

Guide to Transfers of Project Authorisations under Scientific Animal Protection Legislation

AUT-G0135-23

15 JANUARY 2019

This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



CONTENTS

1	SCOPE	3
2	INTRODUCTION	3
3	APPLICATIONS FOR A PROJECT TRANSFER	3
3.1	Existing project authorisation holder declaration	3
3.2	Proposed project authorisation holder declaration and undertaking and compliance officer/ proposed new compliance officer declaration	4
4	MAKING AN APPLICATION	4
5	ADMINISTRATIVE DETAILS	7
1	SCOPE	3
2	INTRODUCTION	3
3	APPLICATIONS FOR A PROJECT TRANSFER	3
3.1	Existing project authorisation holder declaration	3
3.2	Proposed project authorisation holder declaration and undertaking and compliance officer/ proposed new compliance officer declaration	4
3.3	Ethical approval	4
4	MAKING AN APPLICATION	4
5	ADMINISTRATIVE DETAILS	7

1 SCOPE

This guidance is intended to assist applicants in completing a Health Products Regulatory Authority (HPRA) 'Application for Transfer of a Project Authorisation under Scientific Animal Protection Legislation'.

2 INTRODUCTION

An authorisation holder cannot transfer a project authorisation to another user unless granted a transfer of the relevant project authorisation by the HPRA. An authorisation holder can be a person, such as the project manager, or the breeder/supplier/user establishment, or a commercial entity.

3 APPLICATIONS FOR A PROJECT TRANSFER

In order to transfer a project authorisation, the project authorisation holder must submit a completed 'Application ~~Form~~ for Transfer of a Project Authorisation under Scientific Animal Protection Legislation'.

In certain circumstances a project amendment application may also be required (e.g. change of project manager, ~~change of location), therefore~~). Therefore, please refer to the 'Guide to Amendment and Renewal Applications for Projects under Scientific Animal ~~Protection~~. Protection Legislation'.

The HPRA endeavours to complete the assessment of a project authorisation transfer application within 40 working days. Timeframes may be extended if:

- Applications are incomplete or incorrect
- Queries are raised during the assessment
- Responses to queries from the applicant are delayed
- An inspection of the establishment is required

3.1 Existing project authorisation holder declaration

The declaration in ~~section~~Section B must be signed by the existing project authorisation holder or a person signing on behalf of the user: ~~(i.e. if the user is a legal entity rather than a person)~~.

3.2 Proposed project authorisation holder declaration and undertaking and compliance officer/-proposed new compliance officer declaration

The declaration and undertaking in Section C of the application form must be signed by the proposed (new) authorisation holder.

~~If the transfer is between project authorisation holders within the same establishment, then the~~ compliance officer of ~~the~~that establishment ~~where the project is taking place~~ must sign the declaration in Section D on behalf of the user. Where a transfer is requested between two different user establishments, the compliance officer of the newly proposed user establishment must sign the relevant declaration in Section D.

In the event that the project authorisation transfer is granted, by signing the confirmation, declarations and undertaking both persons are assuming the responsibility for the overall implementation and compliance of the project with the scientific animal protection legislation and with respect to fulfilment of the conditions and obligations as set out in the declarations and undertaking. They are also confirming that they will comply with any conditions which may be imposed in the authorisation itself.

3.3 -Ethical approval

In circumstances where a transfer is requested between project authorisation holders in two different establishments, evidence of approval by the local ethics committee in the newly proposed user establishment should be provided. This should include any correspondence and/or documentation to/from the ethics committee in which queries are raised or addressed.

4 MAKING AN APPLICATION

A project transfer application consists of the following:

- A complete and signed project transfer application form;
- Ethics committee approval document, ethics committee review and/or accompanying documentation (if applicable)
- A covering letter (if applicable)

~~Signed copies of all application forms must be submitted to the HPRA through submission of a digital copy or scanned original document.~~

The HPRA requests that applications and their accompanying documents are named appropriately. Each document name should begin with the original project authorisation number. This should be followed by an underscore and one of the following words/phrases:

- Transfer application form: to be used for the transfer application form

- ECR: Ethics committee approval document, ethics committee review and/or accompanying documentation (where applicable)
- Cover letter (where applicable)

See example below:

DOCUMENT	FILE NAME
Transfer application form	AE12345_P001_Transfer application form
<u>Ethics committee application</u>	<u>AE12345 PAN ECR1</u>
<u>Ethics committee approval document</u>	<u>AE12345 PAN ECR2</u>
<u>Ethics committee correspondence</u>	<u>AE12345 PAN ECR3</u>
Cover letter	AE12345_P001_Cover letter

5 ADMINISTRATIVE DETAILS

Due to the possible sensitive nature of information contained in transfer applications, the HPRA provides a secure online system to enable submission of applications and data. This system is known as CESP, the Common European Submission Platform.

Applications can also be submitted by standard e-mail to sapsubmit@hpra.ie.

All information requested must be provided in the application. Applications that do not include the necessary information are not eligible for HPRA evaluation. If an application is incomplete, the applicant is notified as ~~quickly~~soon as possible via the e-mail address on the application form.

Queries in respect of application requirements or communications relating to applications submitted can be made by telephone or e-mail:

Tel:- +353 1 676 4971

E-mail:- sap@hpra.ie

Fees:

 Currently there are no fees for this application.