

Overview activities 2019

Animal Ethical Committee University Maastricht

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Introduction

Animal experimentation requires approval of the CCD (Central Commission Animal testing) and by Dutch law, the Animal Welfare Body (IvD) coordinates a project proposal with the applicant before applying for a project license at the CCD, especially with respect to the technical aspects and the implementation of the 3R's (Replacement, Reduction, Refinement). The project proposal will then be submitted to the CCD by the UM license holder upon which 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, 3R's and ethical merits 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 might provide a permit to the license holder. Further details on the animal experimentation are discussed with the IvD and secured in a work protocol.

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 2019 is given.

The DEC-UM

Composition

In 2019, three DEC members resigned (end of term) and were replaced by a new DEC member. End October also the vice-chair resigned (end of term) and this position has been filled from November onwards by a DEC-UM member with UM affiliation. In line with the composition requirements described in the law on animal testing (WoD), as of January 1, 2020, the DEC-UM is composed of the following members shown in Table 1.

Table 1. Composition DEC-UM op January 1, 2020

Member	Scientific focus	Expertise	Involved in animal research	Affiliated to the license holder
Member 1 (chair)	Veterinary medicine	VM;SA;D;P;HC	I-NL	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	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 2019, the DEC-UM has provided advice for 1 project proposal from an external license holder.

Activities DEC-UM

Meetings

The DEC-UM organized 11 meetings in 2019 to plenary discuss the CCD requests to provide an advice regarding new project proposals or project amendments. Based on these plenary meetings, the DEC-UM prepared advices for the CCD. The responsible researchers of three proposals have been invited to a plenary meeting to provide additional explanations or upon an intended (negative) advice.

CCD-requests to the DEC-UM

In 2019, the DEC-UM completed 20 CCD-requests: 4 amendments, 13 new project proposals, 2 re-submitted proposals and 1 external new project proposal (see Figure 1). Two (amendment) proposals (10%) have been withdrawn by the responsible researcher. The DEC-UM has formulated an advice towards the CCD for 18 proposals (90%). Two proposals (10%) were judged 'not testable/not assessable' and returned as such to the CCD. The CCD informed the applicant about this decision and gave the opportunity to re-submit the proposal. The DEC-UM proved a positive advice for 14 proposals (77,8%) and a positive advice with a clause for 3 proposals (16,6%). For 1 proposal (5,6%), a majority position was taken.

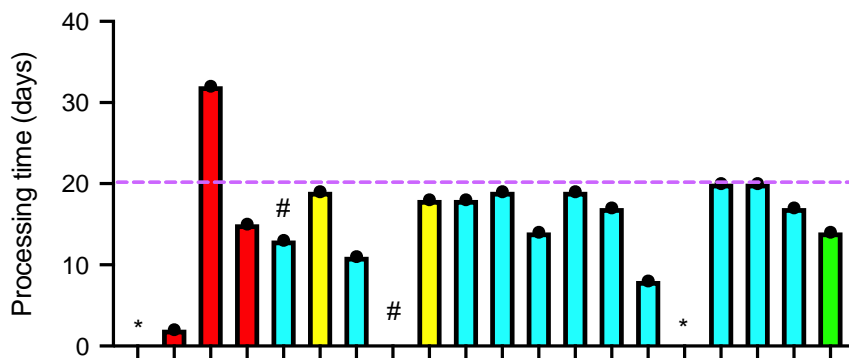


Figure 1. Processing time DEC-UM for completed CCD-requests in 2019

The purple dashed line indicates the maximal allowed processing time of 20 working days to provide advice to the CCD. * = proposal withdrawn by the responsible researcher, # = proposal not testable /not assessable. Red = amendment, blue = new proposal, yellow = re-submitted proposal, green = new proposal from external license holder.

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 2019 was 16 working days. This is well below the maximal allowed processing time of 20 working days (purple line). For one proposal this maximal allowed processing time was exceeded, due to the complexity of the application, submission during summer break, limited accuracy in answering questions and changes in personnel formation. This delay has been communicated with the CCD, however without requesting an official extension of 15 days as indicated by the law (EU 2010/63, Art.41-2).

National meetings

Faculty of Health, Medicine and Life Sciences

The Dutch society for animal ethical committees (NVDEC) is representative for all the 16 DEC's in several meetings, among others with the CCD. In 2019, the DEC-UM participated in the meetings for DEC chairs and secretaries, organized by NVDEC, on January 8 and November 5, as well as in the meetings for CCD-DEC chairs and secretaries, organized by the CCD on April 23 and November 5. The meeting organized by NVDEC always preceded the meetings organized by CCD. The CCD has organized on July 12 a workshop concerning project proposals for the benefit of livestock farming. The DEC-UM chair and ethicist participated in this workshop.

Education

The ethicist acted officially as DEC-representative in several events: 1) the Laboratory Animal Science Course at UM/FHML, 2) an exchange program for American and Chinese students organized by the Center for European Studies and 3) a workshop on "Personalized in silico Cardiology (PIC) where he gave lectures on the new law on animal testing (WoD), the new application procedure, the role of the DEC and from a more general point of view ethics concerning animal testing.