Application for an Amendment and/or Renewal to a Project Authorisation under Scientific Animal Protection Legislation

For details on completing this application form, please see the ‘[Guide to Amendment and Renewal Applications for Projects under Scientific Animal Protection Legislation’](https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=3ccaf925-9782-6eee-9b55-ff00008c97d0). Please note that only the sections that are relevant to this application should be completed, but that all applicants must complete at a minimum **Sections A and J**.

SECTION A: purpose of application

|  |  |
| --- | --- |
| Application type required | [ ]  Amendment[ ]  Renewal |
| Name of project authorisation holder |  |
| Project authorisation number | AE /P  |
| User establishment name (primary and collaborating, where relevant) |  |
| Narrative: explain the reason for this amendment/renewal, the scientific justification, and what the benefits will be (<500 words) |  |
| Has this amendment/renewal been approved by an ethics committee? | [ ]  Yes[ ]  No |
| If ‘yes’, provide a copy of the ethical review application and associated approval documentation from the relevant ethics committee as outlined in the guide to projects.If ‘no’, provide justification as to why an ethical review was not performed. |
|  |

SECTION B: proposed Renewal details *(if applicable)*

*(Please note it is not possible to grant authorisation for longer than a 5-year period)*

|  |  |
| --- | --- |
| Date of expiry of current project authorisation |  |
| Time extension sought (months) |  |
| Justification for request for time extension |  |
| Details of additional funding secured |  |

SECTION C: type of amendment *(if applicable)*

|  |
| --- |
| *Tick all types that apply and enter details in the relevant section(s) below:* |
| [ ]  Change to the project start date (complete **Section D1**)[ ]  Amendment to project manager/amendment to or addition of deputy project manager(s) (complete **Section D2**)[ ]  Addition of user establishment(s)/additional location(s) (complete **Section D3**)[ ]  Amendment(s) to existing procedure(s) (complete **Sections E and I**)[ ]  Addition of new procedure(s) (complete **Sections F, H and I**)[ ]  Amendment to species/strains (complete **Section G**)[ ]  Increase in animal numbers (complete **Sections E and/or F (as relevant), and Sections H and I**)  |

SECTION D: amendmentS NOT INVOLVING PROCEDURES *(if applicable)*

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| **D1: CHANGE TO THE PROJECT START DATE***This section should only be completed if procedures on animals have not commenced within one year of the issue date of the project authorisation. (To change the project expiration date, please complete Section B – Proposed renewal details.)* |
| Original issue date of project authorisation |  |
| Proposed new date of commencement of procedures |  |
| Provide:(i) reason(s) as to why procedures on animals did not commence within one year of the issue date of the project authorisation |
|  |
| (ii) information on how it was ensured that no alternatives to the use of live animals have been made available since the project was first authorised, including keywords used in searches |
|  |
| (ii) information on how it was ensured that this work has not been carried out elsewhere since the project was first authorised |
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| **D2: AMENDMENT TO PROJECT MANAGER/AMENDMENT TO OR ADDITION OF DEPUTY PROJECT MANAGER(S)***Tick which action this box relates to. For multiple amendments/additions, select the entire table and copy and paste as required.* |
| [ ]  Amendment to project manager[ ]  Amendment to deputy project manager | [ ]  Addition of deputy project manager |
| Title |  | Name |  |
| Telephone |  | Email |  |
| Address |  |
| Eircode |  |
| Individual authorisation number | AE / I  |
| If no current individual authorisation is held, state the date of application for an individual authorisation: |
|  |
| To remove any current deputy project manager(s) from the project authorisation list the name(s) below: |
|  |
| **Note:** An application must be made for a project transfer if the project authorisation holder is also being replaced. Please see the ‘Guide to Transfers of Project Authorisations under Scientific Animal Protection Legislation’ for details.  |

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| **D3: ADDITION OF USER ESTABLISHMENT(S)/ADDITIONAL LOCATION(S)***In the case of a collaboration, list the name and authorisation number of the new user establishment(s) at which project work is planned to take place in the table below.* |
| **USER ESTABLISHMENT NAME** | **USER ESTABLISHMENT AUTHORISATION NO.** |
|  | AE |
|  | AE |
|  | AE |
| Outline the reasons for the addition. Please ensure the compliance officer(s) for the additional user establishment(s) signs the appropriate section of the declaration in Section J. |
|  |
| In the case of an amendment to or addition of a location other than an authorised user establishment(s) where procedures are planned to be carried out, list the additional location(s) and provide a scientific justification as to why each additional location is necessary: |
|  |

SECTION E: AMENDMENTS to existing PROCEDURES *(if applicable)*

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| *For amendments to more than one existing procedure, select this entire table and copy and paste as required. In addition, please append the currently approved project protocol with the proposed amendments highlighted in yellow or added as tracked changes. The specific details for each amended procedure must be provided in the updated project protocol.*  |

|  |  |
| --- | --- |
| Approved procedure number to be amended |  |
| Exact title of procedure (as listed in the procedure table of the current HPRA project authorisation document) |  |
| Description of amendment |  |
| Are animal numbers for this procedure changing (increasing or decreasing)? |
|  |
| Number of animals currently approved |  |
| Amended number of animals requested |  |
| Provide detailed justification why it is necessary to amend this procedure. |
|  |
| Provide details about any potential change(s) to the adverse effects and attrition rate. If new adverse effects are expected, detail the likely incidence and the % of animals these are expected to be seen in. |
|  |
| Describe any additional procedure-specific humane endpoints, or changes to the original humane endpoints, relating these directly to the adverse effects. |
|  |
| Has the predicted severity of this procedure changed as a result of this amendment? If yes, provide details of the new predicted severity (non-recovery, mild, moderate or severe).  |
|  |
| Provide details of any additional refinements, including the introduction of anaesthesia/analgesia, which will be put in place to minimise any harm to the animals. |
|  |
| **Note 1: If this amendment also involves a change to species/strains, please complete Section G of this form.** **Note 2: If total animal numbers have increased as a result of this amendment please complete Section H of this form.** **Note 3: Please ensure to complete Section I of this form.**  |

SECTION F: ADDITION OF NEW PROCEDURES *(if applicable)*

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| *To add multiple new procedures, select this entire table and copy and paste as many times as required. In addition, please append the currently approved project protocol with the proposed amendments highlighted in yellow or added as tracked changes. The specific details for each new procedure must be provided in the updated project protocol.* |

|  |  |
| --- | --- |
| **New procedure number:** | **Name of new procedure:**  |
| Description/details of procedure |  |
| Justification/relevance of procedure |  |
| Species |  |
| Life stage or age |  |
| Number of animals to be used |  |
| Will this new procedure increase total number of animals required for this project? |  |
| Frequency of procedure (how many times will the procedure be performed?) |  |
| Duration of procedure (how long will the procedure take/how long will the animal be affected for?) |  |
| Proposed severity classification of the procedure  |

|  |  |
| --- | --- |
| [ ]  Non-recovery | [ ]  Moderate |
| [ ]  Mild | [ ]  Severe |

 |
| List all the potential expected adverse effects of the procedure. Include the estimated % of animals that may experience each effect listed. |
|  |
| If there is an expected attrition rate, give the estimated % of animals and describe the potential reasons (e.g. reaching humane endpoints, anaesthetic deaths, failure of animal model, other). |
|  |
| Relating directly to the adverse effects, list all procedure-specific humane endpoints. |
|  |
| Details of anaesthesia (if not being used, provide justification) |
|  |
| Details of analgesia (if not being used, provide justification) |
|  |
| Other than analgesia and anaesthesia, list all other refinements that will be applied to this procedure (refinement is a legal requirement). |
|  |
| Justify why it is necessary to add this new procedure and explain how this procedure will contribute to the benefits of the project. |
|  |
| What is the fate of the animals at the end of the procedure? |
|  |
| If the fate is euthanasia, what is the method? |  |
| If this method is not an approved Annex IV euthanasia method (see Directive 2010/63/EU), provide justification |  |
| **Note 1: If the new procedures require a new species/strain, please complete Section G of this form.** **Note 2: Please complete Sections H and I of this form.**  |

SECTION G: AMENDMENT TO SPECIES/STRAINS *(if applicable)*

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| *If the amendment includes the addition of a new animal species/genetic strain, please complete the table below. The table can be copied and pasted to add multiple species/genetic strains.* |

|  |  |
| --- | --- |
| New species or strain  |  |
| Number of animals to be used |  |
| Justification for this new species/strain |  |
| Genetic status | [ ]  Not genetically altered [ ]  Genetically altered without a harmful phenotype [ ]  Genetically altered with a harmful phenotype [ ]  Animals used for the creation of a new genetically altered line/strain  |
| Details of genetic alteration (if relevant)  |  |
| Details of any refinements necessary to appropriately manage new strains with a harmful phenotype |  |
| Name of supplier establishment (where animals originate from)  |  |
| Authorisation number of above supplier establishment (if known)  |  |
| Country of origin |  |
| Have any of these animals been previously used in a project (i.e. will this be a ‘reuse’ of these animals)? | [ ]  Yes[ ]  No  |
| * If yes, describe the cumulative effect of the procedures on the animal(s).
 |  |
| * If yes, has the animal’s general state of health and well-being been fully restored?
 |  |
| * If yes, is the reuse in accordance with veterinary advice, taking into account the life-time experience of each animal?
 |  |
| Have the animals to be used in this project been bred for specific use in scientific procedures? | [ ]  Yes [ ]  No [ ]  Not applicable (not an Annex I species)  |
| * If ‘no’, provide justification.
 |  |
| Are the animals to be used | [ ]  a) Taken from the wild [ ]  b) Stray or feral animals [ ]  c) Endangered species [ ]  d) None of the above  |
| * If a), b) or c) were chosen above, provide justification.
 |  |
| **Note: If total animal numbers have increased as a result of this amendment(s), complete Sections H and I of this form.** |

SECTION H: Increase in TOTAL ANIMAL NUMBERS *(if applicable)*

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| *If the amendment involves an increase in animal numbers, please complete the fields below.*  |

|  |  |
| --- | --- |
| Total number of animals currently authorised for use (if multiple species, provide a breakdown of numbers per species)  |  |
| Amended total number of animals proposed (if multiple species, provide a breakdown per species)  |  |

SECTION I: the 3rs *(if applicable)*

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| ***This Section must be completed in full in all instances where procedures have been amended.*** |

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| I1: REplacement  |
| If new procedures or animal models have been added, justify why live animals are required instead of using alternative (non-animal) methods.  |
|  |
| I2: REDUCTION |
| If additional animals are required, or the experimental design has changed, provide justification for this, including statistical calculations (as an appendix) if appropriate. |
|  |
| Has any increase in animal numbers been approved by a biostatistician? If yes, provide details of their level of involvement.  |
|  |
| I3: REFINEMENT  |
| Provide details about any changes to:(i) monitoring/scoring arrangements (including in relation to scoresheets) and the application of humane endpoints to ensure the welfare of the animals  |
|  |
| (ii) the care and accommodation provided, e.g. housing, environmental enrichment, diet |
|  |
| (iii) anaesthetic/analgesic regimes  |
|  |

SECTION j: DECLARATION AND UNDERTAKING

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| *The declarations and undertakings below are to be completed by:* * + *the project authorisation holder (user);*
	+ *the project manager for the project (designated pursuant to Regulation 47 of S.I. No. 543 of 2012), and who is responsible for the overall implementation of the project and its compliance with the project authorisation*; *and*
	+ *the compliance officer(s) (designated pursuant to Regulation 44 of S.I. No. 543 of 2012) of the user establishment and where relevant any collaborating user establishment.*

J1: project authorisation holder (user) *The declaration and undertaking below should be signed by or on behalf of the user (i.e. the user or the project manager (designated pursuant to Regulation 47 of S.I. No. 543 of 2012) on behalf of the user).*I hereby **declare** that:* The information contained in this application is true and correct.
* The person listed below in Section J2 is designated as project manager as per Regulation 47 of S.I. No. 543 of 2012.

I hereby **undertake** that in the event of the project authorisation being granted:* To ensure fulfilment of the obligations arising by virtue of the terms and conditions of the project authorisation.
* To ensure fulfilment of the requirements of S.I. No. 543 of 2012.

Signature of project authorisation holder (user): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(or person signing on behalf of the user)Print/type name: Date:  |
| **J2: project manager SIGNATURE***The declaration below should be signed by the existing or proposed project manager (designated pursuant to Regulation 47 of S.I. No. 543 of 2012).*I hereby **declare** that I will be responsible for the overall implementation of the project and its compliance with the project authorisation and shall ensure that:* Any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped.
* The project is carried out in accordance with the relevant project authorisation.
* In the event of non-compliance, the appropriate measures to rectify it are taken and recorded.

Signature of proposed project manager: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print/type name: Date:  |
| **J3: COMPLIANCE OFFICER SIGNATURE (primary user establishment)***The declaration below should be signed by the compliance officer (designated pursuant to Regulation 44 of S.I. No. 543 of 2012) responsible for ensuring* *compliance with the provisions of S.I. No. 543 of 2012 at the relevant user establishment.*I hereby **declare** that:* I am responsible for ensuring compliance with the provisions of S.I. No. 543 of 2012 at the relevant user establishment referred to in Section A.
* The project authorisation holder (user) is affiliated to the primary user establishment referred to in Section A.
* I understand that if the applicant fails to uphold his/her responsibilities under S.I. No. 543 of 2012, in the user establishment or additional locations for which I am compliance officer, this may have implications for the continued authorisation of the user establishment.

Signature of compliance officer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(on behalf of breeder/supplier/user)Print/type name: Date:  |
| **J4: COMPLIANCE OFFICER SIGNATURE (collaborating USER ESTABLISHMENT, where relevant)***The declaration below should be signed by the compliance officer (designated pursuant to Regulation 44 of S.I. No. 543 of 2012) responsible for ensuring compliance with the provisions of S.I. No. 543 of 2012 at the relevant collaborating user establishment. This table can be replicated by copying and pasting if additional collaborating user establishments are required.* I hereby **declare** that:* I am responsible for ensuring compliance with the provisions of S.I. No. 543 of 2012 at the relevant collaborating user establishment referred to in Section A and/or Section D3.
* The project authorisation holder is affiliated to the collaborating user establishment referred to in Section A and/or Section D3.
* I understand that if the applicant fails to uphold his/her responsibilities under S.I. No. 543 of 2012 in the user establishment or additional locations for which I am compliance officer, this may have implications for the continued authorisation of the user establishment.

Signature of compliance officer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(on behalf of breeder/supplier/user)Print/type name: Date:  |

Checklist of documentation to be submitted with the application

Amended project protocol – highlighted to identify changes [ ]

Copy of ethical review application and associated documentation (where relevant) [ ]

Ethics approval document (where relevant) [ ]