**British Isles Network of Congenital Anomaly Registers**

# BINOCAR Standard Operating Procedure for Confidentiality Advisory Group (CAG) and Ethics approval

Instructions for the Registration and Surveillance of Congenital Anomalies in England and Wales

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| Version number | Date | Comment |
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| 1.1 | 30 January 2015 | First version put together by AS, ED and the BINOCAR Management Committee |
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## Contents

## The background

Congenital anomaly registers achieve high levels of ascertainment and completeness by collecting information from multiple sources. For data validation purposes, and to prevent cases being counted more than once, which is vitally important where rare anomalies and small numbers are involved, personal information about both the mother and baby is required.

Understanding the cases of anomalies and monitoring their occurrence requires data relating to geographical location, maternal age, birth weight, gestational age at delivery and so on. Evaluating the success of screening programmes and auditing maternity care, and the planning for future care requirements, requires accurate outcome data together with knowledge about how and when anomalies were diagnosed.

NHS patients provide information about themselves in confidence and where information is held in confidence, informed consent from the patient is normally required for use of that information in a way that could identify the patient. The Government recognises and is committed to the protection of patient rights regarding disclosure of their personal information and the Health and Social Care Act (2001), together with relevant Data Protection legislation, sets out this commitment very clearly. However, there are certain situations where it is not possible to obtain informed consent from patients. In recognition of this, Section 60 of the Health and Social Care Act 2001 was established to provide a means by which patient identifiable information needed to support essential NHS activity could be used without the consent of patients. This can only be used in circumstances where the medical purpose is in the interest of patients or the wider public, where consent is not a practicable alternative, and where anonymised information is not available or cannot suffice. Similar arrangements are in place for the national system of Cancer Registries.

BINOCAR, CARIS and the PHE CARs are authorised under Section 251 of the NHS Act 2006 to collect personal information without individual consent.

This exemption was initially granted by PIAG (the Patient Information Advisory Group), and was first enacted under Section 60 of the Health and Social Care Act 2001. Section 251 of the 2006 Act permits the common law duty of confidentiality to be set aside in specific circumstances for medical purposes (see below).

PIAG was established to provide advice on issues of national significance involving the use of patient information (data) and to oversee arrangement for its use. It was formally wound up on 31 December 2008, and replaced by the National Information Governance Board for Health and Social Care (NIGB) under Section 158 of the Health and Social Care Act 2008. Then on 1st April 2013, NIGB was replaced by the Confidentiality Advisory Group (CAG).

CAG provides independent expert advice to the Health Research Authority (HRA) and the Secretary of State for Health on whether applications to access patient information without consent should or should not be approved. The role of CAG is to review applications and advise whether there is sufficient justification to access the requested confidential patient information. Using CAG advice as a basis for their consideration, the HRA or Secretary of State will take the final approval decision.

For further information about CAG, please see www.hra.nhs.uk/about-the-hra/our-committees/section-251/.

## The Registers' position

All BINOCAR registers aim to provide timely, accurate and easily accessible information for health professionals and parents, to help them make informed decisions about current and future pregnancies and the care of their children. Ongoing surveillance and the monitoring of anomaly occurrence to check for varying trends or changing patterns of distribution are also very important public health activities.

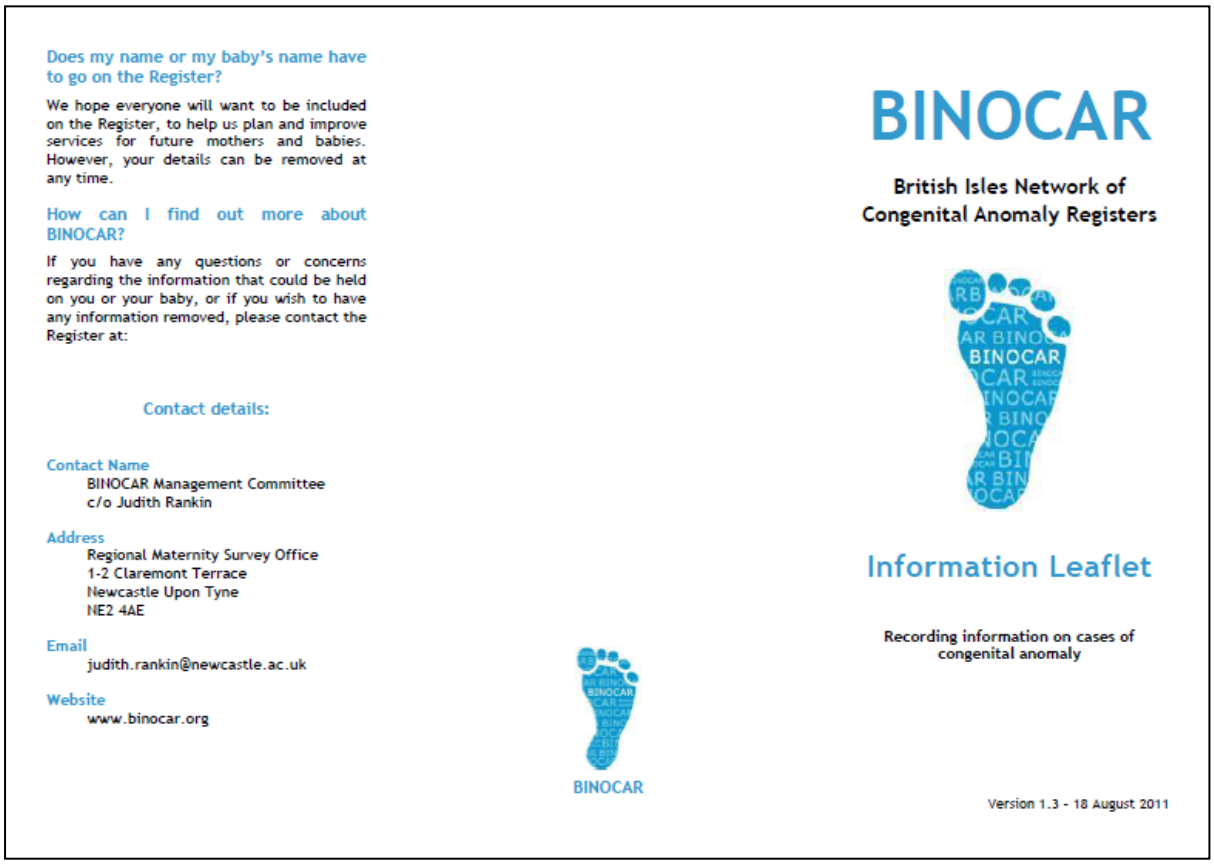
Identifiers are required to avoid double counting and for the validation of cases, ensuring accurate matching between antenatally diagnosed anomalies and postnatal notifications. Since it is currently impractical to obtain explicit parental consent for the inclusion of a case in a BINOCAR register, BINOCAR therefore applied for and was granted exemption under the terms of the 2001 Health and Social Care Act. Permission has to be reviewed annually, and has been granted for the following reasons:

1. Many reliable and valuable notifications sources used by registers involve little or no contact with parents; for instance cytogenetic laboratories and pathology departments.
2. There would be unique and irreconcilable difficulties in matching anonymised antenatal diagnoses in a fetus with similarly anonymised postnatal notifications of a child, often received some months or even years after delivery.
3. Parents understandably become distressed when asked for consent from multiple notifiers.
4. Discussions of congenital anomaly notification may not be appropriate during the period when parents have first been informed about a potential problem, especially prenatally. Assessing the likely outcome of an affected pregnancy is usually very difficult, and properly 'informed' consent is therefore impossible to obtain.
5. The potential for sensitivities surrounding terminations of pregnancy for fetal anomaly may prevent discussions for notification to a register.
6. Anonymisation and pseudonymisation is impossible in those cases where the fetus does not reach 24 weeks' gestation and therefore does not acquire an NHS number. This includes almost all terminations of pregnancy for fetal anomaly, fetal losses and high risk groups e.g. asylum seekers and adoptions.
7. It is the experience of many studies that health professionals do not request consent for notification of congenital anomalies during consultation and that this leads to long delays in notification or failure to notify.

## Patient information leaflet

We have taken steps to ensure that information about congenital anomaly registers are in the public domain, by producing leaflets and posters to inform all women about congenital anomaly registers when they book for antenatal care. These leaflets and posters are available in health care settings used by pregnant women and parents e.g. antenatal clinics, ultrasound departments, maternity wards, neonatal units, paediatric wards and clinics etc.

Information provided on these leaflets and posters provide contact information so that parents can request that identifiable information about their pregnancy and/or child be removed from the register should they so wish. It is our experience, however, that the vast majority of parents welcome the data generated from registers and wish their child's details to be included in order to maximise the information available to themselves and other.



Does my name or my baby's name have to go on the Register?

We hope everyone will want to be included on the Register, to help us plan and improve services for future mothers and babies. However, your details can be removed at any time.

How can I find out more about BINOCAR?

If you have any questions or concerns regarding the information that could be held on you or your baby, or if you wish to have any information removed, please contact the Register at:

Contact details:

Contact Name
BINOCAR Management Committee
c/o Judith Rankin

Address
Regional Maternity Survey Office
1-2 Claremont Terrace
Newcastle Upon Tyne
NE2 4AE

Email
judith.rankin@newcastle.ac.uk

Website
www.binocar.org

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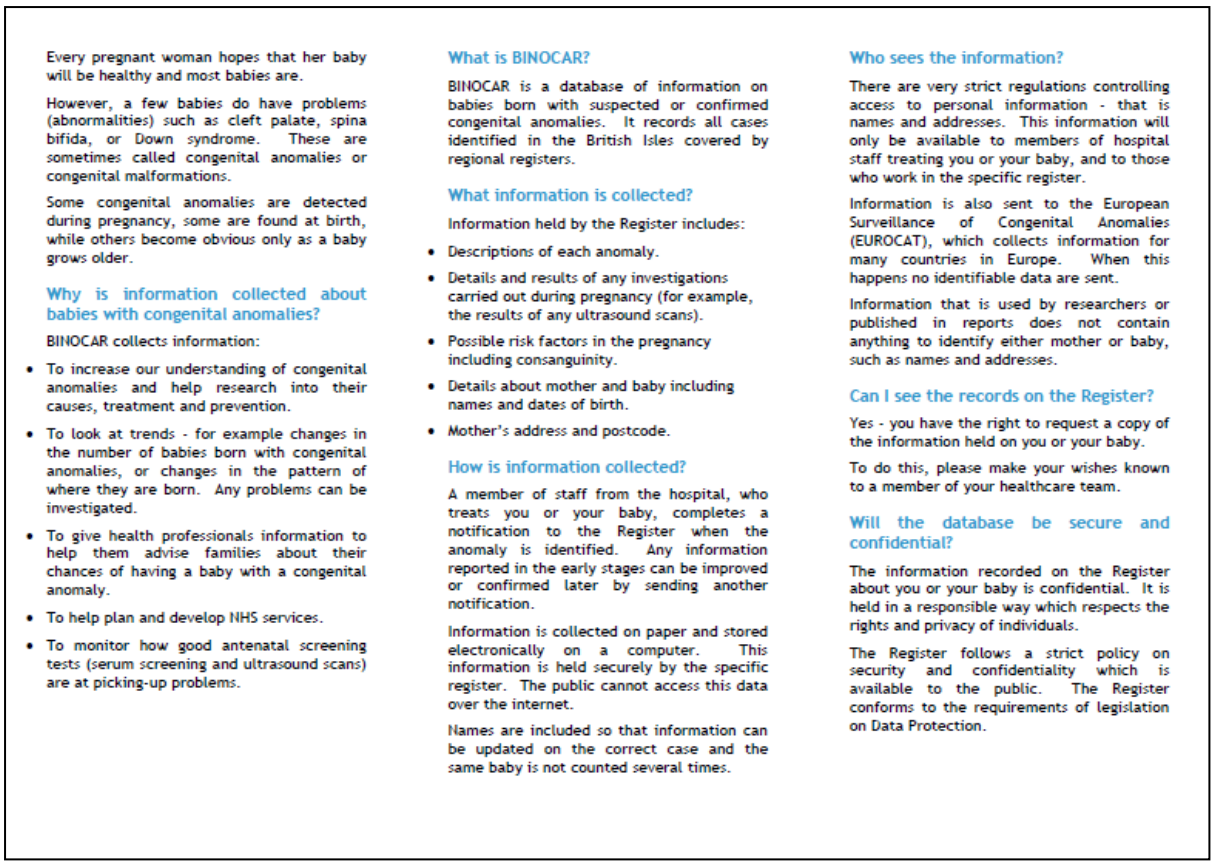
British Isles Network of Congenital Anomaly Registers

Information Leaflet

Recording information on cases of congenital anomaly

Version 1.3 - 18 August 2011



Every pregnant woman hopes that her baby will be healthy and most babies are.

However, a few babies do have problems (abnormalities) such as cleft palate, spina bifida, or Down syndrome. These are sometimes called congenital anomalies or congenital malformations.

Some congenital anomalies are detected during pregnancy, some are found at birth, while others become obvious only as a baby grows older.

### Why is information collected about babies with congenital anomalies?

BINOCAR collects information:

- To increase our understanding of congenital anomalies and help research into their causes, treatment and prevention.
- To look at trends - for example changes in the number of babies born with congenital anomalies, or changes in the pattern of where they are born. Any problems can be investigated.
- To give health professionals information to help them advise families about their chances of having a baby with a congenital anomaly.
- To help plan and develop NHS services.
- To monitor how good antenatal screening tests (serum screening and ultrasound scans) are at picking-up problems.

### What is BINOCAR?

BINOCAR is a database of information on babies born with suspected or confirmed congenital anomalies. It records all cases identified in the British Isles covered by regional registers.

### What information is collected?

Information held by the Register includes:

- Descriptions of each anomaly.
- Details and results of any investigations carried out during pregnancy (for example, the results of any ultrasound scans).
- Possible risk factors in the pregnancy including consanguinity.
- Details about mother and baby including names and dates of birth.
- Mother's address and postcode.

### How is information collected?

A member of staff from the hospital, who treats you or your baby, completes a notification to the Register when the anomaly is identified. Any information reported in the early stages can be improved or confirmed later by sending another notification.

Information is collected on paper and stored electronically on a computer. This information is held securely by the specific register. The public cannot access this data over the internet.

Names are included so that information can be updated on the correct case and the same baby is not counted several times.

### Who sees the information?

There are very strict regulations controlling access to personal information - that is names and addresses. This information will only be available to members of hospital staff treating you or your baby, and to those who work in the specific register.

Information is also sent to the European Surveillance of Congenital Anomalies (EUROCAT), which collects information for many countries in Europe. When this happens no identifiable data are sent.

Information that is used by researchers or published in reports does not contain anything to identify either mother or baby, such as names and addresses.

### Can I see the records on the Register?

Yes - you have the right to request a copy of the information held on you or your baby.

To do this, please make your wishes known to a member of your healthcare team.

### Will the database be secure and confidential?

The information recorded on the Register about you or your baby is confidential. It is held in a responsible way which respects the rights and privacy of individuals.

The Register follows a strict policy on security and confidentiality which is available to the public. The Register conforms to the requirements of legislation on Data Protection.

As children born with congenital anomalies are surviving longer, it may be worth putting an information leaflet together for adults with congenital anomalies.

## Approval coverage

The BINOCAR registers have CAG approval for the following:

- Collect patient identifiable data for surveillance purposes
- Match data with ONS, HES and other outcome datasets for surveillance purposes
- Match data from regional registers with data from the NDSCR and CRANE for surveillance purposes
- Send data to the BINOCAR Hub (including postcode and ethnicity)
- Send data to EUROCAT (including date of birth and date of death)
- Send other registers identifiable data for surveillance purposes
- Send other registers anonymous data for research purposes.

Separate approval will need to be sort from CAG for sending identifiable data between registers and matching with outcome datasets for non-surveillance purposes.

## Data Security Policy

Part of the application to CAG was a system level security policy. Instead of having to have a policy for each register it was decided that we would put a document together for the National Down Syndrome Cytogenetic Register (NDSCR) and then all registers would then sign up and declare that their data security matches or exceeds the NDSCR one.

The following is a checklist to make sure all registers meet the criteria of the NDSCR data security policy:

- Data are stored on servers and processed on PCs
- Servers and PCs are password protected
- Servers are located in rooms with locks and alarms
- PCs are located in staff offices with locks
- Physical access to the building is secure with entry system, CCTV, guards, staff IDs etc.
- Access to data only by authorised staff
- Hard copy notifications via post – nor more than 5 notifications per envelope, envelopes marked private and confidential, addressed correctly, not opened by anyone by register staff, stored in a lock drawer or cabinet, case lists sent at the end of the year to make sure all notifications have been received
- Electronic notifications via email – level 256 encrypted spreadsheets
- All staff sign a confidentiality agreement form
- All patient identifiable data removed before passed onto researchers for analysis, including names, addresses, postcodes, hospital numbers, NHS numbers and mothers and fathers dates of birth
- No patient identifiable data to be copied onto removable device (i.e. CD or USB memory stick) without level 256 encryption and permanently removed immediately after the transfer
- Hard copy notifications – entered manually onto the database
- Electronic notifications – appended to the database if variables match and the rest are entered manually
- No remote access to the data
- No patient identifiable data should be printed except for data checking and validation. Any printouts should be kept in locked drawers or cabinets and shredded immediately after the task is completed and the printout is no longer required
- All paper documents are shredded and data deleted from servers when the study is complete and files are no longer needed
- All hard disks will go through data erasure before disposal
- System audit carried out regularly and review of information security risk every 12 months
- Back-ups are taken regularly and there are systems in place should PCs, Networks or systems go down to recover the data. Back-up tapes are stored securely on and off site
- There is a procedure in place in the event of a security or confidentiality breach

## Identifiable information

Definition: Patient identifiable data comprise information about living people who can be identified from that data, or from combinations of data and other information which the person in control of the data has, or is likely to have in future.

The variables considered identifiable in the register datasets are:

- Names
- Dates of birth and death
- Address/postcode
- NHS number
- Hospital and hospital number

## Approved methods of secure data transfer

- NHS.net to NHS.net
- BINOCAR Gateway
- WinZip
- NHS Secure File Transfer
- Secure delivery via Royal Mail

## IG Toolkit

Since April 2013, anyone applying to CAG for approval needs to have an up-to-date IG Toolkit submission in place. This is the current information for the registers that are part of the BINOCAR approval:

| Register | Organisation code | Reference | Version | Score |
|---|---|---|---|---|
| CARIS (CPiP) | - | Public Health Wales | - | 81% |
| CAROBB | 8J017 | NPEU | 11 | 100% |
| EMSYCAR | EE133832/ECC0013 | TIMMS | 11 | 76% |
| SWCAR | EE133799-ICLH-SWCAR | SWCAR | 11 | 66% |
| WANDA | RHM | UHS | 11 | 71% |
| YHCAR | 8E218 | SEED | 11 | 69% |
| NDSCR & BINOCAR Hub | 8F779 | Wolfson | 11 | 66% |
| PHE* | X25 | Public Health England | 11 | 33% |

*The PHE IG Toolkit includes NorCAS and WMCAR

All registers are working towards level 3 and version 12 which would give them a score of 100%.

## Ethics approval

BINOCAR has research ethics committee (REC) approval as a research database: REC:09/H0405/48.

Medical research is important and the NHS plays an important role in enabling it. The approval of research projects not only involves approval of the resources requested and financial implications of the research, but also of any ethical issues involved in the research. The NHS Research Ethics Committees (REC) have been established throughout the UK for many years to provide independent ethical review of all health and social care research to safeguard the rights, dignity and welfare of those participating in research in the NHS.

The REC is entirely independent of the researcher and the organisations funding and hosting the research. The members of a REC are specially trained in research ethics and are required to review and give opinion on the ethical aspects of a research proposal. These include patients, members of the public, nurses, GPs, hospital doctors, statisticians, pharmacists and academics, as well as people with specific ethical expertise gained through a legal, philosophical or theological background. Research projects cannot proceed without REC approval. The REC's task is to advise the NHS body under which the research is intended to take place but it is the NHS body that has responsibility to decide whether or not the project should proceed, taking into account the ethical advice of the REC.

The BINOCAR approval includes:

- Processing of personal data by the Research Database team for the purposes described in the application. This includes specific research projects undertaken by the Database team using the data given that the project is within the fields of health or social care research, the protocol has been subject to scientific critique, is appropriately designed in relation to its objectives and is likely to add something useful to existing knowledge.
- Supplying and using the data in research projects conducted by researchers and research institutions outwith the Research Database team given that the project is within the fields of health or social care research, the Research Database team are satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and is likely to add something useful to existing knowledge. The research must be conducted in circumstances such that data subjects are not identifiable to the external researchers. Data must be effectively anonymised or pseudonymised prior to release to external researchers. The researchers should undertake to treat datasets in confidence and not to attempt re-identification of data subjects through linkage with other datasets. A data sharing agreement must be in place with all external researchers to ensure processing of the data in accordance with the terms of the ethical approval and any other conditions required by the Research Database team.

The BINOCAR approval excludes:

- Any research project requiring researchers to undertake additional procedures involving subjects. Additional research procedures should be the subject of further ethical review, either as a substantial amendment or a separate application for ethical review of a specific project.
- Any research project requiring external researchers to be able to identify data subjects for purposes of linkage with other datasets, or in order to collect further data from subjects or their care records or undertake other research procedures involving subjects. Such projects should be the subject of further project-specific application for ethical review.