

2. Information for Caldicott Guardians

THE UK IBD REGISTRY

INFORMATION FOR CALDICOTT GUARDIANS OF NHS ORGANISATIONS IN ENGLAND

Equivalent documentation is being drafted for Caldicott Guardians of NHS organisations in Scotland, Wales and Northern Ireland.

JUNE 2014

Contents:

1. Purpose of the IBD Registry
2. Involvement of Caldicott Guardian
3. Ownership of IBD Registry Data and Systems
4. Scope and system of data collection for the IBD Registry
5. Submission and processing of data
6. Patient consent and processing of data
7. Confirmation of s251 Exemption
8. Requests for external access to Registry data
9. Data Protection Compliance
10. Statement on Research Ethics Status from Health Research Authority
11. IGSoc Status of the external contractors involved in the IBD Registry
12. IBD Registry contact details
13. Appendices A and B

1 Purpose of the IBD Registry

The IBD Registry has been established to

- drive continuous improvement in patient care and access to care across the UK
- inform commissioning and service design
- improve our understanding of long term outcomes
- provide local, regional & national data in order to better define the pattern of ulcerative colitis and Crohn's disease
- support IBD research

2 Involvement of the Caldicott Guardian

This document aims to provide Caldicott Guardians of participating hospitals with the information they need to understand the information flows involved in the UK IBD Registry and approve local participation.

Information for Caldicott Guardians

The Registry Team is available to answer any questions you may have about the data security and processing arrangements. (Contact details given below.)

Once you are satisfied that any concerns have been addressed, we would be grateful if you would confirm to the Clinical Lead for your IBD Team that you approve participation in the Registry.

Before the first submission of data the Health and Social Care Information Centre will send you a form for electronic completion and submission direct to them to confirm your authorisation.

3 Ownership of IBD Registry Data and Systems

The IBD Registry is managed by and is legally owned by the British Society of Gastroenterology which is a Registered Charity (No 1149074) located at 3 St Andrews Place, London NW1 4LB. However, the IBD Registry is a collaborative project involving the following national patient and professional organisations associated with Inflammatory Bowel Disease:

Crohn's and Colitis UK (www.crohnsandcolitis.org.uk)

Crohn's in Childhood Research Appeal (www.cicra.org.uk)

**Association of Coloproctology of Great Britain and Ireland
(www.acpgbi.org.uk)**

**British Society for Paediatric Gastroenterology, Hepatology and Nutrition
(www.bspghan.org.uk)**

British Society of Gastroenterology (www.bsg.org.uk)

Royal College of Nursing – Gastrointestinal Nursing Forum

Primary Care Society for Gastroenterology (www.pcs.org.uk)

4 Scope and system of data collection for the IBD Registry

The Registry dataset currently comprises a minimum of 12 items for adult patients and 17 for paediatric patients, with additional data items that are required if surgery has taken place or the patient has been admitted. The intention is that the data should cover all patients with a confirmed diagnosis of IBD who receive NHS care, initially focusing on secondary care. The Registry dataset is available on request.

The preferred approach is for data to be collected using an Electronic Patient Record system in the ordinary course of the clinical contact with the patient. To this end the IBD Registry has developed an IBD Patient Management System (PMS), which is optimised for the delivery of IBD care to meet the national IBD Standards. A Data Submission specification document is available for NHS organisations using other EPR systems.

(For those organisations unable to collect IBD data through an EPR, the Registry is developing an alternative Web-based Portal for data entry and a separate document will be made available covering the Information Governance and Data Security arrangements for that system.)

Data will be uploaded monthly by a standardised electronic extract from the EPR to the Health and Social Care Information Centre as explained below. This system is inbuilt into the Registry Patient Management System and a data extract template is available for users of other EPR systems.

5 Submission and processing of data

The IBD Registry has contracted to use the Health and Social Care Information Centre (HSCIC) to receive data from NHS organisations. This is because the data set includes patient identifiable data and the HSCIC is the NHS England approved data safe haven for this purpose.

Data will be uploaded to the HSCIC through a secure portal. The HSCIC will then process the data through several stages:

- Validation of data content
- Verification of the patient's NHS number and identity
- Pseudonymisation of the demographic information
- Record linkage to defined NHS data sets including HES and mortality data
- Making the pseudonymised demographic, clinical and linked NHS data available for upload to the IBD Registry.
- Maintaining a master file holding the NHS and Registry identifiers for the patients.

A diagram of the data submission and processing system is attached to this document as Appendix A.

6 Patient consent to processing of data

The data submitted to the IBD Registry needs to include Patient Identifiable Data to enable record linkage to other NHS datasets (e.g. bowel cancer audit, mortality records and HES data) and to ensure that where a patient attends more than one hospital either simultaneously or sequentially only one patient record is maintained.

The IBD Registry applied to the Confidentiality Advisory Group for exemption under s251 of the NHS Act from the requirement to obtain patient consent to the use of patient identifiable data. The application was to allow a period of 18 months during which participating hospitals could submit data to the Registry without formal consent, whilst using that time to identify and seek written consent from their



Information for Caldicott Guardians

patients. Approval was granted for this arrangement for 2014 and 2015. After that period only data from consented patients will be submitted to and held by the Registry.

The Registry will provide a pack of information materials for use by participating centres to inform and consent patients.

7 Confirmation of s251 Exemption

The formal approval for a limited period of exemption from patient consent for the IBD Registry under s251 can be verified by accessing the record of Approval decisions provided at <http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions/>. A copy of the first page of the approval letter from the Secretary of State is attached as Appendix B and a full copy can be provided on request.

8 Requests for external and research access to Registry data

Requests for external and research access to the pseudonymised data held by the Registry will be overseen by the Research Sub-committee currently chaired by Dr Keith Bodger, Senior Lecturer in Medicine & Consultant Gastroenterologist Department of Medicine, Aintree University Hospital.

9 Data Protection Compliance

The BSG is registered with the Information Commissioner and a copy of the Registration can be accessed at <http://ico.org.uk/ESDWebPages/DoSearch> by entering the reference Z5064566.

10 Statement on Research Ethics Status from Health Research Authority

The Health Research Authority has confirmed that data collection for the Registry does not constitute research and does not require Ethics approval. A copy of their email statement is attached to this document as Appendix C.

Any additional data collection specifically to meet the needs of a research project will need either national or local ethics approval in the usual way.

11 IGSoc Status of External contractors involved in the Registry

The three organisations contracted to provide data processing and IT services to the Registry all have current approval under the NHS IG Toolkit Scheme. They are:

1. Health and Social Care Information Centre – pseudonymisation and data linkage
2. Chameleon Information Management Services Ltd – Registry software
3. InTechnology Ltd – N3 web server hosting

The current IGSoc status and scores for all three organisations can be confirmed by visiting <https://www.igt.hscic.gov.uk> and selecting the option for members of the public to see organisations' assessments.

12 IBD Registry Contact details and further information

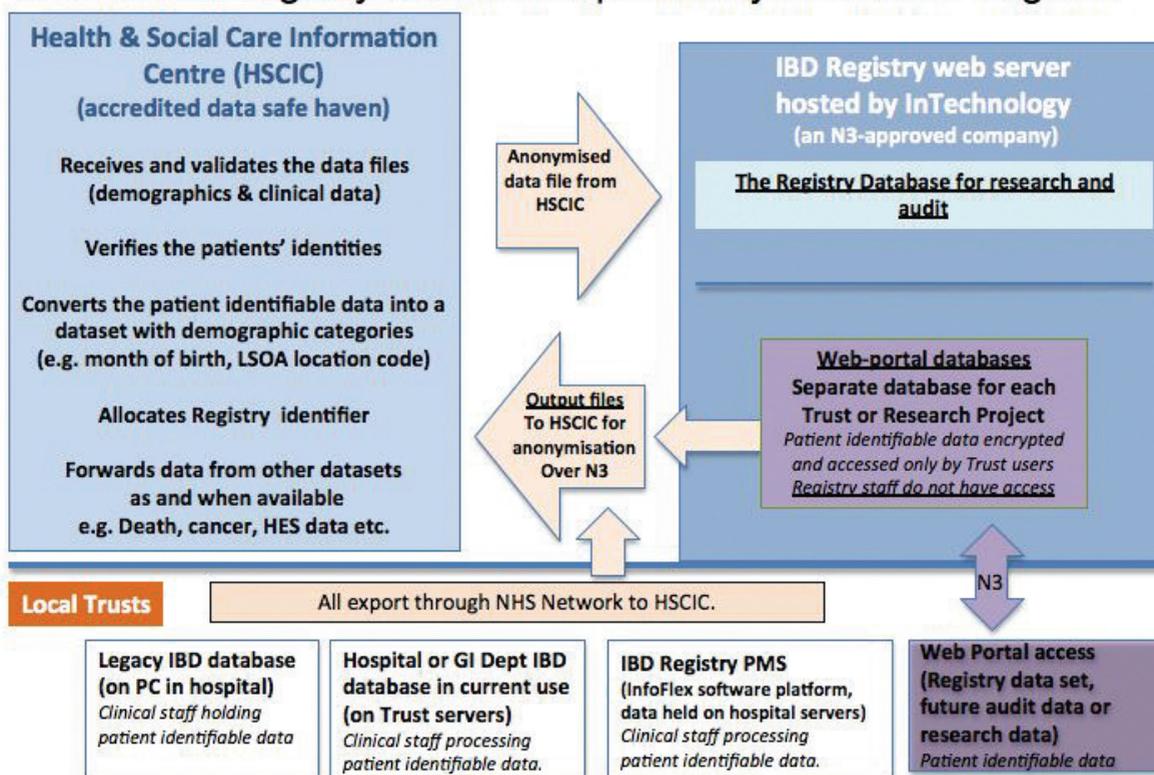
Enquiries to: Simone Cort at the BSG Office

(Tel. 0207 7935 3150, email: simone.cort@ibdregistry.org.uk)

- Further information available at our website: www.ibdregistry.org.uk

Appendix A – Flow chart for data processing from Trust to Registry

Overview of registry data-flow & pseudonymisation in England



Information for Caldicott Guardians

Appendix B – Confirmation from Secretary of State of s251 Exemption



Health Research Authority

Confidentiality Advisory Group

On behalf of the Secretary of State for Health

Richard Driscoll
Director of Development
British Society of Gastroenterology
3 St Andrews Place
Regent's Park
London
NW1 4LB

Skipton House
80 London Road
London
SE1 6LH

Tel: 020 797 22557
Email: HRA.CAG@nhs.net

14 May 2014

r.driscoll@bsg.org.uk

Dear Mr Driscoll

Study title: Inflammatory Bowel Disease Registry
CAG reference: CAG 6-07(d)/2013

Thank you for your audit application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health on whether an application should be approved, and if so, any relevant conditions. This application was originally considered on 3 October 2013 and the CAG were unable to provide a recommendation of support at that time as consent appeared to be feasible. The application was resubmitted and considered again on 28 November 2013.

Secretary of State for Health approval decision

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard and specific conditions of approval.

This letter should be read in conjunction with the outcome letter dated 11 December 2013.

Context

Purpose of application

This audit application from the British Society of Gastroenterology (BSOG) set out the purpose of establishing a national IBD Registry which would feed into national service development planning and fulfil national audit, IBD standards and quality improvement benchmarks. A recommendation for class 4, 5 and 6 support was requested in order to access data, including NHS number, date of birth and postcode in relation to all patients in the UK who had been diagnosed with IBD. Data sources included HES, ONS, Bowel

Appendix C – Confirmation from HRA of Ethics Status of Registry

From: Richard Driscoll richard.driscoll2@icloud.com
Subject: Re: Request for advice - Inflammatory Bowel Disease Registry
Date: 10 October 2013 15:14
To: Queries NRES (HEALTH RESEARCH AUTHORITY) nres.queries@nhs.net

Many thanks for the prompt and helpful response
Richard

Richard Driscoll
Sent from my iPhone

On 10 Oct 2013, at 14:07, "Queries NRES (HEALTH RESEARCH AUTHORITY)" <nres.queries@nhs.net> wrote:

ENQUIRY TO QUERIES LINE

Dear Richard

RE: [Inflammatory Bowel Disease Registry]

Thank you for your email seeking additional clarity on whether your project should be classified as research requiring NHS Research Ethics Committee (REC) review.

Based on the information you have provided, our advice is that the project is not considered to be research and does not require review by an NHS Research Ethics Committee.

In giving this advice, our advisor states....

This is primarily a register and as such a tool for service evaluation. Hence it wouldn't need REC review.

This advice is in line with:

- The harmonised UK-wide edition of the [Governance Arrangements for Research Ethics Committees \(GAfREC\)](#), which came into effect on 01 September 2011;
- The Health Research Authority (HRA) decision tools for determining whether a project is research and whether NHS REC review is required;
- The National Research Ethics Service (NRES) leaflet, [Defining Research](#) and the algorithm [Does my project require review by a Research Ethics Committee?](#)

This response should not be interpreted as giving a form of ethical approval or any endorsement to your project. However, it may be provided to a journal or other body as evidence if required.

You should also be aware that:

- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal requirements under the Data Protection Act 2000. When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation.
- This response only covers whether your project is classified as research and whether it



Information for Caldicott Guardians

Version Control:		
Version 1	25th February 2014	First draft
Version 2	2nd June 2014	Second draft