School of Health Nursing & Midwifery (HNM)

School Ethics Committee (SEC)

Guidelines to Support Ethical Screening and Review of All Student and Staff Academic (Scholarly and Research) Project Work

March 2017
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Background

The School of Health Nursing and Midwifery (HNM) echo the belief, outlined in the University Ethics Committee Guidelines, (available here) that we have responsibilities as a University to maintain the highest ethical standards in research and scholarship: we are committed to ensuring a culture of honesty, rigour, transparency and respect. It is therefore essential that *due ethical consideration* is given to *all student and staff projects.* While the key ethical principle underpinning research ethics is respect for human dignity, such principle applies to all research and scholarly activity within an academic context. Ethical Principles guiding research, which relate to all research involving human participants can be found in the UEC guidelines here.

Within this context research and scholarship can be broadly defined as a *systematic investigation to add to a body of knowledge or theory, or understanding".* Whilst further acknowledging that *non-research* projects will also be undertaken within the HNM setting, ***a 'project'*** is defined simply as "*a temporary endeavour undertaken to create a unique product, service, or result":*

- It is temporary in that it has a definitive beginning and end;
- The end occurs when:
    1. The project's objectives have been reached / achieved;
    2. The project is terminated because its objectives will not / cannot be met;
    3. The need for the project no longer exists.

In recognising the various project types within an academic context (such as systemic reviews, audit / clinical audit, service development / evaluation and / or research), the School of HNM acknowledges that varying levels of ethical consideration may be required for differing project types. Resultantly, systems and processes have been designed to manage individual projects through ethical screening, review, progress and amendment. These guidelines will outline the School of HNM *6-stage Approach to Ethical Scrutiny/Approval of a Project.*

School Ethics Committee Function

The purpose and function of the Ethics committee function can be found here in Regulation 14, pages 19 & 20.

IMPORTANT NOTE:

If you are a member of staff wishing to undertake a project. Please consider the following. Research that may require approval of an NHS Research Ethics Committee (NREC) e.g. work involving NHS patients and carers, access to data, organs or other bodily material of past and present NHS patients, health-related research involving prisoners. This research should be submitted through Integrated Research Application System (IRAS) and the School of HNM ethics committee informed of the decision.

If you are a student (including staff who may be undertaking a research degree). All projects, including those that may require approval of an NREC, must be submitted to the School of HNM ethics committee. Where projects do require approval by an external committee, the School of HNM ethics committee will act as a review body only, providing comment on improving the ethics application prior to submission to the external ethics committee. If your project will require approval through an external ethics committee, please use the application form of that committee rather than the UEC1.1.

If you are a member of staff undertaking a funded research / evaluation project with a non NHS health or social care partner, submission to the School of HNM ethics committee will allow peer review of the proposed study to be offered. Please use the UEC1.1 form here.

School of Health Nursing and Midwifery 6-stage Approach to Ethical Scrutiny / Approval of a Project

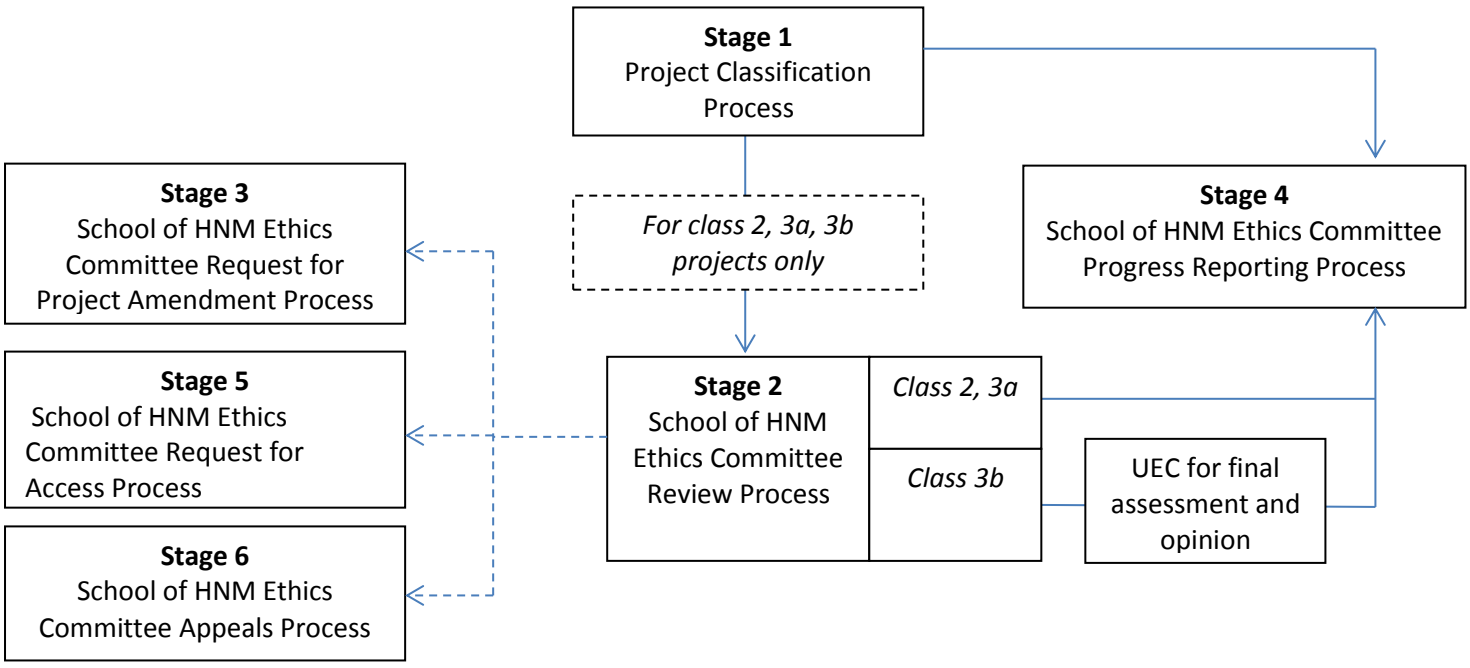
The systems and processes outlined in the 6-stage Approach to Ethical Scrutiny / Approval (See Table 1 and Figure 1):

- Reflect the requirements of the University Ethics Committee Guidelines for Ethical Practice in Research and Scholarship
- Aim to ensure student and staff projects receive an appropriate level of scrutiny, relative to the risk presented by the ethical issues they raise.

Table 1: The 6-Stage Approach to Ethical Scrutiny / Approval

Stage 1	*Project Classification Process* • **For ALL projects**; • Where the project is a student project, supervisors are equally responsible for project classification with the student.
Stage 2	*School of HNM Ethics Committee Review Process (including identification of project risk status)* • **For Class 2, 3, 3b projects only**; • Involves full ethical review by the School of HNM Ethics Committee.
Stage 3	*School of HNM Ethics Committee Request for Project Amendment Process* • **As required**, where changes are to be made to an approved project – whether these changes have ethical implications or not.
Stage 4	*School of HNM Ethics Committee Progress Reporting Process* • **For all projects (Class 1, 2, 3a, 3b);** 1. For PG / staff projects - The principal investigator is responsible; 2. For UG projects - The supervisor is responsible.
Stage 5	*School of HNM Ethics Committee Request for Access Process* • **Subject to nature of project**; 1. Internal – Request via relevant gatekeeper; 2. External – Request via School of HNM Ethics Committee.
Stage 6	*School of HNM Ethics Committee Appeals Process* • **As required**, where an applicant is dissatisfied with the final decision of the School of HNM Ethics Committee.

Figure 1: The 6-Stage Approach to Ethical Scrutiny / Approval



Contact Details for ALL School of HNM Ethics Committee Enquiries: Unless otherwise instructed, all enquiries should be made to: mailto:HNMEthics@uws.ac.uk

Communication with School of HNM Ethics Committee: Unless otherwise instructed, all applications (and subsequent communications to SEC) **MUST be submitted by the principal investigator** (See Table 2)

Table 2: Principal Investigator Communication with School of HNM Ethics Committee

Where the principal investigator is a UWS student:	All applications / communications MUST be sent from the student email account (for example, B00123456@studentmail.uws.ac.uk).
Where the principal investigator is a member of UWS staff engaged in a staff project:	All applications / communications MUST be sent from the staff email account (for example, joe.bloggs@uws.ac.uk).
Where the principal investigator is external to the School of HNM and / or UWS:	All communications MUST be via email.

Supervisors *should not* submit an application (or supporting documents) and / or communicate subsequent responses to the School of HNM Ethics Committee on behalf of a student – instead, supervisors should:

1. Support the student to communicate directly with the School of HNM Ethics Committee;
2. Liaise with School of HNM Ethics Committee administrator / reviewers for advice as required, and thereafter support the student to communicate directly with the School of HNM Ethics Committee.

Submission Dates for School of HNM Ethics Committee

The timeline for submission and review of applications is produced annually by the School of HNM Ethics Committee.

- Applications are accepted monthly (excluding December) and will be sent to reviewers' approximately 1 day post submission.
- Applicants will be informed by letter no later than one week after the ethics committee meeting. Dates available here

Stage 1: Project Classification Process

Stage 1 of ethical scrutiny / review within the School of HNM involves project classification by the principal investigator (student and / or staff). *Where the project is a student project, supervisors are equally responsible for classifying individual projects with the student.*

Within the Stage 1 process, the School of HNM recognises two classes of project (See Table 4): Principal investigators (in conjunction with supervisors for student projects) require to review and classify the project in line with Table 3. The action to be taken by the principal investigator (and supervisor, where the principle investigator is a student) following classification is detailed in Table 4.

As a School we need to be aware of all projects undertaken by staff or students as part of University business. Projects deemed class 1 *do not require* ethical scrutiny as they do not involve contact with human participants or their data. The classification of projects 2, 3a or 3b *do require* ethical scrutiny and our approach to the ethical review of these projects is in line with the UWS ethical regulations.

Students and staff should seek advice from the School of HNM Ethics Committee if, following screening (or due to the type of project), they are unsure of the class of a specific project.

Table 3: Project Classification

Class	Risk Characteristics	Risk response
1	Project exhibits none of the characteristics that indicate the need for independent ethical scrutiny.	Documented and registered self-assessment, reviewed and approved by supervisor / director of studies for student applications.
2	Exhibits one or more characteristics indicating a need for independent ethical scrutiny but none of the risk factors indicating potentially higher risk.	Assessment / approval by the relevant School Ethics Committee.
3a	Exhibits one or more factors considered to be indicators of higher risk. Demonstrates that the risk factors have been adequately addressed through the use of standard protocols and established methodologies for potentially higher risk situations.	Assessment / approval by the relevant School Ethics Committee following scrutiny of the adequacy of the proposed risk mitigation.
3b	Exhibits one or more factors considered to be indicators of higher risk. Proposed risk mitigation and/or research methodology involves novel approaches, heightened residual risk etc.	Initial assessment by the relevant School Ethics Committee. Referral to the University Ethics Committee for final decision.

Table 4: Principal Investigator Action (following Stage 1 project classification process)

CLASS OF PROJECT	DESCRIPTION	STAGE 1 OUTCOME	PRINCIPAL INVESTIGATOR ACTION (FOLLOWING STAGE 1 PROJECT CLASSIFICATION)
Class 1	Projects that DO NOT involve contact with any human participants, OR the use of their data, records or other associated artefact.	The project will be recorded on the School of HNM Ethics Committee database as Class 1: Full ethical review by the School of HNM Ethics Committee ***will not be required*.**	If a project is deemed as **Class 1:** • Complete the **School of HNM Stage 1 Project Classification – Class 1 Project Form (HNMSEC1)** electronically; • Submit completed form to the School of HNM Ethics Committee via the School of HNM Ethics Committee Administrator; • Where appropriate, completed risk assessment documentation must be included as supporting documentation. *The project should only begin once a confirmation of receipt of HNMSEC1 from School of HNM Ethics Committee has been received (and all other risk assessments, as appropriate, have been completed).*
Class 2, 3a, 3b	Projects that DO NOT involve contact with any human participants, but DO involve the use of their data, records or other associated artefact. Projects that involve contact with human participants.	The project will be recorded on the School of HNM Ethics Committee database as a Class 2, 3a, 3b; Full ethical review by the School of HNM Ethics Committee **will be required.**	If a project is assessed as **Class B:** • Completing the **UEC1.1 Form***; • Submit completed UEC1.1 form* (and supporting documents) to the School of HNM Ethics Committee via the School of HNM Ethics committee Administrator; • For all Class 2, 3a, 3b projects, **the School of HNM Stage 1 Project Classification – Class 2, 3a, 3b Project Form (HNMSEC2) MUST** be completed and included with supporting documentation. • *Data collection for the project should only begin once confirmation of School of HNM Ethics Committee approval has been granted (**AND all other permissions are in place**).* **For research that requires scrutiny / approval of an NHS Research Ethics Committee, a copy of the completed IRAS application form can be submitted in place of the UEC1.1 form.*

Stage 2: School of HNM Ethics Committee Review Process

The activity of the School of HNM Ethics Committee will be dependent upon the project classification (See Figure 2):

Class 1 Projects: Where a project has been classified as **Class 1** (low risk) by the principal investigator (and the supervisor, where the principal investigator is a student):

- The project will be recorded on the School of HNM Ethics Committee database.
- Full ethical review by the School of HNM Ethics Committee ***will not*** be required.

Class 2, 3a, 3b Projects: Where a project has been classified as **Class 2, 3a, 3b** by the principal investigator (and the supervisor, where the principal investigator is a student):

- Full ethical review by the School of HNM Ethics Committee **will be** required: This review process will involve:
- Initial review of application by 2 School of HNM reviewing members (pre-Ethics committee meeting), including consideration of project risk level

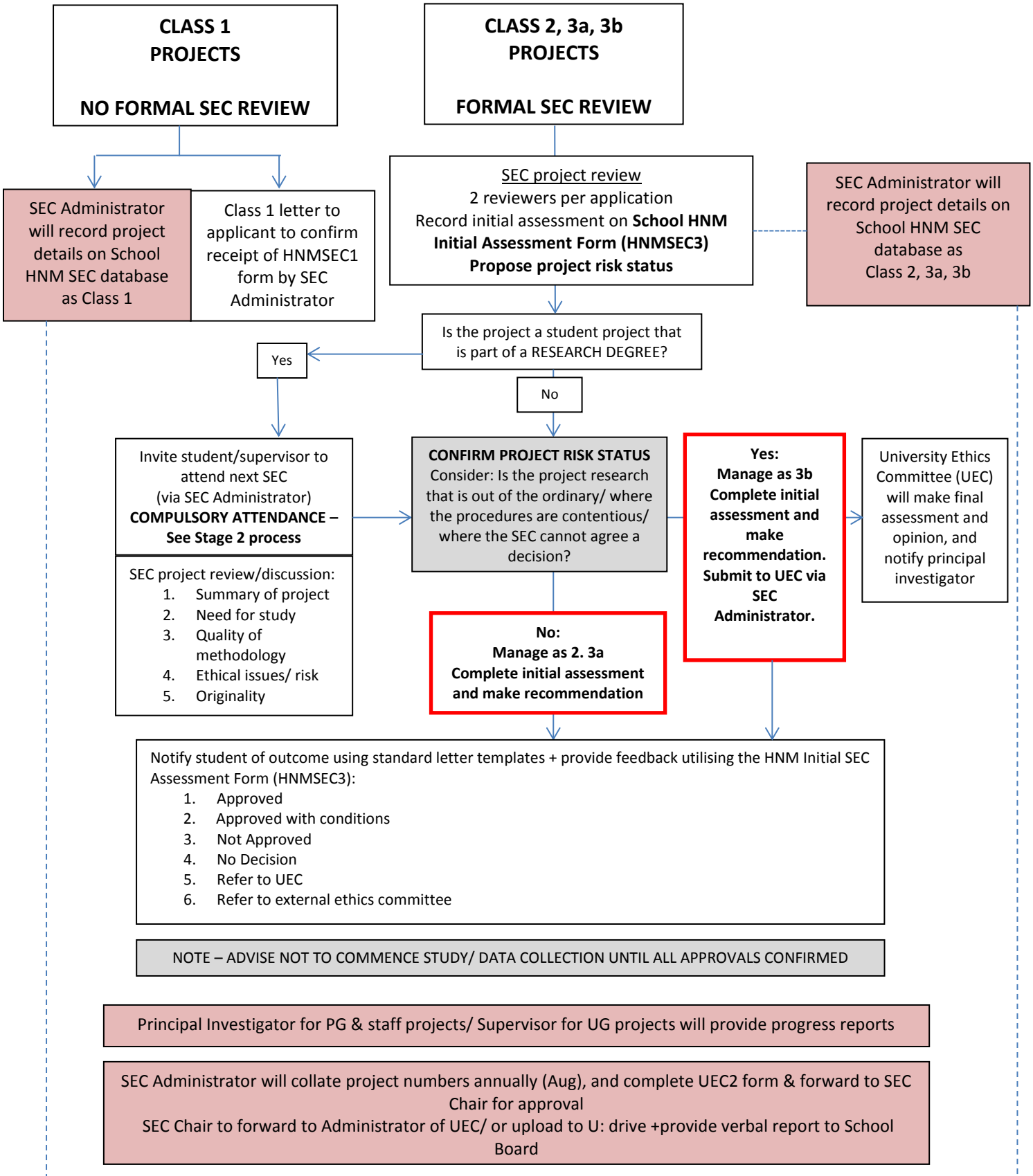
ASSESSMENT CONSIDERATIONS Is the project considered research that is out of the ordinary / where the procedures are contentious / where the School of HNM Ethics Committee cannot agree a decision?	NO:	Propose project as **2, 3a** to School of HNM Ethics Committee
	YES:	Propose project as **3b** to School of HNM Ethics Committee

- Formal consideration of application / initial reviews at School of HNM Ethics Committee meeting;
- *Meeting of principal investigator (at School of HNM Ethics Committee meeting) – research students only.* Attendance at this meeting is compulsory for research degree students - applicants should check dates of meetings and applications should only be submitted if able to attend (NB - a request *not to attend* must be submitted in writing to Chair of the ethics committee along with the application, citing exceptional circumstances. If declined (or no letter received), the application will be deferred until applicant available to attend).
- Referral to UWS Ethics Committee where applicable (complex / high risk projects only);
- Communication of SEC outcome to principal investigator post-SEC meeting.

Applications Requesting Retrospective Ethical Review

The School of HNM Ethics Committee **will decline** all applications requesting retrospective ethical review, and applicants will be offered opportunity to appeal to the UWS Ethics Committee.

Figure 2: School of HNM Ethics Committee Review Process



Stage 3: School of HNM Ethics Committee Request for Project Amendment Process

Approved projects require to be carried out in accordance with the original application and any conditions. If changes are to be made to an approved project – *whether these have ethical implications or not* – a request must be made to the School of HNM Ethics Committee (See Figure 3):

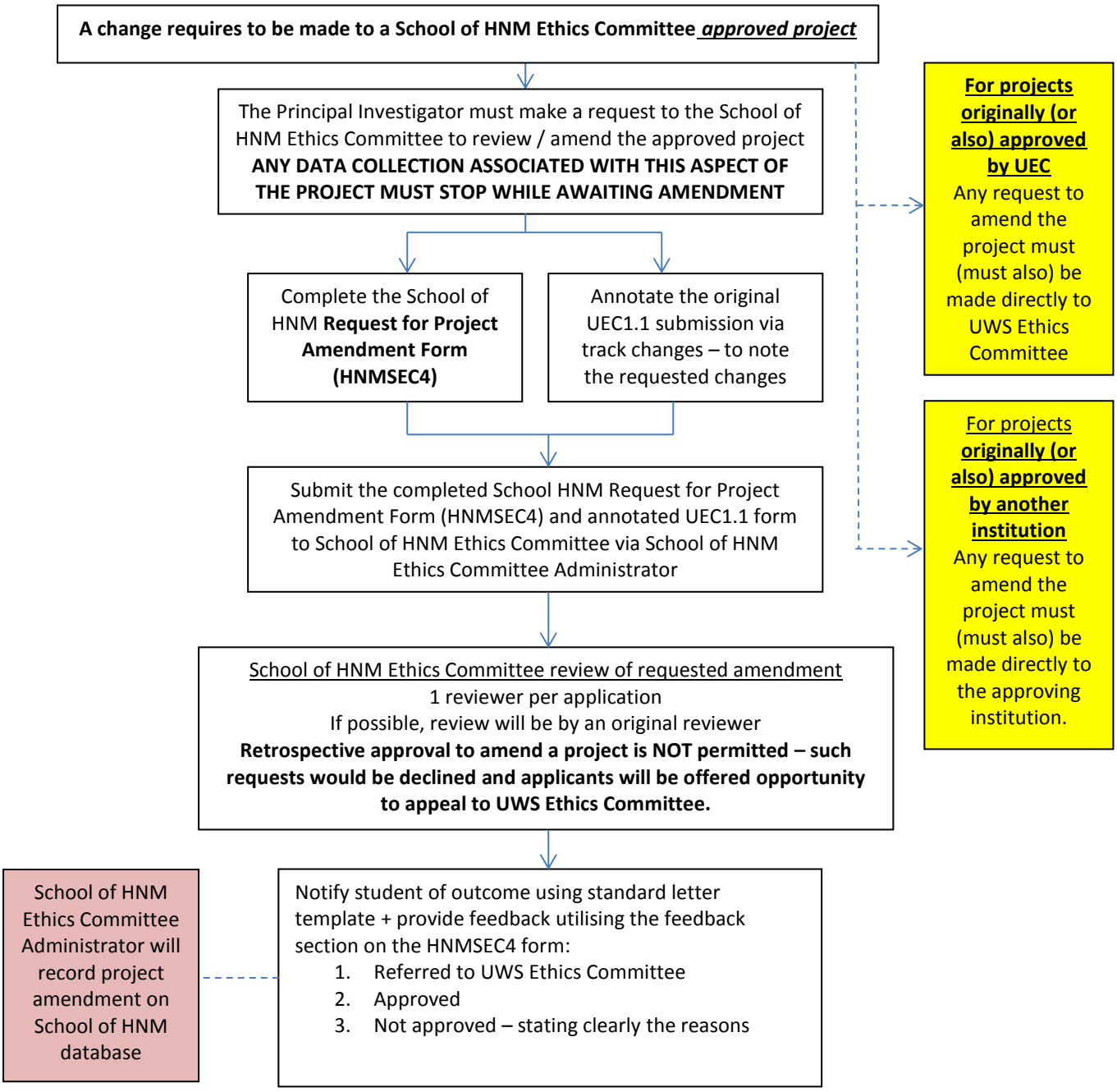


Figure 3: Process to Request Change to Approved Project

Stage 4: School of HNM Ethics Committee Progress Reporting

The progress of all projects must be notified to the School of HNM Ethics Committee. Any concern about the ethical conduct of an approved project will be addressed as part of this progress monitoring process (See Figure 4):

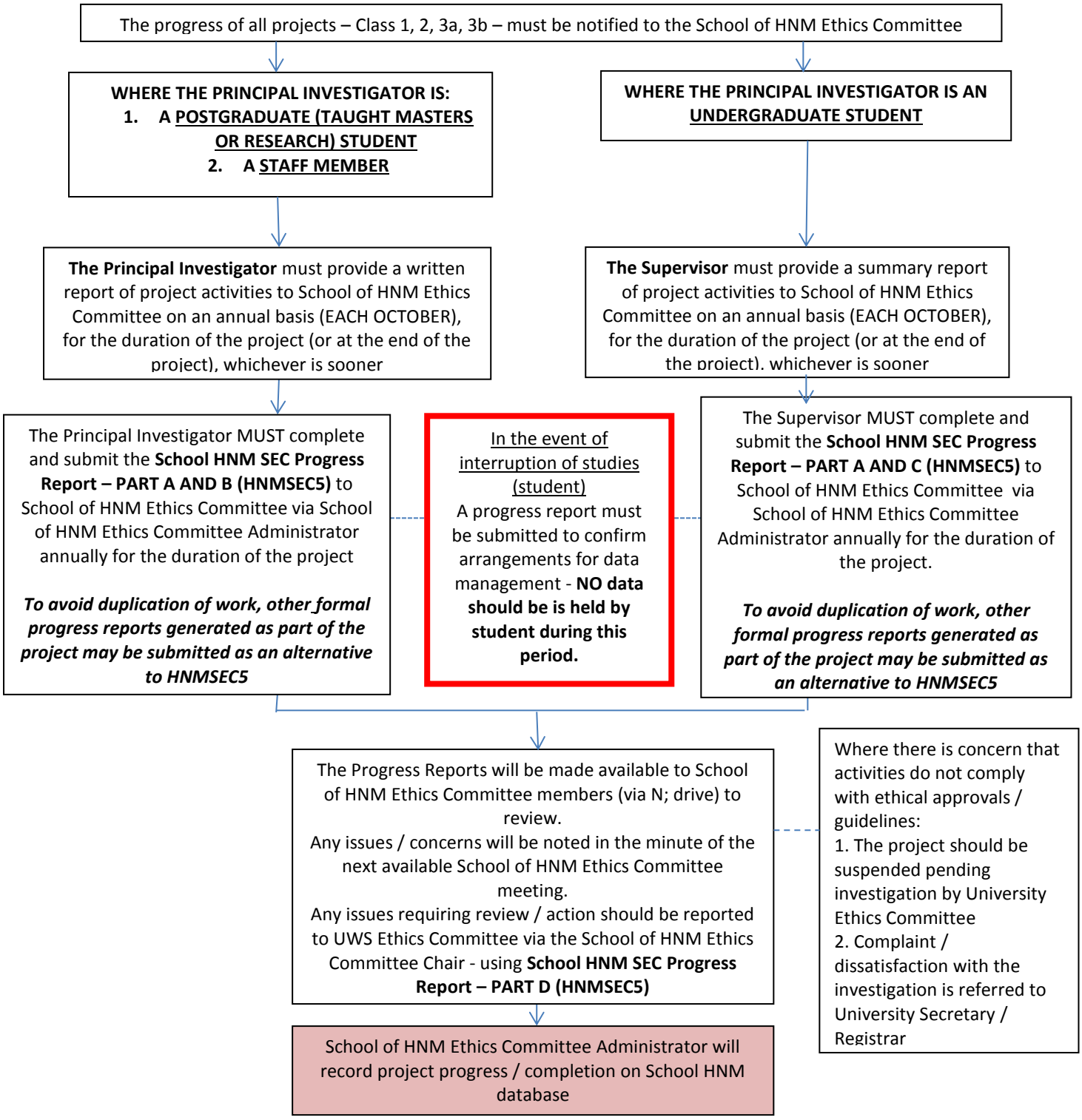


Figure 4: Process to Monitor Progress of a Project

Stage 5: School of HNM Ethics Committee Request for Access Process

The process for accessing School of Health Nursing and Midwifery students and staff as project participants requires management, to avoid any over-burdening of particular groups with such requests. This principle also applies to requests to access existing School of HNM data / datasets. Management of such requests by School of HNM Ethics Committee operate on the principles that:

i. The School of HNM Ethics Committee does not give permission to access potential participants of a study and / or existing data;

ii. The School of HNM Ethics Committee gives permission to contact the gatekeeper of potential participants / data.

Requesting Access to School of HNM Students, Staff and Data

The process for requesting access to School of HNM students and staff as potential study participants and / or existing data differs subject to the internal / external relationship of the project (as opposed to the principal investigator) to the School (See Table 5):

Table 5: Requesting Access for Internal/External Projects

Nature of Project	Examples	Process for Requesting Access
Internal Projects	For example: Those aligned to programmes of study within the School of HNM; Those aligned to funding within the School of HNM; Those with no alignment to students / staff external to the School of HNM.	Requests to access School of HNM students / staff as potential participants and / or existing data should be made to the relevant gatekeeper PRIOR to applying for ethical approval. The permission letter should be including as part of UEC1.1 supporting evidence.
External Projects	For example: Those aligned to programmes of study at other institutions (or other Schools / Departments within UWS); Those aligned to students / staff external to the School of HNM.	Requests to access School of HNM students / staff as potential participants and / or existing data should be made ONCE ethical approval has been granted by the relevant body. The request should be made to HNM School Ethics Committee using the using the 'Request SEC Access to Participant Gatekeeper Form' (HNMSEC6)

If there is any doubt as to the internal / external nature of a project, guidance should be sought from School of HNM Ethics Committee.

Stage 6: School of HNM Ethics Committee Appeals Process

Where an applicant is dissatisfied with the final decision of the School of HNM Ethics Committee, an appeal may be lodged, giving reasons, with the UWS Ethics Committee. The decision made thereafter by the UWS Ethics Committee will be the final one.

The process for lodging an appeal against the School of HNM Ethics Committee is detailed in Figure 5 below:

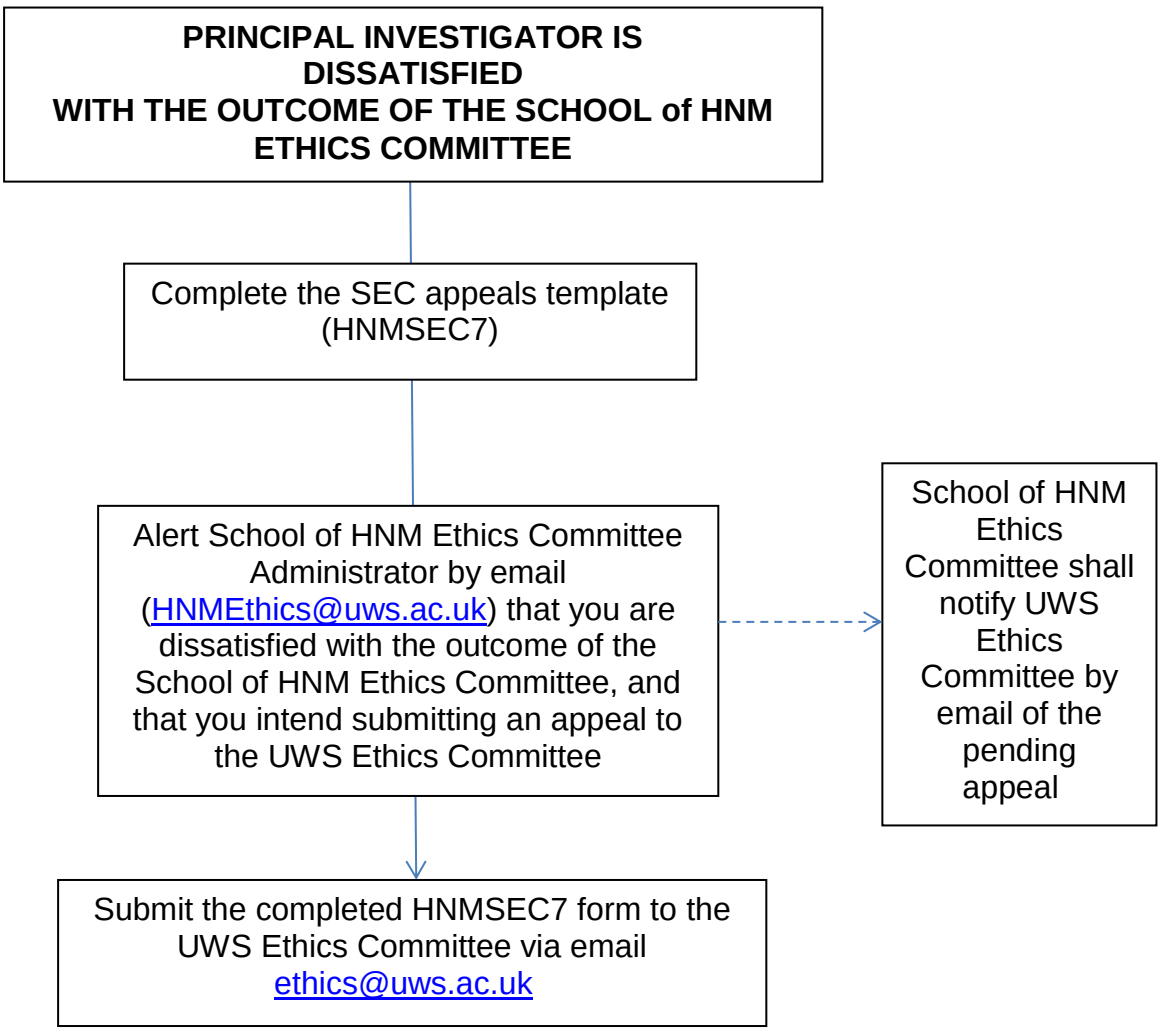


Figure 5: Process for Lodging Appeal against the School of HNM Ethics Committee Decision