V.21/04/06



INITIAL RECRUITMENT FORM Outpatient route

Study number:	
Hospital number:	Please affix
Patient title:	Surname: address
Patient forename:	label here
Sex	M□ F□
Date of birth:	d d m m y y y y
Patient telephone:	Mobile:
GP Surname:	GP Forname:
GP Surgery name:	
GP Address:	
GP Postcode:	GP Telephone:
DETAILS OF REF	ERRAL (Please complete as appropriate and tick (🗸) ALL that apply)
Rectal t	bleeding Abdominal pain Anaemia Weight loss FOBT positive
Change in boy	vel habit Specify:
	Other Specify:
Flexible sigmoid	oscopy performed: Date: d d m m y y y y
Rigid sigmoidos	copy performed: Date: d d m m y y y y
	JESTING INVESTIGATION (Please complete as appropriate)
Clinic type:	Colorectal surgical clinic Gastroenterology
	Other Specify:
Name of cor	
Urgency: Two w	
Route of Referra	
Date of clinic:	d d m m v v v v Attended Clinic: Yes No
If NO, reason:	New clinic date: d d d m m y y y y
DIAGNOSES (If	Trew difficulties.
INVESTIGATION	REQUESTED (Please tick (✓) ONE box that applies – PTO)
	Barium Enema Other specify:
	GREEMENT (Please complete as appropriate)
	es patient suitable for trial Yes No
If NO, reason:	
Urgency of proced	ure: Fast track Urgent Soon Routine NA Comment:
	NT (Please complete as appropriate)
Consent form: giv	ven to patient person who sent form:
Patient signed o	
Letter sent to Gi	Yes Date: d d m m y y y y
	ON (Please complete as appropriate)
	way before randomisation: Colonoscopy Barium Enema
Procedure allo	cated after randomisation: Colonoscopy Barium Enema CT
Date of exam ap	pointment: ddd/m/m/y/y/y/ Time:am/pm
Date of outpatie	nt appointment: d d m m y y y y Time: am/pm N/A
PERSON COMPL	LETING FORM
Name:	Job title:
Date: d d	mm y y y y

Special Interest Group in Gastrointestinal & Abdominal Radiology INITIAL RECRUITMENT FORM Radiology/Endoscopy_route

Study number:
Hospital number: Please affix
Patient title: address label here
Patient forename:
Sex M F P Pate of birthy Cl. Cl. m m, V V V V
Date of Orlot.
Patient telephone: Mobile: CRS reserver
GP Surname: GP Forname: GP Forname:
GP Address:
GI ADDIES.
GP Postcode: GP Telephone:
ASCERTAINMENT OF PATIENT (Please tick (/) ONE box that applies)
Endoscopy ☐ Radiology ☐ CT clinic ☐ A&E ☐ Other ☐ Specify:
INVESTIGATION REQUESTED (Please tick (✓) ONE box that applies – PTO)
Colonoscopy Barlum Enema Other Specify:
REASON FOR REFERRAL (Please tick (-/) ALL boxes that apply – PTO) Rectal bleeding Abdominal pain Anaemia Weight loss FOBT positive
Rectal bleeding Abdominal pain Anaemia Weight loss FOBT positive Change in bowel habit Please specify:
Other Specify:
ROUTE OF REFERRAL (Please tick () ONE box that applies)
Outpatient clinic GP referral Other please specify:
OP CLINIC REQUESTING INVESTIGATION (only complete this section if route of referral is outpatient clinic)
Clinic type: Colorectal surgical clinic Gastroenterology Geriatrics
Other Please specify:
Name of consultant: Clinician seeing patient:
Date of dinic: Q Q (m m) V V V V Urgency: Two week wait Urgent Soon Routine
Urgency: Two week wait Urgent Soon Routine DIAGNOSES (if appropriate)
CONSULTANT AGREEMENT (Please complete as appropriate)
Letter sent to consultant Yes Date letter sent: d d m m y y y y
Consultant agrees patient suitable for trial Yes No
If NO, reason:
Urgency of procedure: Fast track Urgent Soon Routine N/A Comment;
PATIENT CONSENT (Please complete as appropriate)
Consent form: posted to patient Date: a a mm/y y y y y y person who sent form:
Patient signed consent? Yes No If No, reason:
Letter sent to GP Yes Date: C C M M M V V V V V RANDOMISATION (Please complete as appropriate)
Diagnostic pathway before randomisation: Colonoscopy Barium Enema
Procedure allocated after randomisation: Colonoscopy Barium Enema CT
Date of exam appointment: d d m m V V V V Time: am/pm
Date of outpatient appointment:
PERSON COMPLETING FORM
Name:Job title:
Date: [d]d/[m]m/[y]y]y



The North West London Hospitals

NHS Trust

Northwick Park Hospital Watford Road

Vatford Road Harrow Middlesex HA1 3UJ

Tel: 0208 235 4253 Fax: 0208 864 2693

Prof S. Halligan Consultant Radiologist
Prof W. Atkin Clinical Epidemiologist

Please affix address label here

CONSENT FORM

Virtual colonoscopy compared with BARIUM ENEMA for diagnosis of bowel disease

				Please INITIAL box				
1.	I confirm that I have read a May 2005 for the above st	INITIAL						
 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. 								
3.	to my taking part in resear	ls from regulatory ch. I give permiss lerstand that data	authorities where it is relevant ion for these individuals to have collected in this trial may be	INITIAL				
4.	In principle I agree to take decision is not binding at t at least 24 hours further to	his point in time a	study. I understand that this and that I have	INITIAL				
Na	me of Patient	Date	Signature	-				
	me of researcher or person Ing consent	Date	Signature	-				

Thank you.

Please return TOP COPY in the stamped, addressed envelope provided to:
Prof Wendy Atkin. SIGGAR1 Trial, Colorectal Unit, St Mark's Hospital, Level 5, Northwick Park, Harrow. HA1 3UJ

Give one copy to the patient, put one copy in the patient's medical notes and keep one copy for your records

V.1.2-19/04/05



The North West London Hospitals

NHS Trust Northwick Park Hospital

Watford Road Harrow Middlesex HA1 3UJ

Tel: 0208 235 4253 Fax: 0208 864 2693

Please

Prof S. Halligan Consultant Radiologist Prof W. Atkin Clinical Epidemiologist

> Please affix address label here

CONSENT FORM

Virtual colonoscopy compared with conventional COLONOSCOPY for diagnosis of bowel disease

				INITIAL box				
1.	I confirm that I have read and understand the information sheet dated May 2005 for the above study and have had the opportunity to ask questions.							
2.	 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. 							
3.	3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. I understand that data collected in this trial may be used for future research and that I cannot be identified from this data.							
4.	In principle I agree to take decision is not binding at t at least 24 hours further to	his point in time a	study. I understand that this nd that I have	INITIAL				
Na	me of Patient	Date	Signature	-				
	me of researcher or person ling consent	Date	Signature	-				

Thank you.

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Give one copy to the patient, put one copy in the patient's medical notes and keep one copy for your records

V.1.2-19/04/05

Special Interest Group in Gastrointestinal & Abdominal Radiology V.21/04/06 BARIUM ENEMA FORM Study number: Hospital number: Patient title: Surname: Please affix address Patient forename: label here Exam Date: d Time: am/pm Exam not performed: Room Time am/bm Exit: am/bm ∟ Procedure Time am/pm Stop: am/pm Reason/Indications: STUDY PERFORMED BY (Please tick (/) ONE box) Reporting Radiologist Radiographer ____ SpR Other Consultant OVERALL ASSESSMENT OF EXAMINATION (Please tick (/) ONE box) Quite easy Quite difficult Very difficult Very easy TECHNICAL DIFFICULTIES (Please tick (<) where option applies) Poor mobility Redundant colon Other Specify: Incontinence to barium MEDICATION (Please tick (✓) as appropriate and indicate dose) Buscopan L ___ mg Other __ Please specify: BOWEL PREPARATION (Please tick (✓) ONE box) Poor Excellent Good Adequate ___ ADVERSE EVENTS (Please describe – use overleaf if necessary) SEGMENTAL VISUALISATION (Please compete as appropriate) Time taken for interpretation: mins (To the nearest half minute) SEGMENT (Code each box) RM DC Quality (1 Excellent, 2 Good, 3 Adequate, 4 Poor, 8 Not Seen) Diverticula (0 None, 1 MIId, 2 Moderate, 3 Severe) OVERALL FINDINGS WITH RESPECT TO COLONIC NEOPLASIA (Please tick (<) where option applies) Normal if normal, confidence that there are no significant polyps or cancer (1 Excellent, 2 Good, 3 Adequate, 4 Poor) Suspected cancer or polyps (please record below) REPORT ON CANCERS OR POLYPS (Please complete for EACH lesion seen) ABCDE F Lesion G н Segment (RM, RS, SC, DC, SF, TC, HF, AC, CM) Estimated size (mm) Cancer (C), Polyp (P) or Unsure (U) Confidence for presence of lesion (1 Excellent, 2 Good, 3 Adequate, 4 Poor) If cancer (C), confidence in diagnosis (1 Excellent, 2 Good, 3 Adequate, 4 Poor) If polyp (P), confidence not cancer (1 Excellent, 2 Good, 3 Adequate, 4 Poor)

OTHER FINDINGS /COMMENTS (Please describe)

ACTION (Please tick (✓) ONE box)

LLI Discharged	Referred back to clinician	Refe								
f YES , please specify		Dat	e: d	d	m	m	У	У	У	У

RADIOLOGIST(S) reading films (Please PRINT and complete as appropriate)

Grade:

Please return TOP (Green) copy to: Prof Wendy Atkin SIGGAR1, CR-UK Colorectal Unit, St Mark's Hospital, FREEPOST LON 2069, Harrow HA1 3BR

ACTION (Please tick (/) ALL boxes as appropriate)

Cancer detected (tick (/) all as appropriate)

Refer to surgeon Procedure requested? If YES, please specify:

No cancer detected (tick (/) all as appropriate)

Refer back to clinician Exam incomplete? Specify procedure referred for:

Polyp detected: Surveillance in years Specify exam: Check excision site in weeks

Discharged

COMMENTS (Please describe)

Name of endoscopist:
(Please PRINT)

CT COLONOGRA	۱P	ΗY	F	C	R	R N	1					
				-								\neg
Study number:	< Ι											
Hospital number:			-									
Patient title: Surname:			\dashv			I		e af				
Patient forename:	_		┙					dress I hei				
Exam Date: dd d mm/y y y y Time:	<u>ш</u>	am/pr	n				labe	rner	е			
Exam not performed: Reason:			┙									
Room Time Enter:amvpm Exit:	Ш	_am/pi	m L	_								_
Procedure Time Start: amvpm Stop:		am/pr	m									
Reason/Indications:												
STUDY PERFORMED BY (Please tick () ONE box)</td <td></td>												
Reporting Radiologist Radiographer		Other C	onsu	tant						Sp	R	
OVERALL ASSESSMENT OF EXAMINATION (Please tick () ONE		- Juli							her -		
Very easy Quite easy MEDICATION (Please tick (✓) as appropriate and indicate do:	so)	Qui	te diff	ICUIT					very o	difficu	IL	
		Diago	0.500	etter [
Buscopan	mer	Pleas	e spe	JIY. L								
Excellent Good Good		^	dequ	ato						Poo	,	
EXAMINATION (Please tick (<)) where option applies)		1	uequ	acc						100		
Slice Collimation: mm (1-5)			No. (of de	tect	or ro	ws	\Box	\Box	(4-64)	
	ine		Gas: (_	-			
Intravenous contrast administered? Oral labeling use TECHNICAL DIFFICULTIES (Please tick (/) where option app		М	echa	nical	insu	fflate	ors u	ised i	? <u> </u>			
			- 01	her			Co	ecify	. \Box			
Incontinence to gas ☐ Poor mob ADVERSE EVENTS (Please describe – use overleaf if necessar			Ol	ner			Spi	ecily				
The series and the series in the series in the series in the series and the series in the series and the series	,,											7
SEGMENTAL VISUALISATION (for prone & supine scans com	nbined)	1										
Time taken for interpretation : I mins Proportion	of 2D t	o 3D re	adin	g (e.	g. 80	:20)			\prod			
Reading platform used, please specify (e.g. Voxar, Vitrea, GE)												
SEGMENT (Code each box)	RM	RS	SC	D	C	SF	T	С	HF	AC	(М
Quality (1 Excellent, 2 Good, 3 Adequate, 4 Poor, 8 Not Seen) Diverticula (0 None, 1 Mild, 2 Moderate, 3 Severe)		\longrightarrow		╀	+			+			+	\dashv
OVERALL FINDINGS WITH RESPECT TO COLONIC NEOPLA	SIA (F	lease ti	ck (/) wt	ere (ontic	n ar	oolle	s)			
Normal. If normal , confidence that there are no significant										1 Poor	, F	
Suspected cancer or polyps (please record below)			CEI (I	EALC	ilenių, a	E GUL	, a,	Mucq	uate, •	• ruui	, _	_
REPORT ON CANCERS OR POLYPS (Please complete for EAC	H lesion	seen)										
Lesion			Α	В	C	D	E	F	G	Н		J
Segment (RM, RS, SC, DC, SF, TC, HF, AC, CM) Estimated size (mm)												Н
Cancer (C), Polyp (P) or Unsure (U)			\Box									Н
Confidence for presence of lesion (1 Excellent, 2 Good, 3 Adequate												
If cancer (C), confidence in diagnosis (1 Excellent, 2 Good, 3 Ade	quate, 4	Poor)								Ш		Ш
If polyp (P), confidence not cancer (1 Excellent, 2 Good, 3 Adequ OTHER COLONIC FINDINGS (Please describe)	ate, 4 P	oor)										
OTHER COLONIC FINDINGS (Please describe)												
EXTRA COLONIC FINDINGS (Please complete as appropriate	d.											
		of any	furth	or a	tion	SHOO	nosta	od or	n ron	ort		
1	Details	Of ally	raitii	crav	Luon	Juq	qesu.	Lu O	Пер	OIL		コ
2												
ACTION (Please tick (-/) ONE box)			_									
☐ Discharged ☐ Referred back to clinician		l	Re	efern	ed fo	r and	othe	r pro	cedu	ıre		1
If YES, please specify				ate:	cl	CI .	m	m	УЦ	/ У	У]
RADIOLOGIST(S) reporting CT (Please PRINT and complete		en metad	10									

Please return TOP (Blue) copy to: Prof Wendy Atkin SIGGAR1, CR-UK Colorectal Unit, St Mark's Hospital, FREEPOST LON 2069, Harrow HA1 3BR

Special Interest Group in Gastrointestinal & Abdominal Radiology V.21/04/06 FLEXIBLE SIGMOIDOSCOPY FORM Study number: Hospital number: Patient title: Surname: Please affix address Patient forename: label here Exam Date: Time: am/pm Exam not performed: Room Time Enter: am/bm am/bm L Procedure Time Start: Stop: am/pm Reason/Indications: OVERALL ASSESSMENT OF EXAMINATION (Please tick (/) ONE box only) Very difficult Very easy Quite easy Quite difficult BOWEL PREPARATION (Please tick (/) ONE box only) Poor Excellent Adequate ____ OVERALL FINDINGS (Please tick (/) as appropriate) COMPLETENESS OF EXAMINATION Normal Segment reached (RM, RS, SC, DC, SF, TC)? Suspected cancer (record below) Examination complete (to SC/DC junction)? Yes No Polyps (record below) Pain Faeces Other If NO, reason, please tick (✓): Other, please specify below or overleaf specify: Maximum shaft insertion? cm ADVERSE EVENTS (Please describe – use overleaf if necessary) POLYPS/ CANCERS/ BIOPSIES - see overleaf for guide to filling form (Please complete ONE line for each lesion) Please tick (/) ONE box for EACH qu Distance from Anus (cm) PTO PTO Α В c D Ε F G Н ī RM HF SEGMENT (Code each box) CM Diverticula: (0 None, 1 Mild, 2 Moderate, 3 Severe) OTHER FINDINGS/DIAGNOSES (Please describe)

weeks

Discharged **COMMENTS** (Please describe)

Name of endoscopist: Signature: (Please PRINT)

SI	pecial inte	rest Grou	ın in (Gastrointestinal	&	Abdominal	Radiology
-	pecial inte	icst dioc	ф	dasa omicesamai		ADDONISION	naulology

V.21/04/06

Special Interest Group In GastroIntestInal & Abdominal Radiology SURGICAL RECORD FORM

Study number:
Hospital number:
Patient title: Surname: Please affix
Patient forename: address
Procedure not performed Reason:
Reason/Indications:
Date of operation:
Time: Lift Liam/pm
Surgeon name: Grade:
Assistant name: Grade:
OPERATION RECORD (Please tick (✓) as appropriate)
Site(s) of lesion: RM RS SC DC SF TC HF AC CM Anus Appendix
Intra-operative colonoscopy No 🗌 Yes 📗
Indication: Curative Palliative Unsure Other, specify:
Specify operation type:
Please tick (✓) as appropriate:
Anastomosis: Specify type:
☐ Metastasis: ☐ Liver ☐ Peritoneal ☐ Other, specify
Stoma lleostomy: Permanent
Stoma Colostomy: Permanent
POST-OPERATIVE COURSE
Length of hospital stay days
If >16 days, give reason:
MAJOR COMPLICATIONS (Please tick (✓) as appropriate)
Pease specify treatment
Anastomotic leak
Burst abdomen (requiring resuture)
Wound infection (delaying discharge)
Other, please specify:
OTHER COMMENTS: (attach clinical records where relevant)

OUTPATIENT FOLLOW-UP FORM

Study number: Hospital number: Patient title: Patient forename: Sex Appointment date: Appointment time: Did not attend Reason:		Please affix address label here
OP APPOINTMENT DETAILS (Please co	omplete as appropriate)	
Consultant in charge of clinic:		
Name of clinician seeing patient (if diff	erent from above):	
	exams that the patient has had – first pro	ocedure is initial randomised procedure)
Randomised Procedure (Please tick (✓		
List other procedures below (in the ord		
2	4	6
3	5	7
COLONIC FINDINGS AT OR AFTER RA	ANDOMISED PROCEDURE (Pleaase tick	(/) ALL boxes that apply)
	cted cancer confirmed cancer ps detected polyps removed	
	COLONOGRAPHY AT OR AFTER RAN	IDOMISED PROCEDURE (If relevant)
☐ incidental to patient's symptoms bu☐ incidental to patient's symptoms an☐ Cause of symptoms, therefore purs	t I feel obliged to investigate d I am going to ignore this finding	
riocedule/lesc	Details of reason why test perion	med
ACTION (Please complete as appropria	te and tick (🗸) ALL boxes that apply)	
Discharge from clinic? Water	h and wait? – see again in Month	s Date: d d m m y y y y
Cancer found, specify treatment:		
	, specify test, reason and date of appoi	Date: d d m m y y y y Date: d d m m y y y y
Refer for non colonic test(s) if yes,	specify test, reason and date of appoint	
		Date: d d m m y y y y Date: d d m m y y y y
		Date.
ANY OTHER COMMENTS		
ANY OTHER COMMENTS		
PERSON COMPLETING FORM	Job title:	

Please return TOP (White) copy to: Prof Wendy Atkin SIGGAR1, CR-UK Colorectal Unit, St Mark's Hospital, FREEPOST LON 2069, Harrow HA13BR