Global Academic Foundation hosting the University of Hertfordshire (UH-GAF)
University Ethics Committee (UEC)

Mode of Operation
1 Introduction

1.1 This document has been approved by the Academic Board\textsuperscript{1}.

1.2 The operation of the University Ethics Committee is consistent with the operation of Ethics committees at the University of Hertfordshire, UK.

\textsuperscript{1} At the meeting of Academic Board on March 23\textsuperscript{rd} 2021
2 Forms

2.1 The following forms are referred to in this document: EC1 ‘Application Form’ EC2 ‘Application to Modify/Extend an Existing Protocol Approval’ EC3 ‘Protocol Monitoring Form’.

3 The University Ethics Committee (UCEC)

3.1 The University Ethics Committee forms part of the committee structure of the Academic Board and are required to operate in accordance with the Standing Orders of the Academic Board.

3.2 Terms of reference: Core terms of reference will be agreed by the UEC and will be approved by the Academic Board.

3.3 Composition

3.3.1 It is a condition that the University Ethics Committee (UCEC) has at least one (1) external member. An external member is defined as one external to the scope of the UEC but internal (within the staff of the University), preferably with an interest in or experience of Ethics.

3.3.2 The UEC shall comprise, in addition to the external member and Chair, a minimum of three other members of the university who have expertise in working with human subjects.

3.3.4 Changes in membership of the UEC are to be notified to the Chair of Academic Board at the earliest opportunity.

4 Process for review of applications for ethical clearance

(Note for guidance: A flow chart illustrating the review process is given on the final page of this document and is also published at the following location: https://www.xxxxxxxxxxxxxxxx

4.1 Application process

4.1.1 Applications for ethical clearance should be made on Form EC1 and submitted electronically to the Clerk of the UEC.

4.1.2 In order that the Clerk can track effectively the progress of an application, for example, where further information concerning the application is required from the applicant (sections 4.2.4 and 4.3.2, refer), contact between applicants and the subject or other specialist(s) (section 4.1.5, refers) responsible for reviewing that application should be routed through the Clerk.
4.1.3 There are three (3) processes whereby the UEC can examine an application: a ‘Expedited Review’ (section 4.2, refers); b ‘Substantive Review’ (section 4.3, refers); c ‘Full Review’ (section 4.4, refers).

4.1.4 It is not necessary for an application to be subjected to Expedited or Substantive Review before referral for Full Review if, at the time of its submission, the nature of the application is such that a Full Review is deemed appropriate.

4.1.5 Review panels
To enable them to operate the review processes referred to in section 4.1.3, the UEC via the Chair and/or its members are responsible for selecting subject specialists who may be called upon to examine and assess protocol applications. The Substantive Review process provides for the appointment of reviewers who are non-subject specialists.

4.2 Expedited Review

4.2.1 Expedited Review is a limited review process whereby applications will be required to satisfy particular criteria and procedures.

4.2.2 The Expedited Review process requires that a minimum of one (1) subject specialists from a panel of subject specialists examine an application independently and recommend it for approval by the Chair of the UEC.

4.2.4 Expedited Review should be completed within ten (10) working days of the date of the receipt of the application by the Clerk of the UEC or as soon as possible thereafter. It should be noted that the reviewing subject specialists may request further information to inform their consideration of the application and that this may delay the approval process.

4.2.5 These regulations require that both of the reviewing subject specialists are in agreement concerning their final recommendation which may be rejection, approval, referral for revision or referral for Substantive or Full Review. Where the subject specialists cannot reach agreement the decision of the Chair of the UEC should be sought.

4.2.6 Should the application be referred for Full Review, the subject specialist(s) may be required to attend the meeting for the relevant item in order to provide specialist advice.

4.3 Substantive Review

4.3.1 The Substantive Review process requires that a minimum of three (3) reviewers from a panel of specialists (which might include non-subject specialists) examine an application independently and decide whether to recommend it for approval by the Chair of the UEC.
4.3.2 The Substantive Review should be completed within ten (10) working days of the date of its receipt by the Clerk of the UEC or as soon as possible thereafter. It should be noted that the reviewers may request further information to inform their consideration of the application and that this may delay the approval process.

4.3.3 These regulations require that all reviewers are in agreement concerning their final recommendation which may be rejection, approval, referral for revision or referral for Full Review. Where the reviewers cannot reach agreement the decision of the Chair of the UEC should be sought.

4.3.4 Should the application be referred for Full Review, the reviewers may be required to attend the meeting for the relevant item in order to provide specialist advice.

4.4 Full Review

An application may be referred for Full Review by members of the UEC, either at the time of its submission or as an outcome of one or more of the review processes described in sections 4.2 and 4.3 or as a result of a referral by the Chair of the UEC, for example, in cases where the reviewing subject specialists have been unable to reach a unanimous decision. Full Review will be carried out by members of the UEC by email correspondence, unless a scheduled meeting of the UEC is imminent. Subject specialists may be asked to contribute to the review process. The Review should be normally be completed within twenty (20) working days. As with Expedited and Substantive Review, the reviewing members may request further information to inform their consideration of the application which may delay the approval process.

4.5 Approval of applications

4.5.1 Expedited Review and Substantive Review

Approval of applications through the Expedited Review and Substantive Review processes will be given by the Chair or Vice-Chair of the UEC. All decisions concerning approval should be confirmed at the next meeting of the UEC by an appropriate method.

4.5.2 Full Review

i. Applications referred for Full Review will be considered at a meeting of the UEC. It should be noted that UEC may request further information to inform its consideration of the application and that this may delay the approval process.

ii. Where, to inform its deliberations, the UEC requires further information that is not available at the meeting, the members of the UEC might, at their discretion, allow the Chair to approve the application by Chair’s Action following circulation to them of the additional information requested by the UEC and their consent to approval being given by Chair’s Action.
4.5.3 An appropriate method for monitoring approved Protocols, including Class Protocols, should be established by the UEC to ensure that studies are not allowed to continue beyond their expiry date. Should an extension be required, the permission of the UEC should be sought. An extension, where permitted, might be deemed to be a modification (section 5.12, refers).

4.5.4 Should new evidence come to light following the granting of approval such that there is believed to be a risk of harm to either participant or to investigator that was not known at the time of the original review, the Chair of the UEC is authorised to withdraw approval. In such a circumstance, the principal investigator should be asked to complete Form EC7 and submit it to the UEC.

4.6 **Permission to conduct studies on or off campus**

Permission to conduct studies or activities within the Schools should be obtained from the Module Leader or Programme Leader. If a study or activity is proposed to take place elsewhere on University premises, the permission of the manager of the relevant area should be sought. In respect of studies or activities conducted off campus, permission should be sought from the proprietor, manager or other person with relevant authority over the premises/location concerned. The UEC should be provided with a copy of the written permission as part of the application process.

4.7 **Problems encountered during the conduct of a study**

Form EC7 should be used to record any problems encountered during the conduct of a study or activity, such as, for example, adverse reaction by participants. The Form EC7 should be completed and submitted without delay to the UEC Chair, via the UEC Clerk.

4.8 **Completion of studies**

4.8.1 **Students**

All submissions of work should contain a statement that the study (that is, the collection of data from participants) or activity is completed and has been carried out in accordance with the approved Protocol. Alternatively, a student may make the declaration using Form EC7, ‘Protocol Monitoring Form’. When approval has been granted conditionally, the supervisor should indicate this on the submission document or EC7 (if used). Form EC7 should also be completed in respect of studies involving invasive procedures and if a problem had been encountered during the study or activity.

4.8.2 **Staff**

The completion of Form EC7 following completion of data collection is required to be lodged with the UEC Clerk in respect of all studies or activities undertaken by staff.
4.9 Breach of Protocol

4.9.1 Notifying a Board of Examiners of a breach of Protocol

The relevant Dean of School (or nominee), is responsible for notifying the Chair of the Module Board of Examiners of the outcome of any Breach of Protocol case.

4.10 Modification to an approved Protocol

Any modification(s) of an approved Protocol must be notified to the UEC via the Clerk using Form EC2. It is expected that any modifications proposed via Form EC2 will be minor. Should substantial modification be required, it would be necessary to make a fresh application for ethical approval.

4.11 Class Protocols

Class/laboratory activities of an identical nature involving Human Participants which are carried out on a routine or repetitive basis may be granted approval by issuing a Class Protocol. These Protocols are reviewed on an annual basis; staff are required to confirm that the Protocol for which they have responsibility is still required and whether there are any changes to the approved procedures. Minor amendments may be approved by submission to the UEC of Form EC2; more complex amendments will require resubmission using Form EC1.

4.12 Schedule of Protocols

All approved Protocols must be allocated a Protocol number and must be entered on a Schedule of Protocols. The prescribed Schedule should be used in line with the requirements of the University’s insurers and should be reviewed at every meeting of the UEC.

5 Annual Reports

5.1 The UEC is required to submit an annual report to Academic Board.

5.2 Reports should normally be written by the Chair of the UEC in consultation with his or her members.

5.3 Given the nature of the work being undertaken, as a matter of good practice, the Academic Board will welcome Annual Reports which deal openly with the inevitable problems which occur rather than those which are a bland assertion that all Protocols have been routinely approved and monitored.

5.4 Purpose

The purpose of the report is to inform the Academic Board of what the UEC has been doing and, in particular, how it has been discharging its remit.
5.5 Structure and content

The annual report need not be long but will include the following mandatory elements:

i. the current membership of the UEC identifying in particular its external member(s);
ii. the frequency of meetings and the attendance record of its members; the Ethics Committee will wish to note the attendance, in particular, of the external member(s);
iii. Protocol applications statistics showing the number of applications approved, rejected, referred back and pending, indicating the category of Protocol and the programmes and levels of study to which the applications refer. This information should distinguish between University-based programmes and other programmes (in placement partners for example) and should also include any re-approval of standard and Class Protocols;
iv. problems and issues encountered in considering and evaluating proposals and the ways in which those problems have been resolved;
v. monitoring of approved Protocols, together with information about any problems or issues encountered, including any adverse reactions and the action taken to deal with cases where non-observance of a Protocol is suspected or proven;
vi. a schedule and brief summary of all Protocols under the UEC will provide summaries of all Protocols under its management;
vii. administration where relevant, any review undertaken of the paperwork involved in processing applications;
viii. codes of practice where relevant, any review undertaken of the codes of practice relevant to ethics matters within the disciplines or professions;
ix. new developments any developments, for example, within the UEC operating environment or externally, which may impact on the UEC’s activities in the coming year;
x. collaborative programmes information on the ethics management of any collaborative programmes especially with placement partners;
xi. Class Protocols a list of all active Class Protocols, with their expiry dates;
xii. breaches of ethics Protocols information concerning any departure by a student or member of staff from an approved Protocol, to include the extent of this departure and any disciplinary action taken. A Form EC7 should have been completed to record the circumstances of the breach; xii actions arising from the previous Annual Report.

All of the above headings must be included in the annual UEC Report to Academic Board and the report will signify that there is nothing to report where that is the case.

5.6 Timetable for the submission of Annual Report

The Annual Report from the UEC for the previous Academic Year must be submitted to the Autumn meeting of Academic Committee (normally the December meeting).
<table>
<thead>
<tr>
<th>Date of Issue</th>
<th>Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2021</td>
<td>February 2022</td>
</tr>
<tr>
<td>Signed on behalf of Academic Board</td>
<td>Dr. Vincent Emery (President)</td>
</tr>
<tr>
<td>Date</td>
<td>March 23rd 2021</td>
</tr>
</tbody>
</table>
Appendix: Studies Involving Human Participants (Flow Chart)

Triage

No Ethics Approval required

Expeditied Review (1 or 2 reviewers)
Accept
Refer

Substantive Review (not less than 3 reviewers)
Accept
Reject
Refer

Full Review (meeting of UEC)
Accept
Reject

Reject