

ALSPAC Executive

Terms of Reference

1. Introduction

- 1.1 ALSPAC is based within the Bristol Medical School, Faculty of Health Sciences at the University of Bristol. The role of the ALSPAC Executive (AE) is to provide effective management of ALSPAC.
- 1.2 The AE reports directly to the ALSPAC Board (AB).
- 1.3 The Principal Investigator (PI) of ALSPAC has overall responsibility for all areas of activity. Members of the AE support the PI in the execution of the ALSPAC activities outlined below. AE members will, in turn, be supported by members of the Senior Management Team (SMT) for all operational activity.

2. Membership

- 2.1 Membership comprises of the PI, Chief Operating Officer (COO), Executive Director (data) (EDD), Executive Director (bioresource) (EDB) and Executive Director (collection) (EDC). The AE meetings will be chaired by the PI.
- 2.2 One member of the AE will be present at all meetings. When a member is unable to attend a deputy will attend in their place. Deputies are nominated members of the ALSPAC management structure with appropriate experience and current operational knowledge of the study. If a deputy is unable to attend in place of a member the meeting will be cancelled.
- 2.3 Members are appointed for the remaining period of the Strategic Award (August 2019 to July 2024). Members are expected to fully understand and enact the recognised duties and responsibilities of their role.
- 2.4 A representative from the AB may attend any meeting either by necessity of referral or for reasons of review.
- 2.5 Clinical members of the AB will be called upon to provide expert advice as and when is necessary.

3. Remit

- 3.1 The remit and work programme of the AE follows:
 - Management of ALSPAC in respect to science (PI), management and administration (COO), data (EDD), bioresource management (EDB), data collection strategy (EDDC)
 - Determine scientific strategy in consultation with Scientific Advisor (SA) and AB
 - Report to the AB on progress and activity
 - Management of issue log and risk register
 - Approval of new data and sample collection proposals
 - Ensure compliance with policies, protocols and procedures in line with relevant legal, regulatory and ethical requirements
 - Referral of data access requests to ISAB that AE finds itself unable to adjudicate on
 - Referral of unresolved issues/problems to the AB

- Refer issues regarding scientific direction to the Scientific Advisor (SA) where necessary
- Operationalise strategic plans developed by the AB
- Oversee the Information Security Management System (ISMS)
- Ensure that ALSPAC is not brought into disrepute and that participant confidentiality is respected
- Outward representation of the study to encourage use of the resource

4. Objectives and Responsibilities

4.1 Management of ALSPAC:

- a. Review activity/progress reports from the SMT
- b. Oversee the approval of new proposals to access data/samples and manage the data access process
- c. Manage access to data and samples
- d. Approval of publications
- e. Manage the study finances
- f. Manage access policy; reviewing and updating where necessary; management of process audits
- g. Ensure accessible metadata available as widely as possible
- h. Oversee cost recovery process, taking corrective action where required
- i. Refer any complaints about access to data to ISAB
- j. Monitor progress of strategic award programme deliverables, helping work programme leads deliver on time and to budget and to help them with problem solving where necessary
- k. Ensure effective communication with significant stakeholder groups i.e. funders, participants, university and researchers

4.2 Determine scientific strategy in consultation with SA and AB:

- a. Consult with SA and AB in determining future scientific strategy
- b. Consult with SA and AB regarding renewal funding/strategic support

4.3 Reporting to the AB on progress and activity:

- a. Reports prepared and delivered to the AB on progress and activity

4.4 Issue and risk management:

- a. Manage the risk register; identify, assess and prioritise risks regularly; monitor, minimise and control these risks
- b. Manage the issue log; identify, assess and prioritise issues regularly; put in place measures to manage and control these issues

4.5 Approval of new data and sample collection proposals:

- a. Plan new data collection sweeps and sub studies ensuring that consideration is given to the timing, feasibility and acceptability of these studies to study participants in line with ALSPAC aims
- b. Keep abreast of novel methods of collecting data, ensuring they are feasible and acceptable to participants
- c. Ensure that protocols, standard operating procedures and policies are in place to support high quality data collection

- d. Manage incidental findings according to the study protocol that applies
 - e. Oversee complaints by participants on data collection
 - f. Ensure that the data from data collection sweeps are made available to researchers as quickly as possible
 - g. Ensure that protocols, standard operating procedures and policies are in place to support the clinical safety of participants and the safeguarding of vulnerable individuals
- 4.6 Ensuring compliance with legislation/best practice guidance:
- a. Ensure that comprehensive policies and protocols are in place throughout ALSPAC in line with national standards and guidelines
 - b. Ensure that there is a system in place for easy access to policies and protocols for all staff
 - c. Ensure that staff are trained and comply with protocols, standard operating procedures and policies
 - d. Keep abreast of new legislation/best practice guidance and ensure that ALSPAC is compliant with protocols and policies
- 4.7 Referral of data access requests to ISAB that the AE finds itself unable to adjudicate on:
- a. ISAB referrals may reflect scientific uncertainty; first encounter with a substantive new scientific challenge; intrinsic controversy in an application; serious conflict of interest for the AE
- 4.8 Referral of unresolved issues/problems to the AB:
- a. Ensure timely referral of issues where the AE is unable to make a determination to the AB; referrals may require expert advice on clinical or other matters
- 4.9 Refer issues regarding scientific direction to the Scientific Advisor where necessary:
- a. Ensure referral of issues regarding scientific direction to the Scientific Advisor as and when is necessary
- 4.10 Operationalisation of strategic plans:
- a. Offer advice to AB on how strategic plans can be achieved through available and/or future resources
 - b. Implement strategic plans ensuring supporting structures are in place to facilitate success
 - c. Measure the performance of key indicators to evaluate the likely success of the plans
 - d. Report to the AB on progress of strategic plans
- 4.11 Oversight of ALSPAC Information ISMS:
- a. Ensure the confidentiality (including participant transparency and acceptability), integrity (including secure storage) and availability (including secure sharing) of ALSPAC information assets
 - b. COO acts as Senior Information Risk Owner (SIRO)
 - c. Ensure that the ALSPAC ISMS is established, is compatible with the objectives of ALSPAC, is integrated within ALSPAC operations and is operating effectively
 - d. Communicate the importance of, and commitment to, information security to ALSPAC staff and stakeholders

- e. Support information security staff and other relevant staff members to fulfil their information security responsibilities
 - f. Ensure that the ALSPAC ISMS has sufficient resources to operate effectively
 - g. Foster a culture of openness and continual improvement in regard to Information Security in ALSPAC
- 4.12 Ensuring the study is not brought into disrepute and that participant confidentiality is respected:
- a. Ensure all new proposals comply with the ALSPAC Access Policy
 - b. Ensure all draft publications comply with the ALSPAC Access Policy
 - c. Ensure compliance with appropriate data security standards
 - d. Oversee crisis management controls
- 4.13 Outward representation of the study to encourage the use of the resource:
- a. Actively pursue opportunities for engagement with the research community
 - b. Develop, implement and monitor the researcher engagement strategy and action plan
 - c. Monitor progress against the plan taking corrective action where necessary to ensure that the plan is on track

5. Referrals

- 5.1 As above and to clarify, there are three routes of referral from AE:
- SA for scientific direction and development
 - AB for unresolved issues
 - ISAB for specific scientific advice

6. Meetings

- 6.1 The AE meets once a week, either online or in person. The PI is responsible for convening the meetings.

7. AE Minutes and Reporting

- 7.1 The minutes of the meetings are circulated to all members and AB members. Minutes are also circulated to SMT members and other managers in ALSPAC.

8. Constitution

- 8.1 These terms of reference were approved by the ALSPAC Board on 21 April 2023, with minor updates in March 2024.