Ethical recommendations for research at the University of Vigo

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1. Introduction

The quality of the research constitutes one of the essential aims of the University of Vigo and therefore one of its main objectives is the training of researchers and the promotion of the transfer of knowledge to society, as well as the coordination of scientific, technical, humanistic and artistic research. Freedom of research implies the choice of lines and projects and the free use of methodological principles, the choice of suitable targets and the dissemination of the results obtained. Research and development projects shall comply in all respects with the provisions of current legislation on the environment and protection of animals used for research, experimentation and other scientific purposes.

Scientific-thecnological advances in different áreas are leading to the implementation of different measures to cannel the research process and its application, guaranteeing freedom of research but also its balance with other values and rights likely to be affected, in particular in three areas:

- Research with human beings
- Research with animals
- Research with biological agents or genetically modified organisms

This trend is reinforced by two circumstances: the requirement for all projects to be ethically validated in many calls for research funding in recent years; and the request of the editorial boards of scientific journals of this type of validations as a prerequisite to the dissemination of the results obtained by a project.

In general, in order for a project to be considered ethically acceptable it must meet a number of requirements, already common to any type of research as they are :

- Social value or project justification
- Competence/qualification accreditation: concerning the responsible investigator and the research group
- Methodological and scientific validity: suitability and adequacy of means and purposes according to the state of art and existing knowledge
- Compliance with existing documentation, permits and other regulatory requirements
- Monitoring: adjustment of the project to the approved descriptive memory or notification of relevant changes.

However, depending on the type of research to be carried out, there are other more specific requirements, which are developed below.

2. Research with human beings

Research projects with humans, whether these are research subjects or personal samples or data are used, have specific ethical characteristics such as:

- Benefits/risks weighting. Assurance in case of damage.
- Equitable selection of subjects for investigation with special attention to the recruitment process
- Protection of vulnerable groups
- Respect for autonomy and voluntariness (informed consent and right to information)
- Protection of personal data and duty of confidentiality
- No discrimination
- Free donation and use of biological samples
- Ensuring traceability and safety in the use of cells, tissues and any biological material of human origin
- Limits to be respected in genetic analysis.

Informed Consent:

Informed consent, or its requirement, obtaining, prior information, etc... is one of the most important issues of concern to research staff and research funding agencies. An example of the minimum content of this informed consent is attached as an annex to these ethical recommendations.

Investigating staff shall explicitly undertake to maintain confidentiality with regard to the collection, processing and retention of data of the participating subjects, as well as the dissemination of the results. They shall also explicitly undertake not to transfer biological data or samples to other projects or research staff unless they are duly authorized.

In generally, and whenever posible, the anonymity of the persons involved in the research, both during the project and in the preservation and publication of the results, should be guaranteed.

3. Research with animals.

Research and development projects shall comply in all respects with existing legislation on the environment and protection of animals used for experimental and other scientific purposes.

Research staff conducting animal research shall have the accredited training that enables them to do so in accordance with national and European legislation.

The most widely accepted current position is that gratuitous suffering and slaughter of animals is not morally accetable. Animal welfare is ultimately a value to be preserved.

According to this thesis, the rpinciple of the three erres is born (3Rs), a proposal made by the British researchers W. Russell and R. Burch in 1959 that refers to the three basic requirements that must be met in any animal experimentation. These authors establish the concept of humanitarian treatment, one that avoids any unnecessary suffering and pain, and the use of scales of assessment and recognition of suffering to minimize it.

1.- Reduction. Use of any strategy to use the minimum number of animals necessary to achieve the objective proposed in the procedure.

Apply correct statistical designs that allow the use of only the number of animals needed to obtain reliable and accurate information. So inadequate is an experimental procedure that uses more animals than necessary, as the one that uses so few that its results do not provide the required scientific quality, and that in the long term they are useless for their lack of reliability.

2.- Refinement. Use of systems to reduce the severity of the damage inflicted on animals, which is still essential for many procedures.

At present, the use of noninvasive techniques, such as magnetic resonance imaging, which eliminate or reduce pain as well as the number of animals since with these techniques each animal acts as with its own control, increasing the quality of scientific results. In any case, it includes any design in the procedure that affects the life of the animal in experimentation and allows to alleviate or reduce the possible pain or discomfort that it will suffer .

3.- Replacement. Search for alternative techniques which may provide the same level of information as obtained in animal procedures and not involving the use of animals.

Substitution of vertebrate animals by any other method using nonsensitive material, ranging from computational models to in vitro cell models, or trials with less evolved organisms (microorganisms, plants and invertebrates), whose capacity to feel pain is reduced to the maximum due in some cases to the lack of nervous system and in others to the least development of their sensory systems

The use of animals in experimentation must be weighted in order to balance the aim pursued in research or training with the protection of the animal.

The University of Vigo acceded to the "Transparency Agreement in Animal Experiment", promoted by the Confederation of Spanish Scientific Societies (COSCE), with the collaboration of the European Association for Animal Research (CEEA) on November 18th 2013, in order to use the same designation as in Royal Decree 53/2013 of 1 February 2013 for the ethical committees of centres using experimental animals.

The University of Vigo created in July, 2010 the Ethical Committee of Animal(Rude) Well-being (IT)(HE),SHE)) (FEEDS), that changed his(her,your) name to Ethical Committee of Animal(Rude) Experimentation (CEEA), on November 18th, 2013 in order to use the same name that appears in the Royal decree 53/2013 of February 1st, 2013 for the ethical committees of the users' centers of animals of experimentation.

The activities of the CEEA will be realized by the intention of evaluating, from the ethical point of view, the procedures that are going to use animals of experimentation, to guard over the well-being of the animals used in teaching, investigation(research) or in laborator tests(proofs) and to promote courses(years) of training for the persons who use or are going to use animals.

The CEEA of the Uvigo was designate organ enabled by the Autonomous government of Galicia of Galicia on September 6th, 2016; this way, it has the function of evaluation representative in the process of project authorization with animals of the Autonomous government of Galicia of Galicia.

As qualified organ, The CEEA of the Uvigo evaluates the projects checking that fulfill the following aspects:

- Justification from the scientific, educational or legal / regulation point of view
- Justification of the use of animals
- Accomplishment of the procedures of humanitarian and respectful form with the environment
- Conformity with the principles of the 3Rs: " Replacement, reduction and refinement "

The CEEA emits reports of evaluation[1] destined to the competent authorities and realizes, in addition, the vigilance of the projects evaluated according to the current regulation

The Uvigo guarantees that both, staff in charge of the animals and research staff involved in experimentation has the training and necessary knowledge and undertakes to provide the necessary resources for the correct maintenance of the animals of experimentation regarding facilities, subsistence, well-being and veterinary attention.

3. Research with biological agents (BA) and genetically modified organisms (GMO).

The two basic values to be preserved in any research with (BA) and (GMO) are:

- Human health
- Environment

The principles to be taken into account in defending these values are:

[1] The forms and regulations related to this evaluation can be located at www.uvigo.gal

- Precaution or caution principle: applied in specific cases where scientific data are insufficient, inconclusive or uncertain, but a preliminary objective scientific assessment suggests that there are reasonable grounds to fear that the potentially dangerous effects on the environment and human health, animals or plants may be incompatible with the high level of protection chosen
- Principle of prevention: in the face of a certain risk situation, the necessary monitoring and forecasting measures must be taken to avoid possible negative consequences.
- Information principle: links to the principle of people's autonomy and their right to have the necessary, clear and truthful information to be able to exercise their right to participate in the control of certain types of risk activities

The lead investigator is directly responsible for ensuring that both values are respected and for providing for their protection from the initial perspective. Likewise the personnel involved in the project must maintain their commitment to the fulfillment of the principles throughout the development of the same or teaching.

Annex: Minimum information to be contained in the Informed Consent Form

The following is the minimum content that an informed consent document should have, as well as the design of different clauses that will be activated, or not, depending on the research being carried out:

1. **Mandatory minimum iformation**
    a. UVIGO logo
    b. Identification of the Principal Researcher
    c. Identification of the Proyect
        i. Title and funding if applicable
        ii. Project description
            1. Objectives/expected profit
            2. Duration
        iii. Place of performance
        iv. Method
    d. Identification of the reporting person (name, surname…)
    e. Identification of the person ginving consent (name, surname…)
    f. Date and signatures of:
        i. Each participant it she or he is of legal age
        ii. Legal representative if she or he is underage
    g. Person responsible for obtaining consent

2. **Description of the interventions and tests**
    a. Type of test or intervention (for example, survey, blood sample…)
    b. Description of the test or its objective
        i. Number of times to be performed, dates and deadlines
        ii. Whether it will be contacted later on
        iii. Description of risks and/or nuisances and measures to minimise them (including insurance where applicable)
    c. Offer to clarify doubts and further information and form of contacting

3. **Willingness clause**

All participants should be informed that their participation in the project is voluntary and that the refusal to do so will not result in any injury or measure against them

4. **Right of revocation**
    a. All participants should be informed that they may withdraw from the investigation at any time (without explanations being required) and without any prejudice or action being taken against them
    b. All participants must be informed of the person they must contact to make the resignation effective
    c. All participants should be informed that they have the right to choose what should be done with the data obtained by them so far:
        i. Destruction or anonymisation of the sample
        ii. Conservation of research data obtained so far

5. **Free clause**

Participation and/or donation of samples is altruistic and will not be remunerated

6. **Right to decide on the future of the samples**

All participants should be informed of the destination of the samples once the study is over. You may choose one of the following destinations:

- Destruction
- Anonymization for later use
- Free transfer to Biobank (identification of which)
- Preservation in a collection of samples for research related to the one initially proposed
- Another destination

7. **Data protection clause**
    - Name of the file in which the data is to be included (name of the generic research file and project descriptor)
    - File or processing manager
    - Purpose of the file (subject of investigation)
    - Planned divestments, if applicable, and terms and conditions thereof: anonymized or dissociated personal data
    - How to exercise the rights of access, rectification, cancellation and opposition
    - Mandatory or optional nature of responses to questions raised
    - If personal data are collected from sources other than itself

Example of data protection clause:

"The personal data provided for this research project shall be treated with absolute confidentiality in accordance with the Data Protection Law. They will be included in the file of the University of Vigo referenced ..... and will only be used for the purposes of the project. It is possible to transfer the project data to the

collaborating groups, but in no case would there be any data that facilitate your identification. You can check you're the data provided at any time, or ask us to rectify or cancel them, or simply not to use them for any particular purpose of this investigation. The way you must do this is by contacting .....(name and address)"

8. Right to know the results

The ways results of the research can be known are:

- General results (publications....)
- Individual results, if any
- If there are genetic data:
    - Possible unexpected findings
    - Right not to know
    - Information for family members
    - Genetic advice

9. Note at the end of the form of consent

It should be reported that the informed consent form duly signed will be kept and stored in a file on which your rights can be exercised.

Example of Note at the end of the consent form: In compliance with article 5 of Organic Law 15/1999, 13 December on the Protection of Personal Data, the signatory of this document is informed that it will be kept and stored in the registered file.....Rights of access, rectification, cancellation and opposition can be exercised by contacting .....(name and address)