



Institute of
Animal Technology

Road Map Resource Pack

FOCUS ON SEVERE SUFFERING

**PART 1: INTRODUCTION AND
PROSPECTIVE REVIEW**

2nd edition. March 2016

RSPCA Road Map resource pack

Guidance for facilitators

These slide sets were prepared by the Research Animals Department of the RSPCA, and are intended primarily as a practical guide for UK Animal Welfare and Ethical Review Bodies (AWERBS) or other bodies that establishments may set up to address severe suffering locally. The aim is to help them implement the Road Map and establish a mechanism towards reducing and avoiding severe suffering within their establishments.

Each slide has associated notes which provide a guide to the points you can make while giving the presentation, but the intention is for you to use your own script rather than read the notes as they are.

Please contact the Research Animals Department if you would like to receive an editable version of this resource or any additional information: research.animals@rspca.org.uk

Intended context for the slide sets

Each slide set aims to help establishments focus on and address procedures that may (or do) cause severe suffering, with the aim of reducing or entirely avoiding severe suffering. There are 4 sets of slides in this resource:

- 1) Introduction – Outlining the general principles of the Road Map
- 2) Prospective review – for projects that have yet to start
- 3) Retrospective review – for on-going projects
- 4) Retrospective assessment – for projects that have finished

Some form of internal body should be formed that can audit projects and procedures, identify those that do or may cause severe suffering and establish a process to address this. Depending on the nature of the establishment, its culture and internal processes, this could be done by the AWERB, a dedicated 3Rs sub-group, or a special review body set up for the purpose. Suitable members may include the researcher undertaking the project, the Named Veterinarian, the Named Animal Care and Welfare Officer, the Named Information Officer, the local Home Office Inspector and the lay or independent member of the AWERB. In addition, it may be of value to include one or more external experts (with specific animal welfare, Three Rs or scientific knowledge) especially if the project includes novel 'models' or procedures.

Whatever the format of the body undertaking the review, it should have a designated facilitator to provide leadership and ensure that its conclusions are implemented, reviewed and followed up. It should also communicate with and report to the AWERB, as several of the AWERB's tasks are directly related to the Road Map. The approach is also linked to the legal requirements of Directive 2010/63/EU and the Animals (Scientific Procedures) Act 1986 with respect to reducing suffering, so implementing the Road Map is a positive way to help ensure compliance with the letter and spirit of the legislation, as well as defining and reinforcing local values with respect to reducing suffering and improving welfare.

For example, the slide set intended for use at the prospective review stage aims to ensure an in-depth and focused discussion on the animal's potential experience and how this could be refined, but the outcome would not necessarily have to be extensively detailed in the protocol sheet of the final application form. The main aim is for the AWERB, or equivalent body, to fulfil its tasks in the

context of avoiding and reducing severe suffering, e.g. by acting as a discussion forum and advising on the application of the Three Rs.

Preparing to use the Road Map resource

To obtain maximum benefit from this resource, and facilitate discussions and review, it is recommended that AWERB and/or other relevant group members refresh their current knowledge with some background reading beforehand. The following are suggested:

- RSPCA/LASA/LAVA/IAT **Severe Suffering web pages:** www.rspca.org.uk/severesuffering
- **RSPCA Lay Members' Handbook** chapter 4 (reviewing project applications), pages 32-33 (refinement issues) and example 2 on page 40: free download at tinyurl.com/RSPCALMH
- **RSPCA/LASA Good Practice Guidelines for AWERBs** sections 2 (Home Office requirements) and 5 (project review): free download at tinyurl.com/RSPCA-LASA-AWERB
- **European Commission** working document on a severity assessment framework (2012) and accompanying examples (2013):
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf and http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf respectively

If members are especially interested and have time for some further reading, you can refer them to:

- A 'Road Map' toward ending severe suffering of animals used in research and testing, download at: <http://tinyurl.com/RSPCARoadMap>
- A guide to defining and implementing protocols for the welfare assessment of laboratory animals: BVA/AFW/FRAME/RSPCA/UFAW Joint Working Group on Refinement report, download at: <http://tinyurl.com/RSPCAwelfareassessment>

These are essential materials for (i) prospective, (ii) retrospective review and (iii) retrospective assessment:

- 1 **Prospective:** the project licence application form, European Commission document on severity assessment framework and its accompanying document (downloads above), the Road Map resource sheets 1 and 2 with their examples, and the guidance notes relating to lifetime experience.
- 2 **Retrospective review:** the project licence, the outcome of a prospective severity review (if available), all welfare assessment records, actual severity data (if available) and the Road Map resource sheets 3 and 4 (with their examples).
- 3 **Retrospective assessment:** the project licence, the outcome of a prospective severity review and/or retrospective review (if available), all welfare assessment records, actual severity data (if available) and guidance notes for retrospective assessment.

A flexible approach

As facilitator, you will have the opportunity to ensure that the AWERB or review group is prepared to think positively about reducing or avoiding severe suffering, and to challenge the status quo. Examples of questions to bear in mind during the review are: is the group working effectively to identify ways of overcoming obstacles to refining or avoiding severe protocols? What would happen if each protocol was run at a 'moderate' severity limit? Questions like these, addressed with appropriate input and open minds, can really help to move thinking on and identify ways forward.

The intention is for the resource to be tailored to fit the culture and requirements of specific establishments. Please contact the RSPCA Research Animals Department (research.animals@rspca.org.uk) for an editable version of the resource. **We would also very much appreciate any feedback you may have about its content or implementation.**

RSPCA Research Animals Department
March 2016

Part 1

Road Map resource pack

FOCUS ON SEVERE SUFFERING



Slide 1 Road Map resource pack: Part 1; Introduction

This set of slides was prepared by the Research Animals Department of the RSPCA, and is intended primarily as a practical guide for Animal Welfare and Ethical Review Bodies (AWERBs) or other institutional animal care and use committees, to establish a mechanism towards reducing and avoiding severe suffering within their establishments.

The resource is intended to be accessible to all members, each of whom may have sat on the AWERB or committee for some time, or may be relatively new to their role. Some members may thus be very familiar with the information and approaches set out in these slides, whereas the materials, technical details and processes mentioned will be less well known to others.

Each slide has associated notes which provide a guide to the points you can make while giving the presentation, but the intention is for you to use your own script rather than read the notes as they are.

Please read the Guidance for Facilitators before giving this presentation.

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Background

WHY FOCUS ON SEVERE SUFFERING?

- Ethical reasons: All levels of suffering are a concern, but severe suffering is of special concern and there is strong interest in reducing this
- Legal reasons: Directive 2010/63/EU requires Member States to '*ensure refinement of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals*'
- Scientific reasons: All suffering impacts on an animal's physiology and can increase variability in a study

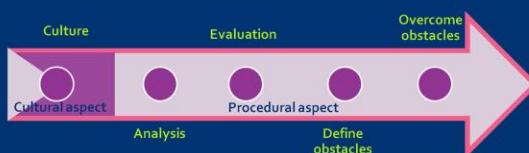
Slide 1.1 Background: Why focus on severe suffering?

Ethical reasons: All levels of suffering are of concern to those involved with animal research. However, severe suffering is of special concern to many people and reducing this will address ethical and animal welfare issues, improve the harm-benefit balance and can often also inspire refinements for use in less severe procedures.

Legal reasons: Directive 2010/63/EU requires pain, suffering, distress and lasting harm to be minimised, so tackling severe suffering will help the establishment to comply with the Directive in letter and in spirit.

Scientific reasons: All forms of suffering – pain or distress – lead to physiological responses as the animal attempts to cope. These responses can increase the variability in an assay or procedure, potentially even confounding the data.

Road Map



KEY POINTS

- Culture of care – commit to acting on severe suffering
- Audit – how many animals do, or may, experience severe suffering?
 - what is the rationale for the procedures?
 - what actually makes the suffering severe?
- Challenge necessity – search for an alternative approach
- Apply refinement – reduce suffering
- Identify obstacles – can these be overcome now, or in the future?

Slide 1.2 The Road Map principle

The RSPCA has developed a 'Road Map' guide towards ending severe suffering (this can be found here: <http://tinyurl.com/RSPCARoadMap>). This approach is designed to guide establishments through a series of steps which will allow them to reduce, and ideally avoid, severe suffering.

Ending severe suffering is ultimately both achievable and desirable. A commitment to act on severe suffering fits within a good 'culture of care' at establishments and this process can support that effort. The first practical step of the process is to perform an 'audit' of all procedures, to establish how much severe suffering occurs and why.

Once this has been done, there can be a systematic evaluation of the necessity of all procedures that can cause severe suffering. This could focus on whether all of the severe procedures are necessary, whether alternative approaches could be taken, and whether more could be done to reduce suffering. Any obstacles preventing the avoidance or reduction of severe suffering need to be identified and clearly defined. Once obstacles are understood, they can be addressed, with the aim of ultimately creating solutions and avoiding severe suffering.

This resource will focus primarily on the audit process, particularly on how to perform a review of severe procedures.

Cultural aspect

AN EFFECTIVE AWERB IS KEY



- The AWERB should:
 - ✓ Promote awareness of animal welfare and the Three Rs
 - ✓ Provide a forum for discussion on all matters related to animal welfare, care and use
 - ✓ Help to promote a culture of care

Slide 1.3 The role of the AWERB

An effective AWERB is integral to a good culture of care.

The Home Office Guidance to the ASPA lists the following tasks for the UK AWERB (in section 10.5):

- promote awareness of animal welfare and the 3Rs;
- provide a forum for discussion (and development of ethical advice to the establishment licence holder) on all matters related to animal welfare, care and use at their establishment;
- support named persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training;
- help to promote a 'culture of care' within the establishment

All of these are vitally important with respect to creating an environment in which refinement can be effectively implemented and severe suffering avoided or reduced.

[Further information: See section 2 of the RSPCA/LASA Good Practice Guidelines: Home Office requirements.]

Specific AWERB tasks



WITHIN DIRECTIVE 2010/63/EU AND THE ASPA

- Advising on matters related to animal welfare
- Advising on the application of the Three Rs
- Establishing and reviewing processes for monitoring, reporting and follow-up in relation to animal welfare
- Following the development and outcome of projects, taking into account the effects on the animals used

Slide 1.4 More on specific AWERB tasks that are relevant to addressing severe suffering

The Home Office Guidance to the ASPA also lists the AWERB tasks that are required by the Directive and ASPA (section 10.4).

The minimum tasks relevant to tackling severe suffering are to:

- advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
- advise on the application of the 3Rs, and keep the establishment informed of relevant technical and scientific developments;
- establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment; and
- follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs.

An additional task that may be allocated under the ASPA is to assist with the retrospective assessment of relevant projects carried out at their establishment.

This resource aims to help AWERBs fulfil these tasks for their establishments.

[Further information: See section 2 of the RSPCA/LASA Good Practice Guidelines: Home Office requirements; see also example 2 on page 40 of the RSPCA Lay Members' Handbook, which sets out potential actions to address severe suffering.]

Some AWERB questions

- **Why** is severe suffering needed?
- What is being done to **reduce/avoid** this?
- Are the benefits sufficiently high to **justify** the suffering?
- Could the protocol be run with a **moderate** severity limit?
- What if we said **“no”**?

Slide 1.5 Some questions the AWERB may like to ask

Whatever the structure of the approach towards reviewing severe procedures, the AWERB should have oversight of the process, with the opportunity to ask thought-provoking questions like these.

A very useful question to ask is “what if we said ‘no’?”, as a way of stimulating deeper thought about potential ways to avoid severe suffering, and how any real or perceived obstacles to this might be overcome. This can help to focus attention on alternative approaches as well as the scientific justification for severe procedures and models.

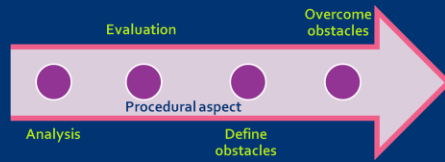
Action: You may find it helpful to write these questions, or alternatives in a similar vein, on a flip chart – as a visible reminder to the AWERB (or other body reviewing the severe procedure) to ensure that they are effectively challenging the *status quo*.

Procedural

DEVELOPING THE ROAD MAP

- Audit/review

- Three stages at which an audit or review of severe procedures can be conducted:
 - Before the project has started (prospective severity assessment)
 - During a project (ongoing, interim or mid-term reviews)
 - After a project has finished (actual severity assessment)



Slide 1.6 The procedural aspect

The next element of the 'Road Map' principle is to audit the severity of procedures planned or undertaken at the establishment, with the aim of reviewing those that may be, or are, severe. This can take place before the project starts (prospective severity assessment), during a project (ongoing or mid-term reviews) or at the end of a project (actual severity assessment).

The approach to each of these assessments as set out in this resource is intended to complement, and in some instances form part of, the requirements of the ASPA.

The aim at each stage is slightly different:

- **prospective severity assessment** aims to prevent or avoid severe suffering wherever possible, and to ensure that effective welfare assessment protocols and humane endpoints are in place – this can be part of the process of preparing the project application for submission to the Home Office;

- **ongoing, interim or mid-term reviews** aim to see whether adverse effects were accurately predicted, to evaluate whether severe suffering is occurring, and to identify ways in which it may be possible to avoid this for the remainder of the project;

- **actual severity assessment** aims to see whether adverse effects were accurately predicted, to evaluate whether severe suffering occurred, and to identify refinements that can be applied to future projects and disseminated more widely. This can be done as part of the retrospective review required for all procedures with a 'severe' severity limit.

Note: the slides addressing prospective severity assessment follow this introductory section; the other two sections are currently in preparation.

- End of introductory section
- Now go to whichever one of these you would like to address:
 - Before the project has started (prospective review)
 - During a project (retrospective review)
 - After a project has finished (retrospective assessment)

Slide 1.7 end of the Introductory session

Now go to whichever one of these you would like to address:

Road map resource pack 2: Before the project has started (prospective review)

Road map resource pack 3: During a project (retrospective review)

Road map resource pack 4: After a project has finished (retrospective assessment)