EU regulations and scientific standards in research planning

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Regulations! Complicated, boring regulations!

We can’t go over them

We can’t go under them

We can’t go around them

We’ve got to go through them!

Outline

- Significance of regulations and scientific standards
- Gender equality
- Ethics guidelines

Significance of regulations and scientific standards

- Protect research subjects
- Risk reduction
- Quality data
- Excellent research

Gender equality

- **The under-representation of women at senior levels across both the public and private research sector is an issue in all European Member States**
- **Gender inequality** in the European research ecosystem, and across wider society, must be addressed for both social and economic reasons (Meehan, 2017)
- SCIENCE is stereotypically associated with senior white men; more with men than with women (Miller et al, 2015)
- all humans are susceptible to **biases in decision making**, and subtle gender biases are often held by the most egalitarian individuals (Dovidio, Gaertner 1994)
- Under equal conditions, women are assessed as less able than men for scientific careers, and women have to perform **better** and display more success than men to achieve the same position
- persisted due to lack of policy or legislation, and due to organisational culture and unconscious bias
- **The motherhood penalty and maternal wall** (Correll et al, 2007): periods of maternity leave, childbearing and caregiving
- **Lack of appropriate mentoring**

Gender equality

- ALL researchers should have the chance to realise their **optimum potential;** research careers of women and men should be equally facilitated
- Participation and **success rates** within research funding and promotion systems
- Researchers should be **objective** in their assessments, basing them, on **rational arguments** relating to **quality** only

How to Avoid Unconscious Bias in Peer Review Processes

- Check **indicators for differences** in the success rates and workplace outcomes (salaries, hiring, promotions) of men and women researchers
- Conduct **awareness-raising activities** in evaluation panels, decision- making bodies, and with staff on a regular basis
- Provide **training** to staff, evaluation panels, and decision-making bodies

How to Monitor Gender Equality

- Organisations should define explicit **objectives** for gender equality: explicit, measurable and monitored
- **Mandatory actions** should be undertaken to meet the objectives; mandatory additional actions if an objective is not met.
- Gender equality **data** should be collected and indicators calculated annually, and the results should be made public
- **Indicators of gender distribution**: for each scientific field, age, academic age, academic position, sector
- Indicators for **Research Funding Organizations** (share of women and men among main applicants, successful applicants, average size of grant/ among reviewers, among heads of review panels, in funding decision-making bodies)
- Indicators for **Research Performing Organisations** (share of women and men among employed researchers, applicants, successful applicants, applicants for promotion, promoted researchers, in recruitment or promotion boards, among heads of recruitment or promotion boards, in decision-making bodies)


Quality Nightmares
by MasterControl
RISK MANAGEMENT BASICS
1. Fix yesterday's mistakes.
2. Don't make any mistakes today.
3. Don't make any mistakes tomorrow.
4. Repeat, as needed.

Ethics guidelines

- Start thinking about ethics while designing your research protocols
- Ethics matter for **grant proposal** and **scholarly publication**
- Your first source should always be at your institution: ethics departments, managers

- WHY? You must ensure **respect** for people and for human dignity and **fair distribution** of the benefits and burden of research, and that you must **protect the values, rights and interests** of the research participants.

Does your research involve human participants?

Question	Information to be provided	Documents to be provided
If your research involve human participants	Confirm that informed consent has been obtained	Informed Consent Forms + Information Sheets
Are they volunteers for social or human sciences research?	Details of recruitment, inclusion and exclusion criteria and informed consent procedures	Copies of ethics approvals (if required)
Are they persons unable to give informed consent (children/minors)?	Details of your procedures for obtaining approval from the guardian/ legal representative and the agreement of the children or other minors. What steps will you take to ensure that participants are not subjected to any form of coercion?	Copies of ethics approvals
Are they vulnerable individuals or groups?	Details of the type of vulnerability, recruitment, inclusion and exclusion criteria and informed consent procedures, demonstrating appropriate efforts to ensure fully informed understanding of the implications of participation.	Copies of ethics approvals
Are they children/minors?	Details of the age range, procedures and parental consent for children and other minors, steps to ensure the welfare of the child or other minor, justification for involving minors?	Copies of ethics approvals
Are they patients?	disease/condition /disability/details of recruitment, inclusion and exclusion criteria and informed consent procedures. What is your policy on incidental findings?	
Are they healthy volunteers for medical studies?		Copies of ethics approvals

Does your research involve physical interventions on the study participants?

If your research involve physical interventions on the study participants?	Information to be provided	Documents to be provided
Does it involve invasive techniques?	Risk assessment for each technique and overall	Copies of ethics approvals
Does it involve collection of biological samples?	What type of samples will be collected? What are your procedures for collecting biological samples?	Copies of ethics approvals

Informed consent

- Participation must be **entirely voluntary** and you must obtain and clearly document participants' informed consent **in advance**
- Written in a **language** and in terms they can fully understand
- Describe the **aims, methods and implications** of the research, the nature of the participation and any **benefits, risks or discomfort** that might ensue
- State how biological samples and data will be **collected, protected** during the project and either destroyed or reused subsequently
- State what procedures will be implemented in the event of **unexpected or incidental findings.** Do the participants have the right to know, or not to know, about any such findings

Declaration of Helsinki

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964; amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

http://www.who.int/bulletin/archives/79%284%29373.pdf

Background documents and further reading

FP7 guidance: Informed consent: http://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf
WMA Declaration of Helsinki
Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997) (Oviedo Bioethics Convention): https://www.coe.int/en/web/bioethics/oviedo-convention
EU Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorization of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf
EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L 158, 27.5.2014): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
FP7 guidance: Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population

Take home message

- **EU regulations and scientific standards**: protect research subjects, risk reduction, quality data
- **Gender equality:** ALL researchers should have the chance to realise their optimum potential; research careers of women and men should be equally facilitated; researchers should be objective in their assessments, basing them, on rational arguments relating to quality only
- **Ethics guidelines:** protect the values, rights and interests of the research participants, informed consent

Thank you!