Application for a Project Authorisation under Scientific Animal Protection Legislation

For details on completing this application form, refer to the ‘Guide to Project Applications under Scientific Animal Protection Legislation’ available at www.hpra.ie.

SECTION A: PROJECT TITLE and proposed project Authorisation holder

(i.e. user)

|  |  |
| --- | --- |
| PROJECT TITLE (≤ 500 characters) |  |
| Name of proposed project authorisation holder (i.e. user) |  |
| Address  |  |
| Eircode |  |
| Email |  |
| Telephone |  |

SECTION B: PERSONNEL AND breeder/supplier/user ESTABLISHMENT DETAILS

|  |
| --- |
| **B1: PROJECT MANAGER** |
| Title |  |
| First name |  |
| Surname |  |
| Address  |  |
| Eircode |  |
| Email |  |
| Telephone |  |
| Individual authorisation number | AE / I |
| If no current individual authorisation is held, state the date of application for an individual authorisation: |

|  |
| --- |
| **B2: DEPUTY PROJECT MANAGER(S)** (*if applicable)* *For multiple deputy project managers, select the entire table and copy and paste as required.*  |
| Title |  |
| First name |  |
| Surname |  |
| Address  |  |
| Eircode  |  |
| Email |  |
| Telephone |  |
| Individual authorisation number | AE / I |
| If no current individual authorisation is held, state the date of application for an individual authorisation: |

|  |
| --- |
| B3: PREVIOUS PROJECT AUTHORISATIONS Where applicable, provide the project authorisation number(s) and expiry date(s) of all HPRA project authorisations currently or previously held by the project authorisation holder, project manager and deputy project manager(s) within the past five years. *Please add additional rows if necessary.*  |
| AUTHORISATION NUMBER | EXPIRY DATE  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

|  |
| --- |
| **B4: USER ESTABLISHMENT DETAILS** |
| NAME OF THE PRIMARY USER ESTABLISHMENT  | PRIMARY USER ESTABLISHMENT HPRA AUTHORISATION NUMBER |
|  |  |
| For establishments with multiple animal facilities, name of facility (or facilities) where project will be conducted:  |

|  |
| --- |
| **B5: COLLABORATING USER ESTABLISHMENT DETAILS** *(if applicable)*In the case of a collaboration, list the user establishment name and authorisation number of each user establishment at which the user will participate in project work. *Please add additional rows if necessary.*  |
| NAME OF THE COLLABORATING USER ESTABLISHMENT | COLLABORATING USER ESTABLISHMENT HPRA AUTHORISATION NUMBER |
|  |  |
|  |  |

|  |
| --- |
| **B6: ADDITIONAL LOCATIONS** *(if applicable)*List any location other than an authorised user establishment(s) where procedures will be carried out (e.g. commercial farms/inland waterways). Please provide justification as to why procedures cannot be performed at an authorised user establishment, and why each additional location is necessary.*Please add additional rows if necessary.*  |
| ADDITIONAL LOCATION  | JUSTIFICATION FOR LOCATION  |
|  |  |
|  |  |

Section C: Project information

|  |  |
| --- | --- |
| 1. Is this project being performed solely to satisfy regulatory requirements? | [ ]  Yes[ ]  No |
| If ‘yes’, provide details in relation to the relevant statutory requirements and/or regulatory guidelines that will be fulfilled by completing the project: |
| 2. Is this project application solely for production or diagnostic purposes using recognised established methods (e.g. production of antibodies, serum-based medicinal products, other biological material)? | [ ]  Yes[ ]  No |
| If ‘yes’, state the likely demands for the service or product in the lifetime of this proposed authorisation: |
| 3. Does this project involve any use of neuromuscular blocking agents (NMBAs)?  | [ ]  Yes[ ]  No |
| If ‘yes’, provide robust justification as to why the objectives of this project cannot be achieved without the use of such an agent: |
| 4. Has this project been approved by an ethics committee? | [ ]  Yes[ ]  No |
| If ‘no’, complete the ‘Fee Application Form for Scientific Animal Protection’ available at [www.hpra.ie](http://www.hpra.ie). Include the appropriate fee and provide a justification as to why an ethical review was not performed: If ‘yes’, provide a copy of the ethical review application, approval documentation and any correspondence/documentation to/from the relevant ethics committee in which queries have been raised and addressed. |
| 5. State the expected duration of project work in months *(maximum is 60 months)*:  |
| 6. State the estimated start date of project work, while considering the HPRA timeline for project evaluation of 40 working days, or subject to a fee, the 21 working day fast-track\* timeline: *\*Please contact* accounts@hpra.ie *to arrange payment for fast-track evaluation.*  |
| 7. In the below table, enter the total number of animals per species to be used for this project.*Please add additional rows if necessary.*  |
| SPECIES | NUMBER OF ANIMALS |
|  |  |
|  |  |

SECTION D: programme of work

|  |
| --- |
| **D1: PURPOSE OF THE PROJECT**Provide information on the proposed purpose(s) of this project, selecting the most relevant from the list below (refer to Appendix IV in the ‘Guide to Project Applications under Scientific Animal Protection Legislation’ available at [www.hpra.ie](http://www.hpra.ie) for explanations of project purposes and sub-fields).In most projects, only one project purpose should be selected.[ ]  Basic research - *select sub-field from drop-down list:*Select subfield[ ]  Translational and applied research - *select sub-field from drop-down list:*Select subfield[ ]  Regulatory use and routine production - *select sub-field from drop-down list:*Select subfield[ ]  Protection of the natural environment in the interests of the health or welfare of human beings or animals[ ]  Preservation of species[ ]  Higher education[ ]  Training for the acquisition, maintenance or improvement of vocational skills[ ]  Maintenance of colonies of established genetically altered animals, not used in other procedures[ ]  Forensic inquiries |

|  |
| --- |
| **D2: PROJECT DETAILS**1. Describe the background and current state of scientific knowledge for the work to be performed on this project, including, where relevant, any goals you have already achieved under previous studies in the area (≤ 5000 characters):  |
|  |
| 2. Describe the overall purpose and specific objectives of this project, setting out clearly the key scientific questions to be addressed. Explain how the objectives of this project differ from the findings of previous studies in this area (≤ 5000 characters):  |
|  |
| 3. Detail the expected scientific benefits of the project and the significance of these benefits. Describe clearly how the benefits are likely to be realised (e.g. by your group, other researchers, the pharmaceutical industry, clinicians, human patients or animals) (≤ 5000 characters): |
|  |
| 4. Describe how the results (including negative results) will be disseminated (≤ 5000 characters): |
|  |
| 5. Describe the resources available (including staffing, experience of personnel and equipment and funding) for the project. It is important to ensure that all of these resources will be in place for the entire duration of the planned project (≤ 5000 characters):  |
|  |
| 6. List the most relevant key references or regulatory guidelines (up to 10) supporting the need for the project:  |
|  |
|  |
|  |
|  |
|  |

SECTION E: NON-TECHNICAL project SUMMARY

Provide a completed ‘Non-Technical Project Summary for a Project under Scientific Animal Protection Legislation’form in **Excel** format, using the template which is available on the Scientific Animal Protection Guides and Forms section of [www.hpra.ie](http://www.hpra.ie).

SECTION F: EXPERIMENTAL DESIGN

Using the table below, provide information on each of the procedures to be carried out as part of this project **in chronological order**.

*Copy and paste the below table if additional procedures are to be added.*

|  |  |
| --- | --- |
| **PROCEDURE NUMBER**  | **PROCEDURE NAME:**   |
| Description/details of procedure |  |
| Justification/relevance of procedure |  |
| Species |  |
| Life stage or age |  |
| Number of animals to be used |  |
| Frequency (how many times will the procedure be performed?) |  |
| Duration (how long will the procedure take/how long will the animal be affected for?) |  |
| Proposed severity classification of the procedure | Select severity |
| 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). |
|  |
| What is the fate of the animals at the end of this procedure?  |
| Select fate | If other, please specify:  |
| If the fate is euthanasia, choose the method | Select method |
| If this method is not an approved Annex IV euthanasia method (see Directive 2010/63/EU), provide justification: |  |

|  |  |
| --- | --- |
| **PROCEDURE NUMBER**  | **PROCEDURE NAME:**  |
| Description/details of procedure |  |
| Justification/relevance of procedure |  |
| Species |  |
| Life stage or age |  |
| Number of animals to be used |  |
| Frequency (how many times will the procedure be performed?) |  |
| Duration (how long will the procedure take/how long will the animal be affected for?) |  |
| Proposed severity classification of the procedure | Select severity |
| 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). |
|  |
| What is the fate of the animals at the end of this procedure?  |
| Select fate | If other, please specify: |
| If the fate is euthanasia, choose the method | Select method |
| If this method is not an approved Annex IV euthanasia method (see Directive 2010/63/EU), provide justification: |  |

|  |  |
| --- | --- |
| **PROCEDURE NUMBER**  | **PROCEDURE NAME:**  |
| Description/details of procedure |  |
| Justification/relevance of procedure |  |
| Species |  |
| Life stage or age |  |
| Number of animals to be used |  |
| Frequency (how many times will the procedure be performed?) |  |
| Duration (how long will the procedure take/how long will the animal be affected for?) |  |
| Proposed severity classification of the procedure | Select severity |
| 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 estimated the % 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). |
|  |
| What is the fate of the animals at the end of this procedure?  |
| Select fate | If other, please specify: |
| If the fate is euthanasia, choose the method | Select method |
| If this method is not an approved Annex IV euthanasia method (see Directive 2010/63/EU), provide justification: |  |

Overall severity

|  |
| --- |
| Select the predicted **overall severity** that the animals in this project may experience, taking into account all the procedures they will undergo, the potentially cumulative nature of multiple procedures and the contingent harms to the animals.Select severity |
| **If different groups of animals are expected to experience different overall severities within this project, provide a breakdown of each severity using percentages:**  |

Project protocol

Please append, as a separate document, the **project protocol(s)**. The project protocol must include the following:

1. Details of each procedure (e.g. methods/SOPs)
2. Chronological timelines outlining at which stage of the study each procedure will be performed, in schematic or illustrative form (e.g. flow charts/diagrams)
3. A breakdown of experimental groups with animal numbers

SECTION G: The 3Rs and welfare monitoring

|  |
| --- |
| **G1: APPLICATION OF THE 3Rs** |
| **REPLACEMENT** |
| 1. What, if any, *in silico*, *in vitro* or *ex vivo* methods have you used to date, or do you plan to use, and how will they integrate into this project (≤ 5000 characters)?  |
|  |
| 2. Provide the reasons why the objectives of this project are not achievable through the use of alternative methods to animal testing. Describe any alternatives you have considered and why they are not suitable (≤ 5000 characters): |
|  |
| 3. State the sources consulted to track possible alternatives and indicate how recently the consultation was performed. Include keywords used in searches. (≤ 5000 characters): |
|  |
| **REDUCTION** |
| 4. Provide justification on the number of animals to be used in this project, specifying the principles of experimental design used to calculate the sample group size, details of pilot studies (where relevant), and details of statistical calculations performed (≤ 5000 characters): |
|  |
| 5. State the experimental unit (e.g. a single animal, group or cage of animals), providing justification for this (≤ 5000 characters): |
|  |
| 6. Provide details of any measures in place to ensure that this study is reproducible and translatable (if relevant, include details on inclusion and exclusion criteria) (≤ 5000 characters):  |
|  |
| 7. Provide details of randomisation and blinding (to prevent bias) (≤ 5000 characters):  |
|  |
| 8. State the sex of the animals to be used, providing justification for this choice (≤ 5000 characters): |
|  |
| 9. Has an experienced statistician approved the experimental design?[ ]  Yes[ ]  No |
| If yes, provide details of their level of involvement:  | If no, please justify:  |
| **REFINEMENT** |
| 10. Explain why: (a) the choice of species, (b) the strain/breed,(c) and the model (if relevant),are the most refined to achieve the aims and objectives of the project (≤ 5000 characters):  |
|  |
| 11. For each procedure explain why this is the most refined choice for this project (≤ 5000 characters): |
|  |
| 12. Provide details on the humane endpoints which will be implemented in this project, and why they are most appropriate (≤ 5000 characters): |
|  |
| 13. Will environmental enrichment be provided?[ ]  Yes[ ]  No |
| If yes, provide details:  | If no, provide justification, and where relevant, details of compensatory refinements:  |
| 14. Will there be any individual housing/penning of animals?[ ]  Yes[ ]  NoIf yes, provide justification on scientific or welfare grounds: *(If individual housing is planned, refer to the ‘Guide to Project Applications under Scientific Animal Protection Legislation’ available at* [*www.hpra.ie*](http://www.hpra.ie) *to determine if individual housing should be entered as an additional procedure under* ***Section F****.)* |
| 15. If farm animals are proposed for use, will they be housed in accordance with the space requirements of Annex III of Directive 2010/63/EU?[ ]  Yes[ ]  No[ ]  Not applicable (not farm animals)If no, please provide a justification: |
| 16. If animals are to be transported to the facility, please confirm the period of acclimatisation they will be provided with prior to the commencement of procedures? |
|  |  |

|  |
| --- |
| **G2: ANIMAL WELFARE MONITORING ARRANGEMENTS** 1. Provide details about how the welfare of the animals will be monitored and scored by the research team throughout the project, including:(a) who will monitor and score the animals,(b) how often they will be monitored and scored and for how long (i.e. over what time period of the entire study), and(c) what action will be taken if welfare concerns are detected. *(If score sheets will be used, these should be included with this application.)* |
|  |

SECTION h: animal information

|  |
| --- |
| **H1: ANIMALS TO BE USED**1. If the species to be used in this project is a species listed in Annex I to Directive 2010/63/EU, have these animals been bred specifically for use in scientific procedures:[ ]  Yes[ ]  No[ ]  Not applicable (not an Annex I species)If ‘no’, provide scientific justification for the reasons the animals were not specifically bred for use in procedures:  |
| 2. Are the animals to be used in this project (select all that apply):[ ]  Taken from the wild [ ]  An endangered species[ ]  Stray/feral animals of a domestic species If any of the above have been selected, provide scientific justification:  |

|  |
| --- |
| **H2: ANIMAL SPECIES AND STRAINS** |
| Provide information on the species of animal(s) to be used in this project in the table(s) below.*The table can be replicated by copying and pasting as many times as required depending on the number of species/strains/breeds requested for use.* |

|  |  |
| --- | --- |
| Species |  |
| Life stage or age  |  |
| Strain/breed |  |
| Genetic status(Please note for the purpose of this application, spontaneous/induced mutants are also considered genetically altered)*(Please refer to the ‘Guide to Project Applications under Scientific Animal Protection Legislation’ available at* [*www.hpra.ie*](http://www.hpra.ie) *for further information on genetic status.)* | Select genetic status |
| Details of the genetic alteration, e.g. what will the phenotypical change be (if any) including chronology and details of any adverse effects of the genetic alteration |  |
| If the phenotype is harmful, provide details of specific refinements and monitoring arrangements, including humane endpoints, that will be put in place to ensure the welfare of the animals *(If relevant, include a score sheet)* |  |
| Name of supplier establishment (from where animals originate)  |  |
| Authorisation number of above supplier establishment (where relevant)  |  |
| Country of origin |  |
| Have these particular animals been previously used in another project (i.e. will this be a ‘reuse’ of these animals)? | [ ]  Yes[ ]  No |
| If yes, specify the actual severity of the previous procedure(s). | Select severity |
| If yes, has the animal’s general state of health and well-being been fully restored? | [ ]  Yes[ ]  No |
| If yes, is the reuse in accordance with veterinary advice, taking into account the life-time experience of each animal? | [ ]  Yes[ ]  No |
| Number of animals to be used |  |

|  |  |
| --- | --- |
| Species |  |
| Life stage or age  |  |
| Strain/breed |  |
| Genetic status(Please note for the purpose of this application, spontaneous/induced mutants are also considered genetically altered)*(Please refer to the ‘Guide to Project Applications under Scientific Animal Protection Legislation’ available at* [*www.hpra.ie*](http://www.hpra.ie) *for further information on genetic status.)* | Select genetic status |
| Details of the genetic alteration, e.g. what will the phenotypical change be (if any) including chronology and details of any adverse effects of the genetic alteration |  |
| If the phenotype is harmful, provide details of specific refinements and monitoring arrangements, including humane endpoints, that will be put in place to ensure the welfare of the animals *(If relevant, include a score sheet)* |  |
| Name of supplier establishment (from where animals originate)  |  |
| Authorisation number of above supplier establishment (where relevant)  |  |
| Country of origin |  |
| Have these particular animals been previously used in another project (i.e. will this be a ‘reuse’ of these animals)? | [ ]  Yes[ ]  No |
| If yes, specify the actual severity of the previous procedure(s). | Select severity |
| If yes, has the animal’s general state of health and well-being been fully restored? | [ ]  Yes[ ]  No |
| If yes, is the reuse in accordance with veterinary advice, taking into account the life-time experience of each animal? | [ ]  Yes[ ]  No |
| Number of animals to be used |  |

SECTION I: DECLARATION AND UNDERTAKING

|  |
| --- |
| *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.*

I1: Proposed 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 I2 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 proposed project authorisation holder (user): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(or person signing on behalf of the user)Print/type name: Date:  |
| **I2: Proposed project manager SIGNATURE***The declaration below should be signed by the 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:  |
| **I3: 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 B4.
* The project authorisation holder (user) is affiliated to the primary user establishment referred to in Section B4.
* 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:  |
| **I4: 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 B5.
* The proposed project authorisation holder is affiliated to the collaborating user establishment referred to in Section B5.
* 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**

Project protocol(s) [ ]  Non-technical project summary form in Excel format [ ]  CV(s) setting out education, training, experience and publication history [ ]  Copy of ethical review application and associated documentation including queries and responses (where relevant)  [ ]

Ethics approval documentation (where relevant) [ ]

Animal welfare score sheets (where relevant) [ ]

Fee application form and the appropriate fee (where relevant\*) [ ]

\*Fees are not required for project authorisation applications submitted for evaluation on the standard 40 working day timeline. Fees are only required for fast-track applications (requesting evaluation on a 21 working day timeline) and/or for applications submitted without prior ethical approval. If applicable, the appropriate fee must be paid before the application can be validated for evaluation. Further information in relation to fees can be found on the HPRA website [here](http://www.hpra.ie/homepage/veterinary/scientific-animal-protection/sap-guides-and-forms/fee-information). Queries in relation to the payment of fees should be submitted to accounts@hpra.ie.