STUDIES INVOLVING THE USE OF HUMAN PARTICIPANTS

SUMMARY OF PRINCIPAL CHANGES

General changes
- Scope: studies and activities not considered as studies

Section changes
- 1.7: Group responsibilities (students)
- 12: HRA applications

(Amendments to version 08.0, UPR RE01 are shown in italics.)

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Programme Specifications contain the following clause which specifies the application of these regulations.

“The programme operates in accordance with the University’s Regulations Governing Studies Involving the Use of Human Participants (UPR RE01) agreed from time-to-time by the Academic Board of the University, unless and until responsibility for ethical standards is transferred to a Partner Organisation (section 6, refers). On transfer, the Partner Organisation will be responsible for all insurance liability in connection with the observance of ethical guidelines.”

Unless a Partner Organisation has obtained the approval of the Academic Board, through the University’s Ethics Committee for Studies Involving the Use of Human Participants, to have responsibility transferred to it for the ethical conduct of studies involving Human Participants, all protocols must be applied for and monitored through the relevant Ethics Committee with Delegated Authority. The member of staff involved in the assessment process will liaise with the Chairman of the appropriate ECDA to assist in the identification of those studies which might need ethics approval and to advise on the application of the procedures in bringing protocol applications forward to the relevant University ethics committee. Those organisations wishing to apply for transferred responsibility should refer to section 6.
1 SCOPe

1.1 These regulations apply to any study or activity involving the use of Human Participants which is undertaken as part of a programme of work for which the University of Hertfordshire is responsible.

1.2 Where the relevant programme of work is offered in collaboration with another organisation there is a requirement that these regulations apply in cases where the University of Hertfordshire is the lead institution and takes responsibility for providing ethical clearance.

1.3 Throughout these regulations ‘University’ must be read as including those organisations with which the University has a formal collaborative agreement and the regulations be so applied, unless and until the University has transferred responsibility for ethical standards to a Partner Organisation, either within the United Kingdom or abroad, or there is a legal requirement to obtain ethical approval.

1.4 Partner Organisations seeking transferred responsibility should refer to section 6.

1.5 These regulations apply to all studies or activities falling within the scope of section 1.1 including:

   i studies or activities conducted at every level;

   ii all studies or activities which include the use of questionnaires and/or interviews conducted either as part of a group or class programme or as individual project work;

   iii all studies or activities which use University employees and/or students as Human Participants in a programme of study and those which use members of the public;

   iv all studies or activities sanctioned by the University and conducted on University premises or elsewhere.

1.6 Those required to comply with these regulations include University employees, University students and researchers contracted or invited to work within the University.

1.7 It is the responsibility of the appropriate members of the University’s academic staff to ensure that students for whom they are responsible are made aware of and comply with the University’s regulations governing studies or activities involving the use of Human Participants (UPR RE01). Academic staff supervising students who conduct a study or activity in a group must therefore ensure that their students are aware that, although one student will complete an application on behalf of colleagues in the group, all those named have responsibility for complying with the terms of the approval. Students conducting a study or activity in a group should also be aware that complicity may be a ground for establishing individual responsibility if they are party to activities that constitute a breach of an approved protocol, including failure to obtain ethical approval.

1.8 Definitions

For the purposes of this document the following definitions will apply:

   i ‘Ethics Committee’:

   the Ethics Committee for Studies Involving the Use of Human Participants of the Academic Board;

   ii ‘ECDA’:

   Ethics Committee with Delegated Authority.
1.9 The regulations and procedures set out in this document have been approved by the Academic Board².

2 PURPOSE

2.1 The purpose of these regulations is to ensure, as far as possible, that any study or activity involving the use of Human Participants is conducted in accordance with proper ethical standards.

2.2 These standards require that any member of the academic staff responsible, either directly or as a supervisor, for any study or activity involving the use of Human Participants takes reasonable steps to ensure that:

i the study or activity is well designed (section 4.2, refers);

ii there is an identifiable objective benefit, which may include the training of researchers, to be gained from the participation of Human Participants in the study (section 4.2, refers);

iii the work is conducted in accordance with UPR HS01³, which may require a risk assessment to be undertaken and the outcome of that assessment incorporated within a protocol for conducting the work safely or used as a basis for determining the appropriate approved School safety procedures to be adopted (section 4.2, refers).

2.3 In particular, these standards are defined in order to ensure that:

i participants are safeguarded against procedures which may be harmful to them, including physical harm, mental or emotional harm, intrusion of their privacy or exploitation;

ii where there is a risk of harm, investigators are expected to take reasonable steps to avoid or minimise harm to participants and to ensure that where any participants do suffer harm, appropriate or professional care will be available promptly, in sufficient quantity, and at no cost to participants;

iii confidentiality is maintained in respect of the identity of those participating in a study or activity and also in respect of any personal information which participants may disclose in the course of the study;

iv participants understand the nature of the study or activity which is to be undertaken and their involvement in it and have given informed consent to their own participation and that, where participants are unable to give informed consent themselves, consent is obtained from a person recognised as having authority to give that consent;

v participants are informed that they may withdraw from the study or activity at any time without disadvantage and without having to give a reason;

vi the purpose of any payment or other reward offered to a participant is to compensate him or her for inconvenience or expense and that it does not constitute an inducement to submit to risk which the participant would otherwise decline;


³ UPR HS01 ‘Corporate Health and Safety Policy’
where a collaborative, commercially-oriented sponsor wishes to make payments or offer other rewards direct to participants, the relevant ECDA satisfies itself that the level of payment or the reward is justifiable and consistent with the sponsor's normal practice.

(Note:

Human Participants resident in the UK, to whom payment is to be made or who are to receive other rewards, must undergo right to work checks, prior to taking part in the study or activity, in accordance with current Home Office regulations and will not be permitted to participate in a study where this would place them in breach of Home Office regulations.)

2.4 Exceptionally, a study or activity may be approved where the consent of the participant(s) is not sought or obtained. Any study so proposed would be required to include full reasons as to why consent was not being sought and the committee approving such a proposal would be obliged to record the terms and limitations on which such an approval was granted.

2.5 A further purpose of these regulations is to satisfy the requirements of the University's insurers that the University has adopted proper ethical standards in respect of any study involving the use of Human Participants and that procedures exist within the University to enforce those standards.

3 ETHICAL STANDARDS

3.1 In determining the standards which should apply to studies or activities carried out within these regulations, investigators and supervisors are required to observe:

i relevant statutory provisions;

ii standards laid down by the University itself;

iii any codes of conduct appropriate to the discipline or profession within which any study or activity is being carried out;

iv any other specified standard identified within an application for approval and agreed by those granting approval for the study or activity to be undertaken.

3.2 Where there is any conflict between the standards identified in section 3.1, ii, iii and iv above, it will be for those granting approval to determine which standard should apply.

4 COMPLIANCE

4.1 The University's Academic Board has established an Ethics Committee for Studies Involving the Use of Human Participants ('Ethics Committee') whose responsibility it is to ensure that proper ethical standards are defined and maintained in respect of all studies involving the use of Human Participants.

4.2 The definition and maintenance of those standards referred to in section 2.2 above, are primarily the responsibility of academic staff devising and/or supervising particular programmes of study and those standards are not subject to approval by the Ethics Committee. However, the Committee reserves the right to comment on and refer back applications for approval which it considers do not meet those standards.

4.3 The definition and maintenance of those standards referred to in section 2.3 above are the direct responsibility of the Ethics Committee or of any other committee to which the Ethics Committee delegates responsibility for ethical standards in respect of studies or activities involving the use of Human Participants (section 5, refers).
4.4 In order to ensure compliance:

i each study or activity which involves the use of Human Participants must be covered either by an approved protocol of the University of Hertfordshire or by an appropriate external approval;

ii the protocol must include the methodology to be applied and the means by which informed consent, where required, will be obtained;

iii every proposed protocol to be approved by the University must be submitted to the Ethics Committee or ECDA and approved prior to the start of the investigative stage of the study or activity;

iv studies or activities with approved protocols must be monitored appropriately;

v the number of the protocol and the name of the ECDA which approved it must be quoted on all correspondence relating to studies or activities which have received ethical clearance.

Failure to do so may lead to disciplinary proceedings being taken.

4.5 It is for the Ethics Committee to determine which other bodies should have authority to grant an external approval. Normally, any such body would be expected to have formal procedures for the approval of protocols. A list of approved bodies is set out in section 10 of this document.

4.6 The Ethics Committee may require, at its absolute discretion, that a study or activity approved by a body which the Ethics Committee has approved to grant external approval of protocol applications (section 10, refers) must also be approved by the relevant ECDA.

5 DELEGATED AUTHORITY

5.1 Under powers granted to it by the Academic Board, the Ethics Committee may, as it sees fit, delegate its authority to approve or reject proposed protocols.

5.2 The structure and number of ECDAs is determined by the Ethics Committee.

5.3 ECDAs should apply in writing for renewal of delegated authority (Section 3.1, Appendix II, UPR RE014, refers). There is no standard application form but applicants are expected to provide information as to:

i their knowledge and experience of the ethical standards applicable to their discipline and/or profession;

ii how those standards would be or have been applied and monitored within the context of the academic work of the University;

iii the proposed or renewed membership of the Committee;

iv the matters (if any) which applicants might wish to have reserved for decision by the Ethics Committee, for example, physically invasive procedures, studies or activities involving deception, studies involving Human Participants unable to give informed consent;

4 UPR RE01, Appendix II 'Ethics Committees with Delegated Authority'
5.4 In considering applications for delegated authority, the Ethics Committee may itself specify matters in respect of which it is not prepared to grant delegated authority.

5.5 Committees granted delegated authority are required to comply with any conditions specified by the Ethics Committee. Standard conditions are:

i the requirement to provide an Annual Report to the Ethics Committee detailing the work undertaken during the previous Academic Year under delegated powers as set out in the notes for guidance to Chairmen of ECDAs (section 6, Appendix II, UPR RE01, refers);

ii the necessity to report as soon as possible to the Chairman of the Ethics Committee any major irregularity including:

a compromises to the safety of participants or breaches of confidentiality;

b other serious breaches of approved protocols or;

c studies or activities undertaken without an approved protocol;

iii the requirement to notify the Ethics Committee of all approved protocols as part of an Annual Report.

5.6 Delegated authority will normally be reviewed after a period of five (5) years, with a view to the delegated authority being renewed, either on existing or revised terms.

5.7 The Ethics Committee reserves the right to withdraw delegated authority in any circumstances which reveal, after enquiry, that the committee with delegated authority has failed to exercise proper responsibility in the granting or monitoring of protocols for which it has delegated responsibility.

6 TRANSFER OF RESPONSIBILITY

6.1 The Ethics Committee may, as it sees fit, recommend to the Academic Board that responsibility for ethical standards be transferred to a Partner Organisation.

6.2 An application for transfer of responsibility must be made in the first instance to the appropriate ECDA.

6.3 There is no standard application form. The appropriate ECDA is expected to work together with the Partner Organisation to prepare documentation to support the application and no application will be considered by the Ethics Committee unless it is accompanied by a recommendation from the appropriate ECDA.

6.4 Documentation should include information as to:

i the establishment, history and terms of reference of the ethics committee within the Partner Organisation;

ii the membership of such an ethics committee and the knowledge and experience of ethical standards applicable to each member’s discipline and/or profession;

iii the regulations which will apply to all studies involving Human Participants, together with a summary of any significant differences between these regulations and the University’s own regulations;

iv how ethical standards will be applied and monitored within the academic work of the Partner Organisation;
v any other information which the applicant Partner Organisation wishes to provide or which is specifically requested by the Ethics Committee.

6.5 The Ethics Committee may recommend to the Academic Board that transfer be subject to conditions and time limits placed on compliance with any condition.

6.6 Following transfer of responsibility, it will be for the Partner Organisation, at any review of the collaborative agreement, to include reference to the work of its ethics committee as appropriate.

7 PROCEDURES FOR PROTOCOL APPROVAL

7.1 One of the following procedures will apply to applications for protocol approval.

i Where the Ethics Committee has granted delegated authority to an ECDA (section 5, refers) applicants within the relevant academic area must comply with the procedures adopted by that ECDA, as approved by the Ethics Committee. A set of standardised application documentation has been developed, effective 1 January 2013, but ECDAs may devise appendices to the standard application Form EC1 to accommodate discipline-specific requirements.

ii The methods for approving applications which may be adopted by ECDAs are set out in Appendix II, UPR RE014.

iii Where an application falls outside the scope of an ECDA or is of an interdisciplinary nature such that it cannot be handled by one ECDA, applicants must comply with the procedures set out in section 7.2.

iv Where, in any circumstances, the Ethics Committee has withdrawn delegated authority from an ECDA, applicants from the relevant academic areas must comply with the procedures set out in section 7.3.

v The regulations and procedures set out in sections 7.4, 7.5, 7.6 and 7.7 have general application, whether submission has been made to the Ethics Committee or to an ECDA.

7.2 Applications coming within the scope of regulation 7.1, iii, above, must be submitted using Form EC1 (regulation 7.3, i, refers). Such applications must be submitted in the first instance to the ECDA that appears most competent to handle the application. Should that ECDA find itself not competent or otherwise unable to handle the application, it should refer the application to the Ethics Committee.

7.3 Where application is to be made to the Ethics Committee the following procedure applies:

i Form EC1 must be completed electronically and submitted electronically from an official email account of the student’s supervisor to the Clerk to the relevant ECDA. All relevant questions on form EC1 must be answered. Failure to comply with these requirements will result in the application being referred back and may lead to delay in approval being granted;

ii applicants will be notified formally by the Clerk that the application has been submitted to the Ethics Committee, for the approval process to be completed.

7.4 Approval will normally be notified to the applicant in writing by the Chairman of the Ethics Committee. Where an application is not approved, the applicant will be notified in writing and reasons for non-approval will be given. In appropriate instances, approval may be granted subject to certain conditions.
7.5 In the case of an individual piece of work, the applicant as the investigator must complete and sign the application form, which must also be countersigned, in respect of undergraduate, taught postgraduate and research students, by the applicant's supervisor.

7.6 In the case of a classwork practical or other group study it is the member of staff responsible for formulating the study or activity, such as the Module Leader or Project Tutor, who must complete and sign the application form.

7.7 Individual protocols will normally be approved for the limited period of time specified on the application. Application may be made for extension of time.

8 CLASS PROTOCOLS

8.1 Standard protocols ('Class Protocols') governing routine and/or repeated procedures such as classwork practicals or other group studies may approved by an ECDA and are subject to review, normally on an annual basis.

8.2 The member of staff responsible for formulating the study or activity, such as the Module Leader or Project Tutor, should make the application using Form EC1B.

8.3 Conducting the studies

8.3.1 Where students are conducting studies or activities involving Human Participants under an approved Class Protocol, the supervisor should record the titles of the individual projects, student names and brief indication of the methodologies being used. For protocol monitoring purposes, the relevant ECDA should be informed that a study or activity has taken place and Form EC7, ‘Protocol Monitoring Form’, should be completed to indicate to the ECDA that the study was conducted in accordance with the agreed Protocol. The supervisor should also submit a list of the names of the students who conducted the studies.

8.3.2 In the case of studies or activities requiring students to act as participants in classroom-based studies, Form EC8, ‘Consent Register for use in Class Practicals Governed by an Approved Class Protocol’, should also be used to record the consent of the participants. The briefing material, including Participant Information Sheet, which will have been reviewed prior to the granting of approval, should be made available to the students to enable them to decide if they wish to act as participants.

(Section 5.12, Appendix II, also refers.)

8.4 Types of study suitable for class protocol approval

8.4.1 Typically, classwork practicals and certain types of data collection are suitable for Class Protocol approval. The methods of data collection under this type of protocol are restricted to questionnaires considered by the ECDA to be harmless and straightforward, individual interviews, focus groups, online surveys and overt observations. Software testing and low-risk studies by foundation degree students, where methodologies are restricted to simple methods, would also be appropriate activities. The triage checklists (lists of activities classified according to their level of risk for ‘Expedited’, ‘Substantive’ or ‘Full’ Review) for each ECDA contain a column listing types of activity suitable for class protocol.

8.4.2 Staff are advised to consult the relevant ECDA if they believe classroom- or group-based activities for a sizeable group of students would be appropriate for Class Protocol approval.
9 STUDIES INVOLVING HUMAN PARTICIPANTS UNDERTAKEN WITHOUT AN APPROVED PROTOCOL

9.1 Studies or activities undertaken without an approved protocol include both:

i failure to obtain ethics approval prior to undertaking work involving Human Participants;

ii failure to comply with the terms and conditions of an ethics approval granted for with involving Human Participants.

9.2 Any employee of the University who acts in contravention of these regulations will normally be subject to the University’s disciplinary procedures.

9.3 Any student of the University acting in contravention of these regulations may be penalised through the assessment process (Appendix III, UPR AS14\(^5\), refers), may have his or her programme of study declared invalid, may not be permitted to graduate or where a student has already graduated, may have his or her award revoked. At its absolute discretion, the University may take disciplinary action. Any alleged breach of these regulations by a student in respect of study which will not be submitted for assessment, may be treated as a disciplinary offence.

9.4 The provisions of UPR RE02\(^6\) also apply. A contravention of these regulations that arises from the participation of a student on a taught module, or credit bearing short course will normally, in the first instance, be dealt with in accordance with the procedures set out in Appendix III, UPR AS14\(^5\). Otherwise, the procedures set down in section 8, UPR RE02\(^6\) will be followed.

9.5 Other studies involving the use of Human Participants

(Note:
From time-to-time, the University receives approaches from individuals or organisations external to the institution who wish to issue requests for human volunteers to participate in studies that they are leading or in activities that they are organising. In some cases, the individual or organisation may wish to conduct the study or activity on University premises. A study or activity may or may not have received ethical clearance from another body but may fall within the scope of UPR RE01.)

9.5.1 Regardless of whether a study or activity proposed by an individual or organisation external to the University has received ethical clearance from another body, the proposal will be referred for consideration and decision by the Chairman of the Ethics Committee.

9.5.2 For the avoidance of doubt, the proposed study or activity will not proceed unless the prior written consent of the Chairman of the Ethics Committee had been obtained.

10 BODIES APPROVED BY THE ETHICS COMMITTEE TO GRANT EXTERNAL APPROVALS OF PROTOCOL APPLICATIONS

10.1 National Health Service

10.1.1 Studies which will be approved by the National Health Service (Health Research Authority (HRA)), including, but not limited to, studies involving patients, require the prior approval of the relevant Research Ethics Committee (REC) specifically recognised within the HRA and working to the ‘Governance arrangements for research ethics committees’ (GAIREC).

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\(^5\) UPR AS14, Appendix III ‘Assessment Offences’

\(^6\) UPR RE02 ‘Research Misconduct’
These Research Ethics Committees are approved under the terms of these regulations (UPR RE01) as external bodies authorised by the University to grant approvals of protocol applications for studies which fall within the scope of their terms of reference.

Studies approved by an REC will not also require approval by the relevant ECDA, unless the ECDA concerned has determined otherwise (section 4.6, refers).

Requirements of other external bodies

The requirements of the following external bodies must be observed in relation to studies which fall within their authority:

- The Gene Therapy Advisory Committee (GTAC);
- The Human Fertilization and Embryology Authority (HFEA);
- The Human Tissue Authority (HTA).

STUDIES OR ACTIVITIES CARRIED OUT IN COLLABORATION WITH ANOTHER ORGANISATION

Research or other work carried out in collaboration between the University and other organisations or by a consortium of which the University is a member, may include studies or activities involving human participants.

In these circumstances, it may be proposed that either the University or other collaborating organisation/consortium member should be made responsible for giving ethical clearance for all studies or activities involving the use of human participants conducted as part of the collaboration/within the consortium.

Where such an arrangement is proposed (section 11.2, refers), University staff and students who will be working under the terms of such collaborations or within such consortia, are required to declare the proposed arrangement to the Ethics Committee through the relevant ECDA, using Form EC1C, 'Declaration of involvement in a non-UH approved study'.

Where the Ethics Committee gives consent, it has discretion to do so on a conditional basis and/or to set aside any requirement that University staff and students who will be working under the terms of such collaborations or within such consortia must, additionally, obtain ethical clearance from the Ethics Committee.

The Ethics Committee, acting on the University's behalf, reserves the right, at its absolute discretion, not to approve such proposed arrangements.

The Ethics Committee will determine appropriate processes to deal with such proposals.

APPLICATIONS REQUIRING CONSIDERATION BY THE HEALTH RESEARCH AUTHORITY (HRA)

The Pro Vice-Chancellor (Research and Enterprise) is responsible to the Vice-Chancellor for the co-ordination and management of the institutional process whereby proposals are made by the University for sponsored studies (including Clinical Trials of Investigational Medicinal Products (CTIMPs)) that require approval by the HRA.

This internal process includes a review of the applications for quality and ethical soundness, is overseen by the Advisory Group on Research Governance for Clinical Studies.

A University of Hertfordshire protocol number will only be issued following receipt and endorsement by the relevant ECDA Chairman of a copy of the application approved by the HRA and their letter indicating a favourable opinion, together with any earlier opinion letters received prior to the favourable opinion.
REFLECTIVE PRACTITIONER WORK

The Committee recognises that, in certain discipline areas, ordinary professional practice may merge into reflection and research. Those engaged in reflective practitioner work will have due regard for the ‘Protocol for Reflective Practitioner Work by Academic Staff’ which is published as Appendix I of this document and are required to obtain any necessary ethics approvals in accordance with the provisions of these regulations (UPR RE01).

PUBLICATION OF REQUESTS FOR VOLUNTEERS TO ENGAGE IN STUDIES INVOLVING HUMAN PARTICIPANTS

14.1 The purpose of the Statement in this Section is to clarify the University’s position in relation to requests for human volunteers, published electronically and/or by means, of any printed notice to participate in studies involving human participants.

14.2 This Statement relates to studies or activities involving the use of human participants which have been approved by the Ethics Committee for Studies Involving Human Participants (the Ethics Committee) of the Academic Board or a committee to which it has delegated authority, including the NHS/Health Research Authority.

14.3 Notices requesting human volunteers to participate in studies approved by the Ethics Committee

The member of staff or student conducting the study or activity is required to ensure that appropriate information, including the name of the body which has given approval for the study or activity and the protocol reference number, is included within any notice inviting volunteers to take part in that study.

14.4 Electronic publication of notices

14.4.1 Requests to members of staff

i The member of staff or student conducting the study or activity may publish general requests to staff for human volunteers via the University's intranets or email addresses available via StaffNet. Requests may be published on any of the University's Special Interest e-mail Lists without having to obtain the prior written consent of the Secretary and Registrar. However, such requests may not be published via the uhq or staffq e-mail lists.

ii The publication of such requests on University intranets, including StudyNet, must be in accordance with the regulations for the use of these services and requests must be removed promptly on an agreed expiry date.

14.4.2 Requests to students

i The member of staff or student conducting the study or activity may publish general requests to students for human volunteers via the University’s intranets without having to obtain the prior written consent of the Secretary and Registrar. The use of uhq or staffq is not appropriate and groups of students should only be approached via the programme or module leader of relevant programmes/modules.

ii The publication of requests on University intranets including StudyNet must be in accordance with the regulations for the use of these services and must be removed on an agreed expiry date.
14.4.3 Requests for volunteers who are external to the University

Members of staff or students who wish to publish requests for human volunteers at another institution or public area should approach the authorities of that institution or manager of the public area (for example local council, shop managers).

14.5 Publication of general notices other than by electronic means

14.5.1 Use of the University’ internal post

The member of staff or student conducting the study or activity may publish general requests for human volunteers via the University’s internal post provided that he or she has obtained the prior written consent of the Secretary and Registrar.

14.5.2 Other methods of publication

The member of staff or student conducting the study or activity may distribute requests for human volunteers by hand or display notices on University premises with the prior consent of the Dean of School or Senior Manager of a specific area, or the Dean of Students for access to more general areas of the University.

14.6 Use of the University’s official stationery and logo

14.6.1 Students

Students (including students who are also members of staff) are not permitted to use the University’s stationery or logo, even where the study to be undertaken has been approved in accordance with this Regulation (UPR RE01). Section K.8 of UPR FR06, ‘Corporate Governance and Financial Regulation’ explains the circumstances under which the University’s official stationery (headed notepaper) and logo may be used.

14.6.2 Members of staff

Members of staff may use the University’s official stationery and logo in connection with requests for human volunteers only where the proposed study or activity has been approved in accordance with this Regulation (UPR RE01) and on condition that the notice complies with the requirements set out this section.

Mrs S C Grant
Secretary and Registrar
Signed: 1 August 2018