



## British Isles Network of Congenital Anomaly Researchers (BINOCAR)

### BINOCAR Management Committee (BMC)

#### 1. Terms of Reference

- 1.1. To manage access to, and facilitate research using, the linked de-identified research database for congenital anomaly outcomes (BINOCARD), ensuring that this valuable resource is appropriately and effectively utilised by researchers.
- 1.2. To review and approve requests for data from the linked de-identified research database for congenital anomaly outcomes, including but not limited to:
  - a. Responding to preliminary enquiries regarding study eligibility and suitability;
  - b. Ensuring that any proposed study is of scientific merit and has the potential to deliver a measurable benefit to the public and the healthcare system in England and/or Wales;
  - c. Applying the principle of data minimisation to determine what volume of data is sufficient to produce definitive research findings, and recommending modifications to the requested data and/or protocol where appropriate;
  - d. Obtaining and retaining evidence of (A) adequate security arrangements (e.g. Information Governance Toolkit) at all the applicant's listed data storage and processing sites, and (B) appropriate permissions for the study being in place, e.g. research ethics committee approval;
  - e. Advising on methods of dissemination so as to optimise the envisaged benefits, as appropriate.
- 1.3. To authorise and oversee data releases to named data processors following approval of the proposal.
- 1.4. To support and review requests for amendments to the Data Sharing Agreement with NHS Digital, and obtain permissions in advance of providing data to researchers who are not substantive employees of one of the listed data processors.
- 1.5. To keep a record of all approved data releases and provide NHS Digital with an annual status report of these projects.
- 1.6. To review and approve drafts of research papers produced by researchers using BINOCARD data, in order to ensure that appropriate disclosure control has been exercised in line with the HES Analysis Guide and the ONS (2006) "*Review of the Dissemination of Health Statistics: Confidentiality Guidance*" and ensure the sound interpretation of findings.
- 1.7. To ensure compliance with the terms and conditions of the Data Sharing Agreement currently in force with NHS Digital whilst carrying out the above tasks.

## 2. Membership

- 2.1. All incumbent registry leaders of the 5 historical regional English Congenital Anomaly Registers (CAROBB, EMSYCAR, SWCAR, NorCAS, WANDA) and National Down Syndrome Cytogenetic Register (NDSCR) at the time of transfer of their surveillance functions to Public Health England (31 March 2015), will be members of the BMC.
- 2.2. An outgoing member will nominate a successor for approval by the rest of the committee.
- 2.3. A Chair, a Secretary and a Treasurer will each be chosen from amongst the group via a mutually agreed process.
- 2.4. The Chair should be reviewed after each four-year term.
- 2.5. A patient and public voice (PPV) representative of a relevant patients' organisation, and a representative of the Caldicott Guardian of the organisation holding the BINOCARD repository (Wolfson Institute of Preventive Medicine) will be appointed.
- 2.6. A representative of NCARDRS will be invited to be a member of the BMC.
- 2.7. A representative of CARIS will be invited to BMC meetings with observer status.

## 3. Meetings and Procedures

- 3.1. Meetings should be held at least once a year; additional ad hoc meetings may be held by teleconference to ensure the timely management of data access requests.
- 3.2. The attendance of five committee members shall constitute a quorum.
- 3.3. Applications for data access should be circulated by the Chair at least one week in advance.
- 3.4. The Chair may invite an individual to attend a particular meeting(s) to give specialist advice to the BMC.
- 3.5. Only BMC members can make the final decision to approve a particular application for data.
- 3.6. If the data requester is also a member of the BMC, he/she should not be involved in deciding whether to approve the request due to a potential conflict of interest.
- 3.7. Committee members must also inform the Chair if they have a financial, personal or any other conflict of interest in a project or with a project funder. The Chair will decide whether the interest disqualifies the member from the discussion.
- 3.8. Members should attend meetings in person insofar as possible but telephone conferencing can be considered an acceptable alternative.
- 3.9. An accurate record of the meeting should be prepared by the Secretary and circulated within two weeks for comments and acceptance by members of the committee.
- 3.10. Members are expected to respond promptly to all committee communications, attend at least one meeting every two years and maintain general contact on a regular basis.