HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Retrospective Assessment Reports under Scientific Animal Protection Legislation

1 SCOPE

This guidance is intended to assist authorisation holders in completing the HPRA retrospective assessment report form for projects authorised under Directive 2010/63/EU (the Directive) and S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013, ~~and~~ S.I. No. 174 of 2014 and S.I. No. 553 of 2018 (hereafter referred to the Regulations). This form must be submitted to the HPRA where a project authorisation has been granted with a requirement for a retrospective assessment.

2 INTRODUCTION

Article 39 of the Directive and Regulation 32 of the Regulations describe the basis for retrospective assessment.

A retrospective assessment is a mandatory requirement for all projects involving procedures classified as severe. In addition, the HPRA uses other criteria during the project evaluation process to determine whether and when a project should be assessed retrospectively. These criteria were developed to reflect those areas where animals have a greater potential for suffering, areas where there may be a challenge to the successful completion of a project, and also, where retrospective assessment of a particular project might be in the public interest. Any project in which the actual severity experienced by the animals is more severe than the severity predicted at the time of authorisation must be retrospectively assessed. Any escalation in severity should always be reported immediately to the HPRA.

3 COMPLETING A RETROSPECTIVE ASSESSMENT REPORT FOR PROJECTS

Complete the required sections of the 'Retrospective Assessment Report for Projects Authorised under Scientific Animal Protection Legislation' form using information from the project authorisation. Additional information to aid completion is outlined below.

3.1 Section A~~B~~ – P~~General p~~roject ~~information~~details

3.1.1 Date of completion of animal work

Enter the actual date that the animal component of this project was completed; this will usually be the date of euthanasia of the last animals on the project but could also be removal of the animals from the project for rehoming or reuse in a different project.

3.2 Section BC – Project objectives

This section requires detailed information about the achievement of the project objectives and any benefits that have been accrued.

3.3 Section CD – Animal use and severity

3.3.1 Animal use

Enter the species and numbers of animals authorised for the project in the table provided as well as the numbers of animals that were actually used for procedures during the course of the project.

If the actual numbers used were greater than those authorised, an explanation as to why the increase was necessary, as well as details on what actions were taken when it was realised that additional animals over and above those approved on the project authorisation would be required.

If the actual numbers used were less than those authorised, a brief explanation regarding how reduction was applied should be provided.

3.3.2 Actual severity

The actual severity experienced by the animals should be entered in the tables provided. The severity experienced by an animal in a project shall be determined by the actual pain, suffering, distress or lasting harm that was experienced by an each animal during the course of the project (which may have involved multiple procedures). It should be noted that the overall severity recorded on the HPRA project authorisation document is a prospective severity (worst case scenario) and in many cases is not the actual severity that each animal experiences. It is essential that actual severity is recorded per animal during the course of the project, and that the numbers entered here are not simply the prospective severities.

There will likely be differences between the prospective and the actual severity in a number of animals within each project. In order to determine actual severity, users should have appropriate recording and assessment systems in place which are tailored to their project. The project manager must determine the overall severity that each animal or group of animals experienced throughout the course of the project. A separate table should be completed for each species. If groups of animals within a single project experienced different cumulative severities, the total number of animals should be provided per severity classification. For example, if within one project of 100 animals, 60 animals experienced an overall moderate severity, and the remaining 40 experienced an overall mild severity, '40' should be entered opposite 'mild' in the table and '60' should be entered opposite 'moderate' in the table. Annex VIII to the Directive and the Commission document 'Illustrative examples for the process of severity classification, day-to-day assessment and actual severity assessment' should be used as references when judging actual severity.

3.4 Section D – Implementation of the 3Rs

3.4.1 Replacement

Provide details about any developments in the relevant scientific field which could replace the use of animals in this type of research. If the animal models could be changed or improved for future studies, please provide more details.

3.4.2 Reduction

This section of the form should include any details about how the experimental design could be improved, based on what has been learned during the course of the project. and how the improved experimental design could further reduce the number of animals required.

3.4.3 Refinement

Provide details about how the breeding, accommodation and care of animals, and the methods used in procedures could be further refined to reduce the harms to the animals, while still being able to achieve the objectives of the study. This section should also include details about how the animal monitoring and scoring regimes could be improved, and how the humane endpoints of the project could be refined.

3.43.5 Section EF – Welfare concerns, unexpected adverse effects and deviations

3.4.13.5.1 Were any issues relating to animal welfare raised during the course of the project?

This section should include details on issues relating to animal welfare that were raised by animal care staff, researchers, the designated veterinarian or other personnel during the course of the project. It should outline the issues clearly and what course of action was taken to rectify the situation and prevent these issues from reoccurring.

3.4.23.5.2 Did any unexpected adverse effects or deviations occur during the course of the project?

An unexpected adverse effect is any mortality, morbidity or injury, which was not originally anticipated, or was expected but occurred at a frequency or severity in excess of that forecasted and which impacts negatively on the wellbeing of the animal(s).

A deviation is any departure from the authorised project protocol and may include unapproved breeding, administration of unapproved substances, an unapproved method of euthanasia being utilised or an unauthorised person carrying out procedures or euthanasia on animals.

These should be described in sufficient detail and information should be provided regarding the steps taken to report and deal with these occurrences, regardless of whether the deviation or unexpected adverse effect was previously discussed with the HPRA at the time of/after the event.

4 ADMINISTRATIVE DETAILS

If required, a retrospective assessment must be submitted by the date given under the terms of the project authorisation. Failure to submit a retrospective assessment by the deadline may result in compliance action being taken by the HPRA.

Queries in respect of the retrospective assessment requirements can be made by telephone, ~~fax,~~ or~~and~~
e-mail~~ or by post to the following address~~:

~~Scientific Animal Protection Section~~
~~Veterinary Sciences Department,~~
~~Health Products Regulatory Authority,~~
~~Kevin O'Malley House,~~
~~Earlsfort Centre,~~
~~Earlsfort Terrace,~~
~~Dublin 2.~~

Tel: +353 1 676 4971
~~Fax: +353 1 676 7836~~
E-mail: sap@hpra.ie

~~HPRA~~
~~12 July 2014~~