ETHICS COMMITTEES WITH DELEGATED AUTHORITY

SUMMARY OF PRINCIPAL CHANGES

General changes	
Section	
5.6	Programme Tutor to read 'Programme Leader'
5.8	Completion of studies
5.12	Class protocols
8	revision, removal and reposition as Section 14 in main document

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*(Amendments to version **07.0,** Appendix II, UPR RE01, are shown in italics.)*

Structure

1 INTRODUCTION

1.1 This document has been approved by the Academic Board[1] and is also subject to amendment from time-to-time on the direct authority of the Ethics Committee for Studies Involving Human Subjects ('the Ethics Committee').

1.2 Forms

The following forms are referred to in this document:

EC1 'Application Form'
EC2 'Application to Modify/Extend an Existing Protocol Approval'
EC7 'Protocol Monitoring Form'
AC1 'Notification of an Alleged Assessment Offence'

2 DELEGATED AUTHORITY

2.1 The Ethics Committee for Studies Involving the Use of Human Participants of the Academic Board may delegate authority to another body elsewhere in the University for the approval and monitoring of studies involving Human Participants, including those involving invasive procedures. These bodies are known as 'Ethics Committees with Delegated Authority' (ECDAs).

2.2 Delegated authority is granted, at the discretion of the Ethics Committee, for periods of between one (**1**) and five (**5**) years subject to the regulations set out in UPR RE01[2] and to any other conditions that may be imposed from time-to-time by the Ethics Committee.

3 APPLICATIONS FOR RENEWAL OF DELEGATED AUTHORITY

3.1 The Ethics Committee will review delegated authority and, before the end of the period of delegation, the ECDA must apply in writing to the Ethics Committee to have its delegated authority renewed. Applications for renewal of delegated authority should accompany the Annual Report which immediately precedes the expiry of the current delegated authority.

3.2 It would normally be the case that, subject to satisfactory Annual Reports, an ECDA's delegated authority would be renewed for such period as the Ethics Committee deems appropriate. However, the Ethics Committee retains the right, at any time, and at its discretion, to withdraw delegated authority from an ECDA. That discretion would only be exercised where the Ethics Committee had evidence that an ECDA had failed to discharge its delegated authority satisfactorily.

3.3 Given the information sought from the ECDAs in respect of Annual Reports (section 5, refers), it is not necessary for that information to be repeated. However, in applying for renewal of delegated authority, ECDAs are invited to:

i provide a brief overview of the period of delegation;

ii raise any policy or procedural issues in respect of ethics matters direct with the Ethics Committee;

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[1] **Academic Board Minutes:** 731, 15 March 2000; 795.2, 14 March 2001; 867.2, 6 March 2002 and 943.2, 5 March 2003; 155.2, 9 March 2005; 188.1, 15 June 2005; 241.2.1, 1 March 2006; 346..2.3, 13 June 2007, 479, 12 March 2008 and 574.3, 11 March 2009; 156; 59.5, 20 June 2012; 282, 19 June 2013; 359, 12 March 2014; 480, 11 March 2015, *600, 22 June 2016,* refer.

[2] UPR RE01 'Studies Involving the Use of Human Participants'

iii request any amendment to the terms of their existing delegated authority;

iv assess the training provided and identify training issues;

v report on any other matter within their terms of reference;

vi include any other relevant comments or suggestions.

4 ETHICS COMMITTEES WITH DELEGATED AUTHORITY

4.1 ECDAs form part of the committee structure of the Academic Board and are required to operate in accordance with the Standing Orders of the Academic Board.

4.2 Terms of reference

Core terms of reference have been determined by the Academic Board for all ECDAs. An ECDA may propose additional terms of reference for consideration by the Ethics Committee which may then recommend them for approval by the Academic Board.

4.3 Composition

4.3.1 It is a condition of delegated authority that every ECDA has at least one (**1**) external member approved by the Ethics Committee. An external member is defined as one external to the scope of the ECDA concerned but internal (within the staff of the University), preferably with ECDA experience.

4.3.2 When establishing an ECDA, the Ethics Committee may, in addition to the required external member, stipulate other categories of membership and will approve the initial membership of the ECDA.

4.4 Changes in membership

ECDAs are required to inform the Ethics Committee at the earliest opportunity of any membership changes.

5 PROCESS FOR REVIEW OF APPLICATIONS FOR ETHICAL CLEARANCE

(**Note for guidance:**

A flow chart illustrating the review process is give on the final page of this document and is also published at the following location:

http://sitem.herts.ac.uk/secreg/upr/RE01.htm)

5.1 Application process

5.1.1 Applications for ethical clearance should be made on Form EC1 and submitted electronically to the Clerk of the relevant ECDA.

5.1.2 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 5.2.4 and 5.3.2, refer), contact between applicants and the subject or other specialist(s) (section 5.1.6, refers) responsible for reviewing that application should be routed through the Clerk.

5.1.3 There are three (**3**) processes whereby an ECDA can examine an application:

a '**Expedited Review'** (section 5.2, refers);
b '**Substantive Review'** (section 5.3, refers);
c '**Full Review'** (section 5.4, refers).

5.1.4 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.

5.1.5 **Review panels**

To enable them to operate the review processes referred to in section 5.1.3, ECDAs 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.

5.2 Expedited Review

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

5.2.2 ECDAs are not required to handle applications for Expedited Review at Committee meetings but are required to specify the conditions under which Expedited Review can be allowed and agree these with the Ethics Committee.

5.2.3 The Expedited Review process requires that a minimum of one (**1**) subject specialist~~s~~ from a panel of subject specialists (which might include the Chairman or Vice-Chairman of the ECDA) examine an application independently and recommend it for approval by the Chairman of the ECDA.

5.2.4 Expedited Review should be completed within ten (**10**) working days of the date of the receipt of the application by the Clerk of the ECDA 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.

5.2.5 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 Chairman of the ECDA should be sought.

5.2.6 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.

5.3 Substantive Review

5.3.1 ECDAs are not required to handle applications requiring Substantive Review at Committee meetings. 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 Chairman of the ECDA.

5.3.2 The Substantive Review should be completed within ten (**10**) working days of the date of its receipt by the Clerk of the ECDA 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.

5.3.3 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 Chairman of the ECDA should be sought.

5.3.4 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.

5.4 Full Review

An application may be referred for Full Review, either at the time of its submission or as an outcome of one or more of the review processes described in sections 5.2 and 5.3 or as a result of a referral by the Chairman of the ECDA, for example, in cases where the reviewing subject specialists have been unable to reach a unanimous decision. Should the requirement for Full Review be at the recommendation of the subject specialist who have considered the application at an earlier stage, these individuals may be required to attend the ECDA meeting for the relevant item in order to provide specialist advice.

5.5 Approval of applications

5.5.1 Expedited Review and Substantive Review

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

5.5.2 Full Review

i Applications referred for Full Review will be considered at a meeting of the ECDA. It should be noted that the ECDA 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 ECDA requires further information that is not available at the meeting, the members of the ECDA might, at their discretion, allow the Chairman to approve the application by Chairman's Action following circulation to them of the additional information requested by the ECDA and their consent to approval being given by Chairman's Action.

5.5.3 An appropriate method for monitoring approved Protocols, including Class Protocols, should be established by the ECDA to ensure that studies are not allowed to continue beyond their expiry date. Should an extension be required, the permission of the ECDA should be sought. An extension, where permitted, might be deemed to be a modification (section 5.12, refers).

5.5.4 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 Chairman of the approving ECDA is authorised to withdraw approval. In such a circumstance, the principal investigator should be asked to complete Form EC7 and submit it to the relevant ECDA.

5.6 Permission to conduct studies on campus

Module Leaders or Programme *Leaders* should approve a list of all projects being carried out as part of a particular module which will contain the names of the students, their supervisors and project titles. The ECDA would be provided with this information together with a copy of their written approval. Any such arrangements are required to be renewed on an annual basis.

5.7 **Problems encountered during conduct of study**

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

5.8 **Completion of studies**

5.8.1 *Students*

All submissions of work should contain a statement that the study (that is, the collection of data from participants) 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.*

5.8.2 Staff

The completion of Form EC7 following completion of data collection is required to be lodged with the ECDA Clerk in respect of all studies undertaken by staff.

5.9 **Breach of Protocol**

Section 9.3, UPR RE01[2], refers).

5.10 **Notifying a Board of Examiners of a breach of Protocol**

In accordance with the provisions of Appendix III, UPR AS14[3], the relevant Associate Dean of School (Academic Quality Assurance) (or nominee), is responsible for notifying the Chairman of the Short Course/Module Board of Examiners of the outcome of any Breach of Protocol case.

5.11 **Modification to an approved Protocol**

Any modification(s) of an approved Protocol must be notified to the ECDA 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.

5.12 **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 ECDA of Form EC2; more complex amendments will require resubmission using Form EC1.*

5.13 **Schedule of Protocols**

In accordance with section 4, UPR RE01[2] ('Compliance'), all approved Protocols must be allocated a Protocol number, including those approved by an NRES ethics committee, 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 ECDA.

6 ANNUAL REPORTS

6.1 Every ECDA is required to submit a written Annual Report to the Ethics Committee.

6.2 Reports should normally be written by the Chairman of the ECDA in consultation with his or her members.

6.3 Given the nature of the work being undertaken, as a matter of good practice, the Ethics Committee 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.

6.4 **Purpose**

The purpose of these reports is to inform the Ethics Committee of what the ECDA has been doing and, in particular, how it has been discharging its delegated authority.

6.5 **Structure and content**

Reports need not be long but will include the following mandatory elements:

i **the current membership of the ECDA**

as approved under delegated authority, 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 collaborative programmes 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**

the procedures adopted by the ECDA for monitoring 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 of all Protocols under the ECDA's management.**

this information is to be supplied on the pro forma provided by the Clerk to the Ethics Committee;

ECDAs will also notify the Ethics Committee of any studies involving the use of Human Participants undertaken by University staff or students under the terms of Protocols approved by bodies permitted under the terms University regulations to grant external approval of Protocol applications;

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 ECDA's operating environment or externally, which may impact on the ECDA's activities in the coming year;

ix **collaborative programmes**

information on the ethics management of collaborative programmes in the academic areas relevant to the ECDA;

x **Class Protocols**

a list of all active Class Protocols, with their expiry dates;

xi **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**

the ECDA's response to any matters raised at the time of the previous year's report which required action from the ECDA.

All of the above headings must be included in the Report and Chairmen of ECDAs will signify that there is nothing to report where that is the case.

6.6 **Timetable for the submission of Annual Reports**

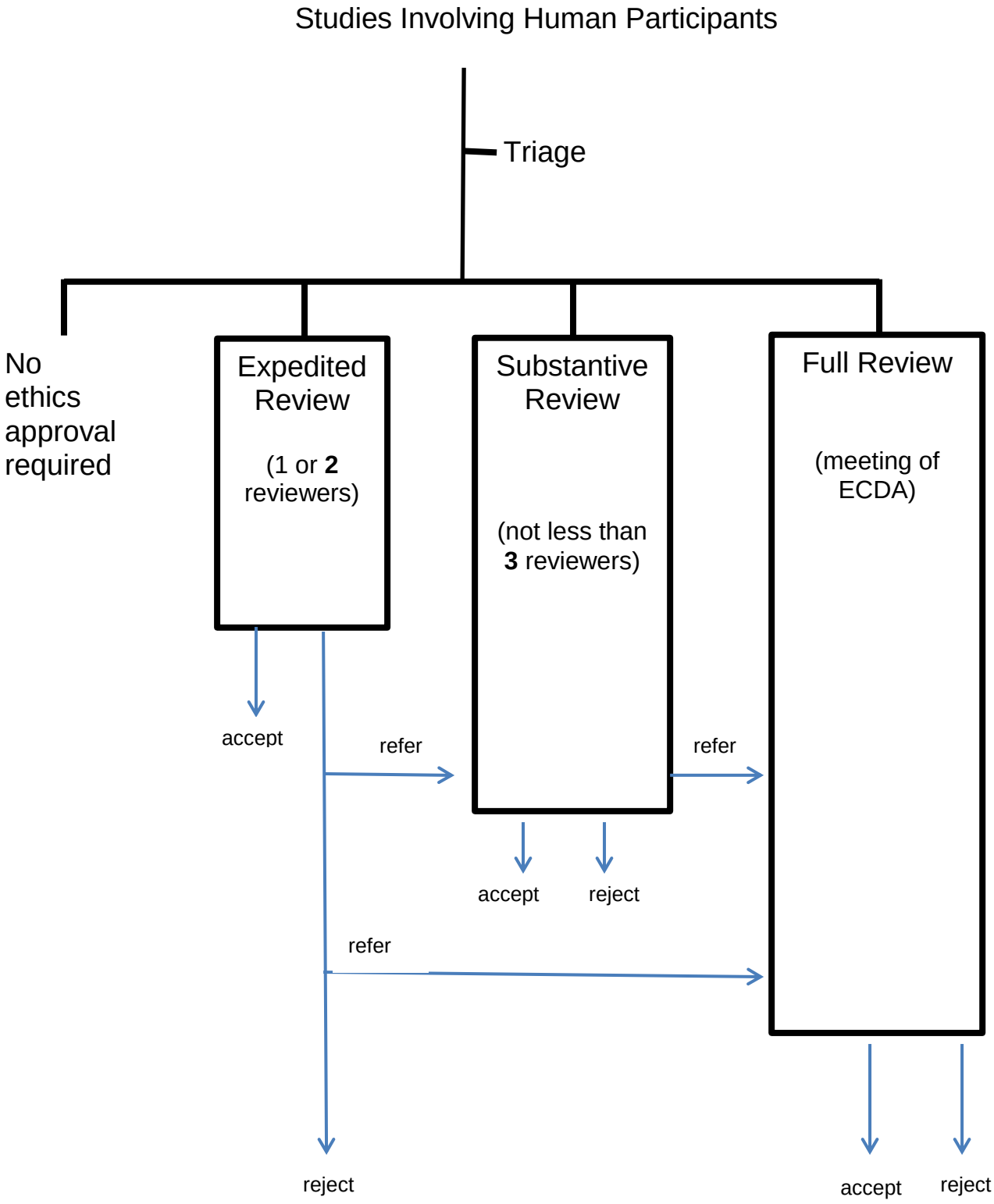
Annual Reports from ECDAs for the previous Academic Year must be submitted to the Autumn meeting of the Ethics Committee. Chairmen of ECDAs will be informed by the Clerk to the Ethics Committee of the date by which they should submit their Reports.

6.7 **Presentation of the Annual Report to the Ethics Committee**

Chairmen of ECDAs are expected to attend to present their Annual Reports. Where attendance is not possible, arrangements for another member of the ECDA to present the report must be agreed with the Chairman of the Ethics Committee in advance of the meeting.

7 **NOTES OF GUIDANCE**

Notes of guidance, prepared by the Ethics Committee, maintained by the Clerk to the Ethics Committee and published to all ECDAs, are available to assist ECDAs. The notes of guidance are also posted at the following location on the open-access Corporate Governance website:



Mrs S C Grant
Secretary and Registrar
Signed: **1 August 2017**