**UNIVERSITY OF HERTFORDSHIRE**

**ETHICS COMMITTEE FOR STUDIES INVOLVING THE USE OF HUMAN PARTICIPANTS (‘ETHICS COMMITTEE’)**

**GUIDANCE NOTES**

**How to apply for approval of a Study Involving the Use of Human Participants**

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**Abbreviations**

GN = Guidance Notes

UPR=University Policies & Regulations

Q=Question

S=Section

Pt = Part

**PART 1: GENERAL MATTERS**

1.1 **Status and function of the Ethics Committee**

1.1.1The Ethics Committee for Studies Involving the Use of Human Participants (“the Committee”) is a standing committee of the Academic Board of the University of Hertfordshire. Its establishment and responsibilities are set out in *Studies Involving the Use of Human Participants* (UPR RE01), which is one of the University Policies and Regulations

1.1.2The Committee’s function is essentially to examine and, as appropriate, to approve proposals for studies which involve human participants, whether or not those participants are members of the University. The Committee is concerned with studies, regardless of where they are to be carried out, which are to be conducted by staff or students as part of their University work or studies, or which could otherwise be associated with the University. (The Committee has no responsibility for studies which its staff or students may conduct away from the university as private citizens.) The Committee’s task is to see that proper ethical standards are maintained in carrying out such studies.

1.1.3 In examining proposals the Committee’s chief objective is to satisfy the University that all proposed studies have received proper scrutiny and to ensure, as far as possible, that participants and investigators are protected from harm

1.2 **Application procedure**

All staff and students proposing to carry out studies involving human participants are required to submit their proposals for ethical scrutiny. This requirement applies equally to undergraduate and postgraduate work; classroom practicals; student projects and studies carried out by members of staff, and includes the administration of questionnaires. Applications should be sent to the appropriate Ethics Committee with Delegated Authority (ECDA). Where an application does not fit comfortably within the remit of just one ECDA i.e. it is a cross-school study, it should be sent to the most relevant ECDA in the first instance. The ECDA will then make a referral of the application to the Clerk of the University Ethics Committee (Mrs Janice Allen).

1.3 **Supervisors’ responsibilities**

1.3.1 Each study must be supervised or conducted by a named member of academic staff, whether it is carried out by him/her or not. In the case of a member of staff who is also registered as a student of the University, it is his/her Supervisor who is responsible for ensuring that the requirements of the protocol are complied with.

1.3.2 In ***particular***, it is the responsibility of the supervisor to ensure that:-

i The investigator obtains ethical approval for the study before it begins (see below, S 2.1);

ii Appropriate arrangements have been made for discussing details of any pre-existing medical conditions, of which participants may or may not have been previously aware, with these participants (see below, S 2.2.12);

iii Where appropriate (see Pt. 3 below, especially SS 3.1 & 3.2), informed consent is obtained fromhuman participants before their involvement in the study begins, and subsequently whenever either the aim(s) or design of the study are revised significantly in ways that could affect participants, or which are inconsistent with the terms on which they agreed to take part;

iv Measures are taken to ensure observance of assurances given on security of information about (and obtained from) participants, and access to such information (see below, S 2.2.10);

v Wherever possible, precautionary measures are taken to protect participants from procedures and methods of investigation which are potentially harmful;

vi Back up facilities, including appropriate professional care, that might be required in the event of harm to participants, are identified, and steps taken to ensure that, were such harm to occur, these facilities could be made available promptly, in sufficient quantity, and at no cost to participants. These steps will include establishing that any persons who may be required to provide care are able and willing to do so, and that sufficient resources would be available to meet the possible costs of such provision. In some cases this may involve consultation with the University’s insurers. (See also below, S 2.2.12);

vii The study is carried out in accordance with principles, guidelines and recognised ethical standards that pertain to the relevant discipline or profession (see below, S 1.6); and

viii Ethical approval is obtained again (using a Form EC2), when any significant modifications or an extension will be needed to alter the protocol originally approved by an ECDA*.*

1.4 **Legal liability**

Once the proposed procedures (i.e. all that is done to or with participants) have been approved by the relevant committee, the University`s insurance will cover investigators (both staff and students) from the financial costs of, or arising from, any litigation which might arise from the operation of such procedures

1.5 **Students` responsibilities**

While responsibility for the conduct of studies rests with academic staff supervisors, students are required to act in accordance with ethical principles and guidelines appropriate to their proposed study. In most cases these will be those of the discipline or profession of a student’s main studies. Students must also comply with any protocol to which they are subject. **Failure to do so may lead to the activation of the University’s disciplinary procedures and may invalidate a coursework/ examination grade and eligibility for an award.**

1.6 **Definition of ethical standards**

How studies should be carried out in a way that satisfies ethical requirements is a topic that has exercised learned societies, and national and international professional bodies, over many years. This has led to the formulation, adoption and periodic revision of numerous statements of ethical principles and guidelines, most of which are intended for a particular discipline or profession. There are some common themes, chiefly consent, confidentiality and harm, but the topic is complicated, so it is not surprising that the answers suggested are themselves typically complex, and that there is wide variation in the extent to which statements of ethical principles and guidelines have been codified. Reference will be made by the Committee, and should be made by applicants, to such statements. In these Guidance Notes published statements of this kind are referred to as “ethical codes”, though actual titles vary, and they may be called, for instance, statements of ethical practice, ethical guidelines, codes of ethics, and declarations of principles. It is in this context that applicants who look for guidance on ethical standards in the relevant UPR will be disappointed, since it has never been seen as the function of each institution to devise its own set of standards. It should be noted, however, that the UPR does affirm that studies should be well-designed, and that as far as possible the participation of human participants in studies should yield some identifiable objective benefit. The UPR also acknowledges that it will not always be appropriate to seek and obtain consent.

1.7 **Conflicts of interest**

There may be occasion when an applicant needs to consider their relationship with potential participants, for example lecturer and student, or researcher with a managerial or leadership role over their potential participants. The design of the study should consider how such a relationship will be managed/mitigated, for example how consent and recruitment will be handled.

**PART 2: PREPARING AN APPLICATION FOR APPROVAL, INCLUDING COMPLETING FORM EC1**, **APPLICATION FOR APPROVAL OF A STUDY INVOLVING HUMAN PARTICIPANTS**

2.1 **Method of obtaining protocol approval**

2.1.1Form EC1 is the University’s standard application form. It should always be used when applying to any ECDA for ethical approval of any study involving the use of human participants. It is designed to elicit the minimum standard of information from the applicant in order for their proposed study to be properly considered by the ECDAs for ethical approval. The Form EC1 has been designed to be general enough for all ECDAs to use; however, an individual ECDA may wish to ask more detailed subject specific questions or direct their students not to answer irrelevant questions. Questions can be added to the Form EC1 by attaching an appendix or appendices to the end of the form.

In respect of student applicants, the Form EC1 should be completed by the applicant in collaboration with their Supervisor. Once the application form is complete the form and other necessary attachments can be sent electronically to the relevant ECDA email address (see Pt 7, below).

2.1.2There are three types of possible review: Expedited Review, Substantive Review and Full Review.

i Expedited Review will be used for the least complicated cases and these applications will be reviewed by two Reviewers. At this point the application can be accepted, rejected or referred for Substantive Review or Full Review if more complex considerations arise.

ii Substantive Review will be used where the application is moderately complicated. Review of the application will be conducted by not less than four Reviewers. At this stage the Reviewers can also accept or reject an application or refer it for Full Review where serious ethical considerations arise.

iii Full Review is for higher risk applications which are reviewed by the full Board of ECDA Members. At this stage the ECDA can request more information, accept or reject an application.

Decisions on applications will be notified to the applicant by the Chair or Clerk of the ECDA.

It may be necessary in some instances for applicants to clarify aspects of their study, or for applications to be resubmitted. Applicants should allow adequate time for their application to be dealt with by theappropriate committee. The length of time for a decision on an application will depend on the type of review the application is initially subjected to and whether a referral for a higher level of review is necessary. Applicants should also note that if the Form EC1 is filled out incorrectly or insufficient information has been provided, the application will be returned for amendments to be made. Reviewers will only be able to review resubmitted applications that are correctly completed and provide all the information requested in sufficient detail. Applicants should bear in mind that complicated proposals may take longer than simple ones. ECDAs may also refer applications to the University Ethics Committee if the application proposes a cross-School study and no single ECDA’s remit covers all aspects of the proposed study. Where approval is withheld, applicants will be notified and given reasons.

2.1.3It is the applicant’s responsibility, if they have a Supervisor, to organise a mutually convenient time and date to meet for both applicant and Supervisor to consider the completed Form EC1. Once Qs1-24 and Appendix 1, if relevant, on Form EC1 have been answered, the applicant must make his/her own Declaration. If the Supervisor deems the Form EC1 to be of the required standard, they must complete the Supervisor Declaration. In signing the Supervisor Declaration, the Supervisor is declaring that both the proposed study and the application are in accordance with the ethical regulations the University complies with and is of the required level of quality of a UH applicant. Therefore the Supervisor should not sign the proposed application if they have not appropriately considered the proposed study and application. If the Supervisor is willing to send the application electronically they must sign the final copy of the electronic form. If they have an electronic signature, this can be attached to the document. If not, they can type their name in the relevant space and this is deemed to constitute their signature. To ensure the authenticity of the electronic signature the application **must** be submitted to the relevant ECDA email from the Supervisor’s email address **only.**

**Supervisors should not approve (sign) any forms which are filled out incorrectly, do not contain enough information and/or which they do not deem to be ethically sound (i.e. do not comply with University, legal and any other regulations recognised by the University of Hertfordshire.)**

2.1.4 Once approval of an application has been given by the Chairman or Vice-Chairman of the ECDA or the Chairman of the University Ethics Committee the applicant will be informed of the decision by the Clerk of the relevant ECDA. If the application is rejected, the ECDA will provide reasons and may provide details of the amendments needed for resubmission. If the ECDA decides to refer the application to the University’s Ethics Committee, the applicant can expect to receive notification of the decision from the Chairman or Clerk of the University’s Ethics Committee*.* **Approval must be obtained before ANY study begins.**

2.1.5 Where studies involving human participants are undertaken without approval, or prior to approval being granted, both investigator and Supervisor are likely to face disciplinary procedures, and there is a risk that the work may not be covered by the University’s insurance arrangements. **In no circumstances will the Ethics Committee or an ECDA grant retrospective approval.**

2.2 **Guidance about individual questions on Form EC1**

***Note:*** *while word limits are not prescribed, the Committee welcomes replies that are as clear and concise as possible and which focus entirely on relevant points.*

2.2.1 **Permission (Declaration and Question 7, refer)**

If you wish to access participant groups from the student body, you will need to obtain the following permission:

i to access student groups across the whole University: obtain permission from Dr Andrew Clutterbuck, Pro Vice-Chancellor (Student Experience);

ii to access student groups within a single or given number of Schools: permission should be sought from the module leader/programme tutor. Student(s) conducting the study are advised to seek the advice of their Supervisor.

If the study is proposed to take place on University premises, you will also need to obtain permission from the manager(s) of areas beyond the Schools in which your study is to be located, for example, the Learning Resources Centres, Refectories, Sports Village, Forum, The Key.

If your proposed study is due to take place off campus, the relevant ECDA will wish to see written permission, given by the proprietor, manager or other person with relevant authority over the premises or location, for use of the premises/location for the purposes of carrying out the proposed study. This is necessary to avoid any claims of illegal trespass. It is recognised that it is not always necessary or possible to obtain permission to use all premises/locations. However, even in the case of public parks and other public open spaces, for example, there are often bylaws or regulations that prohibit certain activities. Hence you should be cautious, not simply assume that permission is not needed, and be prepared to investigate whether it is needed and how to obtain it.

2.2.2 **Question 2**

Applications usually fall into one of the following two categories:

**Q2.1** **An individual or group piece of work:**

In this case the applicant will also be the (principal) investigator and it is this person who should complete the application form. However, guidance should be sought from their Supervisor (should they have one) when filling out the application form. The Supervisor will be responsible for guiding the applicant to ensure that the proposed study and the application are of the required quality and comply with the ethical regulations UH recognises and follows. Such an application is not complete until both applicant and Supervisor have made their Declarations. Staff who are applying as postgraduate students should complete the application form as students. The applicant’s Supervisor will be responsible for guiding the applicant so as to ensure compliance with the approved protocol. However, ultimately, it is the applicant’s responsibility to ensure compliance with the approved protocol.

In cases where a group of students or staff are undertaking a joint study, which is not a class protocol, all the names and student registration numbers should be entered on Form EC1 under Q2.1. One member of the group should nominate themselves as lead applicant and, when they sign the declaration, they will do this on behalf of the group; the declaration includes a statement that the lead applicant has the agreement of the other members of the group to do this. Normally just one member of staff will be responsible for supervision.

**Q2.2** **A class protocol**

In this case it is the member of staff who will be responsible for the class/group who should complete the application form. If a member of staff intends for their class of students to undertake the same research task within a class they intend to hold, they need only make one application on behalf of the whole class rather than individual students applying for ethical clearance. Members of staff making this sort of application **must** complete a risk assessment form (Form EC5). The completed Form EC5 must be attached to Appendix 2 and be submitted to the relevant ECDA along with the rest of the completed Form EC1.

It is expected that the approved protocol will normally have the status of a ‘standard’ protocol, applicable either to a study repeated routinely, or to individual students whose work is identifiable within the ‘standard’. Standard protocols may be agreed subject to periodic review.

2.2.3 **Question 3**

This question has three parts. If an applicant is unsure whether the application should be referred to a National Research Ethics Service (NRES) ethics committee, the ECDA clerks can arrange access to the NHS decision tool. If it is indicated that it is not necessary to submit the application to an NRES ethics committee, or if the application is being submitted to an NRES ethics committee by a collaborating institution, the applicant should continue to complete Form EC1.

**Q3.1** This question is designed to determine whether the proposed study will require approval by an NRES ethics committee whereby the completion of an IRAS form would be required.

**Q3.2** This requires the applicant to give more information regarding the activities involved in the proposed study. It offers multiple specified categories with boxes in which an ‘X’ should be placed if any of the categories are relevant to the proposed study. Not all studies involving NHS or Social Care Staff need to be referred to an NRES ethics committee: if applicants are in doubt they are advised to seek advice from their supervisor or NRES.

It is necessary to ask these questions because applicants with proposed studies which will require NRES ethics committee approval need only fill out Form EC1 as far as Q3.3 and submit this to the relevant ECDA email address (see Pt 6, below). Applicants will be required to complete an IRAS form for NRES ethics committee approval and will also be required to obtain University of Hertfordshire sponsorship. They are advised to obtain further advice from [research-sponsorship@herts.ac.uk](mailto:research-sponsorship@herts.ac.uk).

The use of human tissue is governed by two laws, the Human Tissue Act 2004 and the EU Tissue and Cells Directives. The latter is a EU law that has been implemented in the UK via the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Advice and guidance on these laws is provided by the Human Tissue Authority (HTA) and can be found on their website.

As far as ethical approval of a University research project involving Human Tissues is concerned the situation is as follows:

i If the sample is obtained and not stored for more than seven days (or is stored in a form not containing human cells) and consent has been obtained from the participant the approval may be through an ECDA;

ii If the tissue sample containing human cells (including bodily fluids that contain human cells) is to be used after storage of more than seven days and/or without the participants consent, a favourable opinion from a NRES ethics committee is required;

In the future, if the University were to hold the appropriate licence from the HTA, then a research proposal using stored tissue samples containing human cells (where there is participant consent to the research) could be reviewed through an ECDA. For the avoidance of doubt in any situation where the research is being done without the consent of the participants the review would need to be through a NRES committee.

**Q3.3** This is aimed at ascertaining whether the proposed study is a Clinical Trial of Investigational Medical Products or Medical Devices, and if it is, whether the study involves any of the listed categories. If the proposed study is a Clinical Trial of Investigational Medical Products or Medical Devices which involves any of the listed categories, the University’s insurers will need to review the IRAS application and may need to see further information about the study. If the University’s insurer requires further information on the proposed study for their records, the applicant will be contacted for the additional information.

2.2.4**Question 4**

The Committee will want to see a succinct and reasonably precise statement of what the applicant hopes to achieve. Applicants may wish to include information from their Form EC6 (Participant Information Sheet) and/or include more specialist terminology.

2.2.5 **Question 5**

The Committee requires a sufficiently detailed answer to understand exactly what methods and procedures will be used in relation to the human participants in your study. The Committee will read the answer to this question along with the answer given in Q4 and expects to have been given enough clear information to be able to understand what potential ethical issues may arise from the use of human participants in the context of your study. The Committee must be satisfied that the methods and practices, used in relation to your human participants, are likely to yield sound results which go some way to reaching the stated aims of the study. If the methods and practices are unlikely to yield sound results the study may be open to the objection that the participants, who in most cases will be taking part for no tangible reward, are being taken advantage of and lured into wasting their time and effort. Applicants should note that ECDAs will not review every study in its entirety but will consider the parts of the study which could impact the human participants taking part in this study. However, ECDAs reserve the right (in accordance with Section 4.2 of UPR RE01) to exercise their discretion to comment on and return the application to the applicant if, while reviewing it and the wider study, they consider the study to be ill-conceived and lacking any meaningful purpose (i.e. they fail to meet the standards outlined in S 2.2 UPR RE01).

2.2.6**Questions 6.1 and 6.2**

A study that involves human participants is often part of a wider study. For example, laboratory classwork using human participants may take place in only a few sessions of a programme extending over one or more semesters, or a questionnaire survey may form only one element in a wider project. The information which the ECDAs require is not the start and finish dates of such a wider study, but your best estimate of when, in the absence of unexpected delays, you plan to begin recruiting participants (“intended starting date”) and when you expect to finish collecting data from participants (“expected finishing date”).

2.2.7 **Question 8**

If the applicant intends to carry out the proposed study either on or off-campus, it might be necessary to carry out a risk assessment of the premises/location, to ensure that it is safe for both the participants and the researchers. If undergraduate applicants are not sure whether a risk assessment is necessary, they should consult their Supervisor for further instruction. Postgraduate and Staff applicants may rely on their own judgement to make a decision here and, when reviewing the application, ECDAs will either choose to accept or reject this decision. If applicants are unsure whether a risk assessment in necessary they should bear in mind that the health and safety of both the participants and the researchers are of paramount concern. It might be best for applicants to err on the side of caution and complete a risk assessment so that if there are any potential hazards and risks, these are brought to the applicant’s attention. If a risk assessment is to be carried out, please use the Form EC5 (see Appendix 2) unless the applicant’s School requires a subject specific risk assessment form to be completed. If a risk assessment has been carried out, regardless of the form used, it needs to be attached to Appendix 2 and sent to the relevant ECDA as part of the completed Form EC1.

2.2.8 **Question 9**

This question asks the applicant to consider, in more detail, the environment in which the study will take place.

**Q9.1** The applicant should answer ‘YES’ if anyone other than themselves and the participants/s are present during the study. Their relationship should be clearly stated in the space provided, e.g. a learning support worker may be present to aid the applicant/participant/s during the study.

**Q9.2** This asks whether the study is conducted ‘in confidence’ and what measures are undertaken to ensure confidentiality. Studies will be considered to be ‘in confidence’ if the research is being conducted in private, with only the researcher and participant (and any authorised person detailed in Q9.1). If there are multiple participants, other people are present or if the study is being conducted in an open environment, where questions and answers could be overheard; the study will not be considered to be undertaken in confidence. In this instance, applicants must detail measures they propose to undertake to ensure the confidentiality of the participants and their responses.

2.2.9 **Question 10**

Whether a study is considered to involve invasive procedures will depend on the research being carried out. Where the applicant is unsure, they **must** consult their Supervisor.

2.2.10 **Questions 11 and Appendix 1, Questions A1-A3**

These questions ask the applicant to consider the potential hazards associated with carrying out the proposed study and any steps that need to be taken or necessary precautions instituted to avoid or minimise any risks and adverse effects. Some applicants will already have prepared, or been provided with, a protocol for safe working, which may serve as the answer (or part of the answer) to Q11 and Appendix 1 - Qs A1, A2 and A3. Applicants should consult their Supervisor for advice on the identification of risks and on the adoption of appropriate safeguards. Applicants may then be advised to consult their Faculty Safety Officer or the University’s Director of Occupational Health and Safety.

2.2.11 **Question 12 and Appendix 1, Question A4**

Although Q11 and Appendix 1 – Qs A1-A3 have also asked about the level of risk involved in the study, it can be particularly difficult to gauge the risk of mental or emotional discomfort or distress. That is why this question asks you to judge whether the study “will *or could*” cause discomfort or distress; not whether it definitely will do so. You are expected to attempt an objective assessment of the risk of such discomfort or distress, and to take great care not to underestimate the likelihood of their occurrence. In particular you should be aware that they could arise where an investigation may touch on participants’ background, beliefs or past experiences, and even though participants may initially have agreed without hesitation to take part in the study. You should also note that adverse reactionsmay not be immediate. The Committee would expect the Supervisor to have experience of recognising and dealing with this kind of discomfort or distress, and to be able to advise the applicant accordingly.

2.2.12 **Question 13 and Appendix 1, Question A5**

This question is aimed at ensuring that risks of possible harm to participants have been identified and that appropriate contingency plans for providing care are in place. UPR RE01 S 2.3 (ii) affirms that, “investigators are expected to take reasonable steps…to ensure that where participants do suffer harm, appropriate or professional care will be available promptly, in sufficient quantity, and at no cost to participants”. The term “care” embraces the many and varied kinds of medical intervention and moral and practical aftercare and support that may be required by participants who have been harmed as a result of the research. The kind of care required will depend on the nature of the harm that participants may suffer. Deciding what is required may be unobvious and may call for specialist professional judgment. Hence, before answering this question, applicants should be ready to seek advice from their Supervisor or others. Applicants should note that the “no cost to participants” guarantee applies to care that participants may need where they have suffered harm through their involvement in the study. It does not extend to care participants may require in respect of pre-existing conditions, whether revealed in the course of the study or known about beforehand. (See also 1.3.2(e) & 1.3.2(f) above)

2.2.13 **Question 14 and Appendix1, Question A6**

While the primary focus of QQ 11-13 is on what you would do to avoid or minimise adverse effects, the primary focus of this question is on what you would do should such adverse effects occur. Hence you should be prepared to devote time to thinking about the risks which you have mentioned in your answers to these earlier questions, and the kinds of action that might have to be taken, by yourself or by others, should harm occur. You are in effect being called upon to commit yourself, by declaring that you have given serious consideration to these issues. Your statement may (if you wish) be on a risk assessment form, but this is not obligatory unless your study is being carried out in a part of the University in which use of such forms is generally required. Since your reply to this question will be read by the Committee in conjunction with your answers to QQ 11-13, there is no need for you to repeat anything you have already said in answering these earlier questions.

2.2.14 **Question 17**

There are many possible reasons why participants required for a study may be unavailable. For example, a gatekeeper whose consent is required for access to prospectiveparticipants may deny access, a database from which a sample could be drawnmay be unavailable or turn out to be seriously defective or the refusal rate among prospective participants may be too high. To avoid claims of time wasting by those involved in the research process, it is important to address the issue of recruitment at an early stage when planning your study.

**Please note that any advertisement you make to recruit participants must include the approved ethics protocol number.**

2.2.15 **Question 18**

This question is aimed at determining whether the applicant will seek informed consent from their human participants. There may be good reasons why this consent is not sought and these reasons should be detailed and fully justified in the space provided. If consent is being sought ECDAs must see a copy of the consent form to be used. Form EC3 and Form EC4 are examples of consent forms for applicants use. Form EC3 is a general consent form which can be used, and modified as appropriate for use in individual studies, for gain consent from competent adults who are able to give their own consent. Form EC4 is an example of a consent form that can be used to get consent from someone who is able to consent on behalf of minors or those otherwise unable to give their own consent. Applicants are encouraged to use these forms as a starting point as they illustrate the sort of information ECDAs expect to see on consent forms. However these forms will not be appropriate for every applicant’s study and applicants should modify them as appropriate. Applicants should be aware that participants should be given Form EC6 (Participant Information Sheet) which will detail information about the study, in order for them to be able to give informed consent on any consent form. (See Part 3, below)

2.2.16 **Question 20 and Question 21**

This question relates to the management and use of data collected during the proposed study. Applicants are expected to respect participants’ confidence by giving and honouring assurances on such matters as:

How data will be stored (whether as hard copy or electronically);

Who will have access to the data;

Where the data will be kept;

How the data will be used in the present study;

Whether the data may be retained beyond the study to be re-used in later studies with similar/different aims and perhaps with different investigators;

Whether there will be specific safeguards to ensure that assurances given are honoured and that data are not misused.

You should be prepared to defend your intentions regarding data management and use to the ECDA, and be clear about your intentions (including cases where you wish to keep future possibilities open) on the Form EC6 (Participant Information Sheet), and on the relevant consent form (see Form EC3 and Form EC4). You should note that where there is a possibility of your wanting to get in touch with participants again at a later date, destruction of all identifying personal details will not be possible and should not be promised, since some personal details will be required for making contact. (See Part 3 below). You will be required to adhere to the storage arrangements indicated by you on Form EC1.

2.2.17 **Question 22**

This question is concerned with ensuring that those applicants who propose to involve children and/or vulnerable adults in their studies **must** obtain satisfactory Disclosure and Barring Service (DBS) Clearance. Applicants are given the option of indicating whether a DBS Disclosure is or is not required. ECDA Chairmen **must** see a satisfactory copy of this for **all** proposed studies in which children or vulnerable adults are intended to be involved. If a satisfactory DBS Disclosure is necessary, a copy of it **must** be forwarded to the Chairman of the relevant ECDA, via the ECDA Clerks, who will keep a register of the Disclosures reviewed in a secure place.

**PART 3: OBTAINING CONSENT. NOTES ON THE PREPARATION AND USE OF FORM EC3 & EC4 (CONSENT FORMS) AND FORM EC6 (PARTICIPANT INFORMATION SHEETS)**

3.1It is best to start from the position that participants’ explicit consent is required. The generally accepted principle is that participants, as free individuals, have a right to make informed decisions regarding their participation in a study, both initially and as it proceeds. There will be studies, however, where consent is not needed: where obtaining it is impossible; or where obtaining it would in itself be unduly intrusive; or where obtaining consent would affect the situation to the extent that the research would be invalidated; or where, in the particular circumstances of the proposed study, it is safe and reasonable to **assume** consent without the need for it to be formally requested. Much will depend on the nature of the study and on practice in your discipline or profession, where a relevant ethical code may offer guidance. Where you propose not to seek consent, you should be prepared to discuss the matter with your supervisor or others, and should detail your reasons in your application Form EC1 (Q18).

3.2 Form EC3 is intended for use with competent adult participants, who are able to give their own valid consent. Form EC4 is for use where the participant is a minor or who is otherwise unable to give informed consent on their own behalf. These forms are regarded as the starting point for applicants; who must go on to amend and adapt the forms to suit their study. Applicants should be aware that these forms contain the sort of information ECDAs would expect to see in a consent form and therefore applicants should aim to keep the essence of the information in Form EC3 and Form EC4, but adapt the forms for suitable use within the context of their studies. Although for some studies they may be suitable as they stand. Thus, for instance, it would be inappropriate to ask for contact details in any study where there is no possibility of wanting to make further contact with participants. Similarly, there will be studies that could not possibly reveal that a participant had a pre-existing medical condition, in which case anything like paragraph 5 of Form EC3 and Form EC4 would be inappropriate. In signing a Consent Form, **all** prospective participants will normally be confirming their willingness to take part, acknowledging that they have been informed of the nature of the study, and confirming that they have received assurances that they are volunteers who may withdraw at any time; that their data will be looked after with care; and that they have been given a true account of any risks to which they may be exposed and what would happen should they suffer harm.

3.3 Form EC6 (Participant Information Sheet) is a mandatory form for **all applicants** and must be completed and given to **all** participants (or those people consenting for people who are unable to do so themselves) **before** they sign a consent form, in order for them to be adequately informed when giving their consent. It is an essential requirement that participants are given the opportunity to ask questions, so that as far as possible, they fully understand the Participant Information Sheet and consent form before signing to confirm their participation in the study. They must be advised that it is best for them to retain their own copies of both documents so that they can refer to them at a later point.

3.4 Form EC6 may be modified to accommodate the information required by participants but, as a minimum, it must include all the information which would be made available under the headings used in Form EC6. The Form should include information concerning the following matters:

i the study’s aims, design, duration, methods and procedures;

ii the risks and potential benefits of the study;

iii data security arrangements (storage arrangements, control of access, etc.);

iv plans for the retention of data, including the possibility of its being deposited in one of the national data archives;

v the possibility of data being retained for use in further studies;

vi the possibility of follow-up studies that could lead to participants being approached again;

vii the names and contact details of key people.

In describing the aims of the proposed study on Form EC6, a detailed technical account would be inappropriate. The applicant should ensure that the aim(s) of the study are conveyed in a clear and focused way. Vague formulas such as “to increase the sum of human knowledge” or “to promote the health and wellbeing of mankind” are not acceptable. Participants may also welcome the traditional assurance that, in any published report, their identity remains anonymous.

3.5 When the application Form EC1 is submitted, you should ensure that all consent forms and Form EC6 are attached to Appendix 2. If all the relevant documents are not attached, the application will be deemed to be incomplete and will not be reviewed until a complete application is resubmitted.

3.6Minors are legally incapable of giving consent, so if they are to take part in a study, somebody else will usually have to give consent on their behalf; this is most commonly their parents or legal guardians. Under present legislation in England and Wales, a minor is, for most purposes, a person under the age of 18. For studies considered by NRES ethics committees, 16 is recognised as the age from which consent may be given by a participant. Applicants are advised that, should they wish to allow participants in the age group 16-18 to give their own consent, they will be required to explain why it would be appropriate. Otherwise, it is expected that consent will be given by an adult on behalf of all participants under the age of 18. This can create anomalies, since a prospective participant who is a minor could be anything from a new-born baby to, for example, a mature 6th-former or a young soldier. Where a prospective participant is an “older” minor and is unable to give consent solely because of their age, they should be consulted about whether they are willing to take part in the study before anyone else is asked to give consent on their behalf.

3.7 There will be cases where, for a variety of reasons, prospective participants are unable to give written consent. They may, for instance, be paralysed, illiterate, mentally incapable, have little English or be temporarily unable to write. In such cases it will be necessary either for another person, for example parent/guardian, to be involved in giving their consent on their behalf (using a suitably designed consent form) or for them to be excluded from the study.

3.8 Some studies involve investigations that may have medical relevance, such as blood pressure, heart rate and other vascular functions and blood sampling for estimation of lipid levels. The findings from such investigations will sometimes indicate that the participant may have a pre-existing medical condition and/or may be at risk of a premature medical event. When this happens, the investigator must ensure that the participant is advised of this in a suitable manner and advised on appropriate action. This would usually be to discuss these findings with his/her GP. Similar arrangements should be made where it is found that the participant may have a condition that could be a danger to others. If a potential participant is not willing to agree to take this action, they should not be allowed to take any further part in the study. These aspects must be explained in the Form EC6 (Participant Information Sheet) and endorsed by the participant in writing, via the consent form (see Form EC3 & EC4), before the study is undertaken. (See also S 1.3.2(f) and S 3.2)

**PART 4: COMPLETING A RISK ASSESSMENT**

4.1 Form EC5 is a standard Risk Assessment Form but a subject-specific risk assessment form may be used, depending on the health and safety requirements in each discipline area.\*\* A risk assessment form should be completed in respect of any risks/hazards in connection with the study itself. Equally, the proposed location/premises could present hazards and risks for both the participants and the investigators and therefore a risk assessment may be necessary so that the applicant is aware of the potential dangers of using the proposed location/premises. Potential risks/hazards may be present in both off-campus and on-campus locations. The Form EC5 or alternative risk assessment form ensures that the applicant has thought of the potential risks associated with the use of the chosen premises/location, who might be affected by these hazards, what types of injury could be caused, what steps or precautions have been or need to be put in place to avoid or minimise the stated dangers, hazards and risks. Applicants ~~to~~ should state on the risk assessment form any dangers that cannot be eradicated or minimised. If there are many dangers that could result in serious injury to the participants and the investigators this may require applicants to reconsider their chosen location/premises for another location that poses fewer risks.

\*\***PLEASE NOTE**: Form EC5 is only an example of a Risk Assessment Form which may be used if a more appropriate form for assessing risk is not available. If an applicant is required to use the forms originating in their School, this is perfectly acceptable and the form should be attached to the application instead of Form EC5.

4.2 Any Undergraduates who are carrying out their proposed study off Campus should consult their Supervisor for information and assistance on whether a risk assessment form needs to be completed. As mentioned above, the health and safety of the participants, the investigators and those who could be easily affected by the undertaking of the study in the proposed location/premises are concerns of utmost importance. When there is doubt over the necessity of a risk assessment, applicants are encouraged to complete a risk assessment as further safety concerns could be identified during the course of the assessment.

4.3 Any Postgraduates and members of Staff carrying out research in an off campus (or on-campus) location/premises may also need to carry out a risk assessment. Postgraduates and staff are urged to use their own discretion when deciding whether a specific location requires a risk assessment. Postgraduates and Staff may decide whether or not to carry out a risk assessment and their relevant ECDA/reviewers will decide whether or not to accept their decision.

4.4 Any members of Staff that are applying for a Class Protocol should note that it is compulsory to complete a risk assessment for the location and activities proposed.

4.5 All completed Forms EC5 or alternative risk assessment forms should be attached to Appendix 2 of the Form EC1. If a proposed study requires a risk assessment and the applicant does not attach one to Appendix 2 the application will be considered to be erroneous and will be returned to the applicant for them to resubmit a complete application.

**PART 5: COMPLETING FORM EC2**

5.1 If the applicant finds that during the course of their research any amendments or modifications are needed or an extension to the end date included in the approved protocol is required, applicants **must** apply for ethical approval again so that the modifications or extension can be approved by the relevant ECDA. Applicants **do not** need to apply using a Form EC1 again but **must** use apply using a Form EC2 (Application for modification and/or extension to an existing approve protocol)

5.2 Form EC2 requires the applicant to give the number of the protocol requiring modification or extension, their own details and the details of their Supervisor so that this can be verified against the original approve protocol. If the applicant’s contact details have changed they should indicate that this is the case of the application form. The applicant is also asked to list any additional workers who will be involved in the study if/once the Form EC2 is approved.

5.3 If the applicant requires an extension then they must indicate the new timeframe within which they intend to complete their research and the reasons for needing an extension to the originally approved protocol.

5.4 If the applicant requires the originally approved protocol to be modified, the applicant must give sufficient detail of the required modification/s and include information regarding whether these modifications will have any impact on any aspect of the study with which the human participants are concerned. The relevant ECDA needs to be given sufficient detail to be able to understand exactly how the modifications will or will not affect the human participants. If there are any additional hazards that are associated with the proposed modifications the applicant must detail what these additional hazards entail and how they could or otherwise impact the human participants.

5.5 Applicants should note that if the proposed modification or extension should impact the role that the human participants previously consented to, they must be informed of all the proposed changes and be asked to give their consent again whether they would like to participate in the study in light of the proposed changes. An example of the consent form and Participant Information Sheet that are used must be attached to the Form EC2.

**PART 6: COMPLETING FORM EC7 – PROTOCOL MONITORING FORM**

6.1 Ethics Clerks will send students/staff a Protocol Monitoring Form at the time when it had been indicated on the application form the study would finish, hence Question 6.2 on Form EC1 asks applicants to declare the end date of the proposed study. The form should be completed by the investigator undertaking the study. The Form will be sent electronically so the investigator should simply write their name in the signature box (unless they have an electronic signature). If the investigator is a student, the Form should be submitted to the ECDA clerks via their supervisor who should enter their name on the Form to indicate they have read it.

6.2 Form EC7 also allows an opportunity to feed back on the outcome of the study, for example any problems encountered, adverse reaction by participants or loss of data. If a problem is serious, Form EC7 should be completed and submitted to the ECDA immediately without waiting until the end of the study.

6.3 If it is necessary to inform the ECDA of a serious problem during the course of the study, it will still be necessary to complete an additional Form EC7 at the end of the study to indicate its completion; hence it may be that more than one Form EC7 will have been completed in respect of a study.

6.4 **Please note**: it is a requirement, when ethical approval is granted, that the ECDA is informed of the completion of a study; failure to return Form EC7 at this stage will be treated as a breach of the approved protocol.

**PART 7: ECDA & CLERK CONTACT DETAILS**

**ECDA - Health & Human Sciences**

Chairman – Dr Richard Southern

Vice-Chairman – Mr Fraser Heasman

ECDA email – [hhsecda@herts.ac.uk](mailto:hhsecda@herts.ac.uk)

**ECDA – Science & Technology**

Chairman – Dr Simon Trainis

Vice-Chairman – Dr Rodney Day

ECDA email – [stecda@herts.ac.uk](mailto:stecda@herts.ac.uk)

**ECDA – Social Sciences, Arts & Humanities**

Chairman – Dr Tim Parke

Vice-Chairman – Ms Caroline Large

ECDA email – [ssahecda@herts.ac.uk](mailto:ssahecda@herts.ac.uk)

**ECDA Clerks**

Lesley Powell – [l.powell5@herts.ac.uk](mailto:l.powell5@herts.ac.uk)

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