

# ALSPAC Ethics & Law Committee (ALEC)

## Terms of Reference

### 1. Introduction

The [Avon Longitudinal Study of Parents and Children \(ALSPAC\)](#) is a four-generation prospective study. Pregnant women living in one of three health districts in the former County of Avon with an expected delivery date between April 1991 and December 1992 were eligible to be enrolled in the study, and this formed the initial point of contact for the development of a large, family based resource. Children who matched the entry criteria but were not initially recruited were enrolled into the study at later ages. In mid-2011 the study was extended to include other family members.

From the start of the study ALSPAC has had its own independent ethics committee, the ALSPAC Ethics & Law Committee (ALEC). ALEC comprises clinicians, researchers, and people with legal expertise and lay people, including study participants.

#### 1.1

In 1<sup>st</sup> September 2011, new [Government Arrangements for Research Ethics Committee \(GAfREC\)](#) came into effect. As a result, NHS REC review is required for specific research projects involving the following settings. This is an ALSPAC specific summary of the framework, the full list of project review requirements can be found in Appendix 1:

- Research participants identified from, or because of their past or present use of, services for which the UK Health Departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls
- Research participants identified because of their status as relatives or carers of past or present users of these services
- Collection of tissue (i.e. any material consisting of or including cells) or information from any users of these services, including those who have died within the last 100 years
- Use of previously collected tissue or information from which the research team could identify individual past or present users of these services, either directly from that tissue or information, or from its combination with other tissue or information in or likely to come into their possession.
- Does the research involve exposure to any ionisation radiations, e.g. DXA scans
- Will the research involve at any stage intrusive procedure with adults who lack capacity to consent for themselves, including participants retained in the study following loss of capacity
- Health related research projects involving prisoners
- Clinical Trial of an Investigative Medicinal Product
- Clinical investigation on a non CE mark device

#### 1.2

All other studies such as those involving questionnaire or qualitative data collection, and policy changes to the way the study interacts with participants are reviewed by ALEC.

#### 1.3

The chair of ALEC is accountable to the Dean in the Faculty of Health Sciences in the University of Bristol in the first instance, but their overall responsibility is to sustain and enhance awareness of the University of Bristol research ethics policy within ALSPAC. The ALEC will report to the Faculty of

Health Sciences Research Ethics Committee. The submission of ALEC's annual report will be included for submission in the Faculty of Health Sciences Research Ethics Committee's annual report to the University Ethics of Research Committee (UERC). Appeals will be handled via this route.

#### **1.4**

The [UoB ethics policy](#) applies to everyone carrying out research under the auspices of the University, whether their current place of work is within or outside University premises. This includes, but is not limited to, all staff, visiting researchers, those with honorary posts and registered students. It is the responsibility of the principal investigator on a project to ensure that all researchers involved in the project are aware of and comply with the policies of the University.

## **2. Remit**

### **2.1**

To consider research ethics applications for investigations within these terms of reference and to allow, refer or decline proposals;

### **2.2**

The ALEC will provide full review of all proposals for new studies within ALSPAC, with the exception of those that require approval through the (NHS REC) system;

#### **2.2.1**

During the study design stage for studies that require NHS REC review the Research Governance Team Lead (RGTL) at UoB or equivalent other external sponsor contact will discuss the application with the ALEC Chair to ensure that ALEC specific requirements can be included in the Sponsor feedback prior to authorisation. Any required changes will be fed back to the PI via the Deputy Chief Operating Officer. The PI will return the revised documentation to the RGTL. Once the application has been finalised but before NHS REC submission, the study will be sent to an ALEC sub-committee for review with an expected response time of 5 working days from the date of circulation to the sub-committee. The sub-committee will review the application especially with a view to ALSPAC specific ethical issues and feedback to the Deputy Chief Operating Officer what needs to be addressed prior to submitting the application to the NHS REC. If there are substantial issues raised in the application by the sub-committee that cannot be resolved, then the application will be reviewed by the full committee either virtually or at the next scheduled ALEC meeting and will follow the usual review process. Once reviewed by the NHS REC, the REC decision letter will be fed back to the Chair of ALEC by the RGTL. In the case of a provisional opinion to the application the Deputy Chief Operating Officer will forward the suggested response to the Chair of ALEC and the RGTL for approval prior to submission. The same process will be applied to amendment requests.

#### **2.2.2**

The sub-committee will consist of the chair/deputy chair and 3 additional members. The 3 additional members will consist of professional and participant members. For amendments, the Chair will form the sole member of the sub-committee and undertake the review in the first instance. If the Chair feels that changes outlined in the amendment request are too significant to be reviewed via Chair's action alone, they can request additional sub-committee members to be included in the review of the amendment request. In this instance the 5 working days will restart from the date of circulation to the new sub-committee members.

### **2.3**

To ensure sound ethical review of ALSPAC, in keeping with national and international law and policy;

### **2.4**

To oversee research ethics and integrity principles and practices which govern the conduct of the ALSPAC;

#### **2.5**

To establish guidelines/policy on the key questions of ethics to thereby advise ALSPAC on: eg. Consent, confidentiality and privacy, disclosure of health related results;

#### **2.6**

To consider ethical, legal and reputational issues arising from the conduct of the study;

#### **2.7**

To consider other questions on which its advice is sought.

### **3. Responsibilities**

#### **3.1**

Ensure ALSPAC participants and researchers are fully protected under the policies and practice of the study; including protect participants and researchers from research that might be too intrusive or burdensome.

#### **3.2**

To ensure regular review of ALEC procedures and policies.

#### **3.3**

To ensure the committee obtains and retains Institutional Review Board Status with the United States Department of Health and Human Services, Office for Human Research Protections.

#### **3.4**

ALEC will act as the Research Ethics Committee for the PROBIT Study.

### **4. Membership and meetings**

#### **4.1**

The committee comprises:

- Chair
- Deputy Chair
- Clinicians and other researchers
- Legal, ethical, and other professionals
- Study participants (all generations over 16 years)
- Lay Members

Membership should comprise approximately equal representation from professionals and participants.

#### **4.2**

The membership term will be three years with possibility of renewal for a further two three year term.

#### **4.3**

ALEC will comprise - 15-20 committee members including the chair.

#### **4.4**

A quorum exists when there are at least 5 members present with 2 of those members' ALSPAC participant members. A member may attend by video or telephone conference.

#### **4.5**

ALEC will meet on alternate months, coordinated with the Original Cohort Advisory Panel (OCAP) meetings to enable a smooth pipeline for approval of studies.

#### **4.6**

A representative from the University of Bristol Research Governance Team will be in attendance and will take the minutes.

#### **4.7**

A non-voting member of ALSPAC will be in attendance.

#### **4.8**

Minutes of the meeting will be circulated to all members and will be made available to the public on request (redacted where necessary to maintain confidentiality).

#### **4.9**

Expert Advice: ALEC may on occasion seek specialist advice within the University on scientific, ethical and legal issues pertaining to applications and other matters which come before it. The ALEC Chair may co-opt a specialist onto the committee where an application requires expertise not generally available from ALEC members via the Head of Research Governance. This request will be facilitated by the Research Governance and Ethics Officer at the request of the ALEC Chair. See Appendix 2

## **5. Constitution**

### **5.1**

These terms of reference were endorsed by the ALEC at its meeting on and will be submitted during the annual reporting round to the Faculty of Health Sciences Research Ethics Committee and the University Ethics of Research Committee.



## National Research Ethics Service

### Does my project require review by a Research Ethics Committee?

This algorithm is designed to assist researchers, sponsors and R&D offices in determining whether a project requires ethical review by a Research Ethics Committee under the UK Health Departments' Governance Arrangements for Research Ethics Committees (GAfREC). It encompasses the requirements for ethical review under both the policy of the UK Health Departments and legislation applying to the UK as a whole or to particular countries of the UK.

Researchers requiring further advice should contact their R&D office in the first instance. Further advice may also be sought from a REC office or the NRES Queries Line at [queries@nres.npsa.nhs.uk](mailto:queries@nres.npsa.nhs.uk) by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location.

GAfREC is available at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_126474](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474)

In this document the term "Research Ethics Committee" means a REC within the UK Health Departments' Research Ethics Service, i.e. the National Research Ethics Service (in England) and the equivalent Research Ethics Services in Scotland, Wales and Northern Ireland. It does not include other RECs such as university RECs.

## A. Is the project research?

A1	<p>Is the project classified as research, or is it another type of activity such as clinical audit, service evaluation, public health surveillance, case study, satisfaction survey or equipment/systems testing?</p> <p>Please refer to our leaflet “Defining Research” at <a href="http://www.nres.npsa.nhs.uk/applications/is-your-project-research/">http://www.nres.npsa.nhs.uk/applications/is-your-project-research/</a></p> <p>Specific guidance on the classification of post-market surveillance of CE marked medical devices is available within our guidance on approval for medical devices research at <a href="http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940">http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940</a></p>
<p>If the project is not classified as research, review by a REC is not required. Host care organisations may have other arrangements in place to review the activity. Please seek advice from the R&amp;D office or clinical governance office in the first instance.</p> <p>If the project is research, proceed to Section B.</p>	

## B. Is there a legal requirement for REC review of this research?

The requirements in Section B apply *whether or not* the participants are patients or service users within the services for which the UK Health Departments are responsible.

The requirements apply to the whole of the UK except where stated.

Ref.	Question	Relevant legislation
B1	<p>Is the research a clinical trial of an investigational medicinal product?</p> <p>Refer to the MHRA algorithm at</p>	Medicines for Human Use (Clinical Trials) Regulations 2004

	<p><a href="http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/IsaclinicaltrialauthorisationCTArequired/index.htm#1">http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/IsaclinicaltrialauthorisationCTArequired/index.htm#1</a> to determine whether the trial is subject to the Clinical Trials Regulations. Contact the MHRA Clinical Trials Helpline for further advice.</p>	
B2	<p>Is the research a clinical investigation of a non-CE Marked medical device, or a device which has been modified or is being used outside its CE Mark intended purpose, conducted by or with the support of the manufacturer or another commercial company to provide data for CE marking purposes?</p> <p><i>Refer to our guidance on approval for medical devices research at <a href="http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940">http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940</a> or MHRA guidance at <a href="http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm">http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm</a></i></p> <p><i>Contact MHRA Devices Division for further advice.</i></p>	Medical Devices Regulations 2002
B3	<p>Does the research involve exposure to any ionising radiation?</p> <p><i>Refer to our guidance on research involving radiation at <a href="http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?esctl1428683_entryid62=67014">http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?esctl1428683_entryid62=67014</a></i></p>	Ionising Radiation (Medical Exposure) Regulations 2000
B4	<p>Will the research involve at any stage intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in the study following loss of capacity?</p> <p><i>An adult is any living participant aged 16 or over. Intrusive procedures are those requiring consent in law, including use of identifiable tissue samples or personal information.</i></p> <p><i>Applies in England, Wales and Scotland only.</i></p>	<p>Section 51 of the Adults with Incapacity (Scotland) Act 2000</p> <p>Sections 30-33 of the Mental Capacity Act 2005</p>
B5	<p>Will the research involve storage of relevant material from the living or the deceased on premises without a storage licence from the Human Tissue Authority (HTA)?</p>	Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of

	<p><i>Relevant material means any material from a human body consisting of or including cells, except for hair or nail from the living or embryos outside the body.</i></p> <p><i>Includes storage of imported material. Does not include „storage incidental to transportation“ or temporary storage pending extraction of acellular material for research provided that residual relevant material is disposed of within hours or days (or at most a week).</i></p> <p><i>Applies to England, Wales and Northern Ireland only.</i></p>	Information about Transplants) Regulations 2006
B6	<p>Will the research involve storage or use of relevant material from the living, collected on or after 1 September 2006, and the research is not within the terms of consent for research from the donors?</p> <p><i>Does not include imported material.</i></p> <p><i>Applies to England, Wales and Northern Ireland only.</i></p>	Section 1(9) of the Human Tissue Act 2004
B7	<p>Will the research involve analysis of DNA in material from the living, collected on or after 1 September 2006, and the analysis is not within the terms of consent for research from the person whose body manufactured the DNA?</p>	Section 45 of the Human Tissue Act 2004
	<p><i>For further guidance on B5-B7, refer to <a href="http://www.nres.npsa.nhs.uk/applications/approval-requirements/ethical-review-requirements/requirements-for-ethical-review-under-legislation/human-tissue/">http://www.nres.npsa.nhs.uk/applications/approval-requirements/ethical-review-requirements/requirements-for-ethical-review-under-legislation/human-tissue/</a> or the HTA Code of Practice on Research at <a href="http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm">http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</a></i></p> <p><i>Guidance on defining „relevant material“ is available from the HTA at <a href="http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policiesandpositionstatements.cfm">http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policiesandpositionstatements.cfm</a></i></p>	
B8	<p>Will the research involve either of the following:</p>	Human Tissue (Scotland) Act 2006



	<p>(a) organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal</p> <p>(b) organs, tissue blocks or slides retained from a hospital post-mortem examination, or tissue blocks or slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, unless lawful authorisation has been given for use in research?</p> <p><i>Applies in Scotland only.</i></p>	
B9	<p>Will the research involve access to, or processing of, the confidential information of patients or service users by researchers outside the normal care team without consent?</p> <p><i>Applies in England and Wales only.</i></p> <p><i>In addition to REC review, application must be made to the National Information Governance Board's Ethics and Confidentiality Committee (NIGB ECC). Refer to <a href="http://www.nigb.nhs.uk/s251">http://www.nigb.nhs.uk/s251</a> for further guidance. Specific advice may be sought from the NIGB <a href="http://www.nigb.nhs.uk/contact-us">http://www.nigb.nhs.uk/contact-us</a></i></p>	<p>Health Service (Control of Patient Information) Regulations 2002</p> <p>Section 251 of the NHS Act 2006</p>
B10	<p>Will the research involve processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers without consent?</p> <p><i>Authorisation for the research is required from the Human Fertilisation and Embryology Authority (HFEA). A favourable opinion from a REC is a required condition of authorisation. The NIGB ECC advises the HFEA on applications for authorisation. Please contact the NIGB for further advice <a href="http://www.nigb.nhs.uk/contact-us">http://www.nigb.nhs.uk/contact-us</a>.</i></p>	<p>Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010</p>
B11	<p>Will the research involve patients (or information about patients) receiving care at a nursing home or other independent hospital, clinic or medical agency?</p> <p><i>Applies in England, Wales and Northern Ireland only.</i></p>	<p>Private and Voluntary Health Care (England) Regulations 2001</p> <p>Private and Voluntary Health Care (Wales) Regulations 2002</p>

		Independent Health Care Regulations (Northern Ireland) 2005  Nursing Homes Regulations (Northern Ireland) 2005
B12	Will the research involve residents (or information about residents) at a residential care home?  <i>Applies to Northern Ireland only.</i>	Residential Care Homes Regulations (Northern Ireland) 2005
B13	Is the research a clinical trial involving the participation of practising midwives?	Nursing and Midwifery Council (Midwives) Rules Order of Council 2004
<p>If the answer to any of the questions in Section B is Yes, application for ethical review should be made to a Research Ethics Committee within the UK Health Departments' Research Ethics Service, except for research recruiting through the UK Armed Forces or otherwise within the remit of the Ministry of Defence Research Ethics Committee (MoDREC).</p> <p>Specific requirements apply to the allocation of certain types of application. Further guidance is available from <a href="http://www.nres.npsa.nhs.uk/applications/booking-and-submitting-your-application/">http://www.nres.npsa.nhs.uk/applications/booking-and-submitting-your-application/</a> or from the NRES Central Allocation System or Local Allocation Systems (see link for contact details).</p> <p>If the answer to all the questions in Section B is No, please proceed to Section C to check whether any other policy requirements for ethical review apply to the study.</p>		

## C. Is there a policy requirement for REC review of this research?

The requirements in Section C apply to the whole of the UK.

<i>Ref.</i>	<i>Question</i>	<i>Explanatory comments</i>
C1	Will the research involve research participants identified from, or because of their past or present use of, services for which the UK Health Departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?	The relevant services are:  NHS/HSC healthcare (UK-wide) Adult social care (England, Wales, NI) Children's social care (Wales, NI)
C2	Will the research involve research participants identified because of their status as relatives or carers of past or present users of these services?	
C3	Will the research involve collection of tissue or information from any users of these services, including those who have died within the last 100 years?	Tissue means any material consisting of or including cells.  Includes tissue or information collected in the course of normal care, where research use is intended at the time of collection.
C4	Will the research involve use of previously collected tissue or information from which the research team could identify individual past or present users of these services, either directly from that tissue or information, or from its combination with other tissue or information in or likely to come into their possession?	Tissue means any material consisting of or including cells.  Refer to the " <i>Supplementary notes on research not requiring REC review</i> " below for further guidance on circumstances where review is not required for secondary use of tissue or information previously collected in the course of normal clinical care.
C5	Is this a health-related research project involving prisoners?	A prisoner for this purpose means a person in the custody of the National Offender Management Service (i.e. the Prison Service in England and Wales), the Scottish Prison Service or the Northern Ireland Prison Service?

C6	Does this research involve xenotransplantation?	Xenotransplantation means putting living cells, tissue or organs from animals into people.
C7	Is this a social care research project funded by the Department of Health?	
<p>If the answer to any of the questions in Section C is Yes, application for ethical review should be made to a Research Ethics Committee within the UK Health Departments' Research Ethics Service.</p> <p>Where research approved by the Ministry of Defence Research Ethics Committee (MoDREC) continues within the services for which the UK Health Departments are responsible following transfer of participants into their care, it does not then require separate REC review.</p> <p>Specific 'flags' apply to the allocation of certain types of application. Further guidance is available from <a href="http://www.nres.npsa.nhs.uk/applications/booking-and-submitting-your-application/">http://www.nres.npsa.nhs.uk/applications/booking-and-submitting-your-application/</a> or from the NRES Central Allocation System or Local Allocation Systems (see link for contact details).</p>		

## Supplementary notes on research not requiring REC review

The following types of research do not normally require review by a REC within the UK Health Departments' Research Ethics Service. Alternative sources of ethical review may be available in some cases, e.g. from a university REC.

### 1. Research involving previously collected, non-identifiable information

Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research (see C4 above).

This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

## **2. Research involving previously collected, non-identifiable tissue samples**

Research limited to use of previously collected, non-identifiable material consisting of or including cells in accordance with the terms of donor consent is generally excluded from REC review.

However, REC review would be required if any of the following applied:

- (a) Consent for research has not been given, or the research is not within the terms of the consent (see B6 above)
- (b) The samples will be held on premises in England, Wales or Northern Ireland without a licence from the Human Tissue Authority to store relevant material for scheduled purposes (see B5)
- (c) The research also involves removal, storage or use of new samples from the living or the deceased (see C3)
- (d) The research also involves use of identifiable information held with the samples (see C4).

## **3. Research involving acellular material**

Research limited to acellular material (e.g. plasma, serum, DNA) extracted from tissue previously collected in the course of normal care is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.

This exception applies to research undertaken by staff within a care team using samples previously collected for clinical purposes from their own patients or clients, provided that the samples/data are anonymised or pseudonymised in conducting the research.

However, REC review would be required if the research involved:

- (a) Collection of tissue samples from patients in order to extract acellular material for the research (see C3)

- (b) Collection of information from patients (see C3)
- (c) Use of previously collected information from which patients could be identified by the researchers (see C4)
- (d) Analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA (see B7)

#### **4. Research involving staff**

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role.

*Exceptionally, the Research Ethics Service may accept an application for review of research involving staff at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. Agreement should be sought from the responsible operational manager for the local REC centre prior to submission of the application. Requests should be sent by email, including a summary of the research proposal (maximum one page) and explanation of why the project raises significant issues which cannot be managed routinely in accordance with established guidelines and good practice, and requires ethical consideration and advice from a REC. Contact points for operational managers are at <http://www.nres.npsa.nhs.uk/contacts/nres-office-and-departmental-contact-details/>*

#### **5. Healthcare market research**

REC review is not normally required for healthcare market research conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBI).

*Exceptionally, the Research Ethics Service may accept an application for review of healthcare market research at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. See guidance under paragraph 4 above.*

## **6. Research involving the premises or facilities of care organisations**

REC review is not required for research involving use of or access to a care organisation's premises or facilities, provided that review is not required under any other applicable legal or policy requirement. For example, a Phase 1 clinical trial undertaken by a Contract Research Organisation on premises rented from a NHS Trust would legally require REC review under the Clinical Trials Regulations. But research undertaken by a university department on NHS premises, involving healthy volunteers not recruited as NHS patients and not subject to any legal requirements, would not require review by a REC within the UK Health Departments' Research Ethics Service and could be reviewed by the university's research ethics committee.

## University Ethics of Research Committee

### Virtual Committee of Expertise

#### 1. Background

- 1.1 For certain studies, the University, Faculty or Departmental Ethics Committee ('Committee') will need to seek advice from an expert to inform the ethics review process. Experts provide advice on specialist/specific research areas, legislation, health & safety etc.
- 1.2 In September 2010, the University Ethics of Research Committee agreed it was appropriate to set up a virtual committee of expertise to address this requirement.
- 1.3 The Head of Research Governance has approached a number of potential experts within and outside of the University and maintains a list of those that have confirmed that they would be willing to act as an expert for University of Bristol ethics committees.
- 1.4 Examples of studies that may require expert opinion include:
  - ~ Studies that involve administering medicinal products (or foodstuffs) but which do not attempt to determine safety or efficacy of the product and do not involve the NHS. These studies do not fall under the medicines for human use (clinical trials) regulations or the NHS research ethics service.
  - ~ Studies that involve consent procedures that are unique to the cultural background/setting of the research participants and are therefore difficult to approve without further guidance/input on local customs.
  - ~ Studies that involve using medical and physical devices that have the potential to cause harm or raise risk concerns, but do not involve the NHS.
  - ~ Studies raising complex legal, indemnity or safety issues (e.g. data protection, criminal record bureau etc.) that need clarification for the committee.
  - ~ Studies using Clinical Research and Imaging Facilities

#### 2. Request for expert advice

- 2.1 A Committee can request advice from an expert for any study where the Committee finds it is unable to make a fully informed decision about the ethics of the proposed research.
- 2.2 When advice is sought, the Chair of the Committee shall contact the Head of Research Governance via the Research Governance and Ethics Officer for details of potential experts and, in collaboration with the research team if appropriate, the most relevant expert to deal with the enquiry will be identified. Where the research team is involved in this process, they shall be informed that any contact with the expert will need to be made via the Chair of the Ethics Committee and they must not contact the expert directly. The expert will be under no obligation to engage directly with the research team during the review process.
- 2.3 The Chair of the Committee will send a cover letter/email using the attached template 1, the completed ethics application form and the protocol (including any information



sheets and consent forms etc.) to the expert. The cover letter/email will include any specific questions the Committee would like the expert to address. A date for the response should be given in the cover letter/email, and this should be reasonable to allow the expert enough time to assess the research and prepare the response (at least 10 working days). The request for information should be commensurate with the complexity and risks of the research and should recognise that the experts give their time freely and are unlikely to have administrative support for this activity.

- 2.4 The Head of Research Governance shall monitor the number of requests for expert advice and shall limit the number of requests for input from one expert to no more than five per annum (unless the expert has agreed otherwise). Where capacity for review from an expert is reached, the Head of Research Governance shall work on expanding the list of experts in the field.
- 2.4.1 If it is deemed appropriate and feasible by the Chair of the Committee and the Head of Research Governance that the expert attends a Committee meeting to present their findings then any out of pocket expenses incurred by the expert (particularly for non-University of Bristol experts) shall be reimbursed in line with the University of Bristol policy on expenses.

### **3. Expert criteria**

- 3.1 The experts should be either research active or in a professional role which encompasses the area to be assessed.
- 3.2 The expert will have agreed to undertake reviews of this nature.
- 3.3 The expert must not be involved in the proposed research project or have previously provided a peer review for the research. The expert must declare, to the Head of Research Governance, any potential conflicts of interest with the research they are being asked to review.
- 3.4 Experts from outside the University of Bristol may be required to sign a confidentiality agreement which reflects their involvement in the review of the research. The Head of Research Governance will arrange this as appropriate.

### **4. Review criteria**

- 4.1 The expert is required to review the protocol, supporting documents and the completed ethics application form.
- 4.2 The expert is asked to respond to any specific questions raised in the cover letter/email in the format requested.
- 4.3 The review should also seek to answer:
  - Has there been appropriate safety/risk assessment?
  - Are the outcomes of the study stated and appropriate?
  - Are there any legal or compliance issues that need addressing in the proposed research?
  - Are there any liability issues and how could/should these be resolved?

### **5. Liaison with the Ethics Committee**

- 5.1 The expert shall be free to contact the Chair of the Committee to seek clarification about the request for review or to request more detailed information in order to fully assess the proposed research.
- 5.2 The Committee shall be responsible for the final ethics decision for the proposed research project. The opinion of the expert forms only one component of the decision making process for the Ethics Committee.
- 5.3 Experts are covered by UoB insurance when working on UoB business.

## **Template 1: Letter/Email to Expert**

Dear XX XXXX

I write in relation to our 'Ethics Virtual Committee of Expertise' which helps with providing an expert review for our Faculty / Departmental Research Ethics Committee (F/DREC) when members feel they lack the relevant expertise to review a study. The Terms of Reference (TOR) for this activity are attached for information.

You have kindly indicated to our Research Governance team that you would be willing to undertake this role for us and recently we have received a study from *<insert Chief Investigator name and Faculty/Department>* that would benefit from your input. The study is entitled, *<insert study title>*.

I would be grateful if you could review this study in line with the attached TOR. I attach the study documentation and would appreciate your *<email/written>* response on the following issues by *<insert date/timescales>*:

*<insert relevant issues or a short form to complete or refer to section 4 of the TOR>*

If you have any questions please do not hesitate to contact me.

Many thanks for your time and support.

<Name>

Chair, <Faculty> Research Ethics Committee