

**SECTION 60: SUPPORT FOR USE OF PATIENT IDENTIFIABLE INFORMATION
APPLICATION FORM**

Part A – To be completed by applicant

SECTION 1: APPLICANT'S DETAILS

Name of Applicant(s):	British Isles Network of Congenital Anomalies Registers
Name of Sponsor Organisation: <i>(Sponsor's written recommendation to be attached including approval from Caldicott guardian)</i>	National Statistics
Address for correspondence:	Mrs Beverley Botting British Isles Network of Congenital Anomalies Registers National Statistics B6/09 1 Drummond Gate London SW1V 2QQ
Name and telephone number of information Custodian in case of queries: <i>(See Section 7 below)</i>	Mrs Beverley Botting 0207 533 5195

SECTION 2: BASIC PURPOSE

(i) What is the purpose of the proposed research/ study/ activity for which support is sought?	<p>To provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies for the population of England, Wales, Scotland and Ireland by means of national, regional and disease specific registers of congenital anomalies. The main functions of such registers are:</p> <p>(a) the surveillance and analysis of congenital anomalies; (b) the monitoring and audit of health provision, detection and outcomes for congenital anomalies where such provision has been made; (c) the planning and administration of the provision made for health and social care for pregnancies and infants affected by congenital anomalies; (d) medical research approved by research ethical committees; (e) the provision of information to the parents of affected pregnancies/infants who have suffered from a particular condition where:</p> <p>(i) the information supports an analysis of the risk of developing that condition; and (ii) it is required for the counseling and support of a person who is concerned about the risk of themselves or their offspring developing that condition.</p>
(ii) How will the proposed use of patient information help to improve patient care or serve the wider public interest?	<p>The data are essential for:</p> <ol style="list-style-type: none"> 1. the investigation of the causes, frequency and outcome of congenital anomalies 2. the early identification of clusters or epidemics of specific congenital anomalies. 3. the evaluation of preventive measures for congenital anomalies. 4. the evaluation of screening and diagnostic programmes. 5. to inform the content and provision of counselling services for parents with affected pregnancies and the general public. 6. to provide epidemiological information about congenital anomalies to health professionals and the public. <p>All of the above serve to inform the fulfilment of the duty of Government to protect the public health.</p>

SECTION 3: CONSENT ISSUES

(iii) For what reasons is it not practicable to seek or obtain patient consent for the proposed use of patient identifiable information?

Congenital anomaly registers only achieve adequate levels of ascertainment and completeness of cases if they collect information from multiple sources including cytogenetic laboratories, post mortem laboratories, ultrasound departments, delivery suites, computerised obstetric notes, etc. Identifiers are currently required to avoid double counting and for validation.

Currently it is not practicable to obtain explicit consent for many reasons: (i) many reliable and valuable notification sources involve little or no contact with parents, for instance, cytogenetic and post mortem laboratories; (ii) parents may not understand why they are being asked for consent from multiple notifiers; (iii) discussions of congenital anomaly notification may not be appropriate during the period when parents have first found out about a congenital anomaly; (iv) the potential for sensitivities surrounding terminations for congenital anomalies may prevent discussions for notification to a register; and (v) it is the experience of many studies that health professionals forget to ask about consent during consultation and that this leads to long delays in notification.

However we are taking steps to ensure that knowledge about congenital anomalies registers is in the public domain by producing leaflets and posters to inform all women when they register for antenatal care about congenital anomaly registers. These leaflets and posters will be available in all health care settings used by pregnant women eg. antenatal clinics, GP surgeries, ultrasound departments, maternity wards, neonatal units, paediatric wards etc.

In addition we are working towards producing evidence concerning the effect and practicability of eliciting explicit consent and it's impact on ascertainment. This work will be planned at our annual BINOCAR meeting in October 2002.

One of the aims of all BINOCAR registers is to provide timely, accurate and easily accessible information for parents to help them make informed decisions about current and future pregnancies and the care of their children.

SECTION 4: CALDICOTT

(iv) What is the justification for using patient identifiable information?

Epidemiological research and monitoring is dependent upon high quality registers of congenital anomalies. As stated above congenital anomaly registers only achieve adequate levels of completeness if they collect information from multiple sources. Identifiers are currently required to avoid double counting and for validation and completeness of data purposes.

Congenital anomalies registers use anonymised data in most circumstances however, in the following circumstances patient identifiable data is required:

- (a) obtaining anonymised data from individual patient records to support medical purposes
- (b) Obtaining information about past or present geographical location from patient records (together with necessary information from which patients may be identified) which is required for medical purposes; eg. (i) to carry out cluster analysis in the EUROHAZCON study of landfill sites; (ii) to facilitate the analysis trends in anomaly rates over time allowing for the various NHS/local authority boundary changes; or (iii) to estimate travel times to centers for treatment purposes.
- (c) Obtaining patient identifiable information to:
 - identify patients to be invited to participate in medical research
 - obtain consent for their information to be used
 - contact patients to obtain their consent for the use of tissue and other biological samples

In all these circumstances patients are only approached by the registers following their consent for this approach being obtained by their consultant.

(d) linking for medical purposes patient identifiable information obtained from more than one source which is required to validate the completeness or quality of the patient information or to avoid the impairment of the quality of the data by unintentionally including the same information more than once

(e) processing patient identifiable information for the purposes of audit, monitoring and analyzing patient care and treatment

(f) processing patient identifiable information to provide access to another authorized user for one or more of the purposes given in (a) to (e).

Where identifiable data is not necessary anonymised data is used.

<p>(v) Does the proposed use of patient identifiable information satisfy the requirements of the Data Protection Act and other legislation?</p> <p>Please outline how the requirements of the eight principles outlined in the Data Protection Act 1998 will be met.</p>	<p>All congenital anomalies registers are registered under the Data Protection Act.</p> <p>First principle: All data are lawfully and fairly collected. We believe we are covered under schedule 2 (public function and legitimate interests of data controller) and schedule 3 (medical purposes).</p> <p>Second principle: We are registered under the DPA to use data for medical and research purposes and data uses are limited to those purposes.</p> <p>Third principle: Identifiable data are required for the core purposes of congenital anomaly registration but the uses and releases are rigorously controlled.</p> <p>Fourth principle: Considerable effort is invested in the quality assurance of the data to ensure accuracy.</p> <p>Fifth principle: The nature of congenital anomaly registration is such that the data collected now and in the past increases in relevance and usefulness over time. The purpose of the registration process is to monitor congenital anomaly prevalence, detection and outcomes over time in addition to monitoring changing environmental risks. For this reason data are retained indefinitely.</p> <p>Sixth principle: Procedures are in place to satisfy the rights of data subjects within the DPA and in line with Department of Health guidelines.</p> <p>Seventh principle: Rigorous policies and procedures are in place to protect against unauthorised or unlawful processing of data. Details of the confidentiality and security policies implemented within congenital anomalies registers are provided in Annex X.</p> <p>Eighth principle: Identifiable information is not transferred outside the EEA.</p>
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SECTION 5: MISCELLANEOUS

<p><i>(NHS Organisations only – see Annex B)</i></p> <p>(vi) Provide written confirmation that your organisation has implemented and complies with all NHS standards of Security and Confidentiality.</p>	<p>All congenital anomalies registers comply with NHS standards of Security and Confidentiality.</p>
<p><i>(Non-NHS Organisations only)</i></p> <p>(vii) Provide a copy of the organisation's data security policy.</p>	<p>Data security policies for the various congenital anomaly registers are attached in Annex 1.</p>
<p>(viii) Provide written confirmation that the organisation's data security policy is fully implemented, (and aligned to BS7799 (1995/1999)), and will be adhered to in relation to NWCS data.</p>	<p>This information is contained with the security policies for the resister: Annex 1.</p>
<p>(ix) Provide details of Data Protection Registration (to confirm registration for purposes of analysis and classes of data requested)</p>	<p>All congenital anomalies registers are registered under the Data Protection Act. Annex 2 includes details of the Data Controller in each unit and of the statutory body under which the unit is registered for data protection purposes</p>
<p>(x) How long will the information be retained?</p>	<p>Currently information held by congenital anomalies registers will be retained indefinitely. This policy is reviewed every 3 years and is next due for review at the annual BINOCAR meeting in 2004.</p> <p>One of the main purposes of congenital anomaly registration is surveillance; to provide an early warning following the early detection of clusters of anomalies in time and space. This requires the ability to reliably link data from multiple sources over potentially long periods of time.</p>

SECTION 6: MEASURES TO PREVENT DISCLOSURE OF PATIENT IDENTIFIABLE INFORMATION

(xi) What safeguards have been set in place to limit use of, and access to patient identifiable information?

All congenital anomalies registers have strict confidentiality and security policies in place, specifying the circumstances in which identifiable data are released to third parties (See Annex 1).

All register staff sign confidentiality declarations as part of their contract of employment and are aware of their individual responsibility for the preservation of confidentiality.

Identifiable data is NEVER disclosed to unauthorized users. In future information with patient identifiers will not be released outside registers unless the intended recipients have their own support under section 60 of the Health and Social Care Act 2001.

SECTION 7: INFORMATION CUSTODIAN

This for should be signed and dated by the Information Custodian

SIGNED:

DATE:

Annex 2: Data Protection Registration information

Office for National Statistics – National Congenital Anomaly Notification Systems

Registration Number: X309251X

Expiry date: 22/07/02

Data Controller: Office For National Statistics

Address: Segensworth Road, Titchfield, Fareham, Hants. PO15 5RR

Trent Congenital Anomalies Register

Registration Number: PZ6551415

Expiry date: 20/03/03

Data Controller: University of Leicester

Address: University Road, Leicester LE1 7RH

North Thames (West) Congenital Malformation Register

Registration Number: Z5198763

Expiry date: January 2003

Data Controller: Northwick Park Hospital NHS Trust

Address: Watford Road, Harrow HA1 3UJ

Congenital Anomaly Register and Information Service (CARIS – Wales)

Registration Number: Z4798360

Expiry date: 26/06/02 (annual renewal)

Data Controller: Swansea NHS Trust

Address: IT Department, Morriston Hospital, Swansea NHS Trust, Swansea SA6 6NL

Wessex Antenatally Detected Anomalies Register

Registration Number: X3278991

Expiry date: December 2002

Data Controller: Southampton University Hospital NHS Trust

Address: Princess Anne Hospital, Coxford Road, Southampton, SO16 5YA

Oxford Congenital Anomaly Register

Registration Number: PZ6018442

Expiry date: 04/11/02

Data Controller: Oxford Radcliffe Hospitals NHS Trust

Address: Headington OX3 9DU

West Midlands Congenital Anomaly Register

Registration Number: K3211839

Expiry date: 07/10/02

Data Controller: Birmingham Health Authority

Address: St Chad's Court, 213 Hagley Road, Edgbaston, Birmingham B16 9RG

Northern Region Congenital Abnormality Survey:

Registration Number: Z5470161

Expiry date: 19/11/02

Data Controller: University of Newcastle upon Tyne

Address: 6 Kensington Terrace, Newcastle upon Tyne, NE1 7RU

Mersey Congenital Anomalies Register

Registration Number: Z6390975

Expiry date: 27/01/03

Data Controller: University of Liverpool

Address: Senate House, Abercrombie Square, Liverpool, Merseyside, L69 3BX

South West Congenital Abnormality Register

Registration Number: Z6650067

Expiry date: 16/04/03

Data Controller: University of Bristol

Address: Senate House, Tyndale Avenue, Bristol, BS8 1TH