Mutual Learning Exercise (MLE) on Research Integrity

Dialogue and communication

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Outline

- Entities in Greece at a National level
- Structure of RI overlooking entities in RPOs
- Communication between Greek national entities
- Communication activities of EARTHnet
- Challenges
Entities in Greece at a National level

2nd country visit
Date: 12-13/03/2019
Venue: NTUA, Athens – Greece
Entities in Greece at a National level

National Organization for Medicines (eof.gr)

The National Organization for Medicines (EOF) was established in 1983; it is a public entity of the Ministry of Health. Its mission is to ensure public health and safety with regard to:

- Medicinal products for human and veterinary use
- Medicated animal foods and food additives
- Foodstuffs for particular nutritional uses & food supplements
- Biocides
- Medical devices
- Cosmetics

EOF, in co-operation with the European Union, performs the following tasks:

- **Evaluates** and authorizes new, safe and efficient health related products
- Monitors the post-marketing product quality, safety and efficacy
- **Monitors** product manufacturing procedures, clinical studies and the marketing of products
Entities in Greece at a National level

National Organization for Medicines (www.eof.gr)

EOF is assisted in its work by:

Institute of Medicinal Research and Technology (IFET) SA
Statistical and econometric analysis, research program studies, and organization and computerization applications.

Research Center of Biological Materials (EKEBYL) SA
Certification, quality control, and research regarding medical devices. This organization is a notified body of the European Union since 1997.
The National Committee for the Protection of Animals used for Scientific Purposes (NCPASC) was established in 2013; it is an entity of the Ministry of Rural Development and Food. Its aims are:

- To provide advice to the competent authorities, to the animal welfare bodies as well as to the Protocol Evaluation Committees on matters relating to the acquisition, breeding, accommodation, care and use of animals in procedures, for issues of the continuing education and training of persons who are involved in the implementation of the P.D. 56/2013, as well as to ensure the exchange and communication of best practices.

- To exchange information on the functioning of the animal welfare bodies and the evaluation of projects by the competent central authority, as well as on best practices within the European Union.
The Hellenic National Bioethics Commission is an independent advisory body of experts addressed to public authorities either by its own initiative or upon request. Additionally, the Hellenic National Bioethics Commission:

- Organizes educational activities for schools (Secondary Schools and High Schools) related to bioethics
- Organizes educational seminars, covering a wide range of bioethics issues
- Offers to students, mostly postgraduates, both from human and life sciences, the possibility of training on issues related to bioethics
- Published an e-journal «ΒΙΟΗΘΙΚΑ» on bioethical issues
The General Secretariat for Gender Equality is the governmental agency competent to plan, implement, and monitor the implementation of policies on equality between women and men in all sectors. Its major purposes and objectives include:

- **promoting** women to employment and combating the equality gap in the labor market,
- **preventing** and combating violence against women,
- **combating stereotypic perceptions** about the roles of the sexes through educational procedures,
- **reinforcing** women’s participation in decision-making centers.
The Hellenic Copyright Organization (OPI / HCO) was established in 1993 according to art. 69 of Law 2121/1993, «Copyright, related rights matters and cultural issues»; it is a legal entity under private law, placed under the supervision of the Ministry of Culture and Sports. Its main purposes are:

- to protect the authors and right holders of related rights,
- to take steps for the implementation of Law 2121/1993 and the international conventions,
- to supervise the Collecting Societies and to legislative preparatory work,
- to deal with any issue that might occur in the field of copyright and related rights,
- to represent Greece before the competent international organizations, as well as the Instruments of the European Union,
- to safeguard the rights of the users and the public,
- to balance the interests of copyright sectors with those of industrial property sectors
- to incorporate and adjust in Greece the latest evolutions in community and international level, contributing in this way to the promotion of creativity and culture.
Structure of RI overlooking entities in RPOs
Structure of RI overlooking entities in RPOs

• Deontology Committee (DC) manned by the Deans and the vice-Rector responsible for Academic Affairs, Student Care and Lifelong Education (N.4485/2017, Article 47). Their responsibilities are the following:
  o Draft a Code of Conduct (CoC) for academic, administrative and research issues
  o Safeguard the application of the CoC and pinpoint research misconduct
  o Prepare an annual report concerning the application of the CoC and suggest any needed additions
  o Examine allegation of research misconduct coming from the institute's community. If such an allegation has a basis a report is sent to the Rector to proceed with a formal investigation

• In some cases (as in NTUA) an Advisory Research Ethics Committee aids the work of the institutional REC

• From March 2018, a Research Ethics and Deontology Committee (REDC) is active in each RPO. (N.4521/2018, Articles 21-27)
  o Their main task is to apply ethical assessment in research proposals
Communication between entities in Greece
Communication between entities in Greece (example)

Guidelines for ethical assessment when there are incipient conflict of interest or grey areas in the jurisdiction of Ethics Committees, in scientific research related to:

1. Clinical trials
2. Medically assisted reproduction
3. Experiments in test animals
The EARTHnet network

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EARTHnet stands for Ethical Aspects in Research and Technology for Human network.

EARTHnet has a voluntarily based membership.
EARTHnet members

National Bioethics Commission
National Technical University of Athens
National School of Public Health
University of Crete
Biomedical Research Foundation Academy of Athens
Democritus University
University of Thessaly
National and Kapodistrian University of Athens
University of Patras
National Research Foundation
National Center for Scientific Research “Democritos”
Institute of Preventive Medicine Environmental and Occupational Health
University of Ioannina
Aristotle University of Thessaloniki
EARTHnet – Communication with students

• Coordinators of the Advisory RE Committee of NTUA

• Initiated training courses for RE&RI at the post graduate level (with disciplinary focus) carried out by members of the Advisory RE Committee

• Currently drafting the Code of Conduct for the Research Ethics and Deontology Committees of NTUA
Organising open lectures on RI for the general public in Science Museums

The attendance has, until now, exceeded our expectations
Publications in the official e-magazine of the National Bioethics Commission

Publications in wide circulation newspapers
Contributed presentation:
The new Greek law for the operation of Research Ethics and Deontology Committees: Context and challenges

A questionnaire is about to be circulated among REDCs of EARTHnet’s members RPOs, to map the challenges faced during the creation of the REDCs and during the first 6 months of the implementation of the new law, i.e. from October 2018 until March 2019. It aims to map the challenges concerning:

- selection of the REDC members
- interaction with the institutional agencies and academia
- implementing ethical assessment in publicly funded research.
Challenges

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Challenges – food for discussion

What to do?
Share experiences regarding good practices in promoting the dialogue on RI within and among relevant institutions and the communication with the public.

How to do it?
Create guidance for best practices in relation to two issues: promoting the dialogue with different stakeholders in RI and communication related to RI investigations.

Why do it?
Agree on basic recommendations how to promote the dialogue and communication to foster RI.
Challenges – *Dialogue with different stakeholders in RI*

How to ensure the dialogue and participation of all stakeholders in RI?

1. Policy makers (ministries, government)
2. Research funding organizations
3. Research performing organizations (universities, institutes)
4. Professional societies
5. Individual researchers
6. Journal editors
7. Industry
8. International bodies for RI
9. The public (including advocacy groups, such as patient advocacy groups)

**Data scientists** are deeply connected to the issues of RI and Research Ethics. Research data are a form of communication between scientists, not only at the human level but also on the level of Big Data and machine learning. Non reliable data jeopardize both forms of “communication”.
Challenges – Communication during RI investigation

Which are the good practices in communication, when allegation of misconduct is made?

Which are the good practices in communication, during misconduct allegation investigation?

1. to the individuals (reported and reporting)
2. to the organization
3. to the journal(s)
4. to the research funder
5. to legal/regulatory bodies
6. to the public

How to communicate the outcome of misconduct investigation?
Thank you for your attention