



# Road Map Resource Pack

**FOCUS ON SEVERE SUFFERING**

**PART 4: RETROSPECTIVE REVIEW**

1<sup>st</sup> edition. March 2016

## Key points to consider for retrospective assessment

### How effectively actual harms and numbers were predicted

- Actual vs. predicted harms
- Actual vs. predicted numbers
- Whether there were any unexpected adverse events; did anything go wrong?

### Potential for refinement

- Whether any refinements were introduced during the project, to reduce harm or improve welfare. If so, what were these, how were they evaluated and could they be applied more widely?
- Whether harms could be further reduced, e.g. by altering experimental design or identifying additional refinements to procedures, housing or husbandry.
- Whether animal monitoring regimes could be improved. Did welfare assessment protocols and recording systems work well, or were there any areas where there may have been a delay in detecting important indicators of pain or distress?
- Could humane end-points have been further refined.
- Whether humane killing methods were most appropriate, or in need of refinement.

### Updates to the Non-technical Summary

Taking the above considerations into account, how should the NTS be edited to ensure transparency with respect to the experience of the animals and what was done to reduce suffering?

### How outcomes could be used or otherwise disseminated

- Within future projects by the research team and/or others working in the same field.
- More widely within the establishment, e.g. as the basis for revising SOPs, policy or practice.
- In an in-house Three Rs newsletter, or Three Rs prize or poster day.
- To other users outside the establishment, e.g. within materials and methods of posters or presentations; as dedicated publications describing the refinements; in discussion fora; targeted communications with other user groups.
- Discuss opportunities for dissemination with the Named Information Officer.
- Communicate to relevant learned societies, nationally or internationally.
- To the Animals in Science Committee, either directly or through the hub AWERB for the region.
- To the NC3Rs.

### Materials

- Outcome of the retrospective review
- The Non-technical Summary for the project
- European Commission *Working document on Project Evaluation and Retrospective Assessment* ([http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/Endorsed\\_PE-RA.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf)).
- RSPCA/LASA Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies, 3<sup>rd</sup> edn ([tinyurl.com/RSPCA-LASA-AWERB](http://tinyurl.com/RSPCA-LASA-AWERB)), section 6 and examples of communication activities, p. 19

Part 4

# Road Map resource pack

FOCUS ON SEVERE SUFFERING



## **Slide 1 Road Map resource pack: Part 4; Retrospective assessment.**

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.

You can 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](mailto:research.animals@rspca.org.uk)

# After the project has finished

FOCUS ON SEVERE SUFFERING



## Slide 4.1 After the project has finished – retrospective assessment

These slides assume that the project has undergone retrospective review, as set out in Road Map resource part 3 and RSPCA/LASA Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies (section 6). They will set out benefits and outcomes of retrospective assessment that are specific to projects involving procedures that cause severe suffering, and discuss how the outcomes could be disseminated ‘to ensure a continued focus on the Three Rs’ \*.

In the UK, retrospective assessment is carried out by the AWERB, on the basis of information provided by the user, and then submitted to the Home Office Animals in Science Regulation Unit. It may be helpful for the researcher to be present while the AWERB discusses the information provided on severe suffering, and how outcomes can be shared both within and outside the establishment. This could form part of the full retrospective assessment, or be used as a separate consideration of the project with a view to focus on and address severe suffering.

\* From the European Commission *Working document on Project Evaluation and Retrospective Assessment*

([http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/Endorsed\\_PE-RA.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf)).

# Retrospective assessment

## REQUIRED FOR SEVERE PROCEDURES

- Information provided to AWERB, so it can consider:
  - whether the work has been carried out
  - whether the objectives have been achieved
  - the amount of harm to animals – numbers, species and severity
  - whether lessons can be learnt which may contribute to further implementation of the Three Rs
- Updated Non-technical Summary

### Slide 4.2 Requirements for retrospective assessment

All projects involving procedures classified as severe must be assessed retrospectively, although it is good practice to conduct retrospective assessment for all levels of severity. This is especially important in the case of procedures that were predicted to cause moderate suffering but were severe in practice.

For the retrospective assessment, information must be provided to the AWERB that will enable it to consider whether the programme of work has been carried out, whether the objectives have been achieved, and the amount of harm caused to the animals. This includes numbers, species and actual severity.

Very importantly, the AWERB should also be informed as to whether lessons can be learnt from the programme of work which may contribute to further implementation of the principles of replacement, reduction and refinement. This enables the AWERB to retrospectively assess the project, including the harms and benefits.

The Non-technical Summary must also be updated for projects that are required to undergo a retrospective assessment – this includes not only severe procedures but also those involving non-human primates, cats dogs and equidae, endangered animals and projects for the purpose of education and training. The Home Office may also consider that other projects not on this list should be assessed retrospectively, for example if there are animal welfare, ethical or societal concerns, and it can reconsider this during the life of a project.

# Benefits of retrospective assessment

## EC GUIDANCE ON RETROSPECTIVE ASSESSMENT

- Compare actual vs. predicted harms
- Compare actual vs. predicted numbers of animals
- Identify future refinements
- Analyse and learn from anything that went wrong

### Slide 4.3 Benefits of retrospective assessment

The benefits of carrying out retrospective assessment are set out in the European Commission *Working document on Project Evaluation and Retrospective Assessment* ([http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/Endorsed\\_PE-RA.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf)).

In the context of tackling severe suffering, the benefits include:

- comparison of the actual versus predicted harms;
- comparison of actual numbers of animals used versus estimates and consideration of reasons for variations;
- opportunities to identify future refinement possibilities;
- opportunity, should something unexpected happen during the study, to analyse why it happened and to learn from it.

# Information on refinement needed for retrospective assessment

## FROM EC GUIDANCE

- List of refinements introduced during the project
- Consider whether harms could be further reduced; could procedures be further refined?
- Whether animal monitoring could be improved; were welfare assessment protocols working well?
- Whether humane endpoints could be refined
- Whether humane killing could be refined

### Slide 4.4 Information on refinement needed for retrospective assessment

The EC Guidance includes a requirement for information on refinement as part of the retrospective assessment, including:

- A list of any refinements you introduced during the project to reduce harm to the animals.
- Could harms be further reduced?
- Could the procedures (for example administration/sampling routes; surgery) be further refined?
- Could animal monitoring regimes be improved?
- Were score sheets/welfare assessment protocols working well?
- Could humane end-points be refined?
- Could humane killing methods be refined?

# Retrospective assessment outcomes

1. Feedback to research group
2. Dissemination of information on animal use and Three Rs – both positive and negative
  - Within the establishment
  - Within publications and presentations
  - In dedicated reports
  - Via the National Committee (Animals in Science Committee in the UK)
3. Updated Non-technical Summaries

## Slide 4.5 Outcomes to derive from a retrospective assessment

The EC Guidance also sets out some outcomes that should be derived from a retrospective assessment. In relation to severe suffering, these include:

1. Feedback to the research group. The reviewer(s) (in this case, the AWERB) should provide feedback to the researcher on issues raised by the assessment process. This may include suggestions for future improvements and recommendations to disseminate key information.
2. Dissemination of information on the use of animals and the Three Rs (both positives and negatives). This applies on several levels; within the establishment; externally in publications and presentations by the researcher; through the identification, collation and publication of key issues arising from retrospective assessments; and via the National Committee (Animals in Science Committee) which has to ensure the sharing of best practice.
3. Updated information on Non-technical Summaries. This aims to provide greater transparency on the actual harms and benefits related to the use of animals in scientific procedures.

# Conducting a retrospective assessment

## IN RELATION TO SEVERE SUFFERING

- Outcome of the retrospective review
- Non-technical Summary
- Sheet 5
- RSPCA/LASA Guiding Principles

### Slide 4.6 Materials required for retrospective assessment

Having had an overview of the guidance on and requirements for retrospective assessment, we will now apply these to the project and consider how the outcomes could be disseminated at different levels.

We will use:

- Sheet 5 – *Key points to consider for retrospective assessment*
- The outcomes of the retrospective review (if applicable)
- The Non-technical Summary for the project
- RSPCA/LASA Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies, 3<sup>rd</sup> edn ([tinyurl.com/RSPCA-LASA-AWERB](http://tinyurl.com/RSPCA-LASA-AWERB)), section 6 and examples of communication activities, p. 19

## Key points to consider

- How effectively actual harms and numbers were predicted
- Potential for refinement
- Non-technical Summary

### **Slide 4.7 Points to consider in relation to severe suffering when conducting the retrospective assessment**

**Action:** This is an opportunity to work through the above headings listed on sheet 5, with input from the researcher and AWERB members with a variety of roles and expertise. Each point on sheet 5 under the subheadings shown on the slide can be used to prompt discussion and produce a list of refinements and other outcomes. Dissemination will be addressed in the next slide.

## Using and disseminating outcomes

- Within future projects
- More widely within the establishment
- Outside the establishment
  - materials and methods; publications; discussion fora; targeted communications
- Named Information Officer
- Learned societies, user groups
- Home Office Animals in Science Regulation Unit
- NC<sub>3</sub>Rs
- Animals in Science Committee

### Slide 4.8 Discussion on how the outcomes of the retrospective assessment could be used or otherwise disseminated

The EC Guidance document outlines some potential outcomes of a retrospective assessment, including dissemination at several levels.

The optimum approach will vary with the type of outcome; for example, a refinement introduced during the project should always be included in materials and methods (as in the ARRIVE guidelines) and may be suitable for changing practice more widely within the establishment. If there is an in-house Three Rs newsletter, or Three Rs prize or poster day, these may also be suitable media to raise awareness internally.

If the refinement comprised a significant change to the experimental design or protocol that could benefit other animals (and even improve translatability), then it would be appropriate to write it up in its own right for a suitable journal.

Your Named Information Officer should also be able to advise on sharing new refinements, for example through Named Persons networks or fora, and there may be other avenues for discussion through learned societies or user groups relevant to the research field.

You can also tell your ASRU Inspector about successful refinements, and communicate them to national bodies such as the NC<sub>3</sub>Rs and the Animals in Science Committee, either directly or through the hub AWERB for your region.

**Action:** run through this list and explore the potential to use these routes to disseminate the information listed while working through the previous slide.

# A worked example

## RHEUMATOID ARTHRITIS IN MICE

	Within projects	More widely in establishment	Materials & methods	NIO	AR-UK
Humane endpoint	✓		✓	✓	✓
Reduced study length	✓		✓	✓	✓
Disease scores	✓		✓	✓	✓
Refuges	✓	✓	✓	✓	
Nesting material	✓		✓	✓	
Handling	✓	✓	✓	✓	

### Slide 4.9 A worked example

A researcher listed the following refinements that were introduced during a project using G6PI, CIA and CAIA mouse models of rheumatoid arthritis:

- the humane endpoint for weight loss was reduced from 25 per cent to 20 per cent, and another endpoint added of a 15 per cent weight loss that persisted for 5 days;
- tailored indicators enabled study length to be reduced;
- disease scores were revised to include a range of indicators, as opposed to paw volume only, capturing severity more effectively and enabling endpoints to be further refined;
- additional refuges were provided for DBA/1 male mice, eliminating aggression;
- non-tangling nesting material was provided;
- mice were picked up by cupping in the hands, instead of using the tail.

The AWERB, NIO and researcher discussed how best to use and disseminate these outcomes, and decided that all would apply within future projects, would be included in materials and methods sections of publications, and would be disseminated in appropriate fora by the NIO. Extra refuges for aggressive strains and refinements to capture methods were introduced throughout the establishment and the researcher produced a poster on these for the in-house Three Rs day. The changes to the protocol relating to humane endpoints, study length and disease scores were passed on to Arthritis Research UK.

## After this session, you may have ...

- Identified and listed refinements and improvements to the procedure and/or housing, husbandry and care
- Updated the Non-technical Summary
- Constructed a plan to disseminate the outcomes of the retrospective assessment, to help others reduce severity both in-house and more widely

### Slide 4.10 Review of the session

At the end of the session, you will ideally have covered some these areas (read through these).

**Action:** It is important to ensure that the outcomes and dissemination plan have been recorded and that the plan is acted on – the NIO may be a suitable person to have oversight of this.

**End of the session**