In 2001, the Department of Health issued a document entitled ‘Good Practice and Consent Implementation Guide: Consent to Examination or Treatment’. RLBUHT has subsequently implemented a policy along those guidelines which has been widely circulated. Both documents are available on the hospital web Intranet. Each directorate has been asked to implement the Trust Consent Policy and it has been accepted that implementation at local level will require directorates to develop their own consent policies within the Guidelines. The important components of consent are:

- **Sufficient descriptive information:** Alternatives, what, where, when, lists and delays, who, trainees, monitoring, sedation, biopsies, photos, discomfort, recovery, discharge home, restrictions

- **Weighing Benefits against any Risks:** sedation or unsedated, potential to make diagnosis, further treatment: 0₂ desaturation, dentition, discomfort, perforation, bleeding

- **Understanding of the information:** Do you understand what is going to happen to you, Do you understand and appreciate why the procedure has been requested by your doctor, do you appreciate the potential benefits against the risk?

- **Time to assimilate information and change mind (ideally 1-7 days):** The Process, ask more, consider the consent form and sign it, change their mind

- **Voluntary agreement:** Attendance alone is not consent, no coercion to proceed, sign consent form, sedate or not, abandon if distressed, change mind at any time

This document sets out the Gastroenterology Directorate’s Consent Policy. Further versions of this policy document will be issued as it becomes revised in due course.

It is our aim within the Directorate of Gastroenterology (including outpatients, the inpatient wards and the Endoscopy Unit) to provide the highest quality of care and clinical management to our patients. This includes providing a comprehensive amount of information to patients about their pathology and options for treatment. All investigation, intervention and treatment should be decided on a joint basis between the patient and the clinical team in the best interest of the patient and this Consent Policy should support that requirement.

Various levels of consent are discussed in the documents referred to above. These include implied consent, verbal consent and written consent. For practical purposes this document confines itself to written informed consent in relation to diagnostic and therapeutic endoscopic procedures, liver biopsies and other invasive procedures. At present written consent is not required for blood tests, blood transfusions, immunoglobulin infusions, venous access or treatment of various conditions whether enteral or parenteral. Obviously, patients requiring these procedures or interventions need to be fully informed but verbal consent would normally suffice. The remainder of
this document sets outs the procedures for written informed consent in relation to endoscopic procedures.

Endoscopy procedures are requested by a variety of health practitioners in primary, secondary and tertiary care settings. It is to be hoped (but cannot be completely relied upon!) that the practitioners requesting these investigations or procedures will have discussed them with the patient and informed them of what is involved. However, the ultimate responsibility for ensuring that patients are fully informed will rest with us in the Directorate of Gastroenterology and specifically with the endoscopist/operator undertaking the procedure. Accordingly, there are several levels of interaction during the consenting process within our directorate.

A) Documentation of Information given to every patient

i) **Information leaflets** should be provided to every patient (or their relatives if the patient is incapacitated) for invasive diagnostic or therapeutic procedures. The information leaflets we will use have been approved by the CNST (Clinical Negligence Scheme for Trusts), the Campaign for Plain English, the Endoscopy Committee of the British Society of Gastroenterology and by the Trust’s Quality unit.

ii) **Inpatients** should be give the Information Form by the team requesting the procedure. The patient will have ample opportunity to ask any questions. Anticipated potential complications will be fully discussed with the patient. The patient is also given written information specific to the procedure (see PIFs). This encounter will be documented by filling in Form A of the Trust Written Consent procedure.

iii) **Outpatients**, are sent the information leaflets with their appointment. When a patient attends at the GI Unit, their details and the test for which they have been booked are checked at a clerical level. Thereafter, a professional who is knowledgeable in the area for which the patient has been booked will sit down with the patient in a relaxed setting and go through the procedure in language that the patient can understand. The patient will have ample opportunity to ask any questions. Anticipated potential complications will be fully discussed with the patient. The patient is also given written information specific to the procedure (see PIFs). This encounter will be documented by filling in Form A of the Trust Written Consent procedure.
iv) **Aftercare leaflets** are given to every patient (or their nurse if inpatient) following completion of their investigation or intervention in the Endoscopy Unit.

**B) The practitioner undertaking the procedure (in this case the endoscopist) should be satisfied that the patient fully understands the procedure.** Form B is documentary evidence that this is the case and once the endoscopist is fully satisfied that the patient has been properly informed, the patient and endoscopist will sign part B of the form.

A copy of part A and part B are inserted into the casenotes along with the report of the procedure. The patient will be given a copy of part A to retain in addition to the information leaflets referred to above. Forms A&B will be used for all patients undergoing endoscopy (regardless of whether they have sedation or not). For other procedures not requiring sedation (e.g. Liver Bx), Form C can be used.

**C) Special Consent:** When patients cannot give consent, Form 4 should be used (e.g. commonly for patients requiring PEG). This form requires two health professionals to state that the procedure is in the patient’s best interest– one of these should be from the team caring for the patient but can be be a person with knowledge whose opinion has been sought e.g. the Nurse consultant or Specialist nurse in nutrition, the second should be the endoscopist. Clearly another team will have referred the patient and that should be clearly documented in the case sheet and it is preferable that the procedure has been discussed with relatives but they cannot give consent on the patient’s behalf.
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Information leaflets are available for the following procedures:-

- Diagnostic OGD
- Diagnostic flexible sigmoidoscopy
- Diagnostic colonoscopy
- ERCP
- EUS
- EUS-FNAB
- Oesophageal dilatation
- Oesophageal stent insertion
- PEG tube insertion
- Liver biopsy
- Sedation & Anaesthesia during endoscopy
- Venesection for Haemochromatosis
- Colonic dilatation
- Colonic stent insertion
- Polypectomy
- Enteroscopy
- Aftercare OGD
- Aftercare flexi sigmoidoscopy
- Aftercare colonoscopy
- Aftercare PEG tube aftercare
- Aftercare ERCP
- Aftercare of stents (oesophageal or colonic)
- Aftercare polypectomy
## GASTROENTEROLOGY DIRECTORATE

### CONSENT POLICY

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<th>14&lt;sup&gt;th&lt;/sup&gt; OCTOBER 2002</th>
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<td><strong>Type of procedure/examination</strong></td>
<td><strong>Type of consent i.e. Implied/verbal/written</strong></td>
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<tr>
<td>ALL ENDOSCOPY</td>
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