

EARA working group on Non-Technical Summaries

*Guidance document to improve the
language and understanding of NTS for the
general public*

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October 2018



INTRODUCTION

In November 2017, the EU Commission published its Review of Directive 2010/63/EU on the protection of animals used for scientific purposes. Section Three addressed the issue of improving transparency on animal research and how the Directive has introduced elements aimed at improving transparency to the public.

The Commission reported that there has been some progress on transparency, but suggested that further improvement were needed. In particular further work is needed on the publication of statistical information on animal use and on non-technical project summaries (NTS).

NTS are widely seen as a positive development in improving transparency on animal research to the public. However, it is widely agreed that there are a number of problems in the compilation, accuracy, standardisation and accessibility of NTS.

Working group brief

The European Animal Research Association (EARA) identified clear opportunities to improve the understanding and accessibility of NTS for the general public.

A working group was set up in May 2018 to seek to identify opportunities to improve the language, used in NTS, so that it is more understandable for the lay person/general public.

The working group has brought together representatives from the user community, with a range of experts from backgrounds in animal welfare, communications and private and public biomedical research, including membership of institutional ethics committees and welfare organisations.

The working group has now produced a guidance document, for the Commission to consider, with recommendations to researchers on how to improve the language and understanding of the NTS for the general public. The guidance document gives advice under the various section headings of the NTS template.



THE OVERALL PROCESS OF PRODUCING NTS

The audience

Keep in mind that the project proposal and the NTS have different audiences and purposes. Avoid using technical or complicated terminology (such as Latin or scientific expressions) in the NTS. Where possible, consider writing sections of the NTS before completing the technical proposal, as it may help clarify the arguments and goals of the project proposal without the need to use technical terms.

Use of language

Keep sentences short and use everyday language. If available in your language, try to access a plain language guide – for instance, in English there is a guide to writing medical terminology in a simpler way <http://www.plainenglish.co.uk/medical-information.html>

Another useful source for additional help with NTS has been produced by Understanding Animal Research <http://www.understandinganimalresearch.org.uk/news/communications-media/guidance-for-writing-a-nts/>

External comments

It would be good practice to show the draft NTS to a communications expert at your institution before it is submitted to the evaluation and/or authorisation bodies (Animal Welfare Body, Ethics Committee or Competent Authority). In addition, it would be useful to seek comments from both a scientific colleague and from a non-scientist, such as a family member or the lay member of the institutional oversight body.

As a final check before submitting the NTS and the project proposal make sure the statements and facts in both documents are consistent.



PROJECT TITLE, DURATION OF PROJECT, KEYWORDS, SPECIES, NUMBERS

Project Title: For projects with complex scientific/medical terms, use an everyday language translation of the project proposal title (placed in brackets), ideally including a mention of the animals being used.

For example: 'Effect of oncolytic adenovirus in embryonic high grade pediatric tumours of the central nervous system in NOD.Cg-Rag1tm1Mom Prf1tm1Sdz/Sz mice (*Measuring the effects in mice of different potential treatments for childhood cancers*)'

Duration of Project: Include a breakdown of the duration of the expected periods of animal use.

For example: 'The whole project will last five years, with animals each being used for periods of between two and eight months.'

Make sure these estimates are consistent with any information in the Adverse Effects section of the template.

Keywords: Use a maximum of five keywords. These should be non-technical and should usually include the species used, type/name of disease/biological event to investigate, general purpose/type of research/benefit of the research. These words may come, for instance from the everyday language used in the Project Title (as explained above).

For example: Based on the Project Title used above – 'mice, cancer, treatment, childhood'.

It would be useful if the writer could select from an agreed database of everyday language keywords. An example of this in English is the guide to writing medical terminology in a simpler way <http://www.plainenglish.co.uk/medical-information.html>

Species: Use the common name of the animal (indicating in very general terms the type of genetic modification if that exists).

For example: 'Mice, some of them with a genetic modification that weakens their immune system'

Numbers: Estimate the maximum likely to be used in the project (if appropriate, indicate, depending on results, whether all of the animals listed will be needed or not).

See Template Modifications overleaf.



Template modifications

Purpose of Project:

To make this section more understandable to the public we suggest a modification of the Template/Headings proposed in Annex I of the 2013 European Commission document. The proposed modification focuses on adding a short explanation of the meaning of the 'Purpose of the Project' (right column of Annex I) which is currently based on the options given in Article 5 of the Directive. These explanations could be as footnotes or after each heading. This section would be as follows:

Purpose of Project (as in Article 5): Directive 2010/63/EU Article 5 lists the only accepted purposes for the procedures involving the use of animals in a research project. The list on the right reflects the potential purposes according to the way they have to be reported in the authorised project.

Basic research: Trying to gain a better understanding of how humans' and animals' life processes work, both in health and in illness. It may feed into translational and applied research.

Translational and applied research: The practical application of basic research to try to develop better medicines, surgical procedures, vaccines, or other techniques for the benefit of humans, animals or the environment.

Regulatory use and routine production: A wide range of substances in everyday use, including medicines, and chemicals used in manufacturing, farming and household products are legally required to be tested to assess whether they work effectively and are safe for use in people and animals.

Protection of the natural environment in the interests of the health or welfare of human beings or animals: Assessment of whether new chemicals, or other products, might harm the environment (pollution, air quality).

Preservation of species: When species are in danger of extinction, these projects may focus on avoiding the disappearance of these species.

Higher education or training: Animals are used to teach students facts about biology and bodily functions. Animals are also used to teach specialist vocational skills, such as surgical techniques in medicine.

Forensic enquiries: Developing new forensic tests, or when investigating evidence relating to criminal investigations.

Maintenance of colonies of genetically altered animals, not used in other procedures:¹While not standard research projects, the process of creating genetically altered animals may include certain procedures (e.g. injections, surgery) that must be authorised. Also the breeding and maintenance of genetically altered animals (either created or naturally found) that have harmful traits is usually considered a regulated procedure needing authorisation.

¹ We suggest rewording this heading so that it is in line with the current European Commission documents, so that it says: "Creation, breeding and maintenance of colonies of genetically altered animals, not used in other procedures."



OBJECTIVES

Describe the Objectives of the Project (e.g. the scientific unknowns, or scientific or clinical needs being addressed).

Objectives vs. methods and benefits

Describe the objectives of the project as specifically and realistically as possible from both the scientific and the resources point of view (expertise, available staff, financial). They must reflect the outcomes that are expected to be achieved within the timeframe of the project using available resources and not the methods that will be used or the expected benefits which may come about after the project has ended.

Short summaries

Summarise and describe the aims of the study in one or two sentences, such as:

- 'To better understand and improve a system of creating elongated bones in sheep.'
- 'To evaluate the performance of a new drug in mice which have been induced with heart failure.'

Descriptions to be avoided

Be aware of descriptions which describe a benefit rather than an objective. For example,

- 'The development of treatment for patients with a range of diseases and conditions such bone cancer or dwarfism.'
- 'The project will lead to a new treatment or diagnoses for heart failure'

Or a description that describes the method being used.

- 'The project will aim to use XXX technique' (method)



POTENTIAL BENEFITS

What are the potential benefits likely to derive from this Project (how science could be advanced or humans or animals could benefit from the project)?

Benefits vs. objectives

Do not confuse benefits (long-term outcomes which come about once a project has ended) with objectives (specific results or aims expected to be achieved within the timeframe of the project using the available resources).

For example, the benefits of a study of bone elongation in sheep could be: 'The development of treatment for patients with a range of diseases and conditions such as bone cancer or dwarfism.' But the objective of this study might be: 'To better understand and improve a system of creating elongated bones in sheep.'

There is also no need to outline any of your 3Rs strategy here, as you will have an opportunity to do that in specific sections later on.

Manage expectations

Do not raise people's expectations: being honest and realistic is essential. Think in terms of hoped-for benefits, rather than using terms such as 'we will achieve' - this tentative phrase is more honest about the uncertainty underlying all research.

Think carefully about your audience and about describing the processes you are trying to identify. The potential benefits should be real and should only relate to this specific project and this specific use of animals.

Who is expected to benefit from the work, how will they benefit and on what timescale?

An example of a specific benefit could be 'understanding how the blood supply to a tumour develops, with the aim of informing the development of a drug to stop tumour growth', rather than merely saying that the objective is 'cancer research'.

Longer term benefits

Some benefits may only be known in the longer term, therefore estimating their potential is difficult because your study by definition has yet to be carried out. So if it's hard to guarantee any benefits this must be reflected in your language.

If this is basic research, then acknowledge that it is not yet at the translational stage, but that it could one day lay the groundwork for a practical application. An example of a benefit likely to be associated with basic research could be the furthering of academic understanding of the mechanisms causing heart failure and associated medical problems.



ADVERSE EFFECTS

In the context of what is being done to the animals, what are the expected adverse effects on the animals, the likely/expected level of severity and the fate of the animals?

Try to fully acknowledge the likely harms to the animals involved in the study and describe them simply and honestly. General or vague statements like 'suffering will be minimised' or 'animal welfare is a priority' are not a sufficient explanation.

You can justify the harms caused, and provide details on how procedures and care have been refined to reduce the impacts on animals in the other, relevant sections of the NTS.

Animal perspective

Think about describing the adverse effects from the animal's point of view. For instance, rather than saying what will be done to animals (e.g. 'rats will be injected'), try to describe in everyday language what the animal's experience is likely to be. It may also be helpful to include the terms 'mild', 'moderate' or 'severe' when describing adverse effects. For example,

- 'Rats will likely experience some discomfort, mild pain and bruising to the skin from being injected on four occasions'.
- 'Sheep who have had bone elongation surgery are likely to experience severe pain, and difficulty in moving around, during the first days after surgery.'

You should also try to give an idea of how many of the animals will be affected, and the duration of the effects. For example,

- 'Around half of the mice will gradually lose muscle strength in their limbs and so will find it harder to move around. In the most extreme case, expected to be experienced by only a few of the mice, they may completely lose the use of one or more limbs'. Or,
- 'For a few days, most dogs may feel lethargic or nauseous and may not feel like eating, but all should fully recover within a week'.

Explain if the animals are to be humanely killed at the end of the study, and if not, what will happen to them.



REPLACEMENT

State why animals need to be used and why non-animal alternatives cannot be used.

The sort of responses needed in this section might include explaining how you read previous studies that have been undertaken, searched databases of alternative non-animal methods and discussed your proposal with colleagues and other scientists or organisations that had an expert opinion, including those involved in the development of alternative methods.

Animal vs. non-animal methods

The reason for the choice of animal methods need to be explicitly explained. Do not to use generic statements like: 'animals have to be used', or 'the aspect under investigation has to be demonstrated in a whole organism', without explaining further why. For example,

- 'Non-animal methods are not appropriate for this study as the mechanical systems of bone elongation that need to be evaluated will be the same ones intended for humans. Our evaluation will look at bone growth and the efficacy of the mechanical systems in the living organism (sheep), including how mobility can be recovered and the potential influence of other body systems.'
- 'The genetically modified mice chosen for this study may develop similar or comparable tumours to those found in children. We will study if new treatments have an effect on those tumours and for that reason, we will study the recovery and behaviour of the mice. This information cannot be gained without using live animals.'
- To study how blood vessels grow in this particular cancer tissue, we need to use animals. Cell cultures or organs-on-chips cannot yet replicate this whole process.

Where appropriate, give examples of both where and how non-animal methods have been used in the research. For example:

- 'Lots of our research has been based on looking at donated human cells and tissues kept alive outside the body, and we have also used computers to make models and predictions using data from a number of past studies.'



REDUCTION

Explain how the use of minimum numbers can be assured.

To explain how the number of animals have been minimised, consider whether the following checks have been conducted, and indicate accordingly:

- Taken expert statistical advice to optimise the experimental design and data analyses.
- Considered the use of state-of-the-art technology (e.g. non-invasive imaging, highly sensitive detection methods) which allow more data to be gathered from the same number of animals or fewer.
- Reviewed the results of other studies (including 'negative' findings) to inform the approach being taken.
- Carried out pilot studies to help improve the design of the experiment.
- Shared tissues from animals humanely killed in the proposed study with other researchers conducting other studies (to avoid the additional use of animals to supply tissue for other in vitro studies).
- Considered whether it is appropriate to re-use animals, or tissues which have already been used in other studies. If that is the case, there then needs to be an explanation of the principles being applied to ensure the animals or tissues being re-used are suitable – from an ethical, animal welfare, scientific and legal perspective – and indicate typically how many times, in your study, an animal might be re-used.



REFINEMENT

Explain the choice of species and why the animal model(s) used are the most refined, having regard for the scientific objectives. Explain the general measures to be taken to minimise welfare costs (harms) to the animals.

As well as explaining the reason for selecting the species (including the strain of animal being used) highlight any measures being utilised that can be considered 'best practice'. Things to consider including are:

- Examples of high quality housing and care, including a stimulating environment that enables animals to express their normal behaviours.
- Mention of any special housing or care requirements required by the procedures (e.g. confinement of animals in 'metabolism cages' that allow collection of the animals' faecal and urine output). Then describe how the likely adverse effects on animals will be reduced and/or alleviated. The actual adverse effects experienced by the animals, due to this housing, should then be described in the appropriate section of the NTS. If social animals are to be housed singly at any time, explain why this is considered unavoidable for scientific or welfare reasons and how the adverse effects will be reduced e.g. by providing additional enrichment or, if appropriate for the species and individuals concerned, housing animals within sight, sound and smell of each other.
- Describe how procedures have been refined to cause the least suffering e.g. route/frequency of injections, use of positive reinforcement training techniques.
- Describe the care to be provided after surgical procedures, or care used to reduce any other significant impacts on animal wellbeing, e.g. the use of anaesthesia and pain relief, a heated pad to rest on etc.
- Highlight how tools such as health or welfare monitoring, and the use of specific and tailored humane endpoints will allow pain, suffering and distress to be recognised, assessed and reduced, with examples of how and when intervention would take place.

Explain all of the above in non-technical language (e.g. say 'humanely killed' rather than 'endpoint') and acknowledge the impact on and experience of the animal. For example,

- 'Sheep are used as their bone size and structure are similar to humans. The animals will be housed in groups in pens allowing free movement, with large amounts of straw to serve as bedding and extra feed, so they can rest after surgery. Strong painkillers will be provided to alleviate pain. The sheep will have already given time to get used to the animal care technicians before the surgical period starts, and will be observed every day for signs of pain after surgery to increase the dose of painkillers if needed.'
- 'The housing environment of mice with disease is a key focus of our daily management of sick animals. We use soft bedding, which the mice find comfortable and which reduces sores on their feet. We make it easier for them to eat by providing infant formula mixed with food used for weaning mice plus supplements. We also house sick mice together in smaller numbers which allows them to move around the cage more easily due to their reduced mobility.'

END