

RI Incentives. A Greek Case Study

Stavroula Tsinorema
University of Crete

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH &
INNOVATION

Mutual Learning Exercise (MLE) on "Research Integrity"

Country visit 2

**Incentives and Communication/dialogue
Athens**

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- Greek legal regulations and policies derivative of EU communications and directives
 - Animal Research
 - Clinical trials
 - IREDCs

- **A. Animal research** in the **European Union (EU)** is regulated under **Directive 2010/63/EU** on the protection of **animals** used for scientific purposes. It aims to protect animals in scientific research, with the ultimate aim of replacing all animal research with non-animal methods.
- Based on the principle of the Three Rs, to replace, reduce and refine the use of animals for scientific purposes.
- Greek Authority for the Directive: Ministry of Rural Development and Food, Veterinary Service

- Provision for a designated veterinarian
- “Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body”.
- Provision for a National Committee for the protection of animals used for scientific purposes
- Article 36 para. 2 “Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38”.

Article 38 of Directive 2010/63/EU

The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:

- (a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;
- (b) experimental design, including statistics where appropriate;
- (c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
- (d) animal husbandry and care, in relation to the species that are intended to be used.
- **(NO SPECIFIC MENTION OF RE/RI REQUIREMENTS)**

- **Greek Presidential Decree 53/2013, article 37**

“For the evaluation of a protocol, a **Committee for the Evaluation of Protocols** (CEP-EAP) is instituted in each establishment where animals are used for research. It consists of a) a researcher in the area of **biomedical research**, as chair, with his deputy , b) **the designated veterinarian** of article 24* with his deputy, c) a **biostatistician** and his deputy”

*“ ..a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals”.

- **(NO RE /RI EXPERT, NO RE/RI provisions)**

- **Greek Act 4521/2018, article 23, 2a (REDCs) states:**

“All funded research projects which according to the Principal Investigator’s statement include research on human subjects, material deriving from humans such, as genetic material, cells, tissues and personal data, **research on animals** or the natural and cultural environment shall be submitted necessarily to the REDC for approval, and the project cannot start to be implemented in the Higher Education Institute or Research Centre prior to the relevant approval”.

Sticking points & Unintended consequences

- Different evaluation bodies performing similar or overlapping tasks?
- Challenges and risks of overregulation?
- Or dispersed and fragmented rules of regulation?

- Issues of co-ordination among different institutional ethics committees dealing with specific fields of research (REDCs, Committee for the Evaluation of Protocols (EAP) , clinical trials at the local institutional level) as well as that between the local REDCs and National Bodies, such as the National Ethics Committee for Clinical Trials. The problem may not be particularly Greek(?).

The Greek case of “conflict resolution”

- Co-operation & co-ordination between the different evaluative bodies through dialogue & communication
- Interactive evaluation processes
- Considered desirable to have one member in common (REDC & CEP-EAP)
- Further: a pro-active approach of assessing consequences before introducing new regulations
- Possibly some policy reform may be needed in terms of updating regulations and harmonizing the functions of diverse evaluation committees (national level?).

Thank you for your attention