Routines for planning, application, implementation and reporting of experiments with animals at NMBU

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1. PURPOSE AND SCOPE

The Norwegian regulations on animal research (FOR-2015-06-18-761), hereinafter referred to as the "Regulation", and guidelines from the Norwegian Food Safety Authority (Mattilsynet) set requirements for planning, applying and carrying out experiments with animals.

The purpose of this routine is to provide more detailed requirements and guidance for planning, applications, performing and reporting of experiments with animals at NMBU. The routine shall assist the responsible applicant and users of research animals at NMBU to comply with the requirements set out in the Regulation.

The routine applies to everyone who participates in the planning, application process, and performing experiments with animals at NMBU. The routine deals with conditions authorised by the Regulation.

The *routine does not apply to* matters related to matters regulated by other regulations (i.e. the routine does *not* cover HSE related to gene technology and the working environment, nor matters regulated by aquaculture legislation, medicinal legislation, nor legal requirements following the wildlife and environmental legislation, etc.)

2. REQUIREMENTS FOR PLANNING EXPERIMENTS

- Experiments with animals must be planned in accordance with current legislation and the 3R ("Replace, reduce, refine")

- Everyone who participates in the planning of experiments with animals must have the necessary competence as described in Section 24 of the Laboratory Animal Regulations and in NMBU's "Routines for fulfilling the competence requirements in Regulation on Animal Research"

- If the experiment is to take place at one of NMBU's approved research animal facilities, the responsible applicant is obliged to contact the relevant animal facility early in the planning phase to clarify overall practical and resource-related matters. Factors that should be clarified include (but are not limited to): whether the facility's approval

includes current animal species and type of experiments; capacity; need for infrastructure and resources (incl. personnel).

3. REQUIREMENTS RELATING TO APPLICATIONS FOR EXPERIMENTS WITH ANIMALS

- Experiments with animals shall be applied for in accordance with current legislation and guidelines issued by Mattilsynet[1]

- If the responsible applicant is in doubt as to whether the experiment falls within the scope of the Regulation, the responsible applicant is obliged to obtain written clarification from PMSK NMBU and, if necessary, from Mattilsynet

- Experiments with animals must be applied for by the responsible applicant via Mattilsynet's electronic application system, FOTS.

- Applications and other documents submitted to the Mattilsynet must be complete and prepared in accordance with regulatory requirements and standards

- The responsible applicant must ensure that the application is as complete as possible before it is submitted.

- FOTS-applications must be submitted well in advance (minimum 3 months) before the experiment is scheduled to start.

- All participants involved in planning and performing of the experiment must be listed as co-workers in the FOTS application

- If the experiment is to take place at one of NMBU's animal facilities, a confirmation must be enclosed in the FOTS application that an agreement has been made with the animal facility

- If necessary, a meeting can be held with PMSK and the responsible applicant to review the application.

- PMSK NMBU is the primary point of contact with Mattilsynet. In principle, applicants should not contact Mattilsynet directly. The applicant must copy in PMSK in any communication with Mattilsynet

- Experiments cannot be started until approval from Mattilsynet has been obtained. This includes that animals cannot be ordered or bred for the experiment, or any other type of preparation of animals before approval from Mattilsynet has been obtained.

- The responsible applicant must ensure that any changes to already approved FOTS-applications must be re-applied in advance, either in the form of "application for change" or "notification of change" in FOTS, cf. §§ 5, 6 and 28 of the Regulation.

[1] Søke om godkjenning for å bruke dyr i forsøk | Mattilsynet

- A more detailed description of the application requirements can be provided in dedicated guideline documents

4. REQUIREMENTS FOR A START-UP MEETING FOR APPROVED EXPERIMENTS

Before new approved experiments are initiated, a start-up meeting must be held with those involved. The purpose of the meeting is to make sure everyone is well informed about the content of the FOTS-application, as well as clarifications of animal welfare, practical and other relevant matters.

- The responsible applicant is responsible for arranging a start-up meeting well in advance of the planned start of the experiment.

- For experiments to be carried out at NMBU's approved animal facilities, the following must participate:

    - Responsible applicant
    - Designated veterinarian
    - The facility manger, or a person appointed by the facility manager to represent the animal facility

    In addition, it is recommended that all co-workers in the FOTS application attend the start-up meeting.

    - If co-workers do not participate in the start-up meeting, the responsible applicant is obliged to inform everyone about the FOTS application's content and approval, as well as about all other relevant matters of importance for animal welfare and practical implementation of the experiment

- For field experiments, at least the following must attend the start-up meeting:
    - Responsible applicant
    - Designated veterinarian

    In addition, it is recommended that all co-workers in the FOTS application attend the start-up meeting.

    - If co-workers do not participate in the start-up meeting, the responsible applicant is obliged to inform everyone about the FOTS application's content and approval, as well as about all other relevant matters of importance for animal welfare and practical implementation of the experiment

For experiments that are a direct continuation of previous FOTS applications where methods and expected effects on the animals coincide with previous experiments, a start-up meeting is not obligatory.

5. CHANGE OF APPROVED EXPERIMENTS

- Experiments cannot be changed without new approval from Mattilsynet if the change may impair animal welfare; c.f. §6 of the Regulation. If the change will not impair animal welfare, the change must be notified to Mattislynet c.f. §6 of the Regulation

- The responsible applicant must ensure that the application or notification of changes is submitted via FOTS before any changes to the approved FOTS-application is implemented

- An application for change or notification of change in FOTS are reviewed by PMSK before being sent to Mattilsynet.

6. CONDUCTING EXPERIMENTS

- Everyone who participates in experiments with animals must have adequate education and practice as described in more detail in NBMU's "Routine for Fulfilling the competence requirements in the regulation".

- Everyone participating in experiments with animals must be listed in the FOTS application as co-workers and be familiar with its content, including monitoring requirements and the human endpoints set out in the application.

- Experiments must be carried out in accordance with the approval and any decision made by Mattilsynet.

- It is the responsible applicant that has the legal duty to ensure that the experiment is conducted according to the approval (c.f. §28 in the Regulation).

- It is incumbent upon everyone who performs experiments with animals that unnecessary and unintended pain, fear, permanent injury, or other strain inflicted on animals shall be removed as soon as possible.

- The responsible applicant must ensure that non-compliance with the approval is rectified as soon as possible, and that the nonconformity and the measure are recorded and reported (c.f. §28 in the Regulation).

- Facility managers are responsible for ensuring that the facility has written procedures for follow-up of experiments.

- A more detailed description of the follow-up of experiments and animals may be given in dedicated written procedures.

7. ANNUAL REPORT IN FOTS AND COMPLETION OF EXPERIMENTS

- The responsible applicant must report the use of research animals via FOTS by 1 March each year, and otherwise in accordance with Mattilsynet's guidelines and decisions.

- When the experiment has been completed, the responsible applicant must submit a final report in FOTS.

- Failure to submit required reports to Mattilsynet is to be regarded as a deviation

- More detailed description of reporting requirements can be provided in dedicated guidelines.