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 1st September 2011, new Governance 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.
- Research involving exposure to ionisation radiations, e.g. DXA scans
- Research, at any stage, involving intrusive procedures 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. For reporting purposes, ALEC will report annually to the University of Bristol's University Ethics of Research Committee (UERC), via the Chair.

Any issues, escalations or appeals to ALEC decisions, will be managed through the Health Sciences FREC, and escalated further to UERC if needed.

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. Appendix 3 describes this process.

2.3

The Deputy Chief Operating Officer will attend meetings of ALSPAC's Executive, immediately after ALEC meetings, to present the minutes of the meeting and so close the governance loop, feeding back discussion, salient points and issues in line with the Committee's Remit and Responsibilities. A standing agenda item, 'Feedback to ALSPAC's Executive', also allows the Committee to feedback new ideas or concerns about the content and running of the study (see also 2.7 below).

2.4

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

2.5

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

2.6

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;

2.7

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

2.8

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 protecting 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
The ALSPAC Ethics and Law Committee (ALEC) is registered as an Institutional Review Board (IRB) with the Office for Human Research Protections (OHRP) within the United States Department of Health and Human Services in 2003, in order to facilitate ethical approvals for US funded collaborators. IRB status is usually only relevant to US collaborators; exceptionally it is relevant to other collaborators working abroad and University of Bristol researchers seeking access to US datasets. Applications are submitted to the Chair in the first instance who can review and approve research ethics applications that require an IRB review via Chair action.

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 ALSPAC Participant and Public Advisory Panel (APPAP) meetings to enable a smooth pipeline for approval of studies.

4.6
The Secretary 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 Faculty of Health Sciences Research Ethics Committee on 18th April 2023.

Appendix 1

Algorithm - Does my project require REC review v2.0 20200304.pdf (hra-decisiontools.org.uk)

Appendix 2

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

Appendix 3

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.

2. 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.

3. 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.

4. 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 unless the NHS REC submission is non-substantial or non-notifiable. If an amendment is considered non-substantial AND non-notifiable by the REC amendment process the ALEC chair will be notified but there will be no review by the ALEC committee.

5. 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.