

ALSPAC Senior Management Team

Terms of Reference

1. Introduction

- 1.1 The ALSPAC Senior Management Team (SMT) manages operational activity in ALSPAC within the following areas; administration, data and bioresource management.
- 1.2 SMT reports directly to the ALSPAC Executive (AE) leads in these areas: Chief Operating Officer (operations), Executive Director (bioresource), Executive Director (data) and Executive Director (collections).
- 1.3 The Chief Operating Officer has responsibility for the efficient and effective running of SMT.

2. Membership

- 2.1 Membership comprises senior managers from the key operational teams (operations, administration, data access, data pipeline, data systems, data linkage, clinic and bioresource).
- 2.2 Members are expected to understand fully the duties and responsibilities of their role.

3. Remit

- 3.1 The remit of SMT incorporates:
 - Management of operational activity in the areas of administration, bioresource management and data processing and data access
 - Reporting to and communication to and from AE on operational activity
 - Operational management of ALSPAC's Information Security Management System
 - Management of approval system for data access requests
 - Maintain issue log and risk register
 - Converting approved data and sample collection proposals into live projects
 - Contribute to, write and comply with policies, protocols and procedures in line with relevant legal, regulatory and ethical requirements
 - Escalate issues to AE where relevant
 - Operationalise management plans developed by AE
 - Support AE in ensuring ALSPAC is not brought into disrepute and that participant confidentiality is respected

4. Objectives and Responsibilities

- 4.1 Management of operational activity in key areas:
 - a. Manage teams across three activity areas; administration, bioresources, data processing and data access
 - b. Monitor activity/progress in these operational areas
 - c. Resource management (people, physical, facilities)

- d. Ensure compliance with information security guidelines and adherence to health and safety legislation and guidance
- e. Project management ensuring deliverables are met on time and to budget
- f. Conduct lessons learned reviews to ensure continuous improvement
- g. Advise AE on the feasibility and acceptability of new projects
- h. Support PIs in the provision of ALSPAC costs for grant applications
- i. Support work programme leads in helping to ensure that programme deliverables are met on time and to budget
- j. Manage workflow to other working groups, committees and meetings
- k. Ensure effective communication with significant stakeholder groups i.e. funders, participants, university and researchers

4.2 Reporting to AE and others on operational activity:

- a. Reports prepared and delivered to AE on progress against deliverables and activity
- b. Regular reports covering progress/activity in clinic activity, issue log and risk register, publications, data access, data preparation and legacy data project, participation/engagement and communication activities, funding, SOP's and ethics
- c. Support AE with annual reports to the Wellcome Trust and MRC
- d. Support AE with reports to external bodies as needed

4.3 Operation of ALSPAC's Information Security Management System:

- a. Coordination of Information Asset Owner (IAO) function
- b. Offer advice to AE on how plans can be achieved through available and/or future resources
- c. Monitor permissions process and grant approval to new requests
- d. Review information security events and identified weaknesses; consider root cause analysis and improvements
- e. Report and discuss new or changed requirements; identify new or changed IS risks, new stakeholders or changes in organisational scope.

4.4 Management of the approval system for data access requests:

- a. Manage the online approval system (OPS) for access to data
- b. Manage process of providing data and samples to collaborators through established processes
- c. Undertake regular audits to measure compliance with data access process
- d. Support AE in ensuring accessible metadata are available
- e. Manage cost recovery process
- f. Maintain and update access policy when relevant

4.5 Maintaining an issue log and risk register:

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

4.6 Converting approved data and sample collection proposals into live projects:

- a. Plan and deliver effective data collection sweeps with all cohort groups

- b. Assign a project lead to each new data collection project, and receive regular reports on progress with each project
 - c. Refer key decisions on changes to data and sample collections to the AE
 - d. Support applications to ethics committees
 - e. Manage participant advisory panels, ensuring new data collection projects are reviewed for acceptability
 - f. Support academic staff in identifying and testing novel methods of collecting data ensuring they are feasible and acceptable to participants
 - g. Prepare protocols, standard operating procedures and policies to support high quality data collection and the clinical safety and safeguarding of participants
 - h. Ensure compliance with the above protocols
 - i. Support the handling of incidental findings in accordance with the individual study protocol
 - j. Prepare data from data collection sweeps for researchers in accordance with agreed timescales
 - k. Manage complaints from participants
- 4.7 Contribute to writing and ensuring compliance with legislation/best practice guidance:
- a. Produce protocols, standard operating procedures and policies for all relevant areas in line with all relevant legal, regulatory and ethical requirements
 - b. Train staff to comply with protocols, standard operating procedures and policies and ensure compliance
 - c. Advise AE on new legislation/best practice guidance and ensure that sub-unit teams remain compliant with these
- 4.8 Escalating issues to AE where relevant:
- a. Ensure timely referral of issues where the SMT is unable to make a decision in line with the planned execution of current deliverables to the AE
- 4.9 Operationalisation of management plans:
- a. Offer advice to AE on how plans can be achieved through available and/or future resources
 - b. Support AE in delivering the strategic plan by providing staff and resources from sub-unit teams
- 4.10 Supporting AE in ensuring the study is not brought into disrepute and that participant confidentiality is respected:
- a. Plan and deliver all new projects in compliance with the access policy
 - b. Provide necessary staff time and other resources required to meet data security standards
 - c. Report matters of concern to AE
 - d. Manage the publications process, reporting issues and breaches to AE
- 5. Meetings**
- 5.1 SMT meets once a week, either online or in person. The Chief Operating Officer is responsible for convening and arranging rotational chairing the meetings. Meetings will usually last one and a half hours.

5.2 SMT meets for an away day, usually once every three months. The Chief Operating Officer is responsible for convening and chairing the meetings.

6. Minutes and Reporting

6.1 The minutes of the meetings are circulated to all SMT members and are also made available to staff via the ALSPAC SharePoint site.

7. Constitution

7.1 These terms of reference were endorsed by the AE at its meeting on the 25th April 2024 and will be reviewed annually.