Overview activities 2022

Animal Ethical Committee University Maastricht

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Introduction

Animal experimentation requires approval of the CCD (Central Commission Animal testing). By Dutch law, the Animal Welfare Body (AwB) coordinates a project proposal (PP) with the applicant especially with respect to the technical aspects and the implementation of the 3R’s (Replacement, Reduction, Refinement) before the project proposal will then be submitted to the CCD by the UM license holder. The CCD will request an advice from an Animal Ethical Committee (DEC), usually the DEC preferred by the applicant. For researchers affiliated to UM, this is the DEC-UM. The DEC-UM will judge the project proposal based on its scientific and ethical merits, including the 3R’s, and will advise the CCD within 20 working days. To expedite this process, the DEC-UM is composed of members with expertise in different scientific areas (see Table 1). Whenever necessary, the DEC-UM asks questions to the responsible researcher for clarification and invites them to the plenary meeting if needed. The CCD will make a decision based on the advice of the DEC and can provide a permit or a disapproval of the project to the license holder. After approval of the PP, further details on practical animal experimentation are discussed with the AwB and secured in a work protocol, before the start of the actual animal experiment itself.

The composition of the DEC-UM with the respective expertise of its members is indicated below. Also, an overview of the DEC-UM activities in 2022 is given.

The DEC-UM

*Composition*

In 2022, the composition of the DEC-UM has not been changed. In line with the composition requirements described in the law on animal testing (WoD), as of January 1, 2023, the DEC-UM is composed of the following members shown in Table 1.

**Table 1**. Composition DEC-UM op January 1, 2023

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Member | Scientific focus | Expertise | Involved in animal research | Affiliated to the license holder |
| Member 1 (chair) | Veterinary medicine | VM;SA;D;P;HC | I | NA |
| Member 2 | Cardiology | SA;D | I | A |
| Member 3 (vice-chair) | Oncology | SA;D;P | I | A |
| Member 4 | Neurology | D;SA;HC | I | A |
| Member 5 | Pulmonology | SA;D;HC | NI | NA |
| Member 6 | Ethics | E;SA;D;HC | NI | NA |
| Member 7 | Biomaterials | SA;D;HC | I | NA |
| Member 8 | Pharmacology/Toxicology | SA;D;HC | NI | NA |
|  |  |  |  |  |
| Advisor |  | Chair IvD | I | A |
| Secretary |  |  | NI | A |

**Abbreviations**: SA = the scientific research areas and applications implementing animal testing, taking into account replacement, reduction and refinement on the scientific focus; D = design of animal tests, including statistical aspects; VM = veterinary medicine practice in context of research or wild-life animals; HC = housing and caring of animals applied in research; E = ethics; P = protection of research animals; NI = not involved in animal testing; NI-NL = not involved in animal testing within the Netherlands; I = involved in animal testing; NA = not affiliated to license holder; A = affiliated to license holder

*License holder*

The DEC-UM advised the CCD for project proposals from the UM (UM, FHML). In 2022, no project proposals from an external license holder have been evaluated by the DEC-UM.

Activities DEC-UM

*Meetings*

The DEC-UM organized 8 meetings in 2022 to plenarily discuss the CCD requests to provide an advice regarding new project proposals. Based on these plenary meetings, the DEC-UM prepared advice for the CCD. The responsible researchers of one proposal have been invited to a plenary meeting to provide additional explanations.

*CCD-requests to the DEC-UM*

In 2022, the DEC-UM completed 18 CCD-requests, all new project proposals (see Figure 1), for which the DEC-UM has formulated an advice towards the CCD. The DEC-UM provided a positive advice for all proposals. Advice were given unanimously for 13 proposals (72%), while with a minority point of view for 5 proposal (28%). Reasons for a minority point of view were based on disagreement concerning:

* Quality of methodology including concerns on the translatability of the used animal model toward humans
* Proportionality of the proposed procedures in context of the aim of the proposal
* The possibility to investigate the research questions in humans
* The relevance of the proposed research

The CCD approved 17 proposals (94%) and rejected 1 proposal (6%).



Figure 1. Processing time DEC-UM for completed CCD-requests in 2022. The purple dashed line indicates the maximal allowed processing time of 20 working days to provide advice to the CCD. # = proposal with a minority point of view. Blue = new proposal.

The processing time (working days) to compose an advice towards the CCD is indicated in Figure 1. The average processing time for the DEC-UM in 2022 was 18.3 ± 2.8 working days. This is slightly lower compared with the processing time of 2021 (18.8 ± 5.5 working days), however without reaching statistical difference (P = 0.79) and still below the maximal allowed processing time of 20 working days, given by the CCD to the DEC (purple line). For 4 proposal this maximal allowed processing time was slightly exceeded.

*Animal numbers and discomfort*

All project proposals in 2022 encompassed together 84966 animals for a period of 5 years (Figure 2), 34073 (40.1%) mice, 19427 (22.9%) rats, 514 (0.6%) rabbits, 28600 (33.7%) zebrafish, 1412 (1.7%) sheep, 370 (0.4%) pigs, 280 (0.3%) goats, 145 (0,2%) guinea pigs and 145 (0.2%) Syrian hamsters. The steep increase (2.9-fold) in animal numbers compared to 2021 is attributed to the renewed breeding with discomfort protocol (43140 animals) and to the education and training protocol (9530 animals). In 2022, the request for large animals has also increased compared with 2021 where only 40 rabbits were requested.



Figure 2. Number of animals per species requested in 2022 for a period of 5 years.

Figure 3 indicates the percentage animals per species assumed to be exposed to mild, moderate, or severe discomfort. Most of the animals are exposed to mild (69.1%) or moderate (25.6%) discomfort. For 3.0% of the animals, severe discomfort is expected, while for 2.3% of the animals undergo a non-recovery experimental procedure. Mice (61.2%), rats (58.2%), rabbits (70.2%), zebrafish (89.0%), pigs (45.7%), goats (60.4%), guinea pigs (51.0%) and Syrian hamsters (51.0%) are mainly exposed to mild discomfort. Sheep are mainly exposed to moderate discomfort (60.7%). The 4 project proposals expecting severe discomfort, have been approved with a legal retrospective assessment at the end of the project.



Figure 3. Distribution of animals per species according expected discomfort indication.

*Retrospective assessments*

In 2022, the DEC-UM provided advice on 3 retrospective assessments. For all proposals, much less animals have been used than initially applied for (4.6%, 2.4% and 0%). This discrepancy can be explained by the higher estimation of needed number of animals compared with the animal experiments that actually could be performed, research restrictions as a consequence of SARS-Cov-2 pandemic (project 1), proper go/no-go decision criteria after a ‘proof-of-principle’ study (project 2) and budgetary restrictions (project 3). The cumulative discomfort within project 1, estimated to be maximally moderate, was higher due to complications in experimental executions, resulting in an adjustment of the work protocol to minimize the discomfort. For the other projects, the observed cumulative discomfort was as expected. The important learning points for the DEC-UM for future assessments of comparable projects are the use of ‘proof-of-principle’ studies with clear go/no-go criteria and ensuring, in consultation with IvD, that experimental actions are performed optimally.

*National meetings*

The Dutch association for animal ethical committees (NVDEC) is representative for all the 16 DEC’s in several meetings, among others with the CCD. In 2022, the DEC-UM participated in the meetings for DEC chairs and secretaries, organized by NVDEC, on April 5 and October 28, as well as in the meetings for CCD-DEC chairs and secretaries, organized by the CCD on April 5 and October 28. The meeting organized by NVDEC always preceded the meetings organized by CCD. The DEC-UM also participated to the workshop “assessing discomfort” organized by the FELASA on June 3 in Utrecht.