

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) and Executive Director (data).
- 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 and security, clinic, G2 and bioresource).
- 2.2 Membership is tied to nine specific posts within the ALSPAC structure.
- 2.3 Members are expected to understand fully the duties and responsibilities of their role.

3. Remit

- 2.1 The remit of SMT incorporates:
 - Management of operational activity in the areas of administration, bioresource management and data processing and data access
 - Reporting to AE on operational activity
 - Management of approval system for data access requests
 - Maintain issue log and risk register
 - Converting approved data and sample collection proposals into live projects
 - Managing legacy data project
 - 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
 - Operational management of ALSPAC's Information Security Management System
 - 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; conduct lessons learned reviews to ensure continuous improvement
- f. Advise AE on the feasibility and acceptability of new projects
- g. Support PIs in the provision of ALSPAC costs for grant applications
- h. Support work programme leads in helping to ensure that programme deliverables are met on time and to budget
- i. Manage workflow to other working groups, committees and meetings
- j. 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 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 (ResearchFish)
- d. Support AE with reports to external bodies as needed

4.3 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

4.4 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

4.5 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. Manage participant advisory panels, ensuring new data collection projects are reviewed for acceptability
- e. Support academic staff in identifying and testing novel methods of collecting data ensuring they are feasible and acceptable to participants
- f. Prepare protocols, standard operating procedures and policies to support high quality data collection and the clinical safety and safeguarding of participants
- g. Ensure compliance with the above protocols
- h. Support the handling of incidental findings in accordance with the individual study protocol

- i. Prepare data from data collection sweeps for researchers in accordance with agreed timescales
 - j. Manage complaints from participants
- 4.6 Managing the legacy data project:
- a. Ensure project resources are in place at the start of the project
 - b. Run the legacy data project according to the project plan
 - c. Monitor progress of the project, reporting to AE and taking corrective action where necessary to ensure project is on track
- 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 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 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.
- 4.11 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. The Chief Operating Officer is responsible for convening and chairing the meetings. Meetings will usually last one hour.
- 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 wiki.

7. Constitution

- 7.1 These terms of reference were endorsed by the AE at its meeting on 25 May 2017 and will be reviewed annually.