**Project plan for experiments with mice and rats 2025**

***For AEM use at approval***

|  |  |  |
| --- | --- | --- |
| **P-number:** | **Date:** | **Veterinarian:** |
| P25-xxx |  |  |

|  |  |
| --- | --- |
|  | **Emed-adm: Oplysninger som AEM bruger til tildeling af adgang** |
|  | **AEM: Oplysning til faktura** |

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*A project plan must be filled in before a new experiment can start.* ***Please send the project plan by email to*** [***EMED-Projektplaner@sund.ku.dk***](mailto:EMED-Projektplaner@sund.ku.dk?subject=Projektplan%20-%20FORSØG%2021010)*, where an AEM veterinarian will go through it and return to researcher, when the project plan is approved, with a project plan number* ***P25-xxx****. This P-number has to be put on the animal order form and on the cage card for animals used in the project. The project plan is then* ***valid until 31-12-2026 or earlier if the license expires****.* ***NB all fields must be filled in****.*

## Location and duration of experiment

|  |  |  |
| --- | --- | --- |
| 1.1 Animal unit in AEM\*), where you want access | \*) Please note that there may be space problems, or that space in a particular unit may be reserved for special users or types of experiments. Therefore, an approved project plan is not a guarantee that your experiment can be initiated immediately or can be done in the unit indicated in the plan. | |
|  |
| 1.2 Use of external laboratory: Are the animals at any time during the experiment taken out from AEM’s animal facility and taken to an external laboratory? | 1.3 Use of external laboratory:  Room number of laboratory and duration of stay | 1.4 Use of external laboratory:  Is it for a procedure ending in euthanasia? Or are the animals taken back into AEM?  If taken back, please indicate to which unit? |
|  |  |  |
| 1.5 Expected start of experiment (week/year) | 1.6 Duration of experiment | 1.7 Expected maximum number of animals and animal cages during the experiment |
|  |  |  |

## Special attention in the experiment

|  |  |  |
| --- | --- | --- |
| All fields must be filled in, if yes please give details in the Appendix. | Yes | No |
| 2.1 GMO 1 or 2 microorganisms (Appendix 1) |  |  |
| 2.2 Biological agents (Appendix 2) |  |  |
| 2.3 Biological materials (Appendix 3) |  |  |
| 2.4 Chemicals/drugs (Appendix 4) |  |  |
| 2.5 Survival surgery (Appendix 5) |  |  |
| 2.6 Radioactivity – use of radionuclides or external irradiation (yes/no, if yes please describe and give details in Appendix 6) | | |
|  | | |
| 2.7 Special housing (Single housing, change of bedding etc.) (yes/no, if yes please describe) | | |
|  | | |
| 2.8 Enrichment which differs from AEM standard (yes/no, if yes please describe) | | |
|  | | |
| 2.9 Other (please describe) | | |
|  | | |

## Researcher information

|  |  |  |  |
| --- | --- | --- | --- |
| 3.1 Name of AEM account holder | 3.2 Address, phone, e-mail | 3.3 Account number |  |
|  |  |  |  |
| 3.4 Vendor of animals |  | 3.5 Account number at vendor of animals |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 3.6 Name of holder of animal experimental license | 3.7 Address, phone, e-mail | 3.8 License number, title, and title of relevant extension(s) NB if there is an inspection clause be sure to inform AEM | 3.9 Expiration date of license |
|  |  |  |  |
| \*)3.10 Name of responsible person for the project (contact person): | 3.11 Address, phone, e-mail | 3.12 Certificate from a Danish FELASA course? | 3.13 If no Danish FELASA course - Has the person obtained a dispensation? |
|  |  |  |  |
| \*)3.14 Name of other participants (use the tabulator to add more rows if necessary) | 3.15 Address, phone, e-mail | 3.16 Certificate from a Danish FELASA course? | 3.17 If no Danish FELASA course - Has the person obtained a dispensation? |
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*\*) Outside normal working hours it is the researcher who is responsible for extra monitoring of the animals, and the researcher can also be expected to be called in during weekends if their animals are sick.*

## Animal information

|  |  |
| --- | --- |
| 4.1 Species, sex, other |  |
| 4.2 Please list all strains below (both inbred, outbred, genetically modified, and spontaneous mutants) | 4.3 If the strain is a spontaneous mutant or genetically modified, please describe sickness or other impact caused by the genetic alteration. Do the animals need special care? |
|  |  |
|  |  |

## Experiment information

|  |
| --- |
| **5.1 Short** description (objective, timeline, list of procedures) of the experiment. Do not just copy all the text in the license. **AEM needs to know what happens to the animals in this experiment**. If you are doing more than one type of experiment, clearly state each individual experiment, or write separate project plans for each experiment. |
|  |
| 5.2 Severity: Describe the expected combined severity for the experiment: non-recovery, mild, moderate or severe |
|  |
| 5.3 Anesthesia, analgesia and other treatment: List the drugs used. For analgesia and other treatment provide dose, total duration of treatment, interval between doses. |
|  |
| 5.4 Euthanasia: describe the method(s) |
|  |

## Observations and actions during the experiment

|  |
| --- |
| 6.1 Humane endpoints: Describe the type and degree of expected harmful effects that will lead to the animal being removed from experiment/euthanized. |
|  |
| 6.2 Who will do the observations for humane endpoints, and how often do you plan to observe during the various phases of the experiment? |
|  |
| 6.3 Expected clinical symptoms in the animals: Describe expected clinical symptoms including which alleviating actions that should be taken (euthanasia, analgesia, fluid therapy etc.)? |
|  |
| 6.4 Research endpoints: For the individual animal, when does the experiment end (duration of experiment for the individual animal) |
|  |
| 6.5 In case of survival surgery: Please state how often you plan to observe the surgical wound, and when you plan to remove clips/sutures. Rember to fill in Appendix 5. |
|  |
| 6.6 What should AEM do if an animal needs to be euthanised? Should AEM contact the scientist first or can the animal be euthanized immediately? Please notice that the animal will be euthanized if the scientist does not respond within 1 day. Animals that experience severe suffering, pain or distress will always be euthanized immediately. |
|  |
| 6.7 What do you want AEM to do with euthanised or deceased animals when you are not available? Storage (refrigerator/freezer), necropsy / removal of organs (only by special agreement with AEM), contact person? |
|  |

## Appendix 1 *Genetically modified animals, cells or microorganisms*

***Experiments with genetically modified animals, cells or microorganisms (class 1 or 2):******Genetically modified organisms, according to the executive order, are understood to mean plants, animals, microorganisms, cell cultures and viruses in which new compositions of the genetic material occur that do not occur naturally***

|  |  |
| --- | --- |
| Number and date of permission from the Working Environment Authority |  |
| GMO classification level (class 1, 2 or animal) |  |
| For GMO1 and GMO2 experiments, are there special precautions regarding the work environment?  Please send the risk assessment. | |
|  | |
| Name of persons who are going to work with the GMO microorganism. The person has received written instruction from AEM **(yes/no)**.  Use tabulator to add more rows. | |
|  | |

## Appendix 2 *Use of biological agents*

***Experiments with biological agents.***

***Biological agents in Appendix 2 mean microorganisms (not genetically modified which must be described in Appendix 1), cell cultures and endoparasites in humans, which are capable of causing an infectious disease, allergy or toxic effect   
Guidance can be found in the employee guide:*** [***https://kunet.ku.dk/employee-guide/Pages/HR/Biology.aspx***](https://kunet.ku.dk/employee-guide/Pages/HR/Biology.aspx)

|  |  |
| --- | --- |
| ​*Work with biological agents in risk group 2 or higher must be reported to the Danish Working Environment Authority, before beginning work.*  **Receipt number** from the Working Environment Authority for registration of project with biological agents. |  |
| For experiments with biological agents, are there special precautions regarding the work environment?  Please send the risk assessment. |  |

## Appendix 3 *Use of biological materials*

***Experiments with biological materials:*****Biological materials include body fluids (blood, serum, saliva, etc.), eggs, semen, embryos, cells, cell cultures, tissues, organs, parasites, antibodies which entail a possible risk of containing infectious agents that can be transferred to people or laboratory animals. When biological materials are used, a copy of screening for a number of viruses must be attached. The choice of screening panel depends on the origin of the biological material and the intended use. If screening is not possible special precautions may apply. *Please contact the AEM veterinarians for information*.**

|  |  |
| --- | --- |
| What biological material is going to be used?  Please list all biological material. |  |
| Is the biological material of human origin? |  |
| Copy of screening attached (x) |  |

## Appendix 4 *Use of drugs, test substances or chemicals*

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| --- |
| ***Generally, about AEM handling categories for chemicals in animal experiments:***  **Minor handling category:** substances without information or suspicion of harmful/dangerous properties, and substances which are dangerous via the oral route. Use gloves for handling of the substance, no labelling of pen/box/room (H300, 301,302,303,304,305,312, 313)  **Moderate handling category:** substances with information or suspicion of dangerous properties, excluding carcinogenic, mutagenic, reproductive effects, or organ damage effects. Includes for example allergenicity, skin-eye-respiratory irritation. Rules for handling, advice for working with PPE, labelling of pen/box/room with ”test substance”. (H315,317,318,319,335,066,070)  **Critical handling category:** substances with information or suspicion of carcinogenic, mutagenic, reproductive effects, or organ damage effects. Harmful/dangerous via inhalation. Rules for handling, requirement for handling with PPE if containment is not possible, safe waste handling according to specific instructions, labelling of pen/box/Room with ”hazardous substance”. (H310,311,314,330,331,332,334,336,340,341,350,350i,351,360,360F-D-FD-DF, 361,361F-D-FD, 362,071, 370, 371,372,373)  Other: Drugs, test substances or chemicals used in AEM’s rooms, which are harmful/dangerous but are not administered to animals, for example paraformaldehyde used for fixation of tissue in organ harvest procedures. Handling according to specific instructions, no storage in AEM.  Substances that are used for anesthesia/analgesia/euthanasia are used with relevant precautions for pharmaceutical agents |

***Experiments with drugs, test substances or chemicals***

Please list all drugs, test substances or chemicals. AEM will assign each substance to a handling category based on information in Kemibrug or the supplier´s safety data sheet (sds).

|  |  |  |  |
| --- | --- | --- | --- |
| **Filled in by researcher**  Identity, supplier, and route of administration (injection, gavage, via food/drinking water, other) | **Filled in by researcher**  Harmful properties (“H statements”) | **Filled in by researcher**  Please list the CAS-number or send the supplier’s safety data sheet (sds) | **Filled in by AEM**  **Safety precaution level in AEM (handling category)** |
|  |  |  |  |
|  |  |  |  |
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***Safety precautions according to AEM handling categories***

## Appendix 5 *Survival surgery*

The policy for survival surgery is officially implemented on 1 July 2024.

***Experiments involving surgery***

1. Please read the [Policy for survival surgery](https://emed.ku.dk/documents/Policy_for_survival_surgery_-_final.pdf).
2. Please consult the [flowchart](https://emed.ku.dk/documents/Flowchart_for_assessment_of_competences_for_survival_surgery_-_final.pdf).
3. Please list all the persons performing survival surgery in the table below.
4. Please fill out a [self-evaluation form](https://emed.ku.dk/documents/Policy_for_survival_surgery_-_final_-_self-evaluation_form.docx) for each person performing survival surgery and send these evaluation forms along with the project plan for approval.

|  |  |
| --- | --- |
| Name of participant who will be performing survival surgical procedures | AEM comments |
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## Appendix 6 *Radioactivity - use of radionuclides or closed sourses in animal experiments*

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| AEM needs information to ensure that the use is in accordance with regulation, and that the work has been subjected to a detailed risk assessment. | |
| Use of Radionuclides | |
| **Authorization/notification/ exempt from requirements** | For authorization or notification: Supply copy of authorization or notification  For exemption:  supply calculation |
| **Radiation coordinator** | Name |
| **Data sheet on radionuclide** | Supply copy |
| **Instructions** | |
| **Risk assessment** | **Describe procedure and any safety precautions**  **(containment, personal protective equipment etc.)** |
| Storage |  |
| Use in animals |  |
| Housing of animals following injection *(How and where- state building and room number)* |  |
| Risk of airborne contamination |  |
| Dead animals |  |
| Waste handling |  |
| Cleaning |  |
| Control measurement for contamination |  |
| Action in case of injuries, accidents and incidents |  |
| **Summary and conclusion -** *radionuclides* | |
| **Type of approval**  **(tilladelse/underretning/undtaget)** |  |
| **Radionuclides used:** |  |
| **Building and room numbers in AEM** |  |
| **Terminal/survival** |  |
| **Waste handling, dead animals and cages** |  |
| **Procedure description(short)** |  |
| **Safety precautions for AEM** |  |
| **Conclusion: (By AEM vets)** |  |
| **Summary and conclusion –** *Whole body radiation* | |
| **Responsible for radiation** |  |
| **Responsible for post radiation care** |  |
| **Transport procedure to and from Gammaecell unit** |  |
| **Conclusion: (By AEM vets)** |  |