Overview activities 2023

Animal Ethical Committee University Maastricht

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Internet: [Jaarverslagen](https://www.maastrichtuniversity.nl/nl/over-de-um/faculteiten/health-medicine-and-life-sciences/faciliteiten/dierexperimentencommissie-um) DEC-UM

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 normally 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) and handles a scheme of proposal submission dates (see [website)](https://www.maastrichtuniversity.nl/nl/over-de-um/faculteiten/health-medicine-and-life-sciences/faciliteiten/dierexperimentencommissie-um). 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 2023 is given.

The DEC-UM

*Composition*

In 2023, 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, 2024, 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 2023, no project proposals from an external license holder have been evaluated by the DEC-UM.

Activities DEC-UM

*Meetings*

The DEC-UM organized 9 meetings in 2023 to plenarily discuss the CCD requests to provide an advice regarding new project proposals and retrospective assessments. Based on these plenary meetings, the DEC-UM formulates advices towards 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 2023, the DEC-UM completed 10 CCD-requests (compared to 18 requests in 2022), from which 9 new project proposals and 1 resubmission (see Figure 1), for which the DEC-UM has formulated an advice towards the CCD. Two proposals (20%) were judged ‘not testable/not assessable in current form’. One proposal was returned as such to the CCD. The CCD informed the applicant about this decision and gave the opportunity to re-submit the proposal. The other proposal was retracted by the researcher. The DEC-UM provided a positive advice for the 8 other proposals (80%), 4 of them with a clause. Advices were given unanimously for 6 proposals (75%), while with a minority point of view for 2 proposal (25%). Reasons for a minority point of view were based on disagreement concerning:

* The experimental setup of the proposed study accompanied with high percentages of severe discomfort and drop-out of animals to reach the final goal
* Answering the central moral question, with the emphasis in the ethical consideration is placed on violating the intrinsic value of the animal and the discomfort experienced by the animals.

The CCD approved all 8 proposals following the advice of the DEC-UM.

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Figure 1. Processing time DEC-UM for completed CCD-requests in 2023. The purple dashed line indicates the maximal allowed processing time of 20 working days to provide advice to the CCD. \* = proposal retracted by researcher, $ = proposal not testable / not assessable, # = proposal with a minority point of view. Blue = new proposal, yellow = re-submitted 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 2023 was 18.6 ± 4.4 working days. This is slightly higher compared with the processing time of 2022 (18.3 ± 2.8 working days), however without reaching statistical difference (P = 0.85) 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 2023 encompassed together 6848 animals for a period of 5 years (Figure 2), 5795 (84.62%) mice, 995 (14.53%) rats and 58 (0.85%) goats. A steep decrease (5.3- to 5.8-fold) in animal numbers was observed compared to previous years.

 

Figure 2. Number of animals per species requested in 2023 for a period of 5 years (left) and compared to previous years (right). \* = number of animals requested in 2022, when including breeding protocol with discomfort and protocol for teaching and education purposes.

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 moderate (54.6%) discomfort. For 27.1 and 17.7% of the animals, mild and severe discomfort is expected, respectively, while for 0.6% of the animals undergo a non-recovery experimental procedure. Mice (52.2%), rats (68.6%) and goats (55.1%) are mainly exposed to moderate discomfort. Non-recovery experimental procedures occur mainly for goats (38%). The 4 project proposals expecting severe discomfort, have been approved with a legal retrospective assessment at the end of the project.

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

*Retrospective assessments*

In 2023, the DEC-UM provided advice on 11 retrospective assessments. For all proposals, much less animals have been used (n=2011) than initially applied for (n=53300). From the initially requested number of animals, 1.6% mice, 117.8% rats, 83.3% pigs and 10.2% goats have actually been used (Figure 4). 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, proper go/no-go decision criteria and budgetary, personnel and time restrictions.



Figure 4. Number of animals per species initially requested for a period of 5 years and the actual number of animals used at the end of the project.

The percentage cumulative discomfort estimated as severe was slightly higher for mice (7.5 to 12.9%), while clearly decreased for rats (24.7 to 9.1%). Overall, both for mice and rats, a clear shift is observed towards more cumulative mild discomfort. The cumulative discomfort for goats, initially estimated as maximally moderate, was exceeded for a part of these animals due to surgical complications and unexpected infections (Figure 5).

 

Figure 5. Distribution of animal number per species according to the expected cumulative discomfort at request of the project proposal (left) compared to the end of the project (right).

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 more realistic numbers of animals to increase feasibility of the projects.

*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 2023, the DEC-UM participated in the meetings, organized in Utrecht, for DEC chairs and secretaries, organized by NVDEC, on April 4 and October 31, as well as in the meetings for CCD-DEC chairs and secretaries, organized by the CCD on April 4 and October 23. The meeting organized by NVDEC always preceded the meetings organized by CCD.