



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

Research Ethics Framework

Ethical Approval: Policy, Principles and Process

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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 and the UHI Academic Partnership. 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 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 should also 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:

- 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.
- Participants must give their consent voluntarily, free from any coercion or financial or other inducements.
- Any data and information gathered must be treated confidentially and the anonymity of participants respected.
- Harm to participants must be avoided.
- Research must be carried out transparently and impartially and any potential conflicts of interest declared.
- 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 / research directors **must have completed** the Ethics Reflection and Practice module. For access to the module please contact <mailto:fiona.leiper@uhi.ac.uk>

Prior to submitting applications PGR students **must have completed** the Ethics Reflection and Practice module. For access to the module please contact <mailto:fiona.leiper@uhi.ac.uk>

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

6 Application for ethical approval flowchart

Applicant submits an online application for ethical approval using the link contained in the [university's research ethics webpage](#).

The applicant's supervisor / line manager / research director will receive an email alert to advise that an application is ready for their review after which they should review it.

Application incomplete.

Supervisor / line manager / research director to put relevant notes in the application to advise the applicant that their application is incomplete after which they should return it to them.

Having read the comments left by their supervisor / line manager / research director the applicant must update their application and resubmit it.

Supervisor / line manager / research director to further review the application after they receive the email alert to advise them that it has been resubmitted.

Once the supervisor / line manager / research director is satisfied that the application is complete they will progress it to the next stage, which will be further review by Subject Network Leader (for UG applications only), REC, AWEC or HSC.

The REC meet every 2 months to review applications. Please see their meeting dates on the university's research ethics webpage. The AWEC and the HSC review applications on a daily basis.

The SNL or clerk to the REC, AWEC or HSC will update the application with the committee's decision which will be emailed to the applicant.

Application complete (supporting documentation in addition to the project proposal is attached to the application).

7 A step by step guide to the application process for applying for ethical approval

7.1 Applicant to complete an online application by accessing the link contained in the [university's research ethics webpage](#).

Care must be taken when completing the application; please ensure it is fully completed and all relevant supporting documentation is uploaded. Please refer to the 'i' information buttons throughout the application for guidance.

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

It is essential that the application form is completed fully before being submitted.

A supervisor, line manager, research director, SNL or administrator may request that the REC, AWEC or HSC review an application for ethical approval or may consult members of the committees at any time during the ethical approval process should this be deemed helpful.

Any subsequent significant¹ change in the question, design or conduct of the research throughout the duration of the research activity should be notified to the supervisor / line manager / research director 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 university's research ethics approval process.

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.

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.

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

¹A 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.

7.2 Application is either saved or submitted

An applicant can save their application without submitting it and continue to work on it at a later date by clicking the 'save for later' link.

When you are satisfied that you have accurately completed your application and have attached all relevant supporting documentation submit your application by clicking 'save and continue' on the declaration page of the application.

The PI can delegate the task to allow co-investigators to edit and submit the application. Co-investigators can also take over the task while it's with the PI/other co-investigators.

If it's the first time they are submitting an application, co-investigators can be added on the first tab under "Internal co-investigators". After that tab is saved they will be added to the application and will be able to take over the task.

Note that only the PI can start an application but all investigators can edit and submit it.

7.3 Supervisor / line manager / research director to review the application

It is essential that all supervisors / line managers / research directors undertake the 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 / line manager/ research director and do not already have access to the module, which is hosted on Brightspace, please contact fiona.leiper@uhi.ac.uk and she will set your access up.

Supervisors / line managers / research directors should review applications within 10 working days of them being submitted. If supervisors / line managers / research directors 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 possible delay in their review.

The supervisor / line manager / research director has responsibility to ensure the application is absolutely complete and that all supporting documentation is full and accurate before they progress it to the next stage.

7.4 Supervisor / line manager / research director to liaise with the applicant to gather outstanding information.

The supervisor / line manager / research director must return the application to the application if they require further information by using the 'return application' option and advising, in the 'notes' section the further information that they require.

7.5 Applicant to update their application

The applicant will receive an email to advise them when their application has been returned for further information. It is their responsibility to update their application by using the 'edit application' function after which they should resubmit it by choosing the 'resubmit application' function.

7.6 Supervisor / line manager / research director to further review the application

The supervisor / line manager / research director will receive an email alert to advise them when an application has been updated and is ready for their further review.

7.7 Supervisor / line manager / research director to progress an application once they are satisfied that it is accurate and complete and ready to be taken to the next stage

The supervisor / line manager / research director must, once they have reviewed the application and are happy that it is complete and ready to be taken to the next stage, progress it by selecting the relevant committee in the 'forward' section of the application and selecting 'send to reviewer'.

It is essential that supervisors / line managers / research directors do not endorse incomplete applications as that will delay the research commencing!

7.8 SNL, REC, AWEC or HSC to review application

When the supervisor / line manager / research director has escalated the application to be taken to the next stage, the SNL or committee administrator will receive an email to advise them that the application is ready for further review.

The SNL or relevant reviewing committee have responsibility to ensure the application is absolutely complete and that all supporting documentation is full and accurate.

The SNL should review the application within 10 days receiving their alert. The AWEC and HSC will review applications on an ongoing basis. REC will review applications as per their meeting schedule which is available on the university's research ethics webpage.

7.9 SNL or committee administrator to liaise with the applicant to gather outstanding information

The SNL or committee administrator must liaise with the applicant to gather any outstanding information; this should be done through the 'return application' section of the application form where they can add notes to advise what additional information it is that they require after which they should select the 'request more information' button to return the application.

This can also be done by choosing "Amendments required", under decision. This will allow the committee to send a notification with the details of what needs to be amended and once the applicant resubmits and the committee approves it the application will be closed as "Approved after amendments made" instead of just "Approved".

Both options (return to applicant and amendments required) are valid, but have different behaviours depending on what the committee prefers.

7.10 Applicant to update and resubmit their application

If their application has been returned to them for further information they will receive an email alert. They should then select 'edit application', update their application according to the outstanding information requested of them after which they should 'resubmit application'.

7.11 SNL or committee administrator to approve the application

Once the application has been resubmitted the SNL or committee administrator (on behalf of the relevant committee) will receive an email alert. They then select 'review application' and if they are satisfied that it is up to date and accurate they select 'progress application' and 'approve'. If there are further amendments required they will select 'amendments required' and put notes in the 'notes' field to advise what amendments are required. This will generate an email which can be updated to include the relevant outstanding information after which they select 'review notification' followed by 'send notification'

7.12 Applicant to further update and resubmit their application

If their application has been returned to them for further information they will receive an email alert. They should then select 'edit application', update their application according to the outstanding information requested of them after which they should 'resubmit application'.

7.13 SNL or committee administrator to approve the application

Once the SNL or committee is satisfied that the application is complete and can be approved they select 'approve'.

Note - When trying to progress an application it's possible that a notice appears about needing to return to the applicant because of missing information. This is usually because a date entered by the applicant has since become invalid (i.e. is now in the past).

7.14 Application approved

Once the application has been approved the applicant will receive an email to advise them and their research may then commence.