



University of the  
Highlands and Islands  
Oilthigh na Gàidhealtachd  
agus nan Eilean

# **Research Ethics Framework**

## **Ethical Approval: Policy, Principles and Process**

**August 2019**

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# 1 Introduction

This document sets out the policy, principles and processes which govern ethical approval of all research studies undertaken by staff or students of the University of the Highlands and Islands. The UHI Research Ethics Framework has been designed to support a fair balance between a researcher's right to unrestricted academic enquiry whilst ensuring adherence to appropriate and robust ethical standards in order to ensure the protection of all those participating in research studies.

## 2 Definitions

The UHI Research Ethics Framework employs the following definitions:

**'Research'** is defined in the broadest sense as any gathering of data or facts to facilitate a contribution to the body of knowledge;

**'Student'** is used as the umbrella term for all UHI Undergraduate, Taught Postgraduate and Research Students registered on UHI programmes;

**'Staff'** is used as the umbrella term for all staff members employed by the UHI and its partner colleges;

**'Participant'** is used to describe any person who, either as an individual or as a member of a sample group, is involved in a research study for the purposes of quantitative or qualitative data collection;

**'REC'** – Research Ethics Committee;

**'AWEC'** – Animal Welfare and Environment Committee;

**'HSC'** – Health Sub Committee;

**'SNL'** – Subject Network Leader.

## 3 Ethical policy

UHI requires all research undertaken by students and staff to be carried out to a high ethical standard.

The Research Ethics Framework applies equally to all research projects led or undertaken by UHI staff or students, as well as all research projects involving staff or students as a sample group. This includes activity which:

- is internally or externally funded or unfunded;
- involves paid or voluntary participants;
- is undertaken on UHI/Academic Partner property or at any other location;
- is undertaken in a laboratory or in the field;

- involves data collection undertaken in person or by any other means;
- involves research which is basic or applied, descriptive or experimental.

The UHI Research Ethics Framework is intended to ensure adherence to the Nolan Principles, and the [Ethical Standards in Public Life etc. \(Scotland\) Act 2000](#) and should be read in the context of [UHI's Data Protection Policy](#) and [Freedom of Information Policy](#). It may also require to be read with other Professional Codes of Practice for research involving human participants, human data or material, in particular:

- Health-related research involving the National Health Service which will need to comply with NHS Research Ethics Guidelines.
- Any research involving children under the age of 18, which will need to refer to the [Protection of Children \(Scotland\) Act 2003](#) and all other relevant applicable legislation.
- Research involving animals that comes under the Regulated procedures under the terms of the [Animals \(Scientific Procedures\) Act 1986](#) will be escalated to the AWEC for review. Applicants should also review the [Guiding Principles on good practice for Animal Welfare and Ethical Review Bodies](#) prior to submitting their application.

The UHI Ethical policy may also require to be read alongside legislation giving protection to animal and plant species found in Scotland including the [Wildlife and Countryside Act 1981](#) and [The Conservation \(Natural Habitats, &c.\) Regulations 1994](#). In many cases it is an offence to kill, capture or even disturb animals (including birds), or to uproot plants. Applicants should review the wild species protected under the [Wildlife and Countryside Act 1981](#) and the [Protection of Badgers Act 1992](#) for activities requiring a licence from [Scottish Natural Heritage](#) or from the [British Trust for Ornithology](#).

Some activities also require a license from [Marine Scotland](#) e.g. for work on the seabed, or for work on seals that comes under the Protection of seals under the [Marine Scotland Act 2010](#).

With regards to the releasing of plant material, seeds or animal species – this activity would come under section 14 of the [Wildlife and Countryside Act](#). The [non-native code of practice](#) outlines the responsibilities of researchers working in this area.

Applicants should review guidance applicable to their research with their project supervisor prior to applying for ethics approval.

The UHI Research Ethics Framework is developed in keeping with accepted norms and practices of research in other higher education institutions and professional bodies in the UK and abroad, including:

- consideration of the research risks - '*does not harm*';
- the need for informed and voluntary consent of participants;
- the need to respect confidentiality and the anonymity of participants.

It is the responsibility of all researchers to consider ethical issues from the outset of a research

study and at all subsequent stages, from the design and execution of a research project through to dissemination of the research findings. It is the responsibility of all researchers to be aware of the UHI Research Ethics Review mechanism and to read this document before completing their application for ethical approval.

## 4 Ethical principles

These principles are intended to ensure that all research is designed and undertaken with integrity:

- I. All researchers and participants must be fully informed of the nature of the research being undertaken. In particular, participants must be informed of what their participation entails and of any risks that may be incurred.
- II. Participants must give their consent voluntarily, free from any coercion.
- III. Any data and information gathered must be treated confidentially and the anonymity of participants respected.
- IV. Harm to participants must be avoided.
- V. Research must be carried out transparently and impartially and any potential conflicts of interest declared.
- VI. Researchers should give cognisance to any cultural, religious, gender or other variances in a research population.

The University also works to improve animal welfare and to minimise animal suffering through implementation of the “3Rs”. These are:

- Replacement of animals, wherever possible, with alternative systems with which to conduct research.
- Reduction of the number of animals used to the minimum consistent with the desired outcome (e.g. through careful review of the literature, careful experimental design and rigorous statistical testing).
- Refinement of procedures so that the least possible harm is done in collecting the scientific information.

## 5 Process of ethical approval

The UHI Research Ethics Framework supports a robust process for ethical approval of all research that a UHI staff member or student proposes to undertake. **No research may be allowed to go ahead without ethical approval having been first gained as part of this process.** The UHI Research Ethics Committee (REC), Animal Welfare and Environment Committee (AWEC) and Health Sub Committee (HSC) are actively involved in ensuring that appropriate decisions

regarding ethical approval are taken.

Ethical approval for student research lies initially with the student's lead project supervisor, who is responsible for exercising appropriate professional judgement in the ethical review.

A student will discuss the proposed research project with his/her supervisor, covering such areas as topic understanding, research questions, data requirements, existing sources and possible new sources of information.

Prior to endorsing applications, supervisors / line managers **must have completed** the Ethics Reflection and Practice module. For access to the module please contact [fiona.leiper@uhi.ac.uk](mailto:fiona.leiper@uhi.ac.uk)

The processes for ethical approval of research studies proposed by both staff and students employ the same stages.

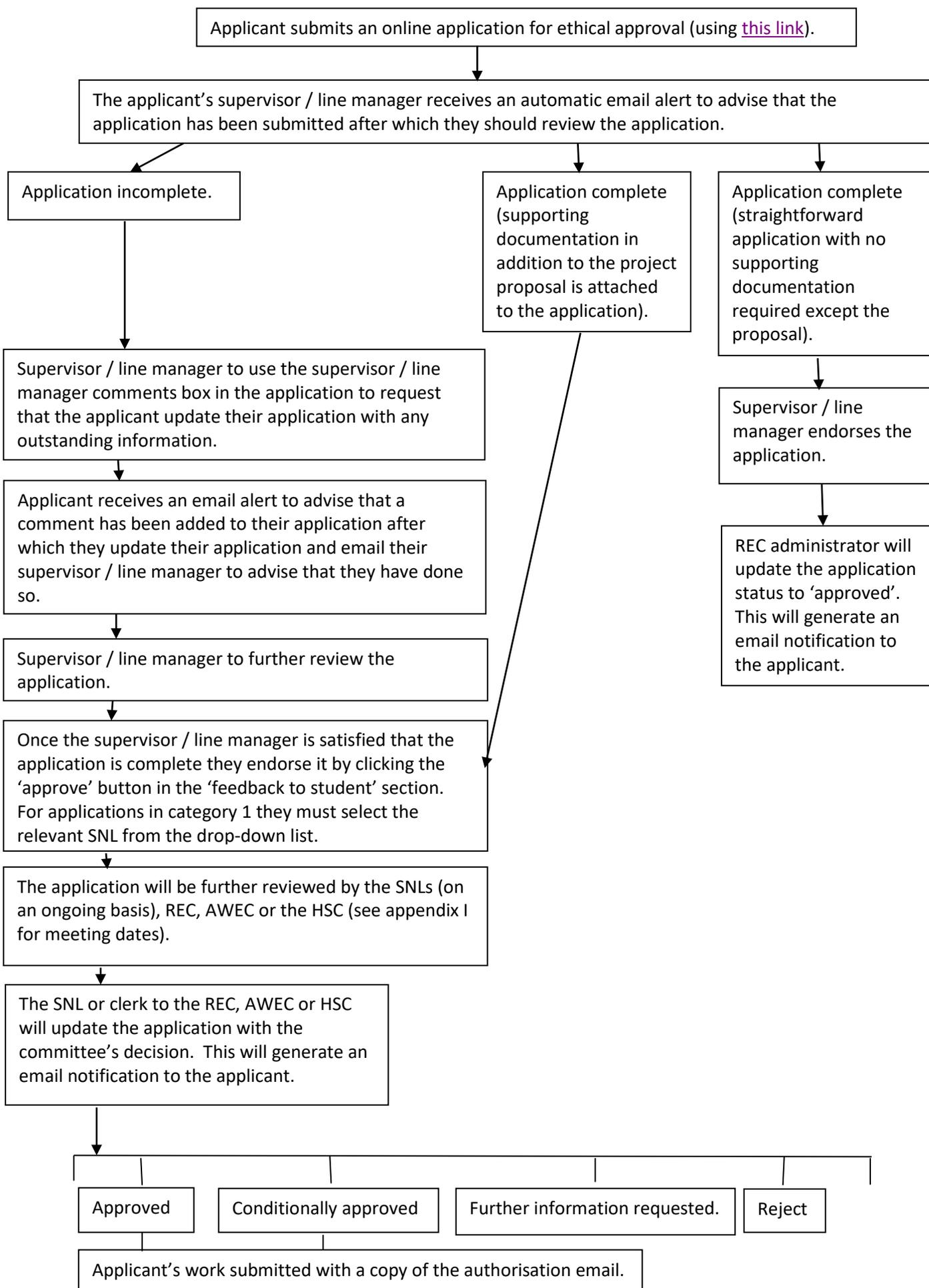
There are 7 different categories of applications as follows:

	<b>Category</b>
1.	Undergraduate, Taught postgraduate / Masters <b>students</b>
2.	Undergraduate, Taught postgraduate / Masters and PhD <b>*clinical students</b>
3.	PhD research <b>students</b> (excluding <b>*clinical</b> )
4.	UHI School of Health, Social Care and Life Sciences <b>staff</b> projects
5.	UHI sponsored <b>staff</b> health projects
6.	UHI non-health <b>staff</b> projects
7.	UHI non-funded <b>staff</b> projects (excluding <b>*clinical</b> )

*\* Where the word 'clinical' is used it means 'involving or relating to the direct medical treatment or testing of participants in the research'*

It is essential that applicants read the undernoted summary of the processes as overleaf:

## 6 Applications for ethical approval flowchart



## 7 A step by step guide to the application process for category 1 applications

### 7.1 Applicant to complete their application by accessing [this link](#) which will take you to the application portal which is hosted on SharePoint

- Care must be taken when completing the application; please ensure it is fully completed and all relevant supporting documentation is uploaded. See appendix II for guidance notes to assist with completing the application form.
- Failure to complete the application in full will lead to a delay in it being processed.
- If you require assistance with completing the application please contact the Research Ethics Officer [fiona.leiper@uhi.ac.uk](mailto:fiona.leiper@uhi.ac.uk) (tel. 01463-279347)

### 7.2 Application is either saved or submitted

- An applicant who has saved (and not submitted) their application will receive an email alert to advise that their application has been saved. That email will contain a link back into their application.
- On submission of an application the applicant will receive an email alert to advise that their application has been submitted. That email will contain a link back into their application. Their supervisor / line manager will receive an email alert to advise that an application has been submitted and is ready for their review.

### 7.3 Supervisor / line manager to review the application

It is essential that all supervisors / line managers undertake the Blackboard module 'Ethics Reflection and Practice' before endorsing applications for ethical approval. The research they are being asked to endorse cannot commence until they have completed the module. If you are a supervisor and do not already have access to the module please contact [fiona.leiper@uhi.ac.uk](mailto:fiona.leiper@uhi.ac.uk) and she will set up your access.

Supervisors / line managers should review the application within 10 working days of receiving their email alert, remembering to select the 'edit' icon in the top left corner to enable them to type comments in the application. If they plan to be on annual leave they should ensure that their staff and students are aware, in advance, so that if applications for ethical approval are submitted in their absence they will be aware of the delay in their review.

The supervisor / line manager has responsibility to ensure the application is absolutely complete and that all supporting documentation is full and accurate.

The supervisor / line manager must, once they have reviewed the application, complete the project supervisor authorisation section of the application form.

#### **7.4 Supervisor / line manager to liaise with the applicant to gather outstanding information**

The supervisor / line manager must liaise with the applicant to gather any outstanding information; this should be done through updating the supervisor / line manager comments box of the application form and selecting the 'place on hold' option.

#### **7.5 Applicant will receive an email alert regards outstanding information**

The applicant will receive an email alert to advise that a comment has been added to their application. It is then their responsibility to update the application by uploading any additional and amended documents and email their supervisor / line manager to advise them when they have updated their application.

#### **7.6 Supervisor / line manager will receive an email to advise that the application has been updated**

The supervisor / line manager will receive an email directly from the applicant to advise that the application has been updated.

#### **7.7 Supervisor / line manager to further review the application**

Please refer back to 7.3.

#### **7.8 Supervisor / line manager to update the project supervisor / line manager authorisation section of the application form**

The supervisor / line manager must, once they have reviewed the application, complete the project supervisor authorisation section of the application form, remembering to select the 'edit' icon in the top left corner to enable them to type comments in the application. When they are satisfied that the application is complete and ready for further review they should endorse the application. **It is essential that supervisors / line managers do not endorse incomplete applications as that will delay the research commencing.**

#### **7.9 SNLs or administrator will receive an application email alert**

When the supervisor / line manager has endorsed a category 1 application, the relevant SNL or administrator (for applications that have no supporting documentation other than the research proposal) will receive an email alert to advise that the application is ready to be further reviewed.

#### **7.10 SNLs to review the application form**

The first and second SNL will review the application within 10 days, remembering to select the

'edit' icon in the top left corner to enable them to type comments in the 'AWEC/REC/SNL private messaging' section of the application, and liaise with the applicant to obtain any outstanding information (for which they must use the 'feedback to student' box in the application form) after which they will approve the application (once they are satisfied that all relevant information is included in the application).

#### **7.11 Applicant will receive an approval email**

Once the first SNL or administrator has approved the application the applicant will receive an email notification to that effect, after which their research may commence.

#### **7.12 Application to be considered by REC, AWEC or the HSC (in exceptional circumstances)**

When the administrator updates the application to indicate that it will be escalated to REC, AWEC or the HSC for review the applicant and their supervisor / line manager will receive an email to advise.

#### **7.13 REC Clerk to escalate the application to REC or AWEC for full review**

The REC Clerk will pass application for REC or AWEC review (see Appendix I for meeting dates).

#### **7.14 Post REC or AWEC update**

Once the REC, AWEC or Health Sub Committee have reviewed the application, the committee clerk will update the application status from the list below:

- Approved by REC
- Approved by AWEC
- Approved by HSC
- REC conditional approval
- AWEC conditional approval
- HSC conditional approval
- REC reject
- AWEC reject
- HSC reject
- Research has been noted

and the applicant and their supervisor / line manager will receive an email notification.

## 8 A step by step guide to the application process for categories 2-7 applications

### 8.1 Applicant to complete their application by accessing [this link](#) which will take you to an application form hosted on SharePoint

- Care must be taken when completing the application; please ensure it is fully completed and all relevant supporting documentation is uploaded. See appendix II for guidance notes to assist with completing the application form.
- Failure to complete the application in full will lead to a delay in it being processed.
- If you require assistance with completing the application please contact the Research Ethics Officer [fiona.leiper@uhi.ac.uk](mailto:fiona.leiper@uhi.ac.uk) (tel. 01463-279347)

### 8.2 Application is either saved or submitted

- An applicant who has saved (and not submitted) their application will receive an email alert to advise that their application has been saved. That email will contain a link back into their application.
- On submission of an application the applicant will receive an email alert to advise that their application has been submitted. That email will contain a link back into their application. Their supervisor / line manager will receive an email alert to advise that an application has been submitted and is ready for their review.

### 8.3 Supervisor / line manager to review the application

It is essential that all supervisors / line managers undertake the Blackboard module 'Ethics Reflection and Practice' before endorsing applications for ethical approval. The research they are being asked to endorse cannot commence until they have completed the module. If you are a supervisor and do not already have access to the module please contact [fiona.leiper@uhi.ac.uk](mailto:fiona.leiper@uhi.ac.uk) and she will set your access up.

Supervisors / line managers should review the application within 10 working days of receiving their email alert remembering to select the 'edit' icon in the top left corner to enable them to type comments in the application. If they plan to be on annual leave they should ensure that their staff and students are aware, in advance, so that if applications for ethical approval are submitted in their absence they will be aware of the delay in their review.

The supervisor / line manager has responsibility to ensure the application is absolutely complete and that all supporting documentation is full and accurate. **Endorsement of incomplete applications will delay the research commencing.**

The supervisor / line manager must, once they have reviewed the application, complete the project supervisor authorisation section of the application form.

#### **8.4 Supervisor / line manager to liaise with the applicant to gather outstanding information**

The supervisor / line manager must liaise with the applicant to gather any outstanding information; this should be done through updating the comments box of the application form and selecting the 'place on hold' option.

#### **8.5 Applicant will receive an email alert regards outstanding information**

The applicant will receive an email alert to advise that a comment has been added to their application. It is then their responsibility to update the application by uploading any additional and amended documents and email their supervisor / line manager to advise them when they have updated their application.

#### **8.6 Supervisor / line manager will receive an email to advise that the application has been updated**

The supervisor / line manager will receive an email directly from the applicant to advise that the application has been updated.

#### **8.7 Supervisor / line manager to further review the application**

Please refer back to 8.3.

#### **8.8 Supervisor / line manager to update the project supervisor / line manager authorisation section of the application form**

The supervisor / line manager must, once they have reviewed the application, complete the project supervisor authorisation section of the application form, remembering to select the 'edit' icon in the top left corner to enable them to type comments in the application. When they are satisfied that the application is complete and ready for further review they should endorse the application. **It is essential that supervisors / line managers do not endorse incomplete applications as that will delay the research commencing.**

The application will then be reviewed by either the Research Ethics Committee, the Animal, Welfare and Environment Committee or the Health Sub Committee. See appendix I for meeting dates.

#### **8.9 Application to be reviewed by the relevant Committee**

##### **Health applications that have ethical approval from another organisation**

Health applications that have ethical approval from another organisation, including the NHS, will be passed to the Health Sub Committee for review. The Health Sub Committee meet on a fortnightly basis and the outcome of their decision will be emailed to the applicant.

### **Animal, Welfare and Environment applications that have ethical approval from another organisation**

Animal, Welfare and Environment applications that have ethical approval from another organisation will be passed to the Animal, Welfare and Environment Committee for review. The Animal, Welfare and Environment Committee review applications on an on-going basis and the outcome of their decision emailed to the applicant.

### **In vitro applications**

In vitro applications will be passed to the Health Sub Committee for review. The Health Sub Committee meet on a fortnightly basis and the outcome of their decision will be emailed to the applicant.

### **8.10 Post committee review update**

Once the REC, AWEC or HSC have reviewed the application, the committee clerk will update the application status from the list below:

- Approved by REC
- Approved by AWEC
- Approved by HSC
- REC conditional approval
- AWEC conditional approval
- HSC conditional approval
- REC reject
- AWEC reject
- HSC reject
- Research has been noted

for which the applicant and their supervisor / line manager will receive an email notification.

## **9 Ethical approval mechanism**

### **9.1 Student Projects/Dissertations**

The Student and the Project Supervisor should then complete the online application form, as above.

It is essential that all supporting documentation (such as project outline/methodology, participant information sheet, gatekeeper consent, questionnaires and consent forms as appropriate) are uploaded to the application form.

## 9.2 Notes

A Project Supervisor may request that the REC, AWEC or HSC review an application for ethical approval or may consult members of the Committee at any time during the ethical approval process should this be deemed helpful.

Any subsequent significant<sup>1</sup> change in the question, design or conduct of the research throughout the duration of the research activity should be notified to the Project Supervisor and may require the submission of a new application for ethical approval.

Following approval, the timeframe for completion of research projects will be as set out in the application. If the research project has not commenced during this time, then a new application for ethical approval should be lodged.

Receipt of NHS ethical approval automatically satisfies the UHI Research Ethics Approval process.

If applying to the BTO or SNH for a licence, this will need to be attached to the application before the research can gain final approval.

**Internet Mediated Research (IMR)** If your research project/ methodology involves use of online surveys (for which [Online Surveys](#) should be used, note that you must not use SurveyMonkey), questionnaires, use of social media e.g. Facebook, or on-line support groups, chat rooms, Skype either for the recruitment of participants or the gathering of data then in addition to completing your online application you should read the [UHI IMR Guidance](#), complete an [IMR checklist](#) in consultation with your supervisor, and submit this with your application for ethical approval.

Complex IMR projects may be referred to [UHI's Information Security Officer](#) for consultation and advice.

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<sup>1</sup> A change is considered to be 'significant' if it results in what had been a 'No' response to any of the questions in the application becoming a 'Yes' response.

at as early a stage as possible.

If the research project depends upon the successful submission of a grant application to an external funding body, ethical approval need not have been secured at the time of application, however the ethical approval process should be initiated immediately following the submission.

A Senior Line Manager may request that the REC, AWEC or HSC review an application for ethical approval or may consult members of the Committee at any time during the ethical approval process should this be deemed helpful.

Following completion of your research project, it is expected that supervisors will check papers (both internal and external) produced from research before they go forward for publication.

## Appendix I – REC, AWEC and HSC meeting dates

A reminder that applications in respect of undergraduate / taught postgraduate / masters students (including non-clinical postgraduate taught students from The School of Health, Social Care and Life Sciences) are not taken to the above meetings but are reviewed and approved by SNLs within 2 weeks of their receipt.

<b>Research Ethics Committee (REC) meeting dates 2019/20</b>
24/09/19 (the deadline for applications to be submitted and endorsed is 03/09/19)
20/11/19 (the deadline for applications to be submitted and endorsed is 13/11/19)
29/01/20 (the deadline for applications to be submitted and endorsed is 22/01/20)
18/03/20 (the deadline for applications to be submitted and endorsed is 11/03/20)
20/05/20 (the deadline for applications to be submitted and endorsed is 13/05/20)
22/07/20 (the deadline for applications to be submitted and endorsed is 15/07/20)
23/09/20 (the deadline for applications to be submitted and endorsed is 16/09/20)
<b>Animal Welfare &amp; Environment (AWEC) meeting dates 2019/20</b>
20/08/19 (the deadline for applications to be submitted and endorsed is 13/08/19)
15/10/19 (the deadline for applications to be submitted and endorsed is 08/10/19)
17/12/19 (the deadline for applications to be submitted and endorsed is 10/12/19)
11/02/20 (the deadline for applications to be submitted and endorsed is 06/01/20)
13/04/20 (the deadline for applications to be submitted and endorsed is 06/04/20)
15/06/20 (the deadline for applications to be submitted and endorsed is 08/06/20)
<b>Health Sub Committee (HSC) meeting dates 2019/20</b>
17/09/19 (the deadline for applications to be submitted and endorsed is 10/09/19)
01/10/19 (the deadline for applications to be submitted and endorsed is 24/09/19)
15/10/19 (the deadline for applications to be submitted and endorsed is 08/10/19)
29/10/19 (the deadline for applications to be submitted and endorsed is 22/10/19)
12/11/19 (the deadline for applications to be submitted and endorsed is 05/11/19)
26/11/19 (the deadline for applications to be submitted and endorsed is 19/11/19)
10/12/19 (the deadline for applications to be submitted and endorsed is 03/12/19)
Further dates will be added in due course.

## Appendix II Guidance notes to assist with completing the application form

The application form has been designed for use by all UHI researchers; it is the same form for staff and students.

The user will be presented with questions relevant to their research, i.e. a researcher working with humans will be presented with different questions to a researcher working with animals and a student will be presented with different questions to a staff member (although there may be some overlap).

The completion of some fields is mandatory; they are highlighted with a red asterisk \*.

### Page 1

You will be unable to progress your application past the first page if you do not complete the mandatory fields contained in the first page.

There are 7 types of applications to choose from in the drop down menu; double check to make sure that you select the correct one. Selecting the incorrect type of application could result in a delay in your application being processed.

It is essential that you enter the email address correctly, including '@uhi.ac.uk'. It is essential that you do not enter SAMS email addresses in any of the address fields as they will not generate alerts. All SAMS staff have UHI email addresses; if relevant please ensure that they are used

If you are not undertaking a module, leave that field blank.

The academic year will automatically populate with the current academic year.

Ensure you set a realistic proposed research start date, giving time for your application to be reviewed and approved.

### Page 2

If your study will involve recruitment of patients or staff through the NHS you may need to apply for NHS ethical approval or NHS R & D approval; ensure you complete the relevant fields and read / follow the notes.

### Page 3

If your study already has ethical approval from another organisation you must attach proof of that to your application; thereafter it will be reviewed by either the AWEC or the HSC and you will not need to complete the application past page 3.

### Page 4

If your study contains in vitro research you must attach your research proposal, which should include a clear outline of your project and a description of the materials you will be working with, e.g. cell lines; thereafter it will be reviewed by the HSC and you will not need to complete the application past page 4.

#### Page 5

If your study involves human participants you will be presented with a page of questions to answer for which you should supply further information and supporting documentation as relevant.

#### Page 6

If your study involves the study of non-human animals (including observations studies) or tissue of animal original you will be presented with a page of questions to answer for which you should supply further information and supporting documentation as relevant.

#### Page 7

If your study involves working in environments with protected status or involve manipulations of the natural environment, plants or animals, including observation, removal or translocation of material you will be presented with a page of questions to answer for which you should supply further information and supporting documentation as relevant.

#### Final page

The final page of the application form contains questions that are relevant for all applications that progress to that stage. Please ensure that you submit all relevant supporting documentation.

You will be unable to submit your application if you do not tick the box to confirm that you have read the UHI Research Ethics Framework. John to update the application to ensure this works.

You will be unable to submit your application if you do not tick the box to confirm that you understand that ticking that box constitutes a legal signature. John to update the application to ensure this works.

You can either submit your application for review or save a draft of your application. Whichever option you choose will result in an automatic notification email alert to your UHI email account along with a link back into your application.

If you need to go back into your application to make amendments you should access the link that is emailed to you and then select the 'edit item' icon from the top left of the screen.