

Isle of Wight Cohort Data Access Group

Terms of Reference

1. Introduction

- 1.1. IOWC is based within the Isle of Wight NHS Trust (The David Hide Asthma & Allergy Research Centre). The role of the Data Access Group (DAG) is to provide effective management of IOWC Resource.
- 1.2. The Principal Investigator (PI) of IOWC has overall responsibility for all areas of activity. Members of the DAG support the PI in the execution of the IOWC activities outlined below. DAG members will, in turn, be supported by members of the Senior Research Team for all operational activity.

2. Membership

- 2.1. Membership comprises of the Principal Investigator (PI), 5 members of the IOWC Senior Research Team based on their contribution to the generation of the cohort resource, and the IOWBC Data Manager. Data Access Group meetings will be chaired by the PI.
- 2.2. The PI, two members of the IOWC Senior Research Team and the Data Manager 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 wider research team 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.

3. Remit

- 3.1. The remit and work programme of the DAG follows:
 - Management of IOWC in respect to science, management and administration, data and bioresource management
 - Determine scientific strategy
 - Report 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
 - Oversee the Information Security Management System (ISMS)
 - Ensure that IOWC 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 IOWC:
 - Review activity/progress reports
 - Oversee the approval of new proposals to access data/samples and manage the data access process
 - Manage access to data and samples
 - Approval of publications
 - Manage access policy; reviewing and updating where necessary; management of process audits
 - Ensure accessible metadata available as widely as possible
 - Ensure effective communication with significant stakeholder groups i.e. funders, participants, university and researchers
- 4.2. Determine scientific strategy.

4.3. Reporting on progress and activity.

4.4. Issue and risk management:

- Manage the risk register; identify, assess and prioritise risks regularly; monitor, minimise and control these risks
- 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:

- 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 IOWC aims
- Keep abreast of novel methods of collecting data, ensuring they are feasible and acceptable to participants
- Ensure that protocols, standard operating procedures and policies are in place to support high quality data collection
- Manage incidental findings according to the study protocol that applies
- Oversee complaints by participants on data collection
- Ensure that the data from data collection sweeps are made available to researchers as quickly as possible
- 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:

- Ensure that comprehensive policies and protocols are in place throughout IOWC in line with national standards and guidelines
- Ensure that there is a system in place for easy access to policies and protocols for all staff
- Ensure that staff are trained and comply with protocols, standard operating procedures and policies
- Keep abreast of new legislation/best practice guidance and ensure that IOWC is compliant with protocols and policies

4.7. Oversight of IOWC Information ISMS:

- Ensure the confidentiality (including participant transparency and acceptability), integrity (including secure storage) and availability (including secure sharing) of IOWC information assets
- Isle of Wight NHS Trust acts as Senior Information Risk Owner (SIRO)
- Ensure that the IOWC ISMS is established, is compatible with the objectives of IOWC, is integrated within IOWC operations and is operating effectively
- Communicate the importance of, and commitment to, information security to IOWC staff and stakeholders
- Support information security staff and other relevant staff members to fulfil their information security responsibilities
- Ensure that the IOWC ISMS has sufficient resources to operate effectively
- Foster a culture of openness and continual improvement in regard to Information Security in IOWC

4.8. Ensuring the study is not brought into disrepute and that participant confidentiality is respected:

- Ensure all new proposals comply with the IOWC Access Policy
- Ensure all draft publications comply with the IOWC Access Policy
- Ensure compliance with appropriate data security standards
- Oversee crisis management controls

4.9. Outward representation of the study to encourage the use of the resource:

- Actively pursue opportunities for engagement with the research community
- Develop, implement and monitor the researcher engagement strategy and action plan
- Monitor progress against the plan taking corrective action where necessary to ensure that the plan is on track

Meetings

The DAG meets as and when required, the PI is responsible for convening the meetings.

AE Minutes and Reporting

The minutes of the meetings are circulated to all members of the DAG, the Senior Research Team and the wider team as required/requested.