Research Ethics & Governance for Human Research

Guidelines for applying for ethical approval at Anglia Ruskin University

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RESEARCH ETHICS & GOVERNANCE FOR HUMAN RESEARCH

Guidelines for Applying for Ethical Approval at Anglia Ruskin University

This booklet is designed to provide researchers with the information they will need when applying for ethical approval from Anglia Ruskin University.

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Definitions

CRB – Criminal Records Bureau

FREP – Faculty Research Ethics Panel

RDCS – Research, Development & Commercial Services

RESC – Research Ethics Subcommittee
RESEARCH GOVERNANCE AND ETHICS APPROVAL

1 Why does research require ethical approval?

As part of good Research Governance, research requires ethical approval. This is:

- to protect the rights and welfare of participants and minimise the risk of physical and mental discomfort, harm and danger from research procedures
- to protect your rights as a researcher to carry out legitimate investigations, as well as the reputation of Anglia Ruskin University, for research conducted by its students and staff
- to minimise the potential for claims of negligence made against you, Anglia Ruskin University and any collaborating individual or organisation
- because, increasingly, refereed journals require evidence of ethical approval
- because a consideration of the ethical issues is likely to influence your research design
- to avoid potential problems later on, by trying to ensure that the main ethical issues are addressed before the research starts.

You need to complete the ethics review checklist for all research taking place at Anglia Ruskin University. Research requires formal ethical approval from Anglia Ruskin University if it involves:

- human participants (including observation or questionnaires)
- accessing personal, sensitive or confidential data
- human tissue, samples, DNA or ‘relevant material’, as defined by the Human Tissue Act (2004)
- participants who are 16 years and over who lack capacity to consent and therefore fall under the Mental Capacity Act (2005)
- NHS patients, staff or premises or social care settings
- research involving animals (see section 1.1)

If you are carrying out research that does not fall into any of the above categories, but that you (and your module leader/supervisor for students) feel presents significant ethical issues, you are advised to submit an application with an explanatory note as to why you think your application should be considered. For example, research that is politically sensitive or involves archaeological remains would both fall into this category.
You must also check whether you need ethical approval from any other body prior to doing your research (for example, research taking place in a prison or from the organisation where you are carrying your research out).

**All researchers must submit the ethics review checklist to their Faculty Research Ethics Panel (FREP) Administrator before undertaking their research. Even if your research does not require further ethical approval, you need to submit the ethics review checklist, signed and dated, to confirm that this is the case. Each faculty has a FREP and these report to the Research Ethics Subcommittee (RESC), which is responsible for overseeing policies and procedures relating to research ethics.**

Failure to comply with our ethics procedures may be construed as misconduct or gross misconduct and dealt with by our Student Disciplinary Procedures or Staff Disciplinary and Dismissal Policy and Procedures, as appropriate.

Please note that, even if you do not require formal ethical approval, there may be permissions that you need to obtain. For example, you may require written permission when undertaking research about an organisation, even if the information is in the public domain. The main reason for this is to protect you as the researcher, to avoid the likelihood of a situation occurring when you have carried out the research, but an organisation is not happy for you to use data that you have collected from it. There may also be ethical issues that you need to think about even if your project does not require formal ethical approval. In addition, although potential ethical issues should be considered during the planning and application stages, unforeseen ethical issues are likely to emerge during the course of your research and it is important to have an understanding of how to deal with these and also be aware of the university’s reporting systems for accidents, adverse events or incidents relating to research (see section 4.1).

### 1.1 Research involving animals

For research involving animals, please see the Faculty of Science and technology website:  
http://www.anglia.ac.uk/ruskin/en/home/faculties/fst/research0/ethics.html

Staff and students should be aware that specific ethical procedures are in place with respect to research involving animals. It is recognised that most research in the University has little or no direct impact on the animal and such research is usually reviewed within the Life Sciences Departmental Ethics panels or the Faculty of Science and Technology Faculty Research Ethics Panel (FREP). Researchers must be aware that the University does not hold licences under the Animals (Scientific Procedures) Act 1986 and therefore any work that constitutes a procedure under that Act is not permitted within the University. If researchers are involved in collaborative work that may fall under A(SP)A, approval must be sought through the collaborating organisation and take place on their premises and under their licences.
1.2 Research ethics training

Research ethics training is compulsory for research students who started from September 2011 and for all supervisors. Supervisors can, however, obtain an exemption from the Director of Research/Director of Research Students from their faculty if they already have substantial experience in research ethics.

If students do not need formal ethics approval they still need to attend training, given there may still be ethical issues relating to their research.

You will also find the below information in sections 3.6 and 3.7 (P14) of the 2011 research degree regulations.

All research degree students who started from September 2011 must either attend 'Introduction to Research Ethics and Integrity' training offered by Research Development and Commercial Services or pass the online Epigeum course: Ethics 1 – Good Research Practice.

All research students who started from September 2011 whose research proposal requires ethical approval are also required to pass the online Epigeum course: Ethics 2 – Working with Human Subjects or an equivalent course approved by the Chair of the appropriate Faculty Research Ethics Panel.

You need to send your certificates from the course(s) to research.training@anglia.ac.uk in order that it can be logged you have completed this

The Research Ethics Guidebook: a Resource for Social Scientists, please see http://www.ethicsguidebook.ac.uk/, also provides comprehensive and helpful guidance on many aspects related to ethics.

1.3 The Human Tissue Act (2004) and the Mental Capacity Act (2005)

University research ethics committees are not authorised to review all of the research that falls under the Human Tissue Act (2004), or any research that falls under the Mental Capacity Act (2005). The review for research falling under either Act in England must be carried out by an ethics committee that is recognised by the Secretary of State. There are certain exceptions to this, where Anglia Ruskin University is able to review studies that fall under the Human Tissue Act, because the research falls under the conditions of our licence from the Human Tissue Authority. For the Human Tissue Act (2004), the ethics committee that is recognised by the Secretary of State is an NHS Research Ethics Committee (NHS REC). NHS RECs and the Social Care Research Ethics Committee (as well as the Welsh Assembly Government) are authorised to review studies that fall under the Mental Capacity Act. For further information about research that Anglia Ruskin University can legally review that falls under the Human Tissue Act (2004), please contact Matt.Bristow@anglia.ac.uk

Please note that you must contact Dr Bristow and inform him about all research you are planning that falls under the Human Tissue Act (2004), including that for which NHS rather than university approval is required.

### 1.4 Obtaining ethical approval before starting your research

As mentioned previously, the research ethics checklist needs to be completed and submitted to your FREP Administrator for all research. If you require further ethical approval, please contact your FREP Administrator to see what process you need to follow.

If you are carrying out research in the NHS you generally need to obtain two sets of approval. Approval usually needs to be sought from an NHS Research Ethics Committee (NHS REC). In addition, approval must be obtained from the Research and Development (R&D) Department or Committee from each NHS Organisation in which you are undertaking your research (or equivalent, as arrangements for R&D approval may vary). In some circumstances (e.g. research involving NHS staff, unless it presents significant ethical issues) NHS REC Approval will not be required, although R&D Approval is still likely to be. When planning NHS research, you need to contact the R&D Department of the NHS Organisation in the first instance. You can find contacts details for R&D Departments on the NHS R&D Forum website at [http://www.rdforum.nhs.uk/044.asp](http://www.rdforum.nhs.uk/044.asp)

You also need to have an organisation which acts as Sponsor, as defined by the Department of Health, for your research. The Sponsor is the organisation that is responsible for initiating, managing and monitoring a study. If you require Anglia Ruskin University to act as Sponsor, you need to speak to your FREP Administrator/Chair in the first instance. Please do not name Anglia Ruskin University as the Sponsor without checking this beforehand, as if the university acts as Sponsor there are certain responsibilities it will need to meet. For further information about responsibilities of a Sponsor, please see the Department of Health’s Research Governance Framework for Health and Social Care (2005).


For NHS research in England, your study may fall under the criteria for proportionate review from the NHS REC, rather than having to be reviewed by the full committee:


If you intend to carry out a pilot study, you must obtain ethical approval for this. Please note that you cannot start any part of your research until you have obtained the appropriate ethical approval.

### 1.5 Undertaking research overseas

If you are carrying out research overseas, in addition to approval from Anglia Ruskin University, you need to ensure that you have obtained any ethical approval required by that country. It is also your responsibility to ensure that you are aware of and comply with any relevant legislation for that country.
You also need to comply with English law. If there is any conflict between the ethical requirements of Anglia Ruskin University and other organisations where you are undertaking your research, please let the ethics committee know as soon as possible and prior to starting your research, in order that we can review this. In addition, if there is any conflict between English law and the laws of the country in which you are carrying out the research, please let us know immediately and prior to starting your research.

It is your responsibility to ensure that you obtain a research permit and research visa (or equivalent visa allowing you to carry out research in that country) if required and obtain any other permission required from authorities to carry out research in that country. You must ensure that you are familiar with all the conditions of your research permit and visa and comply with these. For further information about research visas, please contact Student Services. If you require a research visa you need to start preparing as early as possible as it can take a considerable amount of time (e.g. 6 months) to get appointments and obtain the correct documents.

If you require further advice about research visas, you can contact: Jean Yeadon on 0845 196 2135 or Greg Scott (2073) in Cambridge (HEL 122) and Shauna Madhavan (4285) or Evis Bakiri Read in Chelmsford (4297) 2nd Floor, Student Services, Tindal Building. Alternatively, you can e-mail internationaladvice@anglia.ac.uk

You can also find information on the relevant website for the country.

2 When should I start thinking about applying for ethical approval?

If you are planning research involving or relating to human participants, you are advised to consider ethical issues at the earliest possible stage in the planning and writing of your proposal for several reasons.

- Firstly, practically there must be time allowed for necessary consultation as part of the ethical review process. The FREP may request changes to an application, which then needs to be resubmitted.

- Secondly, additional preparation time should also be allowed because a proper consideration of ethical principles is relevant to, and will almost certainly influence fundamental aspects of the research design, from research methods to sampling. Good research design is essential and will greatly benefit your research project.

- Thirdly, for some studies, you will be required to obtain Criminal Records Bureau (CRB) clearance. This process needs to be started as soon as possible.

Research, Development & Commercial Services (RDCS) run research ethics training sessions for research with human participants (Introduction to Research Ethics and Integrity). They include a basic introduction to ethical issues and applying for ethical approval. For further information, please see: http://www.anglia.ac.uk/researchtraining

You should also refer to the ‘Question specific advice’ for completing ethics applications, which is available on the RDCS website at:
3 Applying for ethical approval

Information regarding our ethics procedures is located on RDCS website at: 
http://www.anglia.ac.uk/ethics

By completing the Ethics Review Checklist, you will then know whether further ethical approval is required. The checklist can be found at: 
http://web.anglia.ac.uk/anet/rdcs/ethics/forms.phtml

Regardless of whether you need to obtain further ethical approval for your research, your completed ethics review checklist must be submitted to your FREP administrator.

The ethics application form and other documents, for example, the participant information and consent form templates may also be found at this address.

Relating to your application for ethical approval, the ‘Procedure for the Investigation of Allegations of Misconduct in Research Procedure’ provides information on, for example, standards of professional behaviour in research. This may be found at: 
http://web.anglia.ac.uk/anet/rdcs/uk_funding/policy.phtml

To apply for ethics approval, first contact your FREP Administrator who will advise you on the requirements for obtaining approval. If required, please submit your application and accompanying documents to your FREP Administrator. If your research involves more than one faculty or you are from a support service, please contact Julie Scott, Research Ethics and Training Manager on telephone 0845 196 4210 or email julie.scott@anglia.ac.uk

All, undergraduate, postgraduate and staff research is subject to the same procedures.

The documents you need to submit to seek ethics approval are:

- the ethics review checklist
- the ethics application form
- a detailed research proposal clearly outlining the research approach and methods to be used
- the participant information sheet
- the consent form
- evidence of Criminal Records Bureau clearance (if applicable) or equivalent, if carrying out research overseas
• any other documentation that will be used for the research, for example, copy of poster or email to be used for recruitment purposes, copy of questionnaire or interview schedule

• if applicable, the insurance questionnaire and response. Further information is provided regarding this in Section 3.4

• if requested risk assessment and the resulting procedure (see Section 3.7). If not requested, you need to confirm that you have completed this and keep it on file

• evidence that you have travel insurance in place, if your research involves an overnight stay (for further information, please see: http://web.anglia.ac.uk/anet/staff/sec_clerk/ins_index.phtml or contact Andrew.Chapman@anglia.ac.uk if you have any queries after looking at this).

• written permission from organisations in which you will be undertaking research (see Section 3.11).

There are templates for the participant information sheet and consent form at http://web.anglia.ac.uk/anet/rdcs/ethics/applicants/apply/application.phtml. These are for guidance only. You do not need to follow these templates if they are not applicable to your type of research, but you must ensure that you have included all the key information in your documentation. You must, for example, always mention any potential risks, together with the fact that participants have the right to withdraw at any time and without giving a reason. The standard formats for the participant information sheet and consent form would not be appropriate in some instances, for example, when asking younger children to consent. If you are asking participants to complete questionnaires that will be anonymous, you do not need to ask participants to sign a consent form. Consent is implied by the return of the questionnaire.

Please ensure that you have submitted all the relevant documents, as without these the ethics committee will be unable to consider your study. This will cause a delay to your research being approved. You must include a date and version number on all documents, including the application form, the research proposal, participant information sheet and consent form, in case changes are required. This means that you can easily identify the current documentation which has received ethics approval. It also should speed up the process for obtaining ethical approval, as the committee will know which are the latest documents.

You must ensure that the documents you submit to FREP are the ones you will use. If you subsequently make any changes to any documentation, for example, the participant information sheet, you will need to submit the revised form to the committee as a substantial amendment. Please submit any revised documents with the text highlighted or in a different colour. This makes your changes much clearer to the ethics committee.

If you have any queries regarding which documents to submit, please contact your FREP Administrator.
Possible decisions of the committee are:

- approve outright
- offer approval subject to certain conditions
- request specific revisions
- request a full resubmission
- reject outright.

Students should ensure that they have consulted their supervisor/module leader/equivalent and that he/she is happy with the ethics application prior to submission.

3.1 Selection of participants

The ethics committee will want to be assured that you have given careful consideration regarding how you will select participants. Selection must be in compliance with the Data Protection Act (1998). If you will be carrying out research in another organisation, you need to give due consideration to how you will access the names of potential participants. You will not be able to access a database or people’s names and addresses that are held by another organisation without the prior permission from the participants. Therefore, the initial approach to participants may need to come from someone working at that organisation. Even if you work at the organisation and already have access to the names, this does not automatically mean that you are allowed to access them for research purposes. You need to check this with an appropriate person in the organisation.

You also need to refer to your sampling technique and think about whether your sample is defined either theoretically, for example, random or purposeful or convenience sampling – this might include choosing participants from your peer group. Your choice of sampling technique must always be justified. This is because it is not ethical to carry out research that is not well designed, because it wastes participants’ time and findings arising from it will not be valid. If results are published, other researchers may replicate it when findings are not valid.

Your inclusion and exclusion criteria must be defined. Please ensure that you do not collect any unnecessary data. For example, if you are using a poster to recruit participants for your research, please clearly identify any exclusion criteria on this to save people who do not meet the inclusion criteria spending their time contacting you. Also, do not ask people to complete a questionnaire to establish whether they meet the inclusion criteria – screen these people out beforehand, if feasible, to avoid wasting their time.

3.2 Consent

This is an important area and one that the committee will focus on when reviewing your application. Consent must be informed and freely given. There must be no coercion. Participants must have the capacity to consent and the right to withdraw without penalty or providing an explanation. You must ensure that you include all relevant information and explain clearly what participants will be asked to do on the participant information sheet.
Participants should be told why they have been selected to take part and how many people have been approached.

As part of the information given to participants, you must state that your research study has ethical approval from Anglia Ruskin University (and any other committee if required). Participants must be informed about any risks. There will always be some; it is not acceptable to say that there are ‘no risks’. Participants must also be informed about their legal rights, the storage and destruction of data, and that they have the right to withdraw at any time, without giving a reason. You must also provide contact details for further information. You must use your Anglia Ruskin email address. You should not give a personal email address or landline telephone number (mobile numbers are acceptable if there is no alternative). In addition, you should provide a contact point for complaints (these should be dealt with by Anglia Ruskin University procedure). For further information about the procedure for complaints, please see:

http://web.anglia.ac.uk/anet/staff/sec_clerk/feedback.phtml

Taking consent must be viewed as a process, not just the potential participant reading a participant information sheet and signing a consent form. There is evidence that people understand much less than we think they do. You should therefore check the readability of your participant information sheet. In addition, you must ensure that people understand what they are being asked to do, by asking them questions about what is on the information sheet to establish that they understand it. The committee will also want to be assured that participants are being given adequate time to decide whether they wish to take part and have the opportunity to discuss the research with family and friends.

If you will be using direct quotes from participants in your dissemination, or recording using audio or visual equipment, this must be stated on both the participant information sheet and as one of the statements on the consent form. If you will be making use of personally identifiable information in dissemination, for example photographs, special care must be taken and participants must be given the opportunity to be contacted on each occasion that these will be used.

It is good practice to notify all participants regarding the last approximate date it will be possible to withdraw their data (for example, prior to publication). You also need to consider whether participants’ data would still be useful if they decide to withdraw. If this is the case, they will need to consent to its use. You can therefore give participants the option to withdraw and also have their data withdrawn, or to withdraw but state that they are still happy for their data to be used. If you are carrying out a focus group, it will not be possible to withdraw one person’s data following the intervention without removing the data for all the participants, because what one person says will affect the responses from others. You must therefore make it clear on the participant information sheet that it will not be possible to withdraw data in this case. You also need to make it as easy as possible for people to withdraw, bearing in mind that they might not feel comfortable telling you directly that they no longer want to participate. You could provide several options, for example, participants could email you or post you a slip you give them at the start of the study saying they would like to withdraw.
You should also guard against unrealistic assurances to participants about data being anonymous. It is essential that every effort is made to remove all identifying information relating to participants prior to dissemination. Information that could identify people is not limited to their names. It is sometimes possible with case studies that people may be identified or people could be identified by their peers if not the general public. This needs to be made explicit in the participant information sheet. The words, ‘anonymous’ and ‘confidential’, are often confused. You must ensure that you refer to these correctly on the participant information sheet.

Please ensure that your documentation is inclusive. For example, if your research sample is likely to include people who cannot speak or write English, the documentation needs to be translated (a professional translator would also need to be employed, unless you are a native speaker or fluent in the language yourself and you also need to think about the translation of cultural norms). You also need to consider people with special needs (for example, visual impairments, dyslexia) and the provision of documentation in alternative formats.

If you are carrying out research that relates to other people, for example asking participants questions about family members, you should also obtain either consent or permission from them, as applicable. Do not make the assumption that because participants are revealing information about family members (as opposed to others outside their family) that this will be ok. Even if you are carrying out research that does not directly ask participants about other people, think carefully beforehand about whether others are likely to be discussed and if so, whether consent is required from them.

**Travel by participants**

If the research will involve participants having to travel to where the study will be carried out, this must be made explicit on the participant information sheet, including how many visits will be required, how frequent they will need to be and whether travelling expenses will be reimbursed. It may not be possible to reimburse travel expenses, in which case this must be stated.

**Access to data**

You should also state who will have access to the data (for example, the research team) and whether it will be in an anonymised format. You also need to consider that confidentiality will be limited in some instances, for example in cases of disclosure by the participant (please see Section 3.14 for further information). Please refer to the template participant information sheet and consent form at: 

http://web.anglia.ac.uk/anet/rdcs/ethics/forms.phtml

### 3.3 Criminal Records Bureau (CRB) Clearance Requirements

It is essential that you obtain this prior to starting your research if it is needed for the purposes of the study you will be undertaking. Your first point of contact should be the organisation that you plan to carry the research out in, to establish their requirements.

All Criminal Records Bureau (CRB) clearance must have been carried out in the last year and through Anglia Ruskin University, unless you are carrying out research in an organisation that you are working in, when we will accept a
copy of the CRB that has been carried out by them, providing that this meets their requirements.

If you are a student you may need to pay for a CRB to be carried out via Anglia Ruskin University and should contact your Supervisor/Faculty Director of Research for clarification. Please contact Fleur.Mitchell@anglia.ac.uk for further information regarding CRB clearance if you are a student and HR Services if you are staff. You need to submit a copy of the CRB clearance with your ethics application.

If you are carrying out research abroad, you will need to obtain the equivalent of CRB clearance for that country, if required and provide evidence of this with your ethics application. For further information, please see:

http://www.homeoffice.gov.uk/agencies-public-bodies/crb/

3.4 Questionnaire for Research Involving Human Participants (Insurance)

It is essential that you complete this questionnaire if your study falls into any of the categories defined in it. This is because your research may not be covered by Anglia Ruskin University’s existing insurance. The questionnaire can be found at:

http://www.anglia.ac.uk/ethics

You must send or email the questionnaire to Andy Chapman, Second Floor, Corporate Risk and Compliance Officer, Second Floor, Rivermead Gate (Andrew.Chapman@anglia.ac.uk)

This must be done prior to submitting your ethics application. You should submit a copy of the questionnaire and the response from Andy Chapman with your ethics application. If you are told additional insurance will be required for the research, please speak to your supervisor/line manager/faculty Director of Research (Students) as a matter of urgency to establish whether your department/faculty will fund any additional costs that may be incurred.

3.5 Requirements of the Funding Body

You must ensure that your ethics application and planned research complies with all the requirements from your funder.

3.6 Professional Codes of Conduct and Practice

It is your responsibility as the researcher to ensure that your proposed research complies with these.

3.7 Risk Assessment

If there are any significant potential risks that will arise from your research, you must complete a Risk Assessment (health and safety) with your Supervisor/Line Manager. When completed, this must be signed as
acceptable by the Faculty Dean. Risks include lone working or hazards. For Doctorate students, your First Supervisor must also keep the risk assessment on record and for staff your Line Manager must do this. If you are a member of staff, your Line Manager must keep a copy on file. Once a form has been completed, a list of procedures for the researcher should be developed to address the risks identified on the form. You must indicate on your application from that the Risk Assessment has been carried out. In certain cases, the ethics committee may ask to see a copy of the risk assessment form.

For further information and a copy of the risk assessment form, please refer to:
http://rmd.anglia.ac.uk/uploads/docs/HSMS22-.doc

If you have any queries regarding when a risk assessment should be completed, or require assistance with completing one, please contact Sarah Day, Risk Management Officer on Sarah.Day@anglia.ac.uk or Paul Varley, Head of Risk Management on Paul.Varley@anglia.ac.uk

A risk assessment for risks relating to the project must be completed for all externally funded research if the funding has been applied through via our university. Please see the RDCS website:
http://web.anglia.ac.uk/anet/rdcs/compliance/index.phtml

If there are any significant potential risks that will arise from your research, you must complete a Risk Assessment (health and safety) with your Supervisor/Line Manager. Risks include lone working or hazards. For Doctorate students, your First Supervisor must also keep the risk assessment on record and for staff your Line Manager must do this. If you are a member of staff, your Line Manager must keep a copy on file. Once a form has been completed, a list of procedures for the researcher should be developed to address the risks identified on the form. You must indicate on your application from that the Risk Assessment has been carried out. In certain cases, the ethics committee may ask to see a copy of the risk assessment form.

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If you have any queries regarding when a risk assessment should be completed, or require assistance with completing one, please contact Sarah Day, Risk Management Officer on Sarah.Day@anglia.ac.uk

A risk assessment for risks relating to the project must be completed for all externally funded research if the funding has been applied through via our university. Please see the RDCS website:
http://web.anglia.ac.uk/anet/rdcs/compliance/index.phtml

in the first instance. If you require further information, please contact Julia Marsh at Julia.Marsh@anglia.ac.uk
3.8 Equipment Checks

Electrical or other safety checks must be carried out on any equipment prior to it being used, if it has not already undergone appropriate checks by Anglia Ruskin University. Researchers must also be trained in the use of any equipment and updates provided as required. You also need to check that your device does not fall under the Medical Device Regulations (2002). Please see section 6.4 for further information about these regulations.

3.9 Travel Insurance

This is a reminder that all staff and students who are travelling in the UK or overseas for the purposes of their research must consult this website: http://web.anglia.ac.uk/anet/staff/sec_clerk/ins_index.phtml

Alternatively, from ‘My Anglia’, go to ‘Support Services’ and then to the ‘Office of the Secretary and Clerk’. You will need to complete the insurance registration form in the first instance.

Please contact Andrew Chapman, Corporate Risk and Compliance Officer on Andrew.Chapman@anglia.ac.uk for further information.

You should submit evidence that this process has been completed with your ethics application.

3.10 Intellectual Property

If any intellectual property could arise from your research, you must ensure that this is addressed at the earliest point. Please see our Intellectual Property Guidelines and Policy at: http://web.anglia.ac.uk/anet/rdcs/compliance/forms.phtml or contact Julia Marsh, Research, Development & Commercial Services on 0845 196 4965 or email address Julia.Marsh@anglia.ac.uk

3.11 Written Permission from Organisations

If you are carrying out research in other organisations, you must obtain written permission from a person in authority from the organisation. The signed letter from the organisation must include permission for your use and ownership of data and your right to publish findings. If you plan to use the name of the organisation in the dissemination, you must also have permission for this. Alternatively, if there is any possibility of the organisation being identified, even if their name or other key information is not used, this must be clarified in writing. This is to try and avoid potential problems later on. We do not want researchers to be in a position where, after undertaking their research and collecting data, an organisation subsequently refuses permission for the data to be used.

Please note that, even when you have obtained written permission, you may also need to seek verbal permission from managers on less senior levels and
will also still need consent from participants. You also need to ensure as far as possible that people working at the organisation have not been told that they have to take part by someone in their organisation and that their consent is voluntary.

Please see Section 3.3 for information about obtaining the equivalent of CRB clearance overseas.

3.12 Research Overseas

If research is to be carried out overseas, it must comply with English law and be approved by our university ethics committee. In addition, you must ensure that you comply with any laws relating to research for that country and obtain any local ethical approval required. Should no local approval be required, please state in your application that you have checked whether you needed to obtain this. If you do need local ethical approval, it is advisable to seek this prior to the approval from our committee. Please submit copies of all the documentation you needed to submit for local ethical approval and their approval letter with your application to our ethics committee. You need to wait until you have both sets of approval before you start your research. It is also essential that you are aware of cultural norms.

You must complete a Risk Assessment (Health & Safety) and clarify whether you will additional insurance (for further information, please see sections 3.4 and 3.9). You must also give consideration to whether you speak the language(s) of the country you will be researching in fluently. If not, you will need to employ a professional translator (please see 3.13 below). You must also be aware of the eight principle of the Data Protection Act (1998); ‘data must not be transferred to a country or territory outside the European Economic Area, unless the country has adequate levels of protection for personal data’.

You must also confirm to the committee that you are meeting all visa requirements (see section 1.5 for further information).

3.13 Participants who do not speak or write English

You need to make adequate provision for participants who do not speak or write English, if you do not speak their language fluently. You must employ a professional translator if your research will involve people who do not speak or write English and ensure that all documents are translated. In addition, you must also be aware of cultural norms and apply these to your research.

3.14 Disclosure

One issue that arises fairly frequently in research is whether information that is revealed during the course of the study should be disclosed, either to the participants themselves or to third parties. The issue as to whether to disclose can arise in a variety of situations, for example:

- incidental findings of medical investigations (e.g. abnormalities found in MRI scans or eye-tests)
• participants expressing the intent to harm themselves or others

• when illegal activities by participants come to light

• if unethical practice is revealed by staff working at organisations where the research is being undertaken.

The issue of whether to disclose needs to be considered on a case-by-case basis for each research project.

Although it may seem that participants should always be informed about abnormalities found in medical tests, this needs to be balanced against their autonomy (right not to be given findings if they do not wish to be). Implications for family members or partners (for example, in the case of genetic conditions or sexually transmitted infections) also need to be taken into account. Another consideration is whether the researcher is qualified to interpret the results and the further support that is available for the participant (e.g. his/her GP, counselling). It should be made clear that the findings indicate a problem that requires further investigation, rather than being a formal diagnosis, unless this is the situation. A further consideration is if the researcher is passing on information about a potentially serious medical condition. Does the researcher have the expertise to do this and how much support should he/she be providing to the participant before referral to another party? How quickly will this further support be available if the findings are highly distressing for the participant? There may be an impact on the participant’s insurance or future employability as a result of the findings and these must also be considered at the planning stages of the research and included on the participant information sheet.

Also of importance is the measure that has been used to obtain the information. If the results of a questionnaire have suggested intent to self-harm, for example, how robust is this measure clinically? The researcher can be seen to have a duty of care to pass this information on to a third party (for example, the person’s doctor/GP), but the point at which this should occur may not always be clear. As well as providing details in the information sheet, researchers should discuss their intent with participants to pass the information on to third parties when the situation arises, providing this is feasible and the safety of the researcher will not be compromised.

The issue of disclosure becomes even more complex in the area of illegal activities. When a researcher is working with certain groups of participants, for example people who take illegal drugs, this issue will arise. Clearly, a great deal of valuable research takes place within these areas, but the issues must be carefully addressed beforehand.

In general, there is no legal obligation to report an offence (except in certain terrorism and money laundering cases), but careful consideration of the Serious Crime Act, 2007 should be undertaken by the researcher. This Act deals with offences such as assisting or encouraging an offender, which may impose a duty to act in order to avoid liability. Legal advice may need to be sought.

In the instance of an employee revealing unethical or bad practice, this should generally be disclosed, but there are also a number of factors that need to be
considered. Is the researcher also employed at the organisation? Is the bad practice likely to be dangerous, for example, if the research is taking place in a medical setting, or illegal (e.g. fraud)? Who should the information be disclosed to? Are there any negative consequences that may arise for the researcher if he/she does this, for example, if he/she works at the organisation?

The FREP will want to be certain that the researcher has weighed up the various factors prior to making their application and that the approach is justified. This will serve to reduce the risk to the researcher, as problems are less likely to occur later on. Researchers also need to ensure that they are complying with any professional codes of practice or any policies within the organisation in which they are working. When working with a group of participants where disclosure is likely to occur, there should generally be a clause on the information sheet stating that if certain details are revealed, they will need to be passed onto third parties. If research involves medical tests, the researcher should consider carefully beforehand whether results should be fed back to participants, their rights in saying they do not want this information and in the case of genetic or infectious conditions, whether others also need to be made aware and who should inform them. Any impact on insurance and employability must be made clear to the participant beforehand. Students must always notify their supervisors should issues of disclosure arise and all researchers must notify the appropriate ethics committee, unless this has been addressed in sufficient detail in the ethics application. Even when all factors have been addressed in detail beforehand, situations may arise when it is not clear whether passing on of disclosed information should take place. These should be discussed by the research team and referred to the Faculty Research Ethics Panel immediately.

3.15 Research Involving Questionnaires

If you are asking people to complete a questionnaire which will be anonymous, consent is implied by its return. You do not need to also ask participants to complete a consent form. You must still include relevant information about the study, although you may choose not to have a separate participant information sheet (you could incorporate the information with the questionnaire). If using a standardised questionnaire, you must ensure that you comply with any copyright regulations. Should you be devising your own questionnaire, it is strongly recommended that you pilot it first (please note that ethical approval will also be required for the pilot study and any changes following it will need ethical approval. These changes can generally be submitted using the process for substantial amendments. You should not need to make a new application). Please highlight any changes in a different colour, in order that the ethics committee can easily identify what the revisions are.

3.16 Internet Research

There are special considerations that you need to give to internet research. If researching documents that are in the public domain, you need to consider whether you should still obtain written permission from any organisations you are researching. In other cases, it is less clear about what constitutes the public domain. For example, although what people say in chat-rooms on internet sites is technically in the public domain, this does not mean that it
would be ethical, or people would expect, for it to be used for research. On the other hand, it may not be possible to obtain consent from people and, if this is the case, you need to justify the approach that you have used. Another issue is how you be can sure that participants are who they claim to be (e.g. can you be sure that they are all over 18 years of age). You also need to consider whether you will be recruiting participants on an international basis, given world-wide access to the internet. If appropriate for your research, you may consider gaining permission from an organisation about advertising for participants on their website, if it is applicable to the type of research you are doing.

3.17 Main Points when Making an Application

Some of the main points to remember when making an application are as follows.

**General advice**

- Allow plenty of time to prepare your application. The ethics committee want to be assured that you have thought about all aspects of your research and addressed potential risks and ethical issues.

- Ensure that you have included all documents with your application, as the ethics committee will need to see a comprehensive set of documentation relating to your research. If you are carrying out emerging research, you need to make this clear in your application. Alternatively, if you do not know what your interview schedule will be at this stage (for example, if it will be designed following the results of an initial questionnaire), you can submit the interview schedule as a substantial amendment at a later point. Please note that you must not implement any component of the study until it has been approved by the ethics committee/Chair.

- Make sure that you have proof read your application and accompanying documents.

- Please ensure that you spell out any acronyms the first time you use them in your application.

- Make sure that the ethics review checklist and your application form are signed by you and for students, also by your supervisor.

- There are templates for the participant information sheet and consent form on the website. These are a recommended format, but you can adapt them if they are not relevant for your research. You do need, however, to ensure that you have included all key information, for example relating to risks, insurance and storage and destruction of data.

- Avoid the use of jargon in the participant information sheet. It may be useful to show your participant information sheet to a friend or a colleague who is not in your field, to check that it is easily understood.

- Please ensure you use the terms confidential and anonymous correctly.
Key information for inclusion in your application

- A telephone number should be included on the participant information sheet for potential participants to contact the researcher, should they have any queries relating to the research. Personal landline telephone numbers should not be used. If an email address is provided, this must be your Anglia Ruskin email address.

- You should make it clear that participants can contact you should they have any concerns (attempt an informal resolution initially). You must include our university contact details for complaints on the participant information sheet, should they wish to take the issue further. Please see:
  
  http://web.anglia.ac.uk/anet/staff/sec_clerk/feedback.phtml

- You must provide clear information about how you plan to recruit participants (Question 8 on the ethics application form) and ensure that your procedure complies with the Data Protection Act (1998). The ethics committee will also want to be sure that there is no coercion. For example, if you are carrying out research in a school or another organisation, you need to be sure as far as possible that people are not being told by those senior to them that they have to take part. The requirement for voluntary consent without coercion can be aided by having an information pack for the organisation, with clear recruitment procedures, that make it clear that people should not take part if they do not wish to and can withdraw at any time.

- You must also provide complete information about the storage and destruction of data (Question 22 of ethics application form) and ensure that all arrangements comply with the Data Protection Act (1998).

- There are questions in the ethics application form relating to risks to the participants and to the researcher (Questions 12 – 14). Please ensure that you consider all risks. Even for a low risk study, there are some issues that you will need to think about. It is not sufficient to say that there are ‘no risks’ in response to these questions. The ethics committee wants to see that you have considered all risks that could reasonably be foreseen and have put procedures in place to deal with any incidents that could arise.

- If applicable to the research, you need to consider what you would do if a participant discloses some information that you would need to pass to a third party. This information might, for example, be participants saying that they might harm themselves or others or discussing planned or actual illegal activities. If you are working with a group of participants where this is likely to occur, you should generally say in the information sheet that if the participant does disclose certain information, you need to pass this on to a third party, unless there is a valid reason for not doing this. Any significant issues must be reported to the ethics committee.

- You should be aware of unrealistic assurances of anonymity. If there is a chance that participants may be identified through dissemination, even though their names or other identifying information are not used,
you must make this clear on the participant information sheet and during the consent process.

- If your research falls under legislation, for example, the Human Tissue Act (2004), you should state in the participant information sheet that your research complies with this. The ethics committee will also want to see that you are familiar with the legislation and evidence that you will adhere to it. It is also your responsibility to be aware of any legislation that comes into place during the course of your study. You would need to make any necessary changes to your research resulting from the legislation and apply for approval for these revisions through the relevant ethics committee. This could usually be done following the procedure for submitting a substantial amendment (please see Section 4.2 for further information regarding this).

**Research in other organisations**
- If you are carrying out research in another organisation you need to follow their ethics standards and procedures. Please ensure that you have sent a copy of any other ethics application you have had to make to the organisation and the subsequent ethical approval to FREP Administrator for our records. In some cases, we may accept the ethical approval from an organisation as equivalent to our own, meaning that you do not also have to apply to the university ethics committee. This will be considered on a case-by-case basis (with the exception of the NHS/Social care, whose approval is routinely accepted as equivalent to our own). Please check this with your FREP Chair.

**Research overseas**
- If you are carrying out research overseas, it is your responsibility to ensure that you obtain any ethical approval required and comply with all legislation relating to research in that country, as well as English law. You also need to ensure that you comply with all requirements for research visas or work permits.

**Any changes following approval of your research ethics application**
- If you subsequently make changes to any documents, these will require further review by the committee and will need to be submitted as a substantial amendment. Please submit the documents with the changes highlighted. Please see Section 4.2.
4 Ethics Committee Procedures

The ethical approval process is detailed below.

The ethics checklist needs to be submitted to your FREP Administrator for all research. To apply for ethics approval, first contact your FREP Administrator who will advise you on the requirements for obtaining approval. If required, please submit your application and accompanying documents to your FREP Administrator. If your research involves more than one faculty or you are from a support service, please contact Julie Scott on telephone 0845 1964210 or email address julie.scott@anglia.ac.uk

If your FREP Administrator informs you that your research will need ethical approval from a committee, the ethics application and relevant documentation will be considered by the Chair or a member of your FREP. If the research is low risk, the FREP will be able to review the study.

You may be allocated a Sponsor. This is a person from the committee who will work with you and suggest any amendments required prior to the committee meeting. You are advised to submit any amendments as soon as possible, in order to give time for the Sponsor to review the revisions prior to the meeting and circulate them to the committee.

Finally, you will be informed of the decision by letter following the meeting. Possible decisions of the FREP are:

- approve the application
- offer approval subject to certain conditions
- request specific revisions
- request a full resubmission
- reject outright.

When minor revisions are required, it may be possible for the Chair to approve the minor revisions on behalf of the committee. Please contact the FREP Administrator if you require clarification on this. Please note that any subsequent amendments to the research will require approval.

Please note that initial approval from the FREP is for a period of three years only.

Any appeals or complaints arising from research activity should be dealt with through the appropriate Anglia Ruskin University procedures. Information on the complaints procedure may be found at:

http://web.anglia.ac.uk/anet/staff/sec_clerk/feedback.phtml

4.1 Adverse Events and Incidents

Any accidents and near misses relating to the research must be reported in line with the Accident Reporting System. They must be reported to a member of the Risk Management team immediately. For further information, please see the Risk Management website:

http://rm.anglia.ac.uk/extlogin.asp
or contact Sarah Day on Sarah.Day@anglia.ac.uk or 0845 196 4239. Please also notify the FREP Administrator. You must report any other adverse incidents or events relating to the research to the FREP Administrator within two working days of their occurrence. This may include, for example, complaints from participants. Any issues that are deemed as urgent must be reported immediately.

4.2 Substantial Amendments

You must not implement any substantial amendments unless they have received approval. This is because the amendment may affect the original decision to grant ethical approval. You should contact your FREP Administrator in the first instance to determine the course of action you should take.

If you wish to make substantial amendments to your research, you will need to submit these in writing to the FREP Administrator. Please clearly detail the changes to the original proposal. You must include the full title of the research study, the project number, your name and the date the study was given ethical approval. In addition, you need to submit any revised documents, for example the participant information sheet or consent form. You should indicate on the documents the changes that have been made by highlighting them. Please also indicate the number of the amendment (first, second etc).

You will need to wait for a letter of acknowledgment from the FREP Administrator prior to implementing a substantial amendment.

Examples of substantial amendments are:

- changes to the design or methodology of the study, or to background information affecting its scientific value
- changes to the procedures participants need to undertake
- any changes relating to the safety or physical or mental integrity of participants
- any changes to the risk/benefit assessment for the study
- changes to study documentation, for example the participant information sheet or consent form, questionnaire or interview schedule
- a change to the insurance or indemnity arrangements for the study
- any other significant change to the protocol
- additions to the research team
- any changes required in order to comply with new legislation.

Examples of minor amendments, which do not require approval, are:
• correction of typographical errors

• changes in the documentation used by the research team for recording study data.

This may not be applicable to certain types of qualitative research, where the content of questionnaires/interviews will evolve. If this will be the case, you need to make this explicit in your original ethics application.

It is advisable to date all your study documentation and give it a version number. This is in order that you can track amendments easily. As the period for ethical approval is three years, it is then clear which of the documentation is currently ethically approved.

4.3 Application for Extensions

If you plan to extend the duration of the project beyond the original approval given for three years, you need to notify the FREP in writing. You need to ensure that you do this in adequate time, in order that approval can be granted before your ethical approval expires.

4.4 Notification Regarding End of Project

When your study has ended, please ensure that you notify the FREP Administrator.

4.5 Monitoring

All research is subject to monitoring as part our Research Governance procedures. Please ensure that you keep a research file, with copies of all the documentation relating to the study and evidence of the original ethical approval and any subsequent approval for amendments. You may also be sent a form to complete for research monitoring purposes.

5 National Health Service (NHS) or Social Care Research

Approval from an NHS Research Ethics Committee (NHS REC) and NHS Research and Development (R&D) Department, Research Governance Group or equivalent from Social Care or the Social Care Research Ethics Committee is usually regarded as equivalent to our own. If you obtain approval from these committees, you do not usually need to obtain approval from Anglia Ruskin University. You do, however, need to ensure that you have sent a copy of the approval documentation to the FREP Administrator prior to starting your research.

If you are carrying out research in the NHS you generally need to obtain two sets of approval. Approval usually needs to be sought from an NHS Research Ethics Committee (NHS REC). In addition, approval must be obtained from the Research and Development (R&D) Department or Committee from each NHS Organisation in which you are undertaking your research (or equivalent, as arrangements for R&D approval may vary).
some circumstances (e.g. research involving NHS staff, unless it presents significant ethical issues) NHS REC Approval will not be required, although R&D Approval is still likely to be. When planning NHS research, you need to contact the R&D Department of the NHS Organisation in the first instance. You can find contacts details for R&D Departments on the NHS R&D Forum website at http://www.rdforum.nhs.uk/044.asp

The R&D Department should be able to advise further on requirements. For NHS research in England, your study may fall under the criteria for proportionate review from the NHS REC, rather than having to be reviewed by the full committee: http://www.nres.npsa.nhs.uk/news-and-publications/news/extension-of-the-proportionate-review-pilot/

You must send your FREP Administrator a copy of:

- NHS Research Ethics Committee Approval
- NHS R&D Management Approval
- sponsor letter or confirmation.

If you required a Research Passport, please also let the FREP Administrator know, stating whether this was a project-specific or three-year passport. For further information regarding the Research Passport, please see: http://web.anglia.ac.uk/anet/rdcs/ethics/applicants/apply/application.phtml

For social care research, you must first clarify the level of review that is being carried out by social care and then contact your FREP to establish if further review will be required. If the approval is deemed as equivalent to ours, you must send a copy of the approval letter and confirmation of the Sponsor to the FREP Administrator.

It is essential that your FREP holds a record of all NHS and Social Care research activity. The documentation must be sent prior to starting your research and you must wait for confirmation that it has been received and is complete.

For NHS research, you must first check whether your research is entitled to support from the National Institute for Health Research (NIHR) Clinical Research portfolio. Please see the (NIHR) Clinical Research Coordinating Centre website:

http://www.ukcrn.org.uk/index.html

or speak to the relevant NHS R&D Department for further information.

For research that falls under the Human Tissue Act (2004) or Mental Capacity Act (2005) and requires approval by an NHS REC or the Social Care Research Ethics Committee for the Mental Capacity Act, but does not involve the NHS, NHS R&D Management Approval will not be required. In this instance, you must send a copy of your application, confirmation of Sponsor and any accompanying documents, as well as the NHS REC Approval letter, to the FREP Administrator.
Please note that it is your responsibility to ensure that you obtain any approvals for amendments or extensions from the NHS REC and also obtain NHS R&D Management Approval for these as required. The same applies for the Social Care REC/Local Governance Group. Copies of this approval must also be sent to the FREP Administrator. You must also comply with any other requirements of the NHS and Social Care committees and all relevant policies and procedures within the organisation e.g. confidentiality.

For further information regarding the NHS REC, please see the National Research Ethics Service website:  http://www.nres.npsa.nhs.uk

and the Integrated Research Application System (IRAS) website:  
https://www.myresearchproject.org.uk/signin.aspx

For contact details for NHS R&D Departments, please see the NHS R&D Forum website:
http://www.rdforum.nhs.uk

For information about the Social Care Research Ethics Committee please see:    
http://www.screc.org.uk

5.1 Sponsorship for NHS and Social Care Research

All NHS and Social Care research requires a sponsor. Please note that this has a different meaning to that used by Anglia Ruskin University (where the sponsor is the person designated to review your study in preparation for an ethics committee meeting). The Department of Health defines a sponsor as the ‘organisation … that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study’.

Anglia Ruskin University is able to take on the role of Sponsorship in certain instances. If we are asked to act as sponsor or co-sponsor for your research, please check with your FREP Administrator or Chair what the arrangements in your faculty are for this. An individual, for example a member of staff or supervisor, may not take on the role of sponsor due to the liabilities involved. Only the Chief Executive of an organisation or someone with delegated authority can approve Sponsorship. Please note that your study will still require a sponsor if it does not involve the NHS, but requires review by an NHS Research Ethics Committee because it falls under the remit of the Mental Capacity Act (2005) or meets the relevant criteria under the Human Tissue Act (2004).

For further information, regarding the responsibilities of a sponsor, please see the Research Governance Framework for Health and Social Care: Second Edition (2005), which is on the Department of Health’s website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962
5.2 The Research Passport Scheme

The Research Passport Scheme was implemented in August 2009. It was developed by NHS R&D and the UK Clinical Research Collaboration. If you are carrying out research involving the NHS, you may require a Research Passport. If so, please ensure that you have read and are familiar with the Research Passport Policy and Guidelines, that are available at: http://web.anglia.ac.uk/anet/rdcs/ethics/applicants/apply/application.phtml

A Research Passport is the mechanism for non-NHS staff to obtain an honorary contract or letter of access when they propose to carry out research in the NHS. It is one set of checks (e.g. Criminal Records Bureau and Occupational Health Clearance) for people carrying out research in the NHS. The aim of the Research Passport is to avoid multiple checks and speed up the process for gaining permission to undertake research within the NHS. You do not need a Research Passport or an honorary contract if you meet any of the following criteria:

- you are employed by an NHS Organisation
- you are an independent contractor (e.g. GP) or employed by an independent contractor
- you have an honorary clinical contract with the NHS (clinical academics)
- you are a student who will be supervised within clinical settings by an NHS employee or HE staff member with an honorary clinical or research contract.

The Research Passport Form is completed by the researcher and by Anglia Ruskin University and presented to all relevant NHS Organisations.

For students your form will need to be signed by staff from Admissions, your supervisory team and Occupational Health. Members of staff will require signatures from Human Resources, their line manager and Occupational Health.

Please note that obtaining a Research Passport does not replace the need to obtain NHS Research Ethics Committee and NHS R&D Management Approval or any regulatory approvals required.

6 Some legislation Relating to Research

It is essential that you are aware of all legislation relating to your research. For overseas research, you need to be aware of and comply with the laws of that country and also comply with English law and accepted standards. If there is any conflict between these and your conditions of ethics approval, please refer to the FREP immediately, prior to starting your research. Some of the key legislation follows; please note that this is not an exhaustive list.
6.1 The Data Protection Act (1998)

You must be familiar with this Act and adhere to all its requirements.

The eight principles of the Act are:

1. fair and lawful processing (participants must be aware of how their data will be used)
2. purposes for holding data – obtained for a specific and lawful purpose
3. data must be adequate, relevant and not excessive – the researcher must only collect what is needed
4. data must be accurate and up-to-date
5. retention and disposal of data – not kept for longer than necessary
6. rights of data subjects – data must be processed in accordance with these
7. data must be kept safe from unauthorised processing, or accidental loss or destruction
8. data must not be transferred to a country or territory outside the European Economic Area, unless the country has adequate levels of protection for personal data.

There are exemptions under the Data Protection Act when data is being collected for research. Data gathered for the purposes of research activity are exempt from being processed in accordance with the second and fifth data protection principles. This means that personal information can be (i) processed for purposes other than those for which it was originally obtained and (ii) held indefinitely. You must, however, take into account that exemptions only apply if the personal data are not processed to support measures or decisions relating to particular individuals or are not processed in such a way that substantial damage or distress may be caused to the data subject(s). Researchers must consider this on a case-by-case basis.

The Act defines personal data and sensitive data. Personal data is that which a living individual can be identified from and includes photographs and email messages.

Sensitive data is information regarding a person’s:

- racial or ethnic origin
- political opinions
- religious beliefs
- Trade Union membership
- physical or mental health
- sexual life
- commission or alleged commission by him/her of any offence
- proceedings for any offence committed or alleged to have been committed.

Greater care must be taking in storing this data and deciding who has access to it.

Please see our Data Protection Policy at:

http://web.anglia.ac.uk/anet/staff/sec_clerk/dpa.phtml
6.2 The Human Tissue Act (2004)

This Act covers England, Wales and Northern Ireland. It came into force on 1 September 2006 and is not limited to healthcare settings. The Act regulates the removal, retention and storage of tissue and organs for people who have died and the retention and storage of such material for people who are living (removal from people who are living is covered by Common Law). The Human Tissue Authority has been appointed to oversee compliance with the Act.

The fundamental principle underpinning the Act is ‘appropriate consent’ for ‘scheduled purposes’. Research is a scheduled purpose.

The definition of relevant material is ‘that which is from a human body and includes or consists of human cells’. This includes saliva and bodily waste products.

There is a new offence of DNA theft (which includes hair and nails in this context) that applies UK-wide.

In some instances, ethical review must be carried out by an NHS Research Ethics Committee, even if the research does not involve the NHS. University Research Ethics Committees are not authorised to review research where it involves either of the following:

- storage of relevant material (including any use of such material involving holding it overnight) otherwise than under the terms of a licence from the Human Tissue Authority to store relevant material for research
- use of relevant material from the living or analysis of DNA in such material, and consent has not been given by the donors to use for research or DNA analysis.

The Salivary Analysis Laboratory at Anglia Ruskin University has a licence from the Human Tissue Authority. Please contact Matt.Bristow@anglia.ac.uk if you require further information regarding whether our Research Ethics Subcommittee is authorised to review your research, or regarding the Human Tissue Act in general. If an NHS REC needs to review your research, but it does not involve the NHS, you need to submit all the documents you have submitted to the ethics committee and all correspondence and approval from them to your FREP Administrator.

There are also Codes of Practice and you need to be familiar with the relevant Code(s).

Offences under the Human Tissue Act (2004) include removing, storing or using human tissue for scheduled purposes without appropriate consent and carrying out licensable activities without holding a licence from the Human
Tissue Authority. Penalties include a fine, up to three years imprisonment or both.

For further information please see:


http://www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1

the Human Tissue Authority website: http://www.hta.gov.uk

and the research section of the Human Tissue Authority website, where you will also find the Code of Practice for Research:

http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/resea
rch.cfm

6.3 The Mental Capacity Act (2005)

This Act applies to England and Wales only. It came into force on 1 October 2007 and generally relates only to people aged 16 years and over. The Act empowers and protects people unable to make decisions for themselves, for example, matters relating to property and financial affairs or healthcare treatments. It also covers ‘intrusive research’ (i.e. that which would have normally required consent). There are a range of factors that can cause incapacity, including learning disabilities, dementia and mental health problems. Loss of capacity can also be temporary, for example due to shock or the effects of drugs or alcohol. The Act introduces two new criminal offences of ill treatment against people who lack capacity – 1) ill treatment 2) wilful neglect - with a penalty of imprisonment for up to five years.

The five key principles that underpin the Act are:

- a presumption of capacity (the starting point is that people have the right to make their own decisions)
- people have the right to be supported to make their own decisions
- people should be allowed to make what may be viewed as unwise decisions
- anything carried out for or on behalf of people who do not have capacity must be in their best interests
- the least restrictive option must be taken.

The two-stage test of capacity is:

- Is there an impairment or disturbance in the functioning of the person’s mind or brain?
- If yes, is this sufficient to cause the person to be unable to make that particular decision at the relevant time?
If the answer is yes, the research will need to meet all the requirements of the Mental Capacity Act. The ability of a person to make a decision should be assessed in each different situation. It is important to acknowledge that people may have the capacity to make some decisions but not others, or their ability to do this may fluctuate over time.

Any research that falls under the Act will need to be reviewed by an ethics committee recognised by the Secretary of State (an NHS Research Ethics Committee or the Social Care Research Ethics Committee, even if it does not involve the NHS or Social Care). University research ethics committees are not authorised to review research that falls under the Act. You need to submit copies of the documentation you submitted to the NHS REC or Social Care REC and all correspondence and approval from them to your FREP Administrator.

Researchers who carry out research that is within the remit of the Act are also legally required to have regard to the Code of Practice, available at: http://www.justice.gov.uk/guidance/protecting-the-vulnerable/mental-capacity-act/index.htm

Other useful links for further information are:


The Office of the Public Guardian: http://www.publicguardian.gov.uk/

The Ministry of Justice website: http://www.justice.gov.uk/about/mental-capacity.htm

If you are carrying out research with vulnerable groups who do have capacity to consent, this can be reviewed by your FREP. You must, however, provide written information about how you will ensure participants are able to consent and therefore do not fall under the remit of the Mental Capacity Act (2005). If one or more participant is unable to consent, the research falls under the Act and legally can only be reviewed by an NHS REC or the Social Care Research Ethics Committee.

6.4 The Medical Devices Regulations (2002) and Medicines for Human Use (Clinical Trials) Regulations (2004)

When you are planning your research, you must ensure check whether it falls under the Medicines for Human Use (Clinical Trials) Regulations (2004) or Medical Devices Regulations (2002). Please check the Medicines and Healthcare products Regulatory (MHRA) website for further information. http://www.mhra.gov.uk/index.htm

If you are unsure whether your study falls under either of these regulations, please email the MHRA for clarification. Should you be proposing a study that does fall under either of these regulations, it is essential you check this immediately with research.ethics@anglia.ac.uk
7. Research Ethics & Governance Checklist Date 23.1.12
These are some of the main points the FREPS will consider

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<thead>
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<tbody>
<tr>
<td><strong>Yes</strong></td>
<td><strong>No</strong></td>
<td><strong>Not applicable</strong></td>
</tr>
<tr>
<td>1.</td>
<td>All documents received, including ethics review checklist, questionnaire and interview schedules &amp; copy of recruitment poster if applicable.</td>
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<tr>
<td>2.</td>
<td>Ethics review checklist and ethics application form signed and dated.</td>
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<tr>
<td>3.</td>
<td>Do participant information sheet and consent form contain all the key information?</td>
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<td>4.</td>
<td>Does participant information sheet include a contact telephone number and email address? (must not be personal number and must be an Anglia email address) and information and details about how to make a complaint?</td>
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<td>5.</td>
<td>Are participant information sheet/consent forms of easy readability?</td>
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<td>6.</td>
<td>Is the procedure for consent satisfactory?</td>
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<td>7.</td>
<td>Are researchers appropriately qualified?</td>
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<td>8.</td>
<td>If using terms ‘confidentiality’ and ‘anonymity’ in participant information sheet, are these terms used correctly?</td>
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<td>9.</td>
<td>CRB clearance carried out in last year and via Anglia Ruskin University (or, if the researcher works for the organisation where the research is being carried out, carried out by that organisation). Equivalent of CRB obtained for overseas research</td>
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<tr>
<td>10.</td>
<td>Insurance questionnaire completed (questionnaire for research involving human participants) and approved by university insurers. Please contact <a href="mailto:Andrew.Chapman@anglia.ac.uk">Andrew.Chapman@anglia.ac.uk</a></td>
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<td>11.</td>
<td>Risk assessment &amp; action plan completed if required (only needs to be seen by FREP is requested by them)</td>
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<td>12.</td>
<td>Travel insurance in place (required if involves a flight and overnight stay, either within the UK or abroad).</td>
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<td>13.</td>
<td>Are all aspect of the study (e.g. recruitment of participants, storage of data) in compliance with the Data Protection Act (1998)?</td>
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<td>14.</td>
<td>Will personally identifiable information e.g. photographs, be used? If so, have measures been put in place for this? e.g. participants have given consent for this and given option to be contacted on each occasion they will be used?</td>
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<td>Yes</td>
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<tr>
<td>15</td>
<td>Research involving children – systems for assent/consent in place and participant information sheet/consent forms for parents and children. Is information for children age-appropriate?</td>
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<tr>
<td>16</td>
<td>Falls under Mental Capacity Act (2005) – needs referral to NHS REC or Social Care Research Ethics Committee</td>
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<td>17</td>
<td>Involves vulnerable adults who can consent – are measures in place to ensure they are able to consent and therefore do not fall under the Mental Capacity Act (2005)?</td>
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<tr>
<td>18</td>
<td>Falls under Human Tissue Act (2004) – checked that our university is authorised to review it (if not, needs referral to NHS REC).</td>
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<tr>
<td>19</td>
<td>Falls under Medical Devices Regulations (2002) – if so requires notice of ‘no objection’ from MHRA and systems to comply with legislation – speak to the Postgraduate Medical Institute or <a href="mailto:Julie.Scott@anglia.ac.uk">Julie.Scott@anglia.ac.uk</a> in the first instance</td>
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<td>20</td>
<td>Has a power calculation been carried out? (clinical studies).</td>
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<td>21</td>
<td>Has equipment been safety checked and are researchers trained in its use?</td>
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<td>22</td>
<td>If participants need to travel for the purpose of the research will expenses be reimbursed? Are participants told on the participant information sheet whether expenses will be reimbursed?</td>
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<tr>
<td>23</td>
<td>Will there be financial inducements – if so are these acceptable?</td>
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<td>24</td>
<td>If research is overseas, confirmation from researcher that has applied for any ethical approval required and will comply with the laws of that country as well as UK accepted laws and standards.</td>
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<tr>
<td>25</td>
<td>Research visas and permits obtained if required</td>
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<td>26</td>
<td>Ethical approval from any other organisations involved in research obtained.</td>
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<tr>
<td>27</td>
<td>If research is taking place in organisations need written confirmation, including regarding ownership and access to data, use of data, if organisation will be identifiable in write-up.</td>
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<td>28</td>
<td>If not possible to ensure complete anonymity of organisations or participants (e.g. there may be a chance they could be identified even if names or other personal information is not used, for example in case studies) has this been stated in participant information sheet?</td>
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<tr>
<td>29</td>
<td>Intellectual Property – agreements in place?</td>
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<tr>
<td>30</td>
<td>Disclosure – measures in place to deal with this (e.g. risk of harm to self or others, illegal activity). Is this included on participant information sheet?</td>
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<tr>
<td>31</td>
<td>Does participant information sheet state that study complies with legislation e.g. the Human Tissue Action (2004)?</td>
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</table>
32. Study involves participants who do not speak/write English. Arrangements in place for Professional Interpreter for oral and written translation and to interpret cultural norms.

33. Involves deception – justification for this provided. No alternative way to carry out study?

34. Does research involved sensitive topics – if so is this addressed sufficiently?

35. Is sufficient funding in place?