

Transparency Agreement on Animal Research in Portugal

Introduction

The signatories to the **Transparency Agreement on Animal Research in Portugal** are all involved in carrying out, funding or supporting animal research in some way.

Fundamental animal research has been crucial in advancing knowledge of how our body works, and it also plays an essential role in medical, pharmaceutical, veterinary and scientific progress. To improve the health and welfare of both humans and animals, further biomedical research is needed. While there is ongoing investment in the development of alternatives to the use of animals in research, it is foreseeable that in the future, an important part of this work will continue to require animal use.

In June 2018, 16 Portuguese organisations involved with life science research signed a declaration, co-ordinated by the <u>European Animal Research Association (EARA)</u> and the <u>Portuguese Laboratory Animal Sciences Association (SPCAL)</u>, on transparency on animal research. Following this declaration, steps were taken to develop it into the current proposal for a **Transparency Agreement on Animal Research in Portugal**.

The aim of this Agreement is to ensure that members of the Portuguese public receive accurate and up-to-date information about **a**) what animal research involves; **b**) how such research is regulated in Portugal; **c**) the role it plays in the overall process of scientific discovery, treatment development and regulatory testing; **d**) the efforts researchers and staff undertake in support of animal care and welfare and; **e**) what is done to eliminate, or at least, to reduce animal usage and minimise suffering and harm to research animals.

The signatories of this Agreement are intended to facilitate access to relevant information about animal research models. Thus, it will contribute to public clarification and, consequently, to a conscious and informed position in this debate of general interest.

About the Agreement

The life sciences sector in Portugal has long been committed to conducting world-leading research and continuing to raise animal welfare standards.

We recognise that we have an obligation to demonstrate and promote these values, entirely in line with the European Directive 2010/63/EU on the protection of animals used for scientific purposes and from the derived local legislation. Further background information on the regulation in Portugal is available at the end of this document.

We recognise and respect the fact that some people are opposed to, or uncertain whether to support, the use of animals in research. For people to make up their own minds on this issue we feel that they should be provided with clear and honest information on the benefits of the research to humans and animals. We also recognise that, to be seen as trustworthy we must be open, transparent, and accountable for the research that we conduct, fund or support. This means doing more to better communicate **a**) the context in which animal research takes place; **b**) the work that organisations undertake in the 3Rs (Replacement, Refinement and

Reduction of animals in research); **c)** the regulations that govern this research, and the systems that are in place to report and rectify poor practice.

The Agreement comprises **Four Commitments**, each underpinned by practical steps that organisations can or may undertake. Exactly how the Commitments are fulfilled will differ between organisations depending on their purpose, their resources and their different legal obligations. Research funders, organisations conducting animal research, representative and membership bodies, all have different roles to play.

Some signatories will be better prepared to meet the Commitments and there are already several examples of best practices on openness and transparency in animal research in Portugal (e.g. clear information available online, active communication with the media, opening the doors for stakeholder visits, etc.). Others, however, may have some way to go before they can take the practical steps as outlined in the Agreement. Nevertheless, all signatories commit to making progress towards implementing the Agreement and helping to increase openness and transparency on the use of animals in research in Portugal. EARA shall be informed annually of each signatory's progress on meeting the four Commitments of the Agreement.

The Four Commitments

Commitment 1: We will be clear about when, how and why we use animals in research This Commitment seeks to ensure that all organisations acknowledge, both internally and externally, that they or their members carry out, or fund animal research. It also seeks to ensure that they are transparent about the use of animals in that research. All signatories are expected to agree to these basic principles of openness, which underpin the whole of the Agreement.

When we communicate about the use of animals in research, we should provide accurate descriptions of the benefits, harms and limitations of such research, be realistic about the potential outputs of such research, and be open about its impact on animal welfare and the ethical considerations involved.

We will take steps to ensure that staff (and students, where relevant) are aware of our organisation's involvement with or support for the use of animals in research. The organisations will be prepared to provide information about the nature of the animal research their support.

In research projects where the signatories of the Agreement work together, all relevant parties should agree to adopt an open approach to communication about the animals used. In the case of partnerships with non-signatory organizations or where confidentiality issues exist, the signatory institutions will be as open as possible in sharing information with the public, respecting these restrictions.

Commitment 2: We will enhance our communications with the media and the public about our research using animals

The purpose of this Commitment is to ensure that relevant details about signatories' involvement in the use of animals in research are readily accessible by the public. It builds on Commitment 1 by outlining some of the practical steps that organisations can or may take to facilitate their communications around animal research.

Within one year of signing up to the Agreement, we will make a policy statement available via our own publicly accessible website, to provide clear information about the nature and the aims of the research using animals. The policy statement will be linked to a central portal publicly available on the EARA website (<u>www.eara.eu</u>) and SPCAL website (<u>https://www.spcal.pt</u>).

Signatory universities, research centres, pharmaceutical companies, learned societies and research funders will report and/or explain on their institutional websites and through other communication channels, how they are working to promote better application of the 3Rs and will make examples of their progress in this area. Where animal research has played a significant role in a scientific advancement and/or product development, we will include information about that animal research in relevant communications.

Signatory institutions will highlight the critical role of animal studies in scientific advancements in their social communication platforms and show that the vast majority of labs involved with animal research are also working with *in vitro* models.

Signatories will support researchers and staff who wish to engage with the public and media, where this does not conflict with normal operational procedures. We will identify a point of contact for information about the organisation's involvement in the use of animals in research and will aim to provide one or more spokespeople to talk about this topic. These communicators should engage with scientists and their research advancements, visit the animal facilities regularly to witness the care and dedication the animals are given, and be knowledgeable about laws and regulations in place to protect the animals in research.

Signatories will encourage researchers to follow acknowledged good practice when publishing the results of their animal research (e.g. applying guidelines such as <u>PREPARE</u> or <u>ARRIVE</u>).

Signatories to the Agreement may, as some already do, allow access to their facilities for groups of accredited journalists and media organisations, policy makers, as well as local school, patients groups or their caregivers. The public and media may consider access to animal research facilities as a pledge of good faith but need to be informed that such visits are not always possible and need to be limited in order to avoid additional stress to the animals.

Commitment 3: We will be proactive in providing opportunities for the public to find out about research using animals.

This Commitment aims to encourage more public discussion in Portugal about animal research. It builds on Commitments 1 and 2 by suggesting ways in which signatories can engage proactively – directly and indirectly – with the public, over and above the provision of information.

We will work co-operatively to provide more comprehensive explanations of animal research projects and procedures. These explanations could, where appropriate, include images and films; they could be presented either as stand-alone materials or accompanying other communications and should include information about the context of the research. The development of an institution's website will make a significant contribution to this effort.

Where relevant, in any talks or public events they take part in - for example at schools or with the local community - representatives of the signatories will include information about the role of animals in their work and what they do to promote a better application of the 3Rs. Signatories will also consider ways in which they can facilitate activities that will encourage public engagement with the issue of animals in scientific, veterinary, pharmaceutical and medical research.

Commitment 4: We will report on progress annually and share our experiences

Monitoring the implementation of the Agreement will be important for its success. We want to be able to demonstrate and share the progress we have made towards being more open about research using animals in Portugal and improving the information that is available to the public. We will also review the Agreement and our own processes to keep them up to date.

We will report annually to EARA on actions we have chosen to take in order to fulfil these Commitments and will share our experience of the effectiveness and impact of the strategies we have adopted. EARA will publish an annual report on the progress of this project.

We believe that the Agreement will give its signatories the opportunity to come together to share and promote good practice in being open and transparent about animal research and in providing the public with better insights into the reasons for, methods of, and progress resulting from, the use of animals in research.

Three years after publication, we will review this Agreement and its impact and amend the document as necessary.

Additional information

Portuguese Legislation

Animal research in Portugal is regulated by the Decree-Law n^o. 113/2013 of the 7th of August, corrected by the Decree-law n^o 1/2019 of the 10th of January, that have transposed the Directive 2010/63/EU of the European Parliament and of the European Council of 22nd September 2010 on the protection of animals used for scientific purposes.

Each research project using animals is subject to prior evaluation and authorisation by the animal welfare body ORBEA (Órgão Responsável pelo Bem-Estar Animal), ethics committees and the competent authority DGAV (Direção Geral de Alimentação e Veterinária).

The signatories to this Agreement operate under Portuguese and EU law. This means that animals must not be used if alternative research methods are available that produce comparable data to those obtained from using animals in research; that the numbers used should be kept to a minimum necessary to conduct statistically robust research; and that researchers must ensure that any discomfort, pain or distress, whether physical or psychological, is minimised.

The Status of the Agreement

In February 2017, EARA invited Portuguese experts from several research institutions for a meeting to discuss how to improve the Portuguese public's understanding and acceptability of animal research.

The EARA proposal was to explore the possibility of developing a Transparency Agreement to help institutions on openness on animal research in Portugal. This initiative was based on the previous examples in Europe as the <u>Concordat on Openness on Animal Research in the UK</u> launched in 2014; the <u>Transparency Agreement on Animal Research in Spain</u> launched at 2016, and the Statement in support of animal research and a transparent approach in Belgium in 2016.

The Portuguese Laboratory Animal Sciences Association (SPCAL) has played a crucial role on the first contact with the institutions and with the public launch of this initiative. On 21st of June of 2018, during the SPCAL Congress held at the University of Minho, 16 Portuguese organisations including Universities and Research Centres signed a declaration on Openness in Animal Research. Following this declaration, steps were taken to develop it into the current proposal for a Transparency Agreement on Animal Research in Portugal.

Organisations that sign up to the Transparency Agreement on Animal Research in Portugal are expected to work towards fulfilling the four commitments. While some actions are expected to be fulfilled by all signatories, others will depend on the type of organizations, its objectives and legal obligations. Both the organizations that finance research and those that carry out research have a relevant role in the communication of animal research. It is expected that most of the commitments will be implemented by all the signatories.

<u>EARA</u>

The <u>European Animal Research Association</u> (EARA) has been established to better inform the European public and political decision makers on the continued need for, and benefit of, the humane use of animals in biomedical research. EARA seeks to provide support, advocacy and reliable communication on behalf of public and private researchers at both national and European levels.

<u>SPCAL</u>

The <u>Portuguese Society of Sciences in Laboratory Animals</u> (SPCAL) is a private, non-profit association made up of people whose activities are related to sciences in laboratory animals. SPCAL aims to standardize and optimize the use of laboratory animals in the sense of promoting animal welfare and health, as well as sponsoring collaborative and interdisciplinary approaches among professionals involved in laboratory animal science. On the other hand, it is also the purpose of this Society to implement and disseminate the ethical and behavioural principles that should accompany the use of laboratory animals for scientific purposes.