



IBD Registry and Patient Consent Information for participating hospitals (August 2016)

Statutory Background

The way patient data is used and processed is governed by the Data Protection Act and NHS legislation. In terms of the Data Protection Act there is at all times a duty to keep data secure and accessible only to those authorised to use the data. The NHS legislation governs how Patient Identifiable Data (PID) can be used.

The following information applies to England and Wales. The IBD Registry is currently applying for consent arrangements to be approved in Scotland and Northern Ireland.

Clinical use of data (PMS or Web Tool) – no consent needed.

Use of patient data for the clinical care of the patient is considered a *primary purpose* and does not require specific consent from the patient. Therefore an IBD Team does not need to have formal consent from the patient to record their clinical information on the Registry PMS or Web Tool (or any other electronic patient record). Nevertheless, if you are going to be recording more IBD data electronically during a consultation than previously, it is good practice to explain to the patient why this is happening.

Submission of data to a registry or audit – when consent is needed.

The submission of clinical data to a registry or audit for service evaluation purposes is a *secondary use* and may need formal consent from the patient.

As has been the case with the national IBD Audit, when data is fully anonymised before it leaves the Trust, the individual patient's consent is not required, but patients collectively should be informed that their data is being submitted and have the opportunity to 'opt out' if they wish.

If the data submitted to a registry or audit includes Patient Identifiable Data, as in the case of the IBD Registry, then the NHS legislation requires that written consent is obtained from each individual patient unless an exemption is granted by the Secretary of State.

There are very limited criteria for an exemption and a strong case has to be made as to why obtaining individual patient consent may be inappropriate or impossible.

The IBD Registry requires some Patient Identifiable Data to ensure that there are not duplicate entries for the same patient where treatment occurs at different hospitals and also to allow linkage to national NHS datasets such as HES data.

What this means for hospitals participating in the IBD Registry

The Secretary of State has ruled that in principle individual patient consent must be obtained for Patient Identifiable Data to be included in the IBD Registry submission. However, in recognition of the additional work and practical issues that arise in obtaining consent from all IBD patients, the Registry has been granted a time-limited exemption up to May 2017. (The exemption is technically called a section 251 exemption as the governing legislation is section 251 of the Health and Social Care Act 2010.)

During this exemption period, clinical teams must ensure that patients are informed about the submission of data to the Registry by making posters and information leaflets available and clearly visible in the clinics and wards regularly used by IBD patients. The approved information materials are provided by the IBD Registry (please contact simone.cort@ibdregistry.org.uk with any queries about these.)

During the exemption period patients must ask to 'opt out' if they do not wish their data to be included.

After the exemption period ends, hospitals will only be permitted to submit data for those patients where written consent has been given and recorded.

Requirement for authorisation from the local Caldicott Guardian

Before data can be submitted to the Registry, it is necessary to get a formal authorisation for the process from the local Caldicott Guardian. The Caldicott Guardian will need to satisfy themselves about the local arrangements and that a named member of the IBD Clinical Team is taking responsibility for data security and consent processes. There is an NHS Digital Registration Form that covers this.

The Registry will provide the necessary form, together with information about the national arrangements for secure data processing and patient consent requirements.

Recording of patients' consent locally

- Consent must be recorded in writing and the approved forms for adults and children are available in pdf format from the Registry. The forms have a space to affix a standard patient label.
- The signed consent form must be safely kept as evidence of consent being given. Forms may be filed in the patient's notes or a separate Registry Consent file, or scanned and stored electronically.
- The IBD Registry Patient Management System and Web Tool both have the necessary data fields to record when a patient gives or refuses consent. If they consent, the consent information is automatically included in the Registry data submission.

- During the s251 exemption period, IBD Teams must have a process for ensuring that data is excluded from their Registry submissions if a patient 'opts out'. This can be recorded in the Registry PMS or Web Tool which will then automatically exclude that patient's data. If a different database is used then similar arrangements must be made.
- The consent form provides an opportunity for the patient to state if they consent to additional uses of their data: for IBD research, for linkage to other NHS data sets, for aggregated and anonymised reporting to health-related companies and to be notified if they are eligible for research projects. Please ensure you invite patients to consent to these purposes also, to enable the Registry to maximise the value of their information for health-related research purposes. It is very important that these consents are also recorded on the PMS or Web Tool.

Suggested ways of administering consent

In outpatient clinics:

Ideally patients should be sent the Patient Information Leaflet with their clinic appointment letter so they have time to read it before attending clinic. It would be beneficial to include a letter from the IBD Lead explaining why the hospital is participating in the IBD Registry and that a Consent Form will be provided at the clinic. (An example letter is available from the IBD Registry.)

Patients could be given the Consent Form to complete and sign in the waiting room. A copy of the Information Leaflet must also be provided if one was not sent in the appointment letter, and a copy should be offered even if sent previously.

Patients can sign and return the Consent Form to the clinic admin staff or take it into the doctor or nurse, depending on local practice.

By post:

If you have a mailing list of IBD patients, then a mailing could be organised to send the Information Leaflet and Consent Form to patients with a covering letter from the IBD Lead explaining why the hospital encourages patients to give their consent and asking them to post it back to the hospital.

Electronic capture of consent:

The Registry is exploring the possibility of capturing consent on a tablet device which would upload direct to the PMS or Web Tool, but this requires development and approvals. We will inform participating hospitals if this option becomes available. Hospitals may choose to develop a local system and we would be pleased to assist any such initiative.

The latest consent materials can be downloaded from the IBD Registry website.

Queries about consent issues should be emailed to Simone Cort at the BSG who will arrange for one of the Registry Team to respond: simone.cort@ibdregistry.org.uk

Additional Note for Hospitals that have recorded patient consent using the Information Leaflet and Consent Forms issued in 2015/16

As the Registry has developed it has become clear that we needed to consider the circumstances in which companies might have access to Registry information. After considerable discussion, and consultation with the patient organisations Crohn's and Colitis UK and CICRA, we have decided it is important to give patients the opportunity to confirm whether they give consent for their data to be included in anonymised reports provided to health-related companies.

The Patient Information Leaflet and Consent Forms have been updated to include this additional consent question and you should use these new forms (dated JULY 2016) from now on.

We appreciate that some hospitals have already obtained consent from patients and we apologise for the change in the requirements at this stage. The change does not invalidate any previous consent that has been recorded, and we hope that, if possible, as you see patients who have previously given consent, you will take the opportunity to ask them to consent to the additional question. This is especially important for those patients on biological therapies.

We have created a specific form containing only the additional question as an addendum to the previous consent form. Please contact simone.cort@ibdregistry.org.uk if you need this form.

Registry Web Tool:

The Registry Web Tool includes the additional consent question so you can record this information once you start using the new consent forms. We will be providing a Worklist that identifies patients with consent recorded previously but who are missing the new question.

PMS Users:

Unfortunately the Registry cannot make changes to your local PMS database, but we can support your local System Manager to do so. We will liaise with all existing PMS users to arrange for the additional question to be added as soon as possible. In the meantime, we suggest you use the new consent materials with new patients, but keep them to one side for data entry later when the extra question is in place in the PMS.

Other systems:

We will notify the technical contact for all other systems that we know to be Registry-compliant and inform them of the need to add the new consent question.

If you have any queries or concerns about this change and how to implement it, please contact Richard Driscoll (richard.driscoll@ibdregistry.org.uk) or Simone Cort (simone.cort@ibdregistry.org.uk)

FAQs for staff about Registry consent

At what age should children sign their own consent form?

There is a Paediatric Consent Form, which includes the words 'me/my child' in each consent question and has spaces for both the child to sign and the parent/guardian to sign. You have the option of asking just the parent to sign, just the older child to sign or both to sign. This is a local decision and you should follow your usual practice in relation to paediatric consent.

What personal data is being sent to the Registry?

NHS Number, Gender, Date of Birth and Postcode. Other information includes details of diagnosis, medications, surgery, admissions, associated conditions such as cancer.

Why is identifiable information being sent?

We need this to ensure that if someone is attending more than one hospital we can link the clinical information for that patient and combine it into one record. It also enables us to link the record to the national information about hospital attendances – clinic appointments, admissions or A&E attendances.

How is the patient's confidentiality protected?

The personal information – NHS number, Date of Birth and Postcode – is sent to NHS Digital (formerly the Health and Social Care Information Centre) not directly to the IBD Registry. NHS Digital is a special organisation approved by NHS England to handle confidential information about everyone's healthcare. They keep the master record to make sure information from different hospitals about the same patient is linked together, but when they forward the information to the IBD Registry they change the format of identifiable information so that no one at the IBD Registry knows who the person is. The NHS Number is changed to a Registry Number, the Date of Birth is changed to Month and Year of Birth and only the first part of the Postcode is used.

Who can see the patient's information at the IBD Registry?

The information held on the Registry will be analysed by clinicians and statisticians who are part of the Registry Team. Academic researchers can apply for access to the Registry information as part of their research and this has to be approved by the IBD Registry Research Committee. Patients' data will be aggregated and anonymised in any reports and no individual data will be published.

What access do companies have to the Patient Data?

Companies have no access to patient level data. They may apply for reports on the data, but these will be fully anonymised and will be aggregated data only. Any application will have to be approved by the Registry Research Committee.

How can patients and staff find out the latest information on the IBD Registry?

By visiting: www.ibdregistry.org.uk