British and Irish Network of Congenital Anomaly Researchers

BINOCAR Standard Operating Procedure for Data requests

Version 4- November 2015

Contents

Introduction

BINOCAR and its management committee encourage the use of data from the Congenital Anomalies Outcomes Research Database for research, but have a responsibility to ensure that such access is appropriate and that those provided with data use it responsibly, particularly with respect to the maintenance of patient confidentiality.
The following guidelines have been prepared for researchers and others intending to apply for access to the data.

Preparatory work

BINOCAR data requests may require:
1. aggregate numbers of cases
2. data file of individual records

Before submitting a data request, applicants are advised to:

1. Determine if this work is novel by consulting:
    a. the full publications list, reports and papers

2. Determine if the data are already available by consulting:
    a. the prevalence data tables where users can specify registers, congenital anomalies and years of interest;
    b. the key public health indicator tables where there are data on rates of terminations of pregnancy and perinatal mortality;
    c. the prenatal detection rate tables where users can specify congenital anomalies

3. Determine if anyone else is carrying out this work by consulting the list of current projects

4.Contact the BINOCAR Management Committee:
Applicants are advised to get in contact early in the process, while the project protocol is being put together. The BINOCAR Management Committee will be able to tell the applicant if the data will be able to answer the research questions, give an idea of the data extract costs for funded projects and assign a member of BINOCAR to work closely with the applicant on the project.

All data requests are subject to approval from the BINOCAR Management Committee and permission from the specific individual registers.

Making an Application

1. Written applications should be made on the appropriate form (attached) to the BINOCAR Management Committee. The information governance checklist and the requested variables should also be completed.

2. The application should set out exactly what information is required in the context of the aims and methods of the study, including a copy of relevant research protocols, such as those prepared for grant applications. No patient identifiers (any information relating to a living individual who can be identified from that information, such as address, postcode, and numerical identifiers such as NHS number) are available.

3. Data requested (subject to approval) must be transferred using a secure transfer method suitable to the level of the data requested –nhs.net to nhs.net email transfer is preferred.

4. If you are provided with data:

- You must ensure that data is stored securely and that confidentiality is maintained at all times. You must comply fully with your employing organisation's confidentiality and security policies. Identifiable data must not be stored on the hard drive of lap top computers due to risk of loss/theft.
- On completion of the study, all identifiable data must be destroyed or archived with appropriate security

5. Any researcher using BINOCAR data may discover errors or further important information relating to cases. It is the duty of all researchers to ensure that this information is drawn to the attention of BINOCAR so that the data can be appropriately amended or updated.

British and Irish Network of Congenital Anomaly Researchers

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Data Request Form

Section 1: Requester details	
Name:	
Job Title/Position:	
Organisation:	
Address:	
Phone number:	
Email address:	
Please list name/s and job title/s of all those who will have access to the data:	

Section 2: Request details (Please attach a research protocol where available)	
Name of Project:	
What question do you wish to answer?	
Intended use of information: (e.g. Background, presentation/meeting/report)	
Reporting requirements: (e.g. numbers, rates, crosstab)	
How do you intend to publish your research?	
Project start date:	/ /
Project completion date:	/ /
Date data required by:	/ /

Section 3: Requester agreement	
Details of funding	☐ No separate funding for this project ☐ Applying for or secured funding from (name funding body)*: *For funded projects, it is expected that a fee for data extraction will be included.

Ethics Committee approval	☐ Ethics Committee approval granted (please attach ethics approval) ☐ Ethics Committee approval pending ☐ Ethics Committee approval not required (please state why):
Name of person responsible for data security: (Please attach data security policy where available, and make sure it meets the criteria in Annex A)	

Section 4: Data required	
Format:	☐ Aggregate data ☐ Unidentifiable case data
Population:	Residents of: ☐ East Midlands and South Yorkshire ☐ Northern England ☐ Oxfordshire, Berkshire and Buckinghamshire ☐ South West England ☐ Wales ☐ Wessex ☐ West Midlands National disease-specific register: ☐ NDSCR - England and Wales - Down, Patau and Edwards syndrome
Case definition:	☐ Live births ☐ Stillbirths (24 weeks+) ☐ Fetal deaths (20-23 weeks) ☐ Terminations of pregnancy
Denominators:	☐ Live births ☐ Stillbirths (24 weeks+)
Time period (births):	from: / / to: / / [data available to 31/03/2015]
Congenital anomalies:	List congenital anomaly subgroups or ICD-10 codes.

Section 5:

For requesting aggregate data, please describe your needs in relation to the variables given on the variable list (Annex B). For example, specific cross tabulations that are required.

Section 6:

For requesting case data, please tick which variables you require on the variable list (Annex B).

Section 7:

Please tick to confirm that you agree to the following:

- ☐ To supply BINOCAR with a 6 monthly update report (requests for case data only).
- ☐ Any publications/reports arising from the use of data supplied must include a standard acknowledgement paragraph:

  Data is supplied by BINOCAR (British and Irish Network of Congenital Anomaly Researchers), and compiled using cases from the following Regional Congenital Anomaly Registers: Register 1, …., Register n.
- ☐ Any publications arising from the use of data supplied must be sent to Register Leads for approval.
- ☐ 5 years after completion of the project all individual records will be destroyed and a BINOCAR data destruction form completed and returned (requests for case data only).
- ☐ The data will not be used for any other project without submission of a renewed application.
- ☐ It is expected that the work would start within 12 month of receipt of the data.

Please note that all requests will need to be approved by BINOCAR Management Committee. It is advised that someone from BINOCAR is directly involved in the project. If you don't already have a person in mind the committee with assign someone.

Please sign and return the BINOCAR Data Request Form and supporting documentation (by post) to Professor J K Morris at the address at the top of the front page.

Signature:	Date: / /

Please ensure that you have enclosed the following:

- Copy of Section 251 support (requests for identifiable case data only).
- Copy of ethics committee approval (requests for case data only).
- Copy of research protocol (no more than 2 pages in length).
- Copy of data protection/security guidelines.

Annex A: Information Governance Checklist

- ☐ 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
- ☐ Electronic transfer via email – encrypted spreadsheets
- ☐ All staff sign a confidentiality agreement form
- ☐ All patient identifiable data removed before passed onto researchers, including names, addresses, postcodes, hospital numbers, NHS numbers and mothers and fathers dates of birth unless relevant Ethics and NIGB approval has been sort.
- ☐ No patient identifiable data to be copied onto removable device (i.e. CD or USB memory stick) without strong encryption and permanently removed immediately after the transfer
- ☐ 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 require
- ☐ 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

Annex B: Variable List

Variable name	Variable Heading	Tick to Select	Reason for requesting
	Identifiable information (only in exceptional circumstances with the appropriate NIGB and Ethics approval)		
centre	Centre number		
numloc	Local ID		
Byear	Year of birth		
sex	Sex		
nbrbaby	Number of babies/fetuses delivered		
nbrmalf	Number of malformed in multiple set		
type	Type of Birth		
civreg	Civil registration status		
weight	Birth weight		
gestlength	Length of gestation in completed weeks		
survival	Survival beyond one week of age		
death_age	Age at death (days)		
agemo	Age of mother at delivery		
whendisc	When discovered		
agedisc	If prenatally diagnosed, gestational age at discovery		
karyo	Karyotype of infant/fetus		
sp_karyo	Specify karyotype		
syndrome	Syndrome or association		
sp_syndrome	Specify Syndrome		
syndromepred	Syndrome detected/diagnosed prenatally or not		
malfo1-8	Malformations (1-8)		
sp_malfo1-8	Specify malformations (1-8)		
malfo1-8pred	Malformations detected/diagnosed prenatally or not (1-8)		
al1 to al107	Congenital anomaly subgroups		
pal1 to pal107	Prenatal diagnosed for each congenital anomaly subgroup		
Mckusick	McKusick code/type of Mendelian Inheritance		
sibanom	Siblings with anomalies		
sp_sibanom	Specify type of anomaly and describe the malformation		
prevsib	Previous malformed sibs notified to register		
sib1	Local ID number		
sib2	Local ID number		
sib3	Local ID number		
Ethnic	Ethnicity of mother		
Msmoke	Maternal smoking during first trimester		
Mbmi	Maternal BMI at conception		
test1-5	What screening or diagnostic test brought mother to attention (1-5)?		
test1-5age	Gestational age at test 1-5		
test1-5txt	Result of test 1-5		
test1-5res	ICD10 / Soft marker codes of anomalies from test 1-5		
Screened	Did mother have screening?		
Scanned	Did mother have anomaly scan?		
Diagnosis	Did mother have diagnostic test?		