

## **ALSPAC Executive**

### **Terms of Reference**

#### **1. Introduction**

- 1.1 ALSPAC is based within the Bristol Medical School, Faculty of Health and Life Sciences, University of Bristol. The ALSPAC Executive (AE) provides the day-to-day strategic and operational 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 and coordination of ALSPAC activities. AE members will be supported by members of the Senior Management Team (SMT) for all operational activity.

#### **2. Membership**

- 2.1 Membership comprises:
  - Principal Investigator (PI)
  - Chief Operating Officer (COO)
  - Executive Director (Data) (EDD)
  - Executive Director (Bioresource) (EDB)
  - Executive Director (Collection) (EDC)
- 2.2 The AE meeting is chaired by the PI. In their absence, a substantive member of the AE may deputise.
- 2.3 Each AE member may nominate a deputy with appropriate seniority, experience and current operational knowledge.
- 2.4 Members are appointed for the duration of the Renewal award (August 2024 to July 2029) or until role changes occur, whichever is sooner.
- 2.5 A representative of the AB may attend meetings as required. Clinical members of the AB may be invited to provide expert advice when necessary.

#### **3. Role and remit**

The AE is responsible for the strategic oversight and coordinated management of ALSPAC across science, operations, data, bioresources and data collection. Its remit includes:

- Setting and implementing scientific and operational strategy, in consultation with the Scientific Advisor (SA) and AB
- Oversight of governance, risk, compliance and information security
- Coordination and approval of data access, data collection and sample use within ALSPAC policies
- Monitoring delivery of strategic awards and work programmes
- Escalation of issues to appropriate advisory or governance bodies
- External representation of ALSPAC to promote responsible and effective use of the resource
- Future planning of study activity.

## **4. Responsibilities**

### **4.1 Strategic and operational management of ALSPAC:**

The AE will:

- Review progress and performance reports from the SMT
- Oversee study finances, cost recovery and audit processes
- Monitor delivery of renewal milestones and support problem-solving where required
- Ensure effective communication with key stakeholders, including funders, participants, researchers and the University

### **4.2 Scientific strategy**

The AE will:

- Determine scientific direction in consultation with the SA and AB
- Advise on and support renewal funding and long-term strategic planning

### **4.3 Reporting and Accountability**

The AE will:

- Prepare and submit regular reports to the AB on progress, performance and emerging issues

### **4.4 Risk and Issue Management**

The AE will:

- Maintain and regularly review the risk register
- Identify, assess and manage operational and strategic risks
- Maintain an issue log and implement mitigation or escalation as required

### **4.5 Data and Sample Collection**

The AE will:

- Approve new data and sample collection proposals from researchers working in academic, government, charity or commercial organisations whose research is health related and serves the public interest
- Ensure ethical approval, appropriate protocols and participant/public acceptability
- Oversee participant safety, safeguarding and management of incidental findings
- Ensure timely availability of collected data to researchers

### **4.6 Data Access and Linked Data Approvals**

The AE will:

- Approve data and sample access requests in line with ALSPAC Access Policy
- Approve linked data projects, ensuring representation from the PI and relevant Executive Directors in decision-making.
- Seek advice from ALEC, APPAP or ISAB where appropriate

- Ensure compliance with the 'Five Safes', funder requirements and data sharing agreements, and projects requesting NHS data are not-for-profit and consider potential benefits to health in England and Wales

#### **4.7 Legal, Ethical and Regulatory Compliance**

The AE will:

- Ensure policies, protocols and procedures meet legal, regulatory and best practice standards
- Ensure staff are trained and compliant with these requirements
- Monitor changes in legislation and guidance and ensure ongoing compliance

#### **4.8 Escalation and Referral**

The AE will:

- Refer unresolved operational or governance issues to the AB
- Refer scientific uncertainty or contentious access requests to ISAB
- Refer matters of scientific direction to the SA when required

#### **4.9 Information Security**

The AE will:

- Oversee the ALSPAC Information Security Management System (ISMS)
- Ensure confidentiality, integrity and availability of information assets
- Support the COO in their role as Senior Information Risk Owner (SIRO)
- Promote a culture of information security and continual improvement

#### **4.10 Reputation and Participant Protection**

The AE will:

- Ensure compliance with ALSPAC Access Policy and data security standards
- Oversee crisis management arrangements
- Safeguard participant confidentiality and public trust

#### **4.11 External Engagement**

The AE will:

- Represent ALSPAC externally to encourage appropriate use of the resource
- Lead and monitor researcher engagement strategies

### **5. Referrals**

#### **5.1 Referrals from AE**

The AE may consult with, take advice from, and/or refer matters to:

- Scientific Advisor (scientific direction)
- ALSPAC Board (unresolved or high-risk issues)
- Independent Scientific Advisory Board (specialist scientific advice)

## **5.2 Referrals to AE**

The AE may consult with, take advice from and/or receive referrals from:

- ALSPAC Board
- ALSPAC Ethics and Law Committee (ALEC)
- Independent Scientific Advisory Board (ISAB)
- ALSPAC Participant and Public Advisory Panel (APPAP), comprising participant and public members
- ALSPAC Clinical Advisory Committee

## **6. Meetings**

6.1 The AE meets weekly, either in person or online. Meetings are convened by the PI.

6.2 A meeting will be quorate if attended by five members of whom three must be substantive members. Up to two deputies may attend in place of substantive members.

## **7. Minutes and Reporting**

7.1 Minutes are circulated to AE and AB members, and to SMT and relevant managers as appropriate.

## **8. Constitution**

8.1 These Terms of Reference were approved by the ALSPAC Board on 21 April 2023, with minor updates approved the Board chair on the on the 30 January 2026.