Centrale Commissie Dierproeven

Guidelines to the form
Retrospective assessment
(version July 11, 2018)

In these guidelines, the two documents that constitute the retrospective assessment will be discussed:

- *Form Retrospective assessment*
- *Addendum Non-technical summary (for the general public);*

Form Retrospective assessment

This form should be used to provide the Central Authority for Scientific Procedures on Animals (CCD) with information required for the retrospective assessment.

Retrospective assessment is mandatory for projects involving non-human primates and/ or projects containing procedures classified as severe. In addition, if considered necessary, the CCD can require a retrospective assessment to be carried out on other projects.

If a retrospective assessment is required, this is stated on your project licence. The deadline for submitting the required information is also mentioned on your licence. If the project is terminated early, the requested information should be submitted at the latest one year after ending the project. Your Animal Welfare Body (IvD) should be involved in completing this form. The retrospective assessment will not only be performed on those procedures classified as severe or procedures in which non-human primates are used, but on the entire project.

The retrospective assessment is considered a powerful tool to facilitate critical review of the use of animals in scientific procedures. In addition, the CCD considers the retrospective assessment an opportunity to both improve the project licence evaluation by the Animal experiments committees (DECs) and the CCD and to reduce and refine animal procedures.

In article 10a2, section 3 of the Animal Procedures Act is stated which aspects the CCD should evaluate. Based on this, the CCD will evaluate
- whether the objectives of the project have been achieved;
- the harm inflicted on animals during the procedures;
- the numbers of animals used;
- any elements that may contribute to the further implementation of the 3Rs (replacement, reduction and refinement).

To enable evaluation of the aspects mentioned above, questions 2 to 6 have been included in the form Retrospective assessment.

In order to optimise the design of future projects, to further implement the 3Rs and to optimise the evaluation of the project licence applications, in question 7, you are asked to describe what lessons can be learnt from this project.

The retrospective assessment process is comparable to the project licence application process. Forms may be submitted to the CCD using the secured connection. The CCD will subsequently ask a DEC for advice on the retrospective assessment. In general, this will be the DEC that has earlier provided the CCD with advice on the project licence application. The CCD aims to provide feedback within 40 business days.

1. General information

1.1 AVD number
Enter the AVD number that has been assigned to your project. This number is stated on the project licence.

1.2 Contact details of the establishment licence holder
The project licence application has been issued to the establishment licence holder. Provide the name of the licenced establishment. If the establishment licence holder is a legal entity, a natural person is mandated to act on behalf of the establishment licence holder. This person is also known as the portfolio holder. Also include the email address of the portfolio holder or his/her contact person. Contact details of the Animal Welfare Body may also be included here. If their details are included here, the Animal Welfare Body will also receive all correspondence on the retrospective assessment.

1.3 Information on the responsible researcher
Enter the name, phone number and email address of the responsible researcher.

1.4 Title project
Enter the title of the project as stated on the project licence.

2. Used animals

2.1 Number of used animals
Provide information on the number of animals that have been used in this project. A breakdown by each animal species and appendix Description animal procedures is required. If the actual numbers differ from the licenced numbers, please provide an explanation. If not all species stated on the project licence have been used, an explanation should be provided. If you have informed the CCD about this at an earlier stage, you may refer to those amendments and/or notifications. Data from the annual report can be used here.

2.2 Severity of procedures
Provide information on the actual severity experienced. A breakdown by each animal species and appendix Description animal procedures is required. Please state to which category of severity the experienced procedures have been assigned (non-recovery, mild, moderate and severe). If some of the species have experienced a different level of reduction in welfare, for each of the classifications should be listed what percentage of the animals have been affected (for example, mice: mild 80%, moderate 20% and rats: mild 60%, moderate 35%, severe 5%). Data from the annual report can be used here. If the actual severity experienced differs from the severity estimated in the application, please provide an explanation. If you have informed the CCD about this at an earlier stage, you may refer to those amendments and/or notifications. If more animals have reached a humane endpoint and/or additional adverse effects on animal welfare have been observed, please provide an explanation for these differences.

3. The 3 Rs

3.1 Replacement
Have there been any developments in your scientific field that could replace some or all of the use of animals? If so, please provide information on these developments and describe to what extent these developments been implemented in this project and may be used in future projects. Both methods/models that have been described in literature and methods/models that have been developed by yourself should be considered here.

3.2 Reduction
Have there been any developments in your scientific field that would lead to a reduction in the number of animals? If so, please provide information on these developments and describe to what extent these developments been implemented in this project and may be used in future projects. Both methods/models that have been described in literature and methods/models that have been developed by yourself should be considered here. Information may be provided on, for example, the performance of systematic reviews, the use of in silico models, the use of in vitro experiments, and new technological developments.

Although the use of too many animals are not acceptable from an ethical perspective, the use of too few animals are also not acceptable when the number is too low to achieve the project's objectives. In the project licence application you have provided an estimate for the required number of animals. Describe whether the estimated numbers for all test groups were appropriate for statistical analysis. If the used methods to estimate the required number of animals were found to be inadequate, please describe how you have adjusted your strategy at this point.

3.3 Refinement
Have there been any developments in your scientific field that would reduce the harm to the animals? Is so, please provide information on these developments. In addition, describe to what extent these developments have been implemented in this project and may be used in future projects? Information may be provided on, for example, observation strategies, pain relieving methods, the envisaged humane endpoints when animals suffer more than anticipated, training of animals, optimising techniques, technological developments such as imaging methods, ex vivo experiments on cells of untreated animals, and inducible animal models.

Describe whether the animal monitoring regimes described in the project licence application were found to be adequate. If not, provide an explanation and describe what improvements have been made to the animal monitoring schemes.

Describe whether the humane endpoints described in the project licence application were found to be adequate. If not, explain that changes you made and/or how the humane endpoints can be further refined in the future.

4. Strategy

4.1 Selection of animal models
Are the animal models described in the project licence application still the most appropriate for this type of study? If not, please describe when this has been observed, to what extent the animal models have been adapted, and/or the project has (temporarily) been stopped? Information should not only be provided on used species and strains, but also on models generated by genetic modification or surgery.

4.2 Go/ no go moments
If go/ no go moments have been described in the project licence application, describe whether those go/ no go moments (and the criteria for deciding whether the procedure/project will be continued or cancelled) were useful and whether they were applied in a consistent manner. Provide an explanation. If go/ no go moments were added or the criteria described in the project licence application were refined, this should be described and explained.
Describe whether the used go/ no go moments were found to be adequate to prevent the undue use and/or suffering of animals.

5. Achievements

5.1 Immediate goal
Describe the immediate goal (main objective) of the project. Explain what you were aiming to achieve, confirm, investigate, produce, test or obtain by undertaking this project. The main objective mentioned here must correspond to the main objective in the project licence application. If the objectives have not been attained (completely), please provide an explanation. Describe to what extent the original strategy had to be altered to achieve the objectives. If the project comprised multiple sub-objectives, provide information on each of these sub-objectives. If a new sub-objective had been added to the projects (and a notification has been submitted to the CCD), you should also describe to what extent this sub-objective has been achieved. Please note that it is only allowed to add a sub-objective for projects in which the severity is classified as 'terminal' or projects in which a 3R method is developed. If the immediate goal has not been attained, explain whether the project has been/ will be continued (for this a new project licence should be obtained). If so, would it be necessary to alter/optimize the strategy? Relevant references may be included here.

5.2 Other benefits

Describe, if applicable, what other benefits have been accrued from the work to date, and whether further benefits may be expected. Information may be provided on additional scientific results, developments in the field of animal welfare, publications, presentations, grants for follow-up projects and patents.

6. Other aspects

6.1 Other aspects

If there are any other aspects that may be important for the performance of the retrospective assessment, these may be described here. Information may, for example, be provided on technical problems, diseases, human errors, supply problems, removals, changes in personnel.

7. Lessons

7.1 Lessons for future projects

Explain what lessons can be learnt with respect to the design and execution of future projects. Please describe whether these lessons may also be applicable for different type of projects.

8. Signature

7.1 Signature

The form must be signed by the establishment licence holder or the portfolio holder. The person who signs the form Retrospective assessment declares that the answers to the questions above have been discussed with the Animal Welfare body and that the form has been completed truthfully.

Addendum Non-technical summary

The responsible researcher is responsible for formulating the addendum to the NTS. The Animal Welfare Body (IvD) may assist the researcher in optimising the content and accuracy. The addendum should be written in Dutch. When filling in the form, you should take into account the maximum number of characters. The project should be explained clearly by using non-technical terms that can be understood by the general public. Avoid the use of concealed language, technical details, abbreviations and jargon. Ensure that the text is unambiguous and comprehensible. Only requested and relevant information should be provided. Ensure that the addendum is anonymous. The addendum should be ready for publication. The addendum should therefore not contain any markings.

General information

Row 2. Country
Choose 'NL' from the drop-down menu.

Row 3. Language
Choose 'nl' from the drop-down menu.

Row 4. EU submission
Choose 'yes [1]' from the drop-down menu.

Row 5. Title
Enter the full Dutch title of the project here, as stated in the project license.

Row 6, 7, 8, 9. Identifiers
These rows are completed by the CCD. Do not fill them in yourself.

Row 10. Reasons for the Retrospective Assessment
Select at least one of the reasons for retrospective assessment from the options 'Contains severe procedures' (11), 'Uses non-human primates' (12), or 'Other reason' (13). If you select 'Other reason' (13), please specify this reason in row 15.

Objectives

Row 17. Achievement of objectives
In the NTS, prior to the start of the project, you indicated the expected benefits of the project. Please state here to what extent these objectives have been achieved and explain your answer. If there are any additional benefits, you may also mention them here. In addition, indicate the scientific and/or societal significance of the stated benefits. If the results of your research have been disseminated, you may elaborate on that here.

Animals

Row 18. Actual harms
In the second tab (Actual harms), specify for each species the total number of animals used during the execution of the project per actual severity category.

Row 20. How do the number of animals used and actual severities compare with those estimated?
If the number of animals used or the distribution across severity categories differs from the numbers or classification stated in the issued permit, please explain how these differences have arisen. Ensure that the reported numbers and percentages correspond with the data in the Retrospective Assessment form.

Row 22. How does the fate of the animals kept alive at the end of the study compare with the estimated fate?
If applicable: explain here what the fate of the animals kept alive at the end of the study has been. Indicate whether this differs from the fate of the animals as initially foreseen.

Implementation of the Three Rs

Row 25. Replacement
Describe any new insights that may contribute to the replacement of animal use in future projects. Also indicate whether you have already applied these insights during the execution of the project.

Row 27. Reduction
Describe any new insights that may contribute to the reduction of animal use in future projects. Also indicate whether you have already applied these insights during the execution of the project.

Row 29. Refinement
Describe any new insights that may contribute to the refinement of animal use in future projects. Also indicate whether you have already applied these insights during the execution of the project.

Row 31. Other
Describe how the insights regarding the 3Rs will be disseminated within the field.

Additions

Row 33. Additional comments
If applicable: describe any additional remarks about the execution of your project that cannot be included under any of the other fields.