GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 01
Page 1 of 2

Participant Demographics

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed before registration and consent

Participant Measurements

Height ☐.☐ m

Weight ☐☐.☐ kg

BMI ☐☐.☐

Co-morbidities

Please indicate comorbidities present by ticking yes or no for each:

	Yes	No
Cardiovascular	☐	☐
Peripheral vascular disease	☐	☐
Respiratory	☐	☐
Renal Failure	☐	☐
Liver Failure	☐	☐

Is the participant diabetic? ☐ Yes ☐ No

If yes, are they taking insulin? ☐ Yes ☐ No → Are they taking tablets? ☐ Yes → Please list tablets ☐ No

Completed by _____ Date Day Month Year *Form continues on next page ▶▶*

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 01
Page 2 of 2

Participant Demographics

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Medications

Please list the medications the participant is receiving: ☐ N/A – No other medications
(Excluding any diabetes medication noted on page 1)

Medication name	Dose	Units	Route	Frequency

Participant Assessment

Only participants with grade ≤3 are eligible for the trial

ASA grade
- ☐ I
- ☐ II
- ☐ III

1 – A normal healthy patient
2 – A patient with mild systemic disease
3 – A patient with severe systemic disease
4 – A patient with severe systemic disease that is a constant threat to life
5 – A moribund patient who is not expected to survive without the operation
6 – A declared brain-dead patient whose organs are being removed for donor purposes
http://www.asahq.org/clinical/physicalstatus.htm Retrieved 26/04/2010

Completed by | Date Day Month Year | Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 02

Eligibility Checklist

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed prior to registration.
Participants must fulfil ALL eligibility criteria in order to be registered into the trial.

Inclusion Criteria

Please tick yes/no for all questions
If any shaded boxes are ticked, the participant is ineligible

		Yes	No
1.	Is the patient 18 years of age or over?	☐	☐
2.	Has the patient provided written informed consent?	☐	☐
3.	Is the patient willing to follow trial protocol?	☐	☐
4.	Does the patient have a histologically confirmed colonic carcinoma? Date of histology report Day Month Year	☐	☐
5.	Does the patient have radiological evidence of colonic carcinoma?	☐	☐
6.	Does the patient have a right sided or sigmoid cancer?	☐	☐
7.	Is the patient's colon cancer suitable for resection by laparoscopic procedure?	☐	☐
8.	Is the patient fit for laparoscopic D3 resection?	☐	☐
9.	Has the patient management been agreed at MDT discussion? *(N.B. Distant metastatic disease should not preclude patients from the developmental phase of the trial provided laparoscopic resection is part of routine clinical care)*	☐	☐
10.	Does the patient have an ASA grade ≤3?*	☐	☐
11.	Does the patient have normal hepatic function?**	☐	☐
12.	Does the patient have normal renal function?**	☐	☐

*ASA grade

1 – A normal healthy patient
2 – A patient with mild systemic disease
3 – A patient with severe systemic disease
4 – A patient with severe systemic disease that is a constant threat to life
5 – A moribund patient who is not expected to survive without the operation
6 – A declared brain-dead patient whose organs are being removed for donor purposes
http://www.asahq.org/clinical/physicalstatus.htm Retrieved 26/04/2010

**Definition of normal hepatic and renal function

- Total bilirubin within normal institutional limits
- AST/ALT <2.5 × institutional upper limit of normal
- GFR ≥60 mls/min/1.73 m^2 or creatinine within 10% of upper value for normal institutional limits. Any concerns should be raised with the SJUH Research Fellow.

Completed by		Date	Day Month Year
Investigator signature		Date	Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Exclusion Criteria

Please tick yes/no for all questions
If any shaded boxes are ticked, the participant is ineligible

		Yes	No	
1.	Does the patient have a PMH of a hypersensitivity reaction to ALA?	☐	☐	
2.	Does the patient have a PMH of a hypersensitivity reaction to colourimetric dye?	☐	☐	
3.	Does the patient have a PMH of acute or chronic or a family history of porphyria?	☐	☐	
4.	Does the patient have a carcinoma of the transverse colon? *(Distal to the proximal border of the falciform ligmant to the initial angualtion of the splenic flexure)*	☐	☐	
5.	Does the patient have a carcinoma of the descending colon? *(From the initial angulation of the splenic flexure to the level of the left iliac crest)*	☐	☐	
6.	Does the patient have a PMH of Crohn's disease?	☐	☐	
7.	Does the patient have a PMH of ulcerative colitis?	☐	☐	
8.	Does the patient have a PMH of any additional on-going colitis, e.g. ischaemic/active diverticulitis?	☐	☐	
9.	Does the patient have a PMH of synchronous colonic or rectal cancer (but not benign polyps)?	☐	☐	
10.	Is the patient pregnant?	☐	☐	☐ N/A – The patient is male
11.	Is the patient breastfeeding?	☐	☐	☐ N/A – The patient is male
12.	Has the patient received any investigational medicinal product at any dose within 28 days before registration?	☐	☐	
13.	Does the patient have any poorly controlled medical illness that, in the Investigator's opinion, is likely to interfere with participation and/or compliance in this clinical trial?	☐	☐	
14.	Does the patient have any poorly controlled psychiatric illness that, in the Investigator's opinion, is likely to interfere with participation and/or compliance in this clinical trial?	☐	☐	
15.	Is the patient involved in the FOxTROT trial?	☐	☐	

Completed by		Date	Day Month Year	
Investigator signature		Date	Day Month Year	Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 03

Registration

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed following informed consent and assessment of eligibility.
Complete Section A and B before telephoning the CTRU to register the participant.

Section A – Caller and Participant Details

Caller name

Name of treating surgeon

Glisten centre number/ NIHR site code

Centre name

Participant initials

Participant gender ☐ Male ☐ Female

Participant date of birth Day Month Year

NHS number
☐ N/A for Irish hospitals

Please use the phonetic alphabet for participant initials

A Alpha	H Hotel	O Oscar	V Victor
B Bravo	I India	P Papa	W Whiskey
C Charlie	J Juliet	Q Quebec	X X-ray
D Delta	K Kilo	R Romeo	Y Yankee
E Echo	L Lima	S Sierra	Z Zulu
F Foxtrot	M Mike	T Tango	
G Golf	N November	U Uniform	

Has the eligibility checklist (Form 02) been completed?	☐ Yes	☐ No
Does the participant satisfy all the eligibility criteria?	☐ Yes	☐ No
Has the participant provided written informed consent to enter the trial?	☐ Yes	☐ No

All answers must be **YES** to proceed with registration

Date of written informed consent Day Month Year

Section B – Planned Operation

Planned operation
(Please tick one only)

- ☐ Right hemicolectomy
- ☐ Extended right hemicolectomy
- ☐ Sigmoid colectomy
- ☐ High anterior resection
- ☐ Hartmann's procedure

Planned operation date Day Month Year

Please ensure all details in Section A and B are completed.
TO REGISTER THE PARTICIPANT, PLEASE CALL THE CTRU OFFICE-HOURS REGISTRATION SERVICE ON 0113 343 4930.
(Monday–Friday 9 am–5 pm except public and university holidays)

Section C – Registration Details

This information will be given at registration

Participant ID Centre No / Trial No

Date of registration Day Month Year

You will only be given the **5-digit trial number** at registration. This forms the second part of the participant ID number.

Completed by

Date Day Month Year

Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 04

Radiology

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed prior to the planned operation

CT Scan Details

Was a CT chest abdomen and pelvis performed?
- ☐ Yes → Date of scan: Day Month Year
- ☐ No

Is this within 8 weeks of the actual date of surgery? ☐ Yes ☐ No

Was a CT colonography performed?
- ☐ Yes → Date of scan: Day Month Year
- ☐ No

Is this within 8 weeks of the actual date of surgery? ☐ Yes ☐ No

Which scan was used to locate nodes?
- ☐ CT CAP
- ☐ CT colon

Was a scan performed in portal venous phase at 65 seconds?
- ☐ Yes
- ☐ No

Was a reconstructed slice thickness 5 mm axial & 3 mm coronal planes for the abdomen performed?
- ☐ Yes
- ☐ No → Slice thickness

Tumour Details

Site of tumour *(Tick one only)*
- ☐ Caecum *(Segment proximal to or involving ileocaecal valve)*
- ☐ Ascending colon *(Segment distal to ileocaecal valve and proximal to the initial angulation of the hepatic flexure)*
- ☐ Hepatic flexure *(Segment distal to the initial angulation of the hepatic flexure to the proximal border of the falciform ligament)*
- ☐ Sigmoid colon *(Segment distal to the level of the left iliac crest to 15 cm proximal to the anal verge)*

Tumour morphology *(Tick one only)*
- ☐ Polypoidal
- ☐ Flat
- ☐ Semi annular
- ☐ Annular

Tumour length ☐☐☐ mm

Completed by | Date: Day Month Year

Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Tumour Details *(Continued)*

Radiological T stage *(Tick one only)*

- ☐ T2 or less (limited by muscularis propria)
- ☐ T3 not breaching serosa
- ☐ T4a penetration of serosa with extension into adjacent organs
- ☐ T4b penetration of serosa and peritoneal surface with perforation of bowel

Radiological N stage *(Tick one only)*

Number of visible nodes ☐☐

Number of malignant nodes

- ☐ N0 – none
- ☐ N1 – 1-3 regional lymph nodes appear malignant
- ☐ N2 – 4 or more regional lymph nodes appear malignant

Size of largest malignant node ☐☐ mm

V stage *(Tick one only)*

- ☐ V1 – Vascular invasion present or probably present
- ☐ V0 – Vascular invasion probably absent or absent

M stage *(Tick one only)*

- ☐ M0 – no distant metastases
- ☐ M1a – distant metastases one organ
- ☐ M1b – peritoneal or distant metastases to more than one organ or distant nodes

→ Please specify other location(s)

- ☐ Liver
- ☐ Lung
- ☐ Peritoneum

Right colon vascular anatomy assessment *(Tick as many as apply)*

- ☐ Ileocolic artery present
- ☐ Right colic artery present (arising directly from the SMA not ileocolic)
- ☐ Middle colic artery present
- ☐ Artery crosses anterior to SMV
- ☐ Artery crosses posterior to SMV
- ☐ N/A – Not a right-sided cancer

Additional Pathology

Additional pathology present?

- ☐ Yes → Please give details
- ☐ No

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment

Figure 1
For right-sided cancers

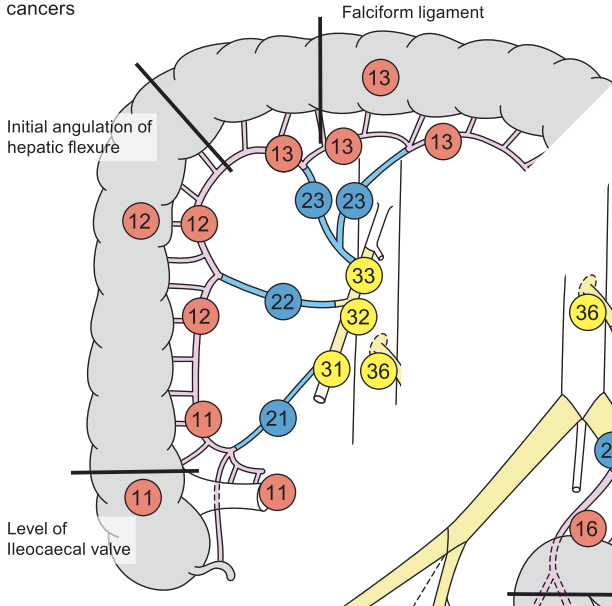


Figure 2
For left-sided cancers

Instructions

- Please mark nodes (by crossing the lymph node station) considered to be malignant on the specimen diagram (Figure 1 for right sided cancers and Figure 2 for left sided cancers) and note nodes considered to be malignant, plus give an estimation of their size on page 4
- Size of nodes to be recorded as the maximum short axis diameter on the table on page 4

Modified Japanese staging subgroups

Pericolic, D1 lymph nodes (red); Intermediate D2 lymph nodes (blue); Main, D3, lymph nodes (yellow).

Coding for lymph node stations

- In the superior and inferior mesenteric arterial system, the first figure of the code indicates the position of the lymph nodes, expressing the epicolic and paracolic (D1) nodes as 1Δ (marked in red on figure 1), the intermediate (D2) nodes as 2Δ (marked in blue on figure 1), the main (D3) nodes as 3Δ (marked in yellow on figure 1) and the para-aortic nodes as 4Δ (marked in white on figure 1).
- The second figure indicates the position of the lymph nodes along the main trunk artery; Δ1 is used for the nodes along the ileo-colic artery, Δ2 is used for nodes long the right colic artery, Δ3 for those along the middle colic artery, Δ4 for those along the left colic artery and Δ5 for the sigmoid artery and Δ6 for the superior rectal artery.
- The inferior mesenteric nodes are expressed as 36.

Completed by		Date	Day Month Year	Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment *(Continued)*

Station number of malignant node – comment on malignant nodes only	Node *(e.g. 1, 2, 3, 4)*	Estimate size of each node: maximum short axis diameter (mm)
11		
12		
13		
14		
15		
16		
21		
22		
23		
24		
25		
26		
31		
32		
33		
36		

Completed by | Date Day Month Year | Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 05 Colonoscopy and Indian Ink

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed prior to the planned operation

Colonoscopy Details

Has a colonoscopy been performed? ☐ Yes ☐ No

If yes, date of colonoscopy Day Month Year

Please indicate the site of of tumour *(tick yes for one only)*:

Right? ☐ Yes → Approximate site of tumour
- ☐ Caecum *(Segment proximal to or involving ileocaecal valve)*
- ☐ Ascending colon *(Segment distal to ileocaecal valve and proximal to the initial angulation of the hepatic flexure)*
- ☐ Hepatic flexure *(Segment distal to the initial angulation of the hepatic flexure to the proximal border of the falciform ligament)*

☐ No

Sigmoid? ☐ Yes → Approximate site of tumour
- ☐ Sigmoid colon *(Segment distal to the level of the left iliac crest to 15 cm proximal to the anal verge)*

☐ No

Recto-sigmoid? ☐ Yes → Distance from anal verge ☐☐.☐ cm

☐ No

Is diverticular disease present? ☐ Yes ☐ No

Is colitis present? ☐ Yes ☐ No

Are benign polyps present? ☐ Yes ☐ No

Administration of Indian Ink

Was indian ink administered to the tumour? ☐ Yes ☐ No

Completed by _____ Date Day Month Year

Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 06

Operative Form

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed on the day of the participant's planned operation

5 ALA Details

Dose of 5 ALA
- ☐ 10 mg/kg
- ☐ 20 mg/kg
- ☐ 30 mg/kg

Total dose of 5 ALA ☐☐☐☐ mg

Timing of 5 ALA prior to surgery ☐☐ hours *(To nearest hour; round up or down from time 5 ALA taken to time of first incision)*

Storz D-light Laparoscopic System

Settings of the Storz D-light laparoscopic system

Operation Details

Date of operation Day Month Year

Name of operating surgeon

Initial Laparoscopy Findings

Adhesions?
- ☐ Yes → Few ☐ Yes ☐ No
- ☐ No
  - Single quadrant ☐ Yes ☐ No
  - Multi-quadrant ☐ Yes ☐ No

Locoregional tumour spread?
- ☐ Yes → Description
- ☐ No

Tumour perforation/ abscess?
- ☐ Yes → Description
- ☐ No

Other organ involvement?
- ☐ Yes → Description
- ☐ No

Completed by Date Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Initial Laparoscopy Findings *(Continued)*

Tumour marked preoperatively (indian ink)? ☐ Yes ☐ No → Tumour visible intraoperatively? ☐ Yes ☐ No

Lymphatic anatomy visible from colorimetric dye tattoo? ☐ Yes ☐ No → Was tumour tattooed at colonoscopy? ☐ Yes ☐ No

Presence of fluorescence (5-ALA) of lymph nodes? ☐ Yes ☐ No → Assessment of intensity of fluorescence: ☐ 1 = barely visible ☐ 2 = easily visible ☐ 3 = intense fluorescence

Presence of fluorescence (5-ALA) of tumour? ☐ Yes ☐ No → Assessment of intensity of fluorescence: ☐ 1 = barely visible ☐ 2 = easily visible ☐ 3 = intense fluorescence

Presence of fluorescence (5-ALA) of parietal or visceral peritoneum? ☐ Yes ☐ No → Assessment of intensity of fluorescence: ☐ 1 = barely visible ☐ 2 = easily visible ☐ 3 = intense fluorescence

Presence of fluorescence on visible liver capsule? ☐ Yes ☐ No → Assessment of intensity of fluorescence: ☐ 1 = barely visible ☐ 2 = easily visible ☐ 3 = intense fluorescence

Any other findings of note? ☐ Yes ☐ No → Description

Actual Mode of Surgery

Please tick one:

☐ Laparoscopic

☐ Laparoscopic converted to open

Conversion to an open procedure will not affect the initial laparoscopic assessment and marking of fluorescent nodes; such patients will still be included in the trial.

Theatre Timings

Laparoscopic start time Hours : Minutes

Laparoscopic finish time Hours : Minutes

Please use 24 hr clock

Total operative time ____ hours ____ minutes

Completed by | Date Day Month Year

Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Operation Performed

Right hemicolectomy ☐ Yes ☐ No

Extended right hemicolectomy ☐ Yes ☐ No

Sigmoid colectomy ☐ Yes ☐ No

High anterior resection ☐ Yes ☐ No

Hartmann's procedure ☐ Yes ☐ No

Other operation ☐ Yes → Description
☐ No

Operative Details

Were fluorescent lymph nodes marked with ligaclips to facilitate subsequent pathological identification? ☐ Yes ☐ No
(See diagrams on page 7 & 8 and table on page 9)

Was a D3 lymphadenectomy performed? ☐ Yes
☐ No → Why not?

Cancers of the Right Colon

Complete this section for cancers of the right colon (caecum to the medial border of the falciform ligament) for participants undergoing a right hemicolectomy:

High, central ligation of ileocolic artery and vein? ☐ Yes ☐ No

High, central ligation of the right colic vessels, when present as separate branches? ☐ Yes ☐ No

If hepatic flexure cancers, were the middle colic vessels taken at their origin? ☐ Yes ☐ No ☐ N/A *(No hepatic flexure cancers)*

If caecal or ascending colon cancer, were the right branches of the middle colic vessels taken at their origin? ☐ Yes ☐ No ☐ N/A *(Not caecal or ascending colon cancer)*

Completed by | Date Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Operative Details *(Continued)*

Cancers of the Sigmoid Colon

Complete this section for cancers of the sigmoid colon (distal to the level of the left iliac crest to 15 cm proximal to the anal verge) for participants undergoing a Sigmoid colectomy/left sided resection:

High ligation and division of the inferior mesenteric artery proximal to the origin of the left colic vessels?
- ☐ Yes
- ☐ No

High ligation and division of the inferior mesenteric vein immediately below the inferior border of the pancreas?
- ☐ Yes
- ☐ No

Mobilisation of the splenic flexure?
- ☐ Yes → Please specify *(Tick one only)*
  - ☐ Complete mobilisation
  - ☐ Partial mobilisation
  - ☐ No mobilisation
- ☐ No

Rectal dissection?
- ☐ Yes → Please specify *(Tick one only)*
  - ☐ Total mesorectal excision
  - ☐ Partial mesorectal excision
- ☐ No

Anastomosis?
- ☐ Yes →

Extracoporeal	☐ Yes	☐ No
Intracorporeal	☐ Yes	☐ No
Doughnuts intact	☐ Yes	☐ No
Air-tight	☐ Yes	☐ No
Hand-sewn	☐ Yes	☐ No
Stapled	☐ Yes	☐ No

- ☐ No

Further Details

For all participants:

Anastomotic complication?
- ☐ Yes
- ☐ No

End stoma?
- ☐ Yes →

Colostomy	☐ Yes	☐ No
Ileostomy	☐ Yes	☐ No

- ☐ No

Defunctioning stoma?
- ☐ Yes →

Colostomy	☐ Yes	☐ No
Ileostomy	☐ Yes	☐ No

- ☐ No

Estimated blood loss ☐☐☐ ml

Completed by ____ Date Day Month Year

Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Operative Outcome

Unresectable? ☐ Yes ☐ No

Curative resection (R0)? ☐ Yes ☐ No

Palliative? ☐ Yes ☐ No →

Local disease remaining (R1 & R2)	☐ Yes	☐ No
Peritoneal disease	☐ Yes	☐ No
Liver metastases	☐ Yes	☐ No

Latrogenic tumour perforation? ☐ Yes ☐ No

Completed by | Date Day Month Year | Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Intraoperative Complications

Did any intraoperative complications occur? ☐ Yes ☐ No

If yes, please record details below, ticking yes or no for each complication:

Damage to organ/structure? ☐ Yes → ☐ Bowel, ☐ Bladder/ureter, ☐ Major vessel, ☐ Nerves
☐ No

Faecal contamination? ☐ Yes → ☐ Local, ☐ Widespread
☐ No

Haemorrhage? ☐ Yes → Action taken?
☐ No

Failure of surgical equipment? ☐ Yes → Failure of laparoscopic equipment/hardware? ☐ Yes → Give details
☐ No ☐ No

Cardiac event? ☐ Yes → Action taken?
☐ No

Respiratory event? ☐ Yes → Action taken?
☐ No

Surgical emphysema? ☐ Yes → Action taken?
☐ No

Other complication? ☐ Yes → Please specify
☐ No
Action taken?

Video Recording

Was a video made of the procedure that was suitable for use to produce guidance for evaluation phase? ☐ Yes ☐ No

Completed by | Date Day Month Year

Form continues on next page ▶▶

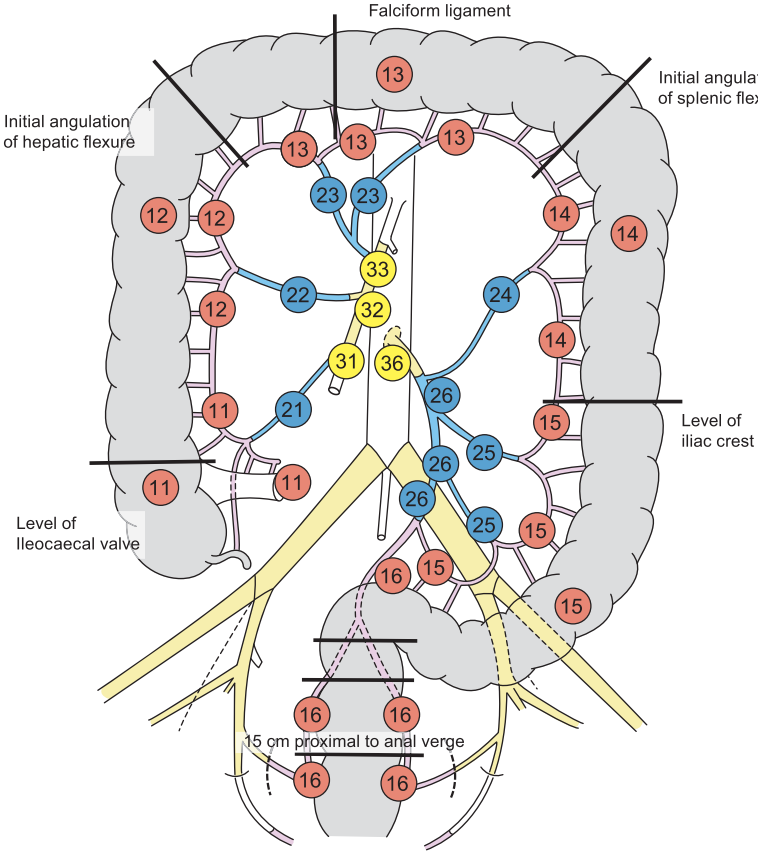
Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment

Figure 1



Instructions

- Please mark flurescent nodes marked with a surgical clip intra-operatively with a cross

Modified Japanese staging subgroups

Pericolic, D1 lymph nodes (red); Intermediate D2 lymph nodes (blue); Main, D3, lymph nodes (yellow).

Coding for lymph node stations

- In the superior and inferior mesenteric arterial system, the first figure of the code indicates the position of the lymph nodes, expressing the epicolic and paracolic (D1) nodes as 1Δ (marked in red on figure 1), the intermediate (D2) nodes as 2Δ (marked in blue on figure 1), the main (D3) nodes as 3Δ (marked in yellow on figure 1) and the para-aortic nodes as 4Δ (marked in white on figure 1).
- The second figure indicates the position of the lymph nodes along the main trunk artery; Δ1 is used for the nodes along the ileo-colic artery, Δ2 is used for nodes long the right colic artery, Δ3 for those along the middle colic artery, Δ4 for those along the left colic artery and Δ5 for the sigmoid artery and Δ6 for the superior rectal artery.
- The inferior mesenteric nodes are expressed as 36.

Completed by		Date	Day Month Year	Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment *(Continued)*

Figure 2
Note the anatomy of the right colic artery – draw in

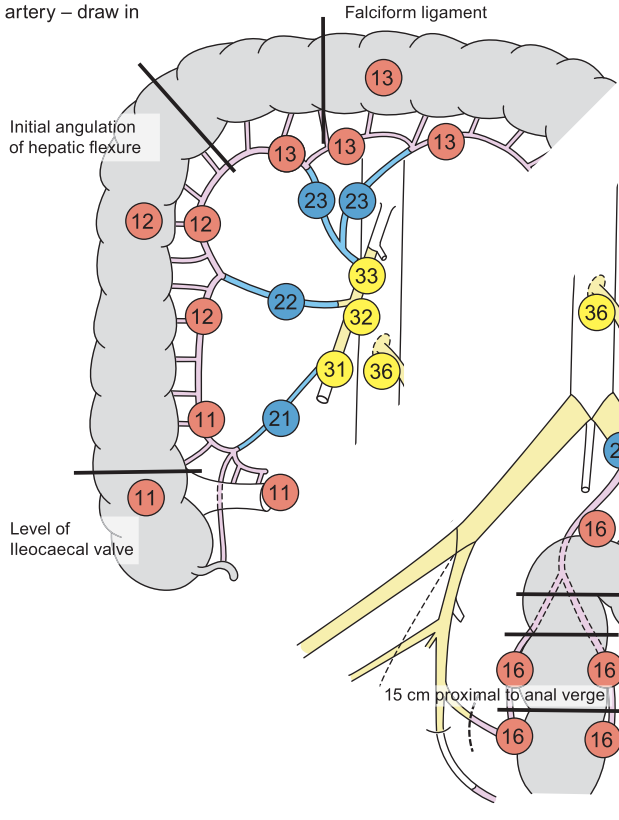


Figure 3
Note any anomolies for left sided cancers – draw in

Instructions

- Please mark nodes (by crossing the lymph node station) considered to be malignant on the specimen diagram (Figure 2 for right sided cancers and Figure 3 for left sided cancers) and note nodes considered to be malignant, plus give an estimation of their size on page 9
- Size of nodes to be recorded as the maximum short axis diameter on the table on page 9

Modified Japanese staging subgroups

Pericolic, D1 lymph nodes (red); Intermediate D2 lymph nodes (blue); Main, D3, lymph nodes (yellow).

Coding for lymph node stations

- In the superior and inferior mesenteric arterial system, the first figure of the code indicates the position of the lymph nodes, expressing the epicolic and paracolic (D1) nodes as 1Δ (marked in red on figure 1), the intermediate (D2) nodes as 2Δ (marked in blue on figure 1), the main (D3) nodes as 3Δ (marked in yellow on figure 1) and the para-aortic nodes as 4Δ (marked in white on figure 1).
- The second figure indicates the position of the lymph nodes along the main trunk artery; Δ1 is used for the nodes along the ileo-colic artery, Δ2 is used for nodes long the right colic artery, Δ3 for those along the middle colic artery, Δ4 for those along the left colic artery and Δ5 for the sigmoid artery and Δ6 for the superior rectal artery.
- The inferior mesenteric nodes are expressed as 36.

Completed by		Date	Day Month Year	Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment *(Continued)*

☐ **N/A – no fluorescent nodes present**

Station number of fluorescent node – comment on fluorescent nodes only	Node *(e.g. 1, 2, 3, 4)*	Vessel	Estimate size of node: maximum short axis diameter (mm)	Comments	Colorimetric dye visible? Yes	No
11		Ileocolic D1			☐	☐
12		Right colic D1			☐	☐
13		Middle colic D1			☐	☐
14		Left colic D1			☐	☐
15		Sigmoid branches D1			☐	☐
16		Superior rectal D1			☐	☐
21		Ileocolic D2			☐	☐
22		Right colic D2			☐	☐
23		Middle colic D2			☐	☐
24		Left colic D2			☐	☐
25		Sigmoid branches D2			☐	☐
26		IMA			☐	☐
31		Ileocolic D3			☐	☐
32		Right colic D3			☐	☐
33		Middle colic D3			☐	☐
36		Origin of IMA			☐	☐
		TOTAL				

Any additional areas of fluorescence; size, approximate location and whether excised as separate specimen	

Estimated tumour location *(Tick one only)*

- ☐ Caecum *(Segment proximal to or involving ileocaecal valve)*
- ☐ Ascending colon *(Segment distal to ileocaecal valve and proximal to the initial angulation of the hepatic flexure)*
- ☐ Hepatic flexure *(Segment distal to the initial angulation of the hepatic flexure to the proximal border of the falciform ligament)*
- ☐ Sigmoid colon *(Segment distal to the level of the left iliac crest to 15 cm proximal to the anal verge)*

Completed by | Date Day Month Year

Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 07

Post-operative Care

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed post the planned operation.
(Post-op care defined as until participant's discharge from hospital or until 10 days post-op if not discharged)

Liver Function Tests (LFTs)

	Day 1 post-op			Day 2 post-op			Day 3 post-op			Day 4 post-op ☐ Tick if N/A			Day 5 post-op ☐ Tick if N/A		
	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No
Bilirubin **(µmol/L)**		☐	☐		☐	☐		☐	☐		☐	☐		☐	☐
ALT or AST **(IU/L)**		☐	☐		☐	☐		☐	☐		☐	☐		☐	☐
ALP **(IU/L)**		☐	☐		☐	☐		☐	☐		☐	☐		☐	☐

Urea and Electrolytes (U&Es)

	Day 1 post-op			Day 2 post-op			Day 3 post-op			Day 4 post-op ☐ Tick if N/A			Day 5 post-op ☐ Tick if N/A		
	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No	Result	Abnormal? Yes	No
Urea **(mmol/L)**	.	☐	☐	.	☐	☐	.	☐	☐	.	☐	☐	.	☐	☐
Creatinine **(µmol/L)**		☐	☐		☐	☐		☐	☐		☐	☐		☐	☐

Was the participant kept in ward environment for 72 hrs? ☐ Yes ☐ No → Reason

Potential Side-effects

In the opinion of doctors involved in post-op care, has the participant experienced any of the following symptoms **due to 5 ALA administration**? ☐ Yes → Please tick yes or no for each complication below and give details where applicable ☐ No

		Action taken?		Description
Photosensitivity reactions	☐ Yes ☐ No		☐ Yes ☐ No	
Skin hypersensitivity reactions	☐ Yes ☐ No		☐ Yes ☐ No	
Nausea	☐ Yes ☐ No		☐ Yes ☐ No	
Vomiting	☐ Yes ☐ No		☐ Yes ☐ No	
Tachycardia	☐ Yes ☐ No		☐ Yes ☐ No	
Hypotension	☐ Yes ☐ No		☐ Yes ☐ No	
Other, please specify	☐ Yes ☐ No		☐ Yes ☐ No	

If any of these fulfil the seriousness criteria as listed in protocol section 14.1, please also complete **F10 SAE** / **F11 SUSAR** report as appropriate within 24 hours of becoming aware

Completed by | Date Day Month Year

Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 08

Pathology Assessment

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed at the time of the pathological assessment post the planned operation.
N.B. specimens should be sent to the lab fresh (Acceptable to refridgerate for 24 hrs post surgery)

Assessment Details

Date of assessment: Day Month Year

Operation date: Day Month Year

Pathology reference

Name of pathologist completing work

Photography Details

Digital photographs taken of surface

Required:

Anterior ☐ Yes ☐ No
(Prior to inking of non-peritonealised surfaces – clips should be clearly visible)

Posterior ☐ Yes ☐ No
(Prior to inking of non-peritonealised surfaces – clips should be clearly visible)

Mesocolic defects ☐ Yes ☐ No ☐ N/A

Perforations ☐ Yes ☐ No ☐ N/A

The site of the tumour and high vascular tie should be clearly marked (e.g. with forceps) and the photograph should include a ruler/tape measure to enable sizing of the specimen. The whole specimen should be visible in the image and mesentery should be laid out flat (not folded or over stretched). The proximal and distal aspects can also be labelled if not obvious.

Photographs should be taken directly above the specimen to reduce distortion and while a white background is ideal, any other plain colour is acceptable The photographs should not contain any direct identifiers (e.g. name or date of birth) but should be identifiable by trial number, histopathology number and patient initials.

Photography following formalin filtration for 48 hours but prior to Indian Ink application to all non-peritonealised surfaces

Digital photographs taken of surface

Required:

Anterior ☐ Yes ☐ No
(Prior to inking of non-peritonealised surfaces – clips should be clearly visible)

Posterior ☐ Yes ☐ No
(Prior to inking of non-peritonealised surfaces – clips should be clearly visible)

Mesocolic defects ☐ Yes ☐ No ☐ N/A

Perforations ☐ Yes ☐ No ☐ N/A

It should be remembered that the circumferential margin only applies to the surgically incised mesocolic planes (e.g. the retroperitoneal margin in right sided specimens and the upper mesorectal margin in left sided specimens) and not to the peritonealised surfaces.

Completed by | Date: Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Photography Details *(Continued)*

Photography of the serial cross-sectional slices from the resection specimen

Specimen cross-sectional slices photographed? ☐ Yes ☐ No
(Thinly (3–5 mm) sliced transversely from 2 cm below to 2 cm above the tumour)

It should be clear which are the most proximal and distal slices (e.g. by using labels)

Additional close ups of all tumour bearing slices ☐ Yes ☐ No

Plane of Dissection *(See protocol Appendix 3)*

Please indicate the plane of dissection *(Tick one only)*

- ☐ Mesocolic Plane
- ☐ Intramesocolic Plane
- ☐ Muscularis propria Plane

Position of the Tumour

Site of tumour *(According to the pre-operative assessment, Tick one only)*

- ☐ Caecum *(Segment proximal to or involving ileocaecal valve)*
- ☐ Ascending colon *(Segment distal to ileocaecal valve and proximal to the initial angulation of the hepatic flexure)*
- ☐ Hepatic flexure *(Segment distal to the initial angulation of the hepatic flexure to the proximal border of the falciform ligament)*
- ☐ Sigmoid colon *(Segment distal to the level of the left iliac crest to 15 cm proximal to the anal verge)*

Maximum dimension of tumour		mm
Distance of direct tumour spread beyond the muscularis propria*		mm
Distance from the tumour to the nearest non-peritonealised margin*		mm
Distance of the primary tumour to the closest high tie vessel		mm
Distance from tumour to distal margin		mm
Is there involvement of the distal margin? *(This should be defined as 0 mm)*	☐ Yes ☐ No	
Distance from tumour to proximal margin		mm
Is there involvement of the proximal margin? *(This should be defined as 0 mm)*	☐ Yes ☐ No	

*These should initially be measured macroscopically and then confirmed histologically (please alter the histological measurement if necessary)

Perforations

Is there evidence of perforation within tumour? ☐ Yes ☐ No

Is there evidence of bowel perforation away from tumour? ☐ Yes ☐ No

Completed by | Date Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 08
Page 3 of 6

Pathology Assessment

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Tumour Morphology

Is the tumour type adenocarcinoma?
- ☐ Yes
- ☐ No → Specify type

What is the differentiation? *(By predominate type, tick one only)*
- ☐ Poor
- ☐ Well / Moderate

Local Invasion

Please stage the maximum extent of tumour invasion:
- ☐ Submucosa
- ☐ Inner circular muscle layer
- ☐ Outer longitudinal muscle layer
- ☐ Mesocolic fat
- ☐ Through peritoneum
- ☐ Adjacent organ(s) → Specify organ(s)

Is there peritoneal involvement?
- ☐ Yes ☐ No

Extramural Vascular Invasion

Is there extramural vascular invasion?
- ☐ Yes ☐ No

Metastatic Spread

Number of lymph nodes examined*

Number of positive lymph nodes*

**Excluding tumour deposits outside lymph nodes, irrespective of their size*

All of the local lymph nodes in the specimen should be identified, mapped, embedded and examined.

The high tie (apical node) should be blocked separately to allow Dukes' staging to be conducted as should any lymph nodes marked (e.g. with a clip) by the surgeons to allow comparison with the intra-operative staging.

Lymph nodes should be embedded in their entirety either by submitting whole, bisecting or serial slicing if large.

Is the apical node positive?
- ☐ Yes
- ☐ No

Are there tumour deposits outside lymph nodes?
- ☐ Yes → Number of deposits measuring 3 mm or more in maximum diameter
  - Are there any deposits measuring less than 3 mm in diameter? ☐ Yes ☐ No
- ☐ No

Likely level of lymphadenectomy based on vascular anatomy
- ☐ D1
- ☐ D2
- ☐ D3

Completed by | Date (Day Month Year)

Form continues on next page ►►

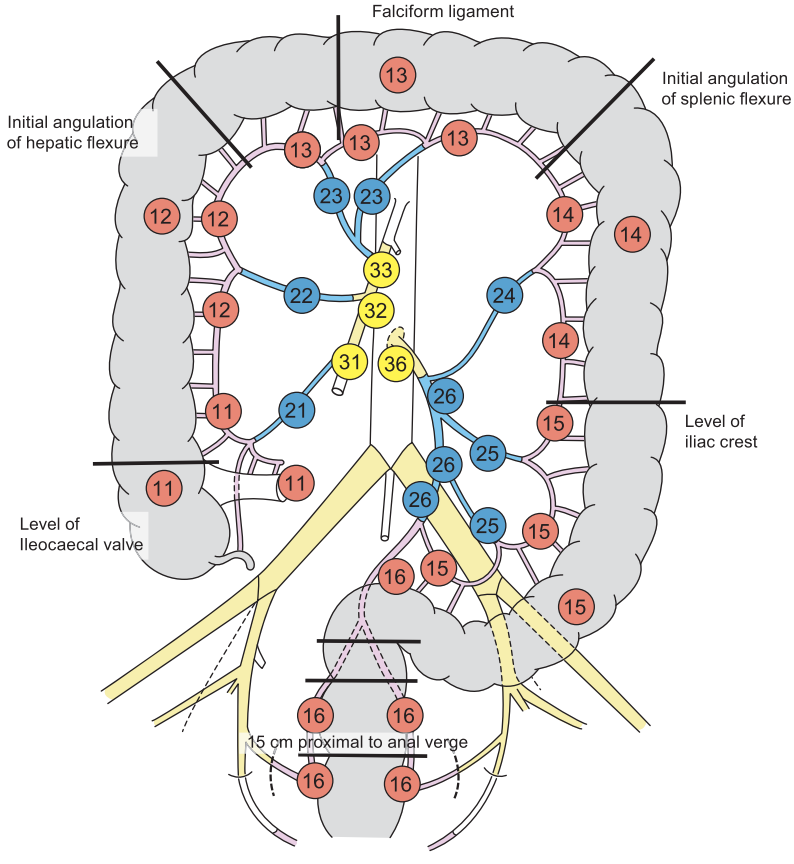
Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment

Figure 1



Instructions

The pathologist will mark on a specimen diagram and lymph node mapping table the number of nodes in each station and how many of these were fluorescent intra-operatively.

Key

Please mark on modified Japanese station sub-groupings diagram

If node is...		Mark as
Fluorescent &	Malignant	FM
	Benign	FB
Non-fluorescent &	Malignant	NFM
	Benign	NFB

Modified Japanese staging subgroups

Pericolic, D1 lymph nodes (red); Intermediate D2 lymph nodes (blue); Main, D3, lymph nodes (yellow).

Coding for lymph node stations

- In the superior and inferior mesenteric arterial system, the first figure of the code indicates the position of the lymph nodes, expressing the epicolic and paracolic (D1) nodes as 1Δ (marked in red on figure 1), the intermediate (D2) nodes as 2Δ (marked in blue on figure 1), the main (D3) nodes as 3Δ (marked in yellow on figure 1) and the para-aortic nodes as 4Δ (marked in white on figure 1).
- The second figure indicates the position of the lymph nodes along the main trunk artery; Δ1 is used for the nodes along the ileo-colic artery, Δ2 is used for nodes long the right colic artery, Δ3 for those along the middle colic artery, Δ4 for those along the left colic artery and Δ5 for the sigmoid artery and Δ6 for the superior rectal artery.
- The inferior mesenteric nodes are expressed as 36.

Completed by | Date Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Lymph Node Assessment *(Continued)*

☐ **No fluorescent nodes present**

Station number	Node number	Notes *(See guidance below)*	Fluorescent? Yes	Fluorescent? No	Cassette	Involved? Yes	Involved? No
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐
			☐	☐		☐	☐

Completion guidance

- *Please list each individual node on a separate line.*
- *Please state if the node is an apical node (there may be more than one apical node if the tumour lies between two vascular ties)*
- *Describe the distance of the pericolic D1 nodes from the tumour centre (either within 5 cm, between 5 cm and 10 cm, or more than 10 cm)*
- *Add any other comments as necessary.*

Please use another copy of this page if you need more space

Page ☐ of ☐

Completed by | Date Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Computerised Initials	Verified/Checked Date	Verified/Checked Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 08
Page 6 of 6

Pathology Assessment

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Metastatic Spread

Please indicate TNM (Version 5) staging:

pT
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4 *(Peritoneal involvement (pT4) should be diagnosed if tumour cells penetrate the peritoneal surface)*

pN
- ☐ 0
- ☐ 1
- ☐ 2

pM
- ☐ 0
- ☐ 1
- ☐ X

- ☐ R0
- ☐ R1 (0 mm)
- ☐ R1 (<1 mm)
- ☐ R2

Dukes'
(Tick one only)

- ☐ Dukes' A *(Tumour growth limited to the bowel wall (pT1 or pT2) but no further, nodes −ve)*
- ☐ Dukes' B *(Tumour growth beyond the bowel wall (pT3 or pT4), nodes −ve)*
- ☐ Dukes' C1 *(Any pT stage, nodes +ve and apical node −ve)*
- ☐ Dukes' C2 *(Any pT stage, apical node +ve)*
- ☐ Stage D *(Presence of distant metastases)*

Are there pathologically-proven metastases present?

- ☐ Yes → Please specify type *(Tick all that apply)*
  - ☐ Liver
  - ☐ Lung
  - ☐ Peritoneal
  - ☐ Other, please specify:
- ☐ No

Other Comments

Submitting for Central Review

	Yes	No
Photographs – intact fresh resection specimen?	☐	☐
Photographs of the whole formalin-fixed resection specimen?	☐	☐
Photographs of the serial cross-sectional slices from the resection specimen?	☐	☐
Specimen sketch detailing the estimated position of all lymph nodes (positive and negative) according to station number ?	☐	☐
Submitting the final histopathology report with full histopathological staging data for review?	☐	☐
Submitting all of the H&E stained glass slides (or copies) for central review?	☐	☐
Submitting the formalin-fixed paraffin-embedded tissue blocks of all of the lymph nodes (and the additional two blocks of tumour and one of normal mucosa if the participant has consented)?	☐	☐

Completed by | Date: Day Month Year

Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised: Date / Initials	Verified/Checked: Date / Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 09

30 Day Follow-up

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

To be completed 30 days post the planned operation

Assessment Details

What is the participant's status?

- ☐ Alive
- ☐ Dead → Date of death: Day Month Year

Was the 30 day assessment undertaken?

- ☐ Yes → Date of assessment: Day Month Year
  - Location of assessment:
    - ☐ In clinic
    - ☐ By telephone
    - ☐ On ward
- ☐ No → Reason not undertaken:
  - Date last known to be alive: Day Month Year
- ☐ N/A – participant has died

Has the participant been discharged?

- ☐ Yes → Date fit for discharge: Day Month Year
- ☐ No
  - Date of actual discharge: Day Month Year
  - Reason for delay in discharge:
  - ☐ N/A – No delay

Length of postoperative hospital stay: ☐☐ days

Has the participant had further surgery?

- ☐ Yes → Date of further surgery: Day Month Year
- ☐ No

Was the surgery cancer-related? ☐ Yes ☐ No

Was the surgery a consequence of the original surgical procedure? ☐ Yes ☐ No

Description of further surgery:

Completed by: Date: Day Month Year

Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Postoperative (30-day) Complications

Operative Complications

Has the participant experienced any operative complications following surgery? ☐ Yes → Please tick yes or no for each complication below and give details where applicable ☐ No

Altered bowel habit/diarrhoea	☐ Yes → C. difficile related? ☐ Yes ☐ No ☐ No	Action taken?	☐ Yes → Description ☐ No	
Anastomotic leak	☐ Yes → Intervention required? ☐ No		☐ Yes → Description ☐ No	
Post-operative peritonitis	☐ Yes → Intervention required? ☐ No		☐ Yes → Description ☐ No	

Cardiac event	☐ Yes → / ☐ No	Specify	Action taken?	Description
		☐ Arrhytmia	☐ Yes → / ☐ No	
		☐ Cardiac failure	☐ Yes → / ☐ No	
		☐ Myocardial infarction/ Ischaemic heart disease	☐ Yes → / ☐ No	
		☐ Cardio-respiratory arrest	☐ Yes → / ☐ No	

Respiratory event	☐ Yes → / ☐ No	Specify	Action taken?	Description
		☐ Acute respiratory distress syndrome/ respiratory failure	☐ Yes → / ☐ No	
		☐ Aspiration	☐ Yes → / ☐ No	
		☐ Atelectasis	☐ Yes → / ☐ No	
		☐ Pleural effusion	☐ Yes → / ☐ No	
		☐ Bronchospasm	☐ Yes → / ☐ No	
		☐ Pneumonia/ chest infection	☐ Yes → / ☐ No	
		☐ Pulmonary embolus	☐ Yes → / ☐ No	

Cerebrovascular attack/stroke	☐ Yes → Action taken? ☐ No		☐ Yes → Description ☐ No	

Completed by | Date: Day Month Year

Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised: Date / Initials	Verified/Checked: Date / Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Postoperative (30-day) Complications *(Continued)*

Deep Vein Thrombosis	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description	
Gastrointestinal fistula	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Gastrointestinal ischaemia/necrosis	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Gastrointestinal obstruction	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Gastrointestinal perforation	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Gastrointestinal stricture/stenosis	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Gastrointestinal ulceration	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Haemorrhage	☐ Yes ☐ No	Transfusion required?	☐ Yes ☐ No	No. units transfused	
		Intervention required?	☐ Yes ☐ No	Description	

Hernia	☐ Yes ☐ No	Specify	Action taken?	Description
		☐ Port	☐ Yes ☐ No	
		☐ Wound	☐ Yes ☐ No	

Intra-abdominal/ pelvic abscess	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Lower limb ischaemia/ compartment syndrome	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Protracted ileus	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Renal failure (acute)	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	
Stoma prolapse/ necrosis	☐ Yes ☐ No	Intervention required?	☐ Yes ☐ No	Description	

Completed by | Date (Day Month Year) | Form continues on next page ►►

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Postoperative (30-day) Complications *(Continued)*

Stoma – high output	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Urinary incontinence	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Urinary retention	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Urinary tract infection	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Wound infection	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Wound dehiscence	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Back pain	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Disseminated intra-vascular coagulation	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Necrotising fasciitis	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Pressure sore	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Metabolic acidosis	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Pseudomembranous colitis	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Scrotal swelling	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Sepsis	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Delirium	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description
Other, please specify	☐ Yes ☐ No	Action taken?	☐ Yes ☐ No	Description

Completed by | Date Day Month Year

Form continues on next page ▶▶

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

GLiSten
Intraoperative lymph node staging for stratified colon cancer surgery

FORM 09

30 Day Follow-up

Participant Initials		Date of Birth	Day Month Year	Participant ID	Centre No	Trial No

Stoma

Does the participant currently have a stoma?

☐ Yes → Is it: ☐ Permanent ☐ Temporary

☐ No

Have they had a colostomy or ileostomy? ☐ Yes → Which? ☐ Colostomy ☐ Ileostomy

☐ No

What type? ☐ Loop ☐ End

Complications Related to 5 ALA after Discharge from Hospital

Has the participant experienced any complications related to 5 ALA after discharge from hospital? ☐ Yes → Please tick yes or no for each complication below and give details where applicable

☐ No

Photosensitivity reactions	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Skin hypersensitivity reactions	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Nausea	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Vomiting	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Tachycardia	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Hypotension	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		
Other, please specify	☐ Yes ☐ No → Action taken?	☐ Yes ☐ No → Description		

Completed by | Date Day Month Year | Last Page ■

Prior to returning this form you must make a copy of the form and any amendments for retention at site.
Gemma Gossedge, Room 7.17, Clinical Science Building, St. James's University Hospital, Leeds, LS9 7TF

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

The Leeds Teaching Hospitals NHS
NHS Trust

John Goligher Colorectal Unit
Research Office
Ground Floor Lincoln Wing
St James University Hospital
Beckett Street
Leeds
LS9 7TF
Tel: 0113 20 64672

GLiSten

5-ALA in Bowel Cancer Surgery

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study called "GLiSten". Before you decide if you want to take part, we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

Once you have read this information, the study team will talk to you about the study again and you can ask any questions you like.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

The purpose of this study is to find a new way of looking at bowel cancer to determine whether it has spread beyond the bowel. The most common place that bowel cancer spreads to is the small nodes next to the bowel. These are called “lymph nodes” and help to stop the spread of cancer. It is important to know if cancer has spread to lymph nodes as this can affect the extent of surgery you require, and whether you need further treatment, such as chemotherapy.

The study will use a substance called 5-ALA. This will be given as a liquid you will drink 4 to 6 hours prior to you operation. 5-ALA will detect the cancer along with any spread to lymph nodes that surround your bowel by causing them to glow red under blue light during your operation. This study aims to find the best dose of 5-ALA. The best dose will be the lowest dose that causes the cancer and any spread to lymph nodes to glow. This study will involve approximately 50 participants. Once the best dose is known, the results of this study will feed into a larger evaluation study involving approximately 300 participants.

Why have I been chosen?

You have been chosen for this study because you have a bowel cancer that can be removed by an operation. Your surgeon has suggested that your cancer is suitable for a “key-hole” or laparoscopic operation.

Do I have to take part?

No, your participation in GLiSten is voluntary and you may withdraw your consent to take part at any time, without giving us a reason.

If you decide to take part you will be given this document to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, your doctor will be happy to talk through how your cancer will be treated. Your treatment and care will not be affected in any way.

If I want to, will I definitely be able to take part?

Although your doctor thinks you might be suitable to take part, they still need to ask you some questions about your medical history and any medications you take to make sure you are suitable.

What is the standard treatment?

You have already had a colonoscopy to diagnose and mark your bowel cancer with a special dye. A CT scan has been performed to ensure the cancer can be removed with an operation.

If you haven’t already had some blood tests, these will be required. However, these tests are not specific to the study and would need to be performed prior to this type of operation.

Standard treatment for your bowel cancer involves an operation to remove part of the bowel containing the cancer and the surrounding lymph nodes. This is to minimise the chance of the cancer coming back.

This study will not change any further treatment you may require after recovering from the operation.

Your CT scan gives us an impression of whether cancer has spread to the lymph nodes but we only know for definite after the lymph nodes have been removed and have been examined by a pathologist.

What is being tested?

The substance being tested is called 5-aminolevulinic acid (5-ALA).

5-ALA will not be used to "treat" your cancer, but will be used during your operation to detect the cancer along with any spread to lymph nodes that surround your bowel.

The purpose of the study is to find the lowest dose of 5-ALA that causes the cancer and any spread to lymph nodes to glow. To do this different doses of 5-ALA will be given to different groups (or cohorts) of participants.

The first group of participants will be given a dose of 20mg/kg of 5-ALA. Depending on how well this detects the cancer and spread to the lymph nodes, the second group will be given either 30mg/kg or 10 mg/kg.

A final group of participants will be given the most successful dose to confirm how well it detects the cancer and spread to lymph nodes.

Although only the dose of 20mg/kg is licensed for use, doses of up to 50mg/kg have been used in clinical studies. If you have private medical insurance you should check whether this will be affected by taking an unlicensed dose.

Your doctor will be able to tell you what dose of 5-ALA you will be given before your operation.

What will happen to me if I take part?

If you choose to take part in the study the management of your bowel cancer will differ only slightly from the standard treatment in that you will take 5-ALA before your standard operation.

5-ALA will be given to you as a liquid to drink (about 100mls) approximately 4 to 6 hours before your operation. 5-ALA is naturally occurring in human cells. When this substance is given in higher doses it is preferentially taken up into cancer cells. The drink is clear and slightly yellowish in colour. It tastes slightly acidic, similar to lemon juice diluted in water.

During the operation we will shine blue light from the camera used in keyhole surgery, and any cancer cells in the bowel and in the lymph nodes will glow red when you have taken 5-ALA. This might help us to identify the cancer and any spread to the lymph nodes.

The parts of your bowel and surrounding lymph nodes that glow red will be marked with surgical clips and will be removed as part of your standard operation. This study does not involve removing additional tissue.

The tissue removed will be examined in detail, by a pathologist to confirm whether cancer cells are present. This is part of the standard procedure following bowel cancer surgery. However, as part of the study the pathologist will assess whether the areas with confirmed cancer cells glowed red during the operation. This will not affect the standard pathology process, or how the results from your removed tissue are interpreted. It will however, allow us

to see how accurately the substance (5-ALA) detects bowel cancer and its spread to lymph nodes. If 5-ALA detects bowel cancer and its spread to lymph nodes accurately it might be used in the future to decide how much tissue a surgeon needs to remove during an operation.

5-ALAhas been used extensively before in other cancers, such as bladder cancer, brain tumours, and ovarian cancer. It has only been used before on a very small scale in colorectal cancer. This is one of the reasons why this study is important, as we plan to test the substance in a large number of patients with colorectal cancer.

In order to see how effective this substance is at detecting bowel cancer we will perform a standard cancer operation with the aim of removing all the cancer, including any cancer that might have spread to lymph nodes. Participating in this study will not mean that extra tissue is removed.

In order to help the researchers obtain as much useful information as possible from the study, videos and photographs may be taken during your operation. These will not identify you by name, and will be anonymised.

How long does treatment go on?

Participants in GLiSten will undergo standard postoperative care, with monitoring for any unwanted effects to the 5-ALA. This will include daily blood tests following surgery, whilst you are in hospital. These blood tests are part of standard practice.

At the end of the study, 30 days after the operation, you will be reviewed in the outpatient clinic (as is standard practice). Your participation in the study will then end.

What are the unwanted effects of treatment?

5-ALA can cause photosensitivity (make your skin more sensitive to bright lights). This means you should stay away from bright lights for 24-48 hours after taking the substance. The standard ward environment after the operation will be satisfactory as long as you avoid bright sunlight. During your operation your eyes and skin will be protected from the operating lights.

Occasional unwanted effects include nausea, vomiting and fast heart rate for 48 hours after taking 5-ALA. You will be monitored for all of these effects. However, this happens as part of standard post-operative monitoring and to experience nausea after an operation is quite common. In addition, biochemical testing occasionally show raised levels of certain enzymes (chemicals) made by the liver. If this occurs, it is usually a mild change for the first 48 hours following surgery, with the enzymes returning to normal as the effect of the drug wears off. Blood tests will be performed on a daily basis when in hospital (as is standard care) to monitor for this. Very occasionally, when 5-ALA has been given prior to brain tumour surgery side effects have included excess accumulation of fluid within the brain. Whether this applies to bowel surgery is not known.

Studies that have used this substance in the past have not seen any greater frequency of these possible unwanted effects in patients who took the substance compared to those who did not.

Women of childbearing potential and men with partners of child bearing potential should use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry and for the duration of study participation. We will perform a pregnancy test on any woman of child bearing potential (any woman who has experienced menarche and who is

not postmenopausal or permanently sterilized) and will need evidence of a negative result prior to entry into the study.

The following drugs should be avoided before participating in the study and for 30 days after your operation:

• Medicines known to have a photosensitising effect e.g. tetracylines, sulphonamides, quinolones

• Medicines associated with acute porphyria e.g. diclofenac, barbiturates, carbamazepine, phenytoin

•Medicines associated with hepatic or renal dysfunction e.g. NSAIDs, ACE-inhibitors, loop diuretics, phenytoin

Your doctor will go through your medication prior to your entry into they study to ensure it does not include any of the above. If you have any concerns about any medication prescribed to you during your involvement in the study your doctor will be happy to discuss it with you.

How is my condition monitored?

During your stay in hospital you will be seen on a ward round on a daily basis to ensure you are recovering at a satisfactory pace after the operation. At this time all your routine observations (pulse, blood pressure and temperature) will be reviewed. Again, this is no different to standard post-operative care.

You will be seen in the outpatient clinic at roughly 30 days after the operation to again check on your recovery.

This study will not change any further treatment you may require after recovering from the operation. Neither will the study change any long-term follow up including regular checks in the outpatient clinic.

What are the possible disadvantages and risks of taking part?

The disadvantages and risks of taking part in GLiSten include the unwanted effects mentioned above. As stated, if these are experienced there are usually mild and do not require any intervention. The most frequent unwanted effects are

- nausea, vomiting, and fast heart rate (common after any operation),
- sensitivity to bright sun-light (specific to 5-ALA).

What are the possible benefits of taking part?

Participants will benefit from high quality keyhole surgery by experienced surgeons, with proven short-term benefits, including less post-operative discomfort, quicker recovery, improved cosmetic result and possible shorter hospital stay. Tissue removed at the time of the operation will be subject to in-depth analysis by experienced pathologists. You will also be monitored closely following your surgery.

By participating in a clinical trial you will receive at least the best treatment currently available. However, there is no guarantee that you will benefit from taking 5-ALA before your operation. 5-ALA may or may not be effective in detecting the spread of cancer to lymph nodes. Whatever the outcome of this research, information from this study will benefit patients who develop bowel cancer in the future by allowing doctors to learn more about the disease.

The main beneficiaries, should 5-ALA prove to be effective in detecting lymph node spread, will be future generations of colon cancer sufferers. The ability to accurately determine lymph node spread may enable surgeons to vary surgery to suit each patient's needs; patients with no lymph node spread may benefit from less extensive surgery compared to patients with lymph node spread who need a more extensive operation to eradicate their cancer.

What if something goes wrong?

If you become unwell whilst taking part in the study you should contact your clinical care team as soon as possible for advice. Any serious unexpected unwanted effect you may have will be reported to the GLiSten research team immediately. A Steering Group will be set up which will closely monitor the study on an ongoing basis so that if there are any problems then they will be detected as soon as possible so that the study can be changed or stopped if necessary.

You will find detailed information in Part 2 about what procedures are available to you if you have a complaint about the way you have been dealt with during the study, or if you suffer harm as result of being in this study.

What happens when the research study stops?

Your involvement in the GLiSten study will stop 30 days following your operation. After this your follow up will be as standard treatment with outpatient appointments on a regular basis for up to 5 years following your operation.

An outpatient appointment usually includes a physical examination by your doctor and some blood tests. As part of the standard practice following bowel cancer treatment you will also undergo regular CT scans and a colonoscopy. These tests will not be part of this study.

Will my taking part be kept confidential?

If you decide to participate in GLiSten the information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Please refer to Part 2 for further details.

Contact Details

If you have any further questions about your illness or clinical studies, please discuss them with your doctor.

You may also find it helpful to contact Macmillan Cancer Support, an independent cancer information charity (Tel: +44 (**0)808 808 00 00**; address: 89 Albert Embankment, London, SE1 7UQ; website www.macmillan.org.uk)

or

CancerHelp, an information service about cancer and cancer care for people with cancer and their families by Cancer Research UK (Tel: +44 (0)20 7061 8355; website www.cancerhelp.org.uk).

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: +44 (0)207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

……

……

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study treatment, and/or follow-up, your data and samples will remain on file and will be included in the final study analysis.

If you leave the study and do not wish for any further information to be collected, you should inform your clinical care team of this in order that no further follow-up information is collected from your medical records.

Please note the GLiSten study team may be required to continue to collect some limited information about you in the case of any unwanted effects you may have as a result of taking part in the trial. This will only be collected if required by the regulatory authorities. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

What will happen if a patient loses mental capacity during the study period?

There is no reason why taking part in this study should affect mental capacity and so this is expected to be an exceptionally rare occurrence. It could however happen to any patient whether or not they are a participant in this study, for example due to an entirely separate event (e.g. a head injury). If this did occur, your doctor would discuss any changes in your treatment with your family/ carer including whether you should be withdrawn from the study. In any event, the GLiSten study team would continue to collect safety and follow up data about you from your medical records via your clinical care team until the end of the study.

Who has organised, funded and reviewed the research and who will be supervising it?

The GLiSten study is being organised by St James's University Hospital, Leeds, UK in collaboration with the Clinical Trials Research Unit at the University of Leeds, UK.

The study is funded by the National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme. The study was also reviewed by experts on behalf of the funder.

The study has been reviewed by a Research Ethics Committee, the Medicines and Healthcare products Regulatory Agency (MHRA), Irish Medicine Board (IMB) and the Research and Development Department at your hospital. A Data Monitoring & Ethics Committee and Steering Committee will monitor and supervise the study. These committees are independent of the researchers and funder.

What if there is a problem?

Complaints:

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal local complaints services are available to you.

Leeds:

Please contact the Patient Advice and Liaison Service (PALS) at Leeds Teaching Hospitals NHS Trust on **(0113) 2066261 or (0113) 2067168 or email patient.relations@leedsth.nhs.uk** Complaints will be dealt with via the National Health

Service. These are unique to your local NHS trust and your doctor or nurse can give you their information,

Dublin:

Please contact the patient representatives at Beaumont Hospital on (01) 809 3234 or email patientrepresentative@beaumont.ie

Harm:

If you are harmed by taking part in this research project compensation arrangements are in place. If you have grounds for legal action you may have to pay your legal costs.

Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

Will my taking part in this study be kept confidential?

If you decide to participate in GLiSten, the information collected about you will be handled in accordance with the consent that you have given and also the 1998 Data Protection Act.

- The information needed for study purposes will be recorded on paper forms and collected by or sent to (usually using standard post but in some cases by fax or email) the researcher at St James's University Hospital Leeds. Some data will also be sent to the researchers at Clinical Trials Research Unit (CTRU)
- You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be collected by or sent to the researchers by fax, post or email.
- Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it; this information will usually be removed by a member of the study team at your hospital, but may also be removed by the researchers upon receipt.

Your data will be entered onto a secure database held at St James's University Hospital in accordance with the 1998 Data Protection Act.

Your healthcare records may be looked at by authorised individuals from the research team, the University of Leeds (the study Sponsor) or the regulatory authorities to check that the study is being carried out correctly.

The information collected about you may be shared with other research teams to answer new research questions in the future. Wherever possible, information will be anonymised (for example; your full name will not be disclosed)

Your name, date of birth, and NHS number and address/postcode will be submitted to standard NHS patient registries (e.g. Medical Research Information Service; Hospital Episodes Statistics etc) held at the NHS Information Centre for Health and Social Care, and cancer registry. This is so that information about your health status may be obtained by the researchers if necessary.

- Your data may be passed to other organisations (possibly in other countries where the data protection standards and laws are different to the UK) to monitor the safety of the treatment(s) that you are receiving; this data will have your name removed.
- CT scans and pathology blocks will be sent for central review to ensure that results are consistent across hospitals. These will be sent via standard hospital processes (such as Royal Mail or courier). Wherever possible, this data will be anonymised and your name removed
- Tissue that is removed will be held in a Human Tissue Act compliant storage facility at the University of Leeds.

Involvement of the General Practitioner/Family Doctor (GP):

Your GP, and the other doctors involved in your healthcare, will be informed of your participation in this study.

Additional research

Bowel cancer research is very important. We do not know all of the important questions which need to be researched at the present time. Therefore, with your permission, the surplus specimens from your cancer operation that will be stored in the hospital pathology laboratory may be used in the future for cancer research.

Strict confidentiality will be maintained at all times and your name and individual details will not be stored with your tissue samples (i.e. they will be anonymised). However, a unique reference number will be allocated to the samples which may allow them to be linked back to data we have collected about your condition in future for research purposes; this will be in strict confidence and you would not be identified in any way.

The samples and information you give may be made available to researchers in the UK or overseas. They may work in universities, hospitals, or in private/commercial companies that do medical research. You will not receive any personal financial award for your gift.

Your donation will be used only for medical research and will not be provided for any other purpose. The people who will store your tissue may ask researchers for fees to cover some of the costs it incurs. This is known as ‘cost recovery’ as it is for reinvestment to ensure the highest standards of safety and professionalism and to enable further medical research. The samples you have gifted will never be sold for profit.

If you have questions or concerns about the donation of samples and information or the possible uses of them, please ask the person discussing donation with you and seeking consent.

If you do not want to your surplus tissue to be used in this way, you can still take part in the study

Will any genetic tests be done?

No.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor.

The Leeds Teaching Hospitals NHS
NHS Trust

John Goligher Colorectal Unit
Research Office
Ground Floor Lincoln Wing
St James University Hospital
Beckett Street
Leeds
LS9 7TF
Tel: 0113 20 64672

Participant ID:	Initials:
Date of Birth:	NHS/Hospital Number:
EudraCT Number: 2012-002623-15	Principal Investigator:

GLiSten

5-ALA in Bowel Cancer Surgery

PARTICIPANT CONSENT FORM

Please initial each box

1. ☐ I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

2. ☐ I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study. In some cases further information about any unwanted effects of my treatment may need to be collected by the study team.

3.

☐ I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.

4.

☐ I agree to allow any information or results arising from this study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous wherever possible.

5.

☐ I agree for my details (which will include my name, date of birth, NHS number and addressto be submitted to the e.g. Medical Research Information Service; Hospital Episodes Statistics via the NHS Information Centre for Health and Social Care, so that information about my health status may be obtained by St James's University Hospital Leeds if necessary.

6.

☐ I agree to a copy of this Consent Form being sent to St James's University Hospital.

7.

☐ I agree that my GP, or any other doctor treating me, will be notified of my participation in this study.

8.

☐ I agree to take part in the study.

The following points are OPTIONAL.

Even if you agree to take part in this study, you do not have to agree to this section:

I give permission for surplus samples from my cancer that have been stored in the hospital pathology laboratory to be retrieved and used in the future for bowel cancer research.

No ☐

Yes ☐

I understand that my tissue sample is a 'gift' that may be used in future research that receives ethical approval. I understand that my sample and data collected from it may be shared on a collaborative basis with researchers in the UK and potentially, centres abroad, including outside the European Economic Area.

No ☐

Yes ☐

Patient:
Signature……

Name (block capitals)……

Date……

Investigator:
I have explained the study to the above named patient and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……

(If used)Translator:
Signature……

Name (block capitals)……

Date……