the investigator (time, staff, infrastructures, material)
- Independance of the researcher / IP
- IT support
- Good Governance Practice of Research Institution (including a Human Protection Administrator)
- Favorable opinion of the competent Research Ethics Committee (REC)/IRB
- Registration of the research
- **Re-use** of personal data and biological material, etc…

How to Cope with this Complexity?

FACE IT !

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Welcome to the TRREE on-line tra … he ethics and regulation of health research involving human participants. Read More »

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October 8 2024
New record of participation!

September 2 2024
Publication of the Ivory Coast's Regulatory Framework

August 23 2024
ISFM/FMH recognition of TRREE modules

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TRREE Participants & Statistics

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National or local regulatory frameworks

local experts explain requirements in their country

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- Romania [RO]
- Tanzania [EN]

Q. 3/4

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How to Cope with this Complexity?

Primacy of the Individuals

The respect for and protection of the integrity, well-being, rights and dignity of the participants must always be the priority. When in doubt, one must adopt their point of view (**universal ethical principles or human rights based regulation**).

Q. 3/4

Convention of the Council of Europe on Human Rights and Biomedicince (Oviedo Convention)
Article 2 – Primacy of the human being
The interests and welfare of the human being shall prevail over the sole interest of society or science.

Declaration of Helsinki (2013)
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

Jerry Menikoff, Protecting Participants Is Not the Top Priority in Clinical Research, *JAMA* 2024 Jul 16;332(3):195-196. doi: 10.1001/jama.2024.7677

«Equivalent Protection» Assurance and the Rule of Law

US law perspective

Legally or contractually ☑

DoH, CIOMS Guidelines

Ethics ☑

International perspective

Law

Other national laws perspective ☑

§46.101 To what does this policy apply?

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

Q. 1

Q. 4

Convention of Oviedo, CoE
Additional Protocol on Biomedical Research, CoE
Clinical Trial Regulation, EU
General Data Protection Regulation, EU
etc

«Equivalent Protection» Assurance depending on the scope of foreign laws

Q. 2

Comparison

Jurisdiction	1. Regulatory Framework 1. Is there a regulatory fram
Senegal	a. Yes
Poland	a. Yes
Germany	a. Yes
Argentina	a. Yes
France	a. Yes
Nigeria	a. Yes
Kenya	a. Yes
Portugal	a. Yes
Lithuania	a. Yes
Armenia	a. Yes
Switzerland	a. Yes
South Africa	a. Yes
Cameroon	a. Yes
Mali	a. Yes
Côte d'Ivoire	a. Yes
Burkina Faso	a. Yes
Finland	a. Yes
Niger	a. Yes

Comparison

Jurisdiction	1. Regulatory Framework 4. Does the regulatory framework applicable to research involving human beings apply to research on health-related humanities and social sciences?
Senegal	a. Yes
Poland	b. No
Germany	a. Yes
Argentina	a. Yes
France	a. Yes
Nigeria	a. Yes
Kenya	a. Yes
Portugal	a. Yes
Lithuania	a. Yes
Armenia	b. No
Switzerland	a. Yes
South Africa	a. Yes
Cameroon	a. Yes
Mali	a. Yes
Côte d'Ivoire	a. Yes
Burkina Faso	a. Yes
Finland	a. Yes
Niger	a. Yes

Assessing Available Resources and Oversight Capacities

The Economist

Menu | Weekly edition | The world in brief | Search

China | Thousands of bodies for sale

A gruesome corpse scandal sparks outrage in China

The government's reaction has been to stifle any discussion of 4,000 stolen bodies

https://www.newsweek.com/china-thousands-corpses-smuggled-bone-graft-medical-health-scandal-1936276

ILLUSTRATION: JOVANA MUGOSA

Aug 15th 2024 | BEIJING

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"WHEN A PROPER respect towards the dead is shown at the end and continued after they are far away, the moral force of a people has reached its highest point." That precept appears in the "Analects", a collection of sayings attributed to Confucius. What, then, to make of the news that from 2015 to 2023 a Chinese crime ring stole, dismembered and sold more than 4,000 corpses for use in manufacturing bone grafts?

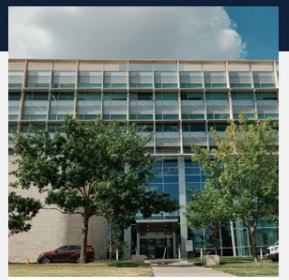
NBC NEWS HURRICANE MILTON 2024 ELECTION MIDDLE EAST POLITICS U.S. NEWS PRIME DAY DEALS TIPLINE WORLD WATCH LIVE

DEALING THE DEAD

NBC News exposed how a Texas medical school dissected the unclaimed bodies of the poor and leased them out without people's consent or the knowledge of their families.

INVESTIGATION

As families searched, a Texas medical school cut up their loved ones



TAKEAWAYS

5 things to know about NBC News' investigation into unclaimed bodies used for research in Texas

IMPACT

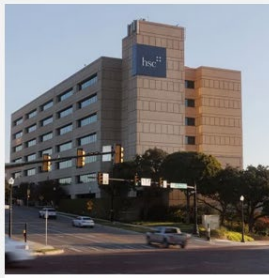
Texas medical program stops using unclaimed bodies following NBC News investigation

IMPACT

Texas lawmaker vows to ban medical research on unclaimed bodies after NBC News investigation

"NIGHTLY NEWS," PART 1

Investigation reveals Texas medical school leasing out body parts of unclaimed corpses



"NIGHTLY NEWS," PART 2

How a Texas medical school's body donation program harmed families

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Q. 1/4

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The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs (DoH, preamble)

Q. 4

Developing a path for equivalent protections determinations

Country level evaluation

Q. 5

1. Defining the adequate level of respect for and protection of research participants
   a. US perspective, other countries perspectives, **global research ethics** perspectives
   b. Health-related research, including in human and social sciences
   v. other types of research involving human participants
2. At the light of the agreed upon level of of respect for and protection of research participants, how to compare US v. other countries laws and regulation?

When authorized by a national law adopted through a democratic process in respect of human rights, other procedures could be adopted to protect the dignity, autonomy and privacy of the individuals. Such procedures are only acceptable when strict rules on data protection are implemented (DoT, art. 6 par. 2)

Developing a path for equivalent protections determinations

Institutional level evaluation

Q. 5

3. Assessing the adequacy of the available resources and oversight capacities

[2023 CIOMS International Guidelines on Good Governance Practice for Research Institution](#).

Figure 1: Main domains to consider in the governance of research institutions, p. XV

See also the coming **WHO clinical research capacity metrics**

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CIOMS

kia ora
ありがとう
rahmat
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matondo
paldies
faafetai lava
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dhanyavadagalu
trugarez
kam sah hamnida
köszönöm
rahmet
kop khun krap
mercé
leat
krap
sagolun
dziękuję
nanni
taiku
didi madloba
mahalo
nandri
tapadh
grazie
asante
хвала
blagodaram
thank you
gràçie
chokrane
mèsi
Баярлалаа
ευχαριστώ
mauruuru
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謝謝
vinaka
xièxie
dankie
sobodi
dankon
manana
tenki
danke
go raibh maith agat
kiitos
спасибо
murakoze

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- *2023 CIOMS International Guidelines on Good Governance Practice for Research Institution*