



# IBD Registry Web Tool

## Caldicott Guardian information sheet

NHS Trusts in England (EWTSP5: February 2019)

This is a request from the Gastroenterology Department for approval to participate in the Inflammatory Bowel Disease (IBD) Registry and to use the IBD Registry Web Tool as the means of data collection.

To meet the Registry's information governance requirements, we ask that the Caldicott Guardian or Information Governance Manager confirm approval for the IBD team to use the Web Tool to participate in the IBD Registry, and authorise the IBD clinical lead to arrange access to the Web Tool for the appropriate clinical and administrative staff. The IBD clinical lead will have forwarded an 'Authorisation for use form' (EWTSP4) for this purpose along with this information sheet.

### Who owns the IBD Registry?

The IBD Registry Limited is an independent not-for-profit company whose offices are at The Ebbisham Centre, 6-7 Derby Square, Epsom KT19 8AG. Our Board is made up of our three Member organisations: the British Society of Gastroenterology (BSG), the Royal College of Physicians and Crohn's & Colitis UK. (Our Registered Office address is at the BSG at 3 St Andrews Place, Regent's Park, London NW1 4SA).

The objectives of the IBD Registry are 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

### Participation in the Registry

This involves submitting pseudonymised demographic and clinical data on patients who have inflammatory bowel disease via NHS Digital to the central IBD Registry database. The data captured will be of benefit to the day-to-day care of patients, but is primarily intended to enable your local Gastroenterology Department to participate in the UK IBD Registry and also our Quality Improvement Programme. Based on the pseudonymised data received by the Registry, fully anonymised and aggregated data is returned to the Trust to provide quarterly feedback on the quality metrics relating to their use of biologic drugs.

The IBD Registry Biologics Audit is a continuation of the National IBD Biological Therapies Audit previously funded by NHS England and managed by the Royal College of Physicians. As of January 2017, this audit became part of the IBD Registry Programme, managed by the IBD Registry.

NHS England and the Welsh Government have decommissioned IBD as part of the NCAPOP; however, participation in the IBD Biologics Audit remains part of the Quality Accounts reporting requirements for Trusts in 2019/20. In the absence of NHS England funding, the IBD Registry makes a small cost-recovery charge for the work involved in analysing and producing the Quality Accounts metrics.

### The IBD Registry Web Tool

The Web Tool has been developed for those hospitals that do not have a local electronic patient record (EPR) system capable of capturing the information required by the Registry. The Web Tool holds patient identifiable data and clinical staff usernames linked to a unique site code that ensures each hospital can only enter, view and report on the data relating to their patients.

The IBD Registry has contracted with NHS Digital so that the identifiable data goes directly and securely from NHS Trusts to NHS Digital. When data is submitted to the Registry this is done by the local hospital staff downloading an extract of data and then uploading to NHS Digital through a secure portal. The data is then pseudonymised by NHS Digital before onward transmission to the IBD Registry. Authorised IBD Registry staff have administrative access to the Web Tool for essential system and user maintenance purposes. A diagram of the data submission and processing system is attached to this document as Appendix A.

Use of the Web Tool service by hospital staff will be governed by the hospital's normal IT and information governance policies and procedures. The hospital remains the Data Controller for the patient data; the IBD Registry (as provider of the Web Tool) is a Data Processor for the hospital. The IBD Registry has sent (as part of this setup pack) a Data Processing Agreement (for the Web Tool) and also a Data Sharing Agreement (for the sharing of data via NHS Digital).

The IBD Registry Web Tool is located on NHS approved secure servers outside the Trust IT system. The Web Tool is accessed across the NHS HSCN (formerly known as N3) network and the secure servers are provided and maintained under contract to the IBD Registry by AIMES Ltd, a company approved by NHS Digital to operate HSCN services. The data centre is in Liverpool and encrypted backups of data are undertaken daily to the data centre. The server firewalls are to HSCN standard and data in transit across HSCN is encrypted using an extended SSL Certificate licensed from GlobalSign. The InfoFlex software used for the IBD Registry Web Tool is provided by Chameleon Information Management Services Ltd (CIMS), who provide the same software (called the Patient Management System) to NHS Trusts around the UK. The use of the Web Tool to hold patient data has been approved by the Confidentiality Advisory Group (CAG); this can be confirmed on the CAG website. The IBD Registry, AIMES and CIMS all have satisfactory and up to date IG Toolkit scores; these are listed later in the document and can be confirmed on the IG Toolkit scores.

## Patient data required by the Registry

The Registry dataset comprises a minimum of 12 data items for adult patients and 17 for paediatric patient; the Registry's data submission framework (available on our website) with additional data required for any surgery, medication (including biologics), cancer diagnosis, hospital admission or death. The current focus of quality improvement is on patients receiving biological therapy.

## Patient consent to processing of data

Patient consent is not required for entering information onto the Web Tool but we request that participating sites seek consent for the future for reasons explained below. The patient identifiable data submitted onwards to the IBD Registry enables record linkage to other NHS datasets (e.g. bowel cancer audit, mortality records and HES data) and ensures 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 (CAG) for exemption under s251 of the NHS Act 2006 from the requirement to obtain patient consent to the use of patient identifiable data. This has been granted and renewed until September 2020 to allow a period of time during which participating hospitals can submit data to the Registry without formal consent, whilst using that time to identify and seek written consent from their patients. The Registry is undertaking a number of projects to study ways of making requesting and recording consent easier, to reduce the burden on clinical teams.

Once the s251 approval has expired, only data from consented patients will be submitted to and held by the Registry. The Registry has made available a pack of information materials for use by participating centres to inform and consent patients. (The NHS Digital system will ensure that only data from consenting patients is uploaded after expiry of the s251 approval.)

The CAG has also approved the Registry as the Data Controller for the data once transmitted via NHS Digital. These approvals can be verified by accessing the Health Research Authority website on the Confidentiality Advisory Group registers.

## Data Protection Compliance and GDPR

IBD Registry Limited is registered with the Information Commissioner. Our ICO code is ZA334069 and our external Data Protection Officer is Clare Sanderson of IG Solutions Liverpool Ltd. A copy of the registration can be accessed by entering our code at the ICO Website: <http://ico.org.uk/>. We are approved as the Data Controller by the Confidentiality Advisory Group effective from 10<sup>th</sup> September 2018.

## 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 ethical approval. A copy of their email statement is attached to this document as Appendix B.

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

## Data Security and Protection (formerly Information Governance) Toolkit Status:

**IBD Registry** – Supplier of the Web Tool service

- Organisation Code 8JX66– Version 14.1: 61% (Satisfactory)

**NHS Digital** – Data safe haven, pseudonymisation and linkage

- Organisation Code x26 – Version 14.1: 90% (Satisfactory)

**Chameleon Information Management Services Ltd** – Web Tool software (InfoFlex)

- Organisation code 8HA87 – Version 14.1: 66% (Satisfactory)

**University of Liverpool** – Analysis of Registry data

- Organisation code 8HN20 – Version 14.1: 82% (Satisfactory)

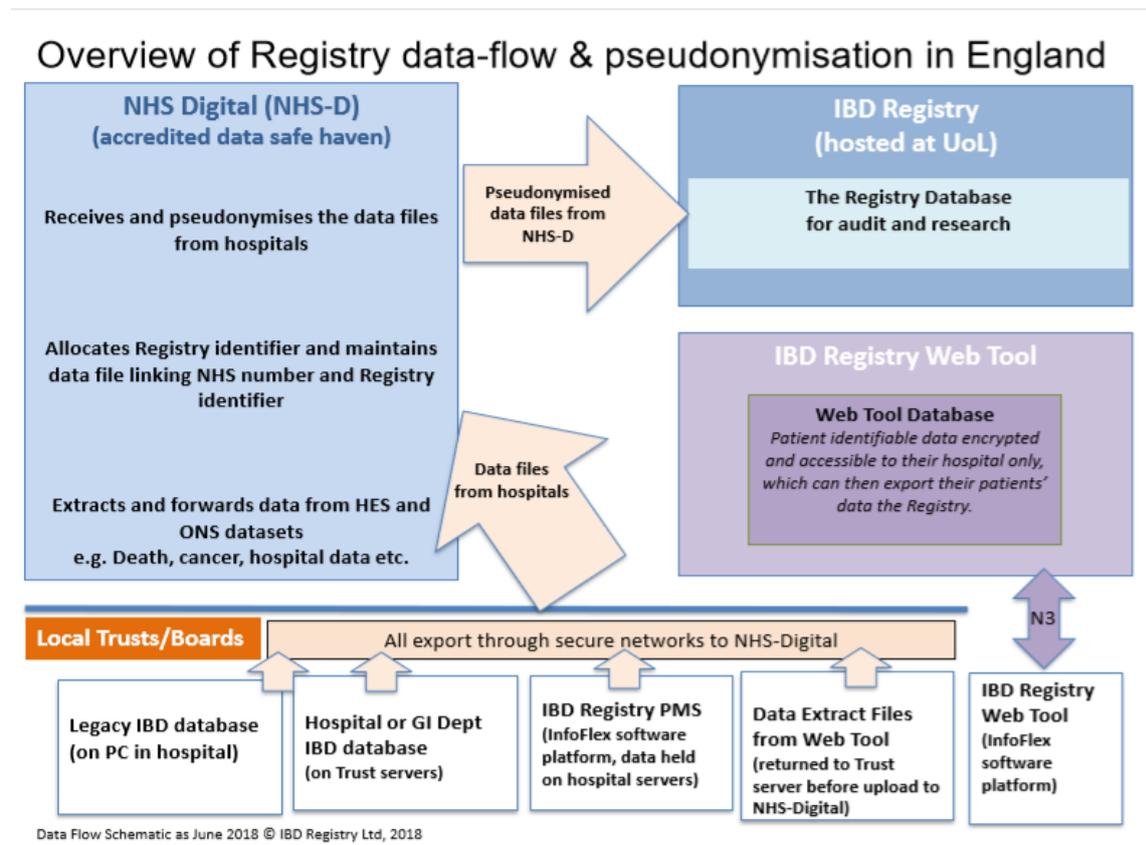
**AIMES** – HSCN connection and server hosting

- Organisation code 8J121– Version 14.1: 100% (Satisfactory)

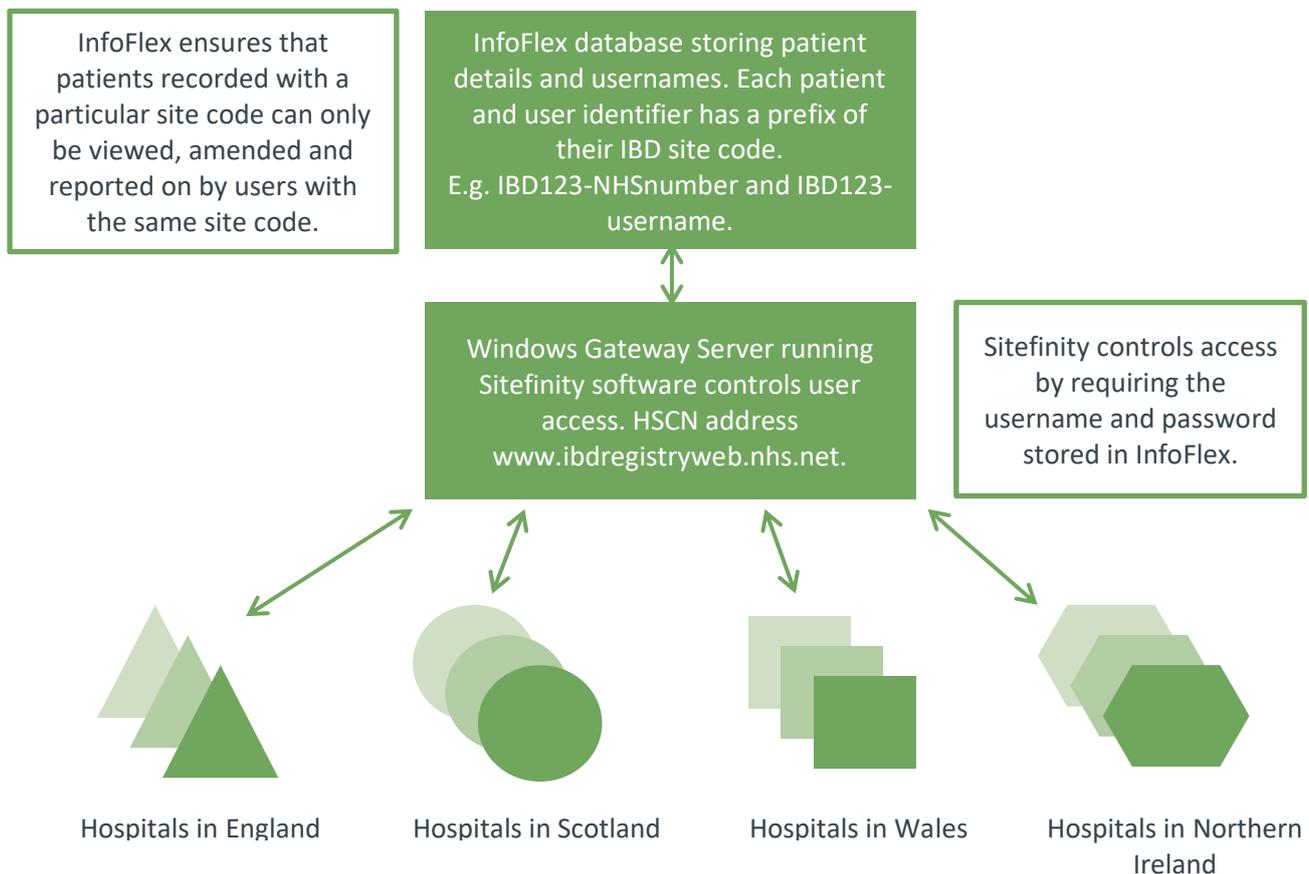
(The current data security and protection status and scores for all the organisations can be confirmed by visiting <https://www.igt.hscic.gov.uk> and selecting the option to see organisation’s assessments.)

## Appendix A

### IBD Registry Web Tool data flow and pseudonymisation in England



### IBD Registry Web Tool dataflow and access controls (April 2016)



### Opinion by HRA on ethical status

**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.

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*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.

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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.