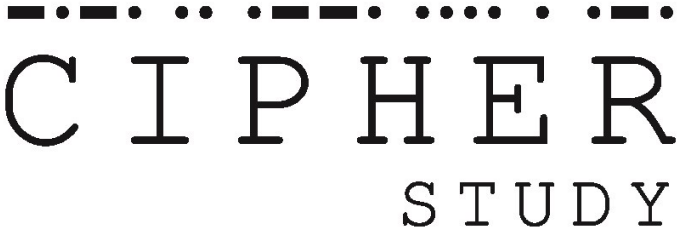


UK Cohort study to Investigate the prevention of Parastomal Hernia

Appendix A—Data Collection

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

SURGEON DETAILS

Most senior surgeon scrubbed in at time of stoma formation:

Name: _____ GMC number: _____

PATIENT DETAILS

Operation date: __ __ /__ __ /__ __ __ __
d d m m y y y y

Operation start time
(defined as knife to skin: time): __ __ : __ __

Operation end time
(defined as time of final skin suture in wound): __ __ : __ __

Month of birth: __ __ Year of birth: __ __ __ __

Patient's Sex: *Male* ☐ *Female* ☐

SURGICAL APPROACH TO STOMA FORMATION

Indication for surgery (***please select one option***):

- Tumour – benign ☐
- Tumour – malignant ☐
- Diverticular Disease ☐
- Functional Intestinal Disorder ☐
- Inflammatory Bowel Disease (IBD) ☐
- IBD – Crohn's ☐
- IBD – Ulcerative Colitis ☐
- Other ☐

If other, specify: _____

ASA Classification:

- I ☐
- II ☐
- III ☐
- IV ☐
- V ☐

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

Name of procedures (tick YES or NO as appropriate for each):

	Yes	*No*
Small bowel resection	☐	☐
Colectomy: left (including sigmoid colectomy and anterior resection)	☐	☐
Colectomy: right (including ileocaecal resection)	☐	☐
Colectomy: subtotal or panproctocolectomy	☐	☐
Hartmann's procedure	☐	☐
Colorectal resection – other	☐	☐
Reduction of volvulus	☐	☐
Stricturoplasty	☐	☐
Drainage of abscess/collection	☐	☐
Debridement	☐	☐
Abdominoperineal excision	☐	☐
Posterior pelvic exenteration	☐	☐
Repair or revision of anastomosis	☐	☐
Repair of intestinal fistula	☐	☐
Resection of other intra-abdominal tumour(s)	☐	☐
Stoma formation	☐	☐
Other	☐	☐

If other, specify: _____

If **YES** to ***abdominoperineal excision*** or ***posterior pelvic exenteration***:

Vertical rectus abdominis myocutaneous (VRAM) flap *Yes* ☐ *No* ☐

Intended type of access used (***please select one***):

- SLS ☐
- Laparoscopic ☐
- Robotic ☐
- Open ☐
- Trephine ☐

Intended type of procedure converted to open: *Yes* ☐ *No* ☐
***(Do not answer if intended type of access* was open)**

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

Envisaged longevity of stoma: Permanent ☐ Uncertain ☐

Type of stoma formed (***please select one***):

- End ☐
- Loop ☐ → If **loop**, with or without rod: With ☐ Without ☐
- Loop end ☐
- Double barrelled ☐
- Other ☐

Section of bowel used to form functioning end of stoma (***please select one***):

- Jejunum ☐
- Ileum ☐
- Ascending colon ☐
- Transverse colon ☐
- Descending colon ☐
- Sigmoid colon ☐

Stoma site pre-marked (***please select one***):

- Not preserved ☐
- Preserved with suture ☐ →
- Pre-marked with pen ☐ →

If ***preserved with suture*** or ***pre-marked with pen***,

Stoma site marked by (***please select one***):

- Stoma nurse ☐
- Surgeon ☐
- Non-specialist nurse ☐
- Other ☐

If other, specify: _____

Stoma formed at pre-marked site: *Yes* ☐ *No* ☐

Route of stoma: Trans-peritoneal ☐ Extra-peritoneal ☐

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

TREPHINE FORMATION

Subcutaneous tissue excised: *Yes* ☐ *No* ☐

Relationship of the muscle layer incision to the rectus abdominis (***please select one***):

- Outside of the rectus sheath (within oblique abdominal muscles) ☐ → **Continue on next page**
- Within the rectus sheath - though the belly of the rectus abdominis ☐
- Within the rectus sheath - lateral to the belly of the rectus abdominis ☐

Complete the box below

Anterior sheath: was a laparoscopic trocar used to puncture the anterior sheath ***(Only answer for laparoscopic or robotic procedures)*** *Yes* ☐ *No* ☐

Anterior sheath: size of incision [widest diameter in mm] _____

Anterior sheath: Shape of incision (***please select one***)

Linear - horizontal	—	☐
Linear - vertical	|	☐
Cruciate	+	☐
Circular	○	☐
Other	?	☐

Anterior sheath: was any of the anterior sheath removed *Yes* ☐ *No* ☐

Anterior sheath: adjustments made to the size of the incision *Yes* ☐ *No* ☐

Posterior sheath: was a laparoscopic trocar used to puncture the posterior sheath ***(Only answer for laparoscopic or robotic procedures)*** *Yes* ☐ *No* ☐

Posterior sheath: size of incision [widest diameter in mm] _____

Posterior sheath: Shape of incision (***please select one***)

Linear - horizontal	—	☐
Linear - vertical	|	☐
Cruciate	+	☐
Circular	○	☐
Other	?	☐

Posterior sheath: was any of the posterior sheath removed *Yes* ☐ *No* ☐

Posterior sheath: adjustments made to the size of the incision *Yes* ☐ *No* ☐

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

Muscle fibres separated with blunt dissection *Yes* ☐ *No* ☐

Intra-operative vessel damage - epigastric vessel *Yes* ☐ *No* ☐

Location of trephine in relation to port site (***please select one***):
(Only answer for laparoscopic or robotic procedures, **including procedures converted to open)**

- Trephine created at the port site as the beginning of procedure (then subsequently used as port site) ☐
- Trephine created at end of procedure (conversion of port site to trephine) ☐
- Trephine created in a location other than port site ☐

Were sutures used to buttress the incision (***please select one***):
(Only answer if relationship of the muscle layer incision to the rectus abdominis is "within rectus sheath")

- Anterior sheath only ☐
- Posterior sheath only ☐
- Both anterior and posterior sheath ☐
- Anterior and posterior sheath sutured together ☐
- No ☐

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

REINFORCING THE STOMA TREPHINE WITH MESH

Was mesh used to reinforce the stoma trephine *Yes* ☐ *No* ☐ → If **NO,** continue on next page

If **YES**, complete the box below

Mesh product code (attach product sticker) — ***Attach product sticker here***

Mesh cut or adjusted *Yes* ☐ *No* ☐

If **YES**,

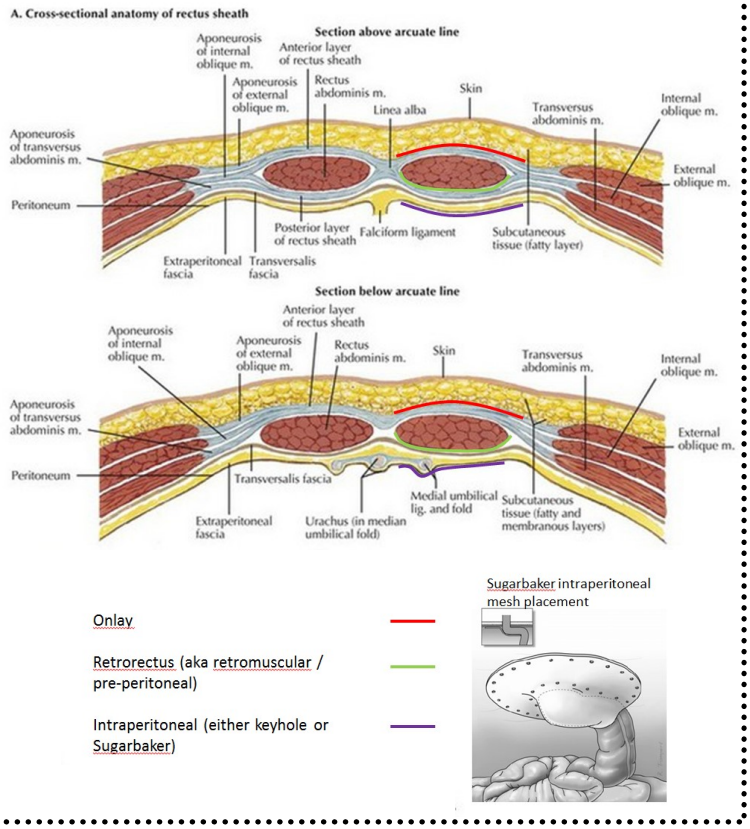
Craniocaudal length of mesh inserted if changed from original [in cm] _____

Medio-lateral length of mesh inserted if changed from original [in cm] _____

Diameter of mesh inserted if changed from original [in cm] _____

Shape of mesh inserted if changes from original (***please select one***):

- 3D/funnel ☐
- Circular/Oval ☐
- Square/rectangular ☐
- No change in shape ☐



Location of mesh replacement (***please select one***):

- Sublay/pre-peritoneal/retro-rectus ☐
- Underlay/intra-peritoneal ☐
- Onlay ☐

Route used to position mesh (***please select one***):

- Through the main operative incision ☐
- Through the stoma trephine ☐
- Via a port ☐

What shape was the hole in the mesh?

Cruciate ☐ Circular/oval ☐ Slit ☐ None (Sugarbaker) ☐

What size was the hole in the mesh [in mm] _____

Mesh secured to abdominal wall (including sheath, muscle, peritoneum) *Yes* ☐ *No* ☐

Mesh secured to stoma serosa *Yes* ☐ *No* ☐

SURGICAL TECHNIQUE

Patient Initials: ☐☐☐

CIPHER Study ID: ☐☐☐-☐☐☐☐

USE OF THE STOMA TREPHINE AS A SPECIMEN EXTRACTION SITE

Stoma trephine used as an extraction site *Yes* ☐ *No* ☐

CLOSURE OF OTHER WOUNDS FORMED DURING THE PROCEDURE

Main abdominal incision (***please select one***):

Small bite closure ☐

Large bite closure ☐

N/A ☐

Biggest port size [in mm] _____
(Only answer for laparoscopic or robotic procedures, including procedures converted to open)

Closure of deep layer *Yes* ☐ *No* ☐
(Only answer for laparoscopic or robotic procedures, including procedures converted to open)

SPOUTING THE STOMA LUMEN

Has the stoma been spouted *Yes* ☐ *No* ☐

COMMENTS

_____

_____

_____

_____

Who has collated this data?

GMC/NMC number: _____

Date completed: __ __ / __ __ /__ __ __ __

CIPHER STUDY

The CIPHER Study

PATIENT DETAILS

A1

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

ELIGIBILITY CRITERIA AND CONSENT DETAILS

Inclusion criteria	YES	NO
Aged ≥ 18 years of age	☐	☐
Undergoing NCEPOD elective or expedited surgery to create an ileostomy or colostomy	☐	☐
If **YES,** specify stoma type		
Ileostomy	☐	
Colostomy	☐	

Exclusion criteria	YES	NO
Undergoing NCEPOD urgent or immediate stoma formation surgery	☐	☐
Intention to form double barrelled stoma	☐	☐
Urostomy formation	☐	☐
Previous abdominal wall stoma	☐	☐
Life expectancy <12 months from index operation	☐	☐

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS NOT ELIGIBLE FOR THE TRIAL

Did the patient consent to participate? *Yes* ☐ *No* ☐ If **YES,** specify date: __ __/__ __/__ __ __ __ (d d / m m / y y y y)

Was the patient consented retrospectively? *Yes* ☐ *No* ☐ Was the patient consented by post? *Yes* ☐ *No* ☐

Did the patient consent to their information being stored for use in future research? *Yes* ☐ *No* ☐

Did the patient consent to be contacted about future ethically approved studies? *Yes* ☐ *No* ☐

PATIENT DETAILS

Patient's name: _____ NHS/CHI Number: ☐☐☐☐☐☐☐☐☐☐

Patient's Sex: *Male* ☐ *Female* ☐

Patient's title *(tick one):* *Dr* ☐ *Miss* ☐ *Ms* ☐ *Mrs* ☐ *Mr* ☐

Please complete the patient address below or apply addressograph.

Patient address: _____

_____

Patient post code: _____

PATIENT CONTACT DETAILS

Can the patient be contacted by:

Post	*Yes* ☐	*No* ☐		
Home phone	*Yes* ☐	*No* ☐	If **YES,** provide phone number:	_____
Mobile phone	*Yes* ☐	*No* ☐	If **YES,** provide phone number:	_____
Can answer messages be left?	*Yes* ☐	*No* ☐		
Text / SMS	*Yes* ☐	*No* ☐		
Email	*Yes* ☐	*No* ☐	If **YES,** provide email address:	_____

Patients preferred method of completing follow-up questionnaires *(tick one)*: *Post* ☐ *Online* ☐

Would the patient like to receive a summary of trial results? *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

BASELINE DETAILS

B[1]

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

BASELINE CLINICAL DETAILS

Height ☐☐☐ *cm* Weight ☐☐☐.☐ *kg*

MEDICAL HISTORY

	Yes	*No*		
Diabetes	☐	☐	If **YES**, specify type:	Type 1: ☐ Type 2: ☐
Chronic kidney disease	☐	☐	If **YES**, specify stage:	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Previous abdominal surgery	☐	☐	If **YES**, specify:	At site of planned stoma ☐ Other site ☐
Abdominal wall hernia	☐	☐	If **YES**, specify:	Previous ☐ Existing ☐

Muscular or connective tissue disorder (*tick as many as apply)*:

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Aneurysm disease	☐	☐	Osteogenesis imperfecta	☐	☐	SLE	☐	☐
Ehlers-danlos syndrome	☐	☐	Scleroderma	☐	☐	Other:	☐	☐
Marfan syndrome	☐	☐	Rheumatoid	☐	☐	If yes, specify: _____		

Parity (number of pregnancies over 20 weeks) ☐

Frailty score ☐

Canadian Study of Health and Ageing (CSHA) Frailty Score (Rockwood Score)

DALHOUSIE UNIVERSITY *Inspiring Minds*

1 – Very fit	Robust, active, energetic, well-motivated and fit; these people commonly exercise regularly and are in the most fit group for their age.
2 – Well	Without active diseases, but less fit than people in category 1.
3 – Well, with treated comorbid disease	Disease symptoms are well controlled compared with those in category 4.
4 – Apparently vulnerable	Although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms.
5 – Mildly frail	With limited dependence on others for instrumental activities of daily leaving.
6 – Moderately frail	Help is needed with both instrumental and non-instrumental* activities of daily living.
7 – Severely frail	Completely dependent on others for activities of daily living, or terminally ill.

**Non-instrumental activities of daily living are basic everyday tasks such as walking, bathing, dressing, toileting, brushing teeth and eating. Instrumental activities of daily living are further tasks such as cooking, shopping, driving etc.*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

BASELINE DETAILS

B²

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

CURRENT HEALTH STATUS

Smoking status (*please select one option):*

Non-smoker ☐ Ex-smoker (minimum 3 months tobacco free) ☐ Current smoker ☐

Is the patient taking:

	Yes	*No*
Therapeutic oral or injected corticosteroids (e.g. prednisolone, cortisone, dexamethasone, other…)	☐	☐
Immuno-suppressive medication (e.g. renal and transplant-related, such as cyclosporin)	☐	☐
Disease modifying agents (e.g. methotrexate, sulfasalazine, hydroxychloroquine, azathioprine) or biological agents (e.g. etanercept, adalimumab, infliximab)	☐	☐

COMPLETE FOR PATIENTS UNDERGOING RESECTION + STOMA FORMATION FOR CANCER

	Yes	*No*
Is the patient undergoing stoma formation for cancer?	☐	☐
If **YES,** has the patient had a previous resection and / or neoadjuvant treatment?	☐	☐

If **YES**, tick all that apply:

	Yes	*No*
Disease resection / debulking	☐	☐
Neoadjuvant chemoradiotherapy	☐	☐
Neoadjuvant chemotherapy only	☐	☐
Neoadjuvant radiotherapy only	☐	☐

PATIENT QUESTIONNAIRES

Has the patient completed the baseline questionnaires:

	Yes	*No*
EQ-5D-5L	☐	☐
SF-12	☐	☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

DISCHARGE

C[1]

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

OPERATION AND DISCHARGE DETAILS

Operation date: __ __/__ __/__ __ __ __ (d d m m y y y y)

Discharge date: __ __/__ __/__ __ __ __ (d d m m y y y y)

POST OPERATIVE CARE

Date the patient was mobilised (*definition: getting out of bed*): __ __/__ __/__ __ __ __ (d d m m y y y y)

Admitted to HDU/ITU: *Yes* ☐ *No* ☐ If **YES**, specify: Planned: ☐ Unplanned: ☐

POST OPERATIVE GENERAL SURGICAL COMPLICATIONS

	Yes	*No*	If yes, date started (d d m m y y y y)	Select Severity for all complications
Bleeding	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Transfuse; **Moderate** - Embolisation (IR); **Severe** - Return to theatre)				
Chest infection	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Antibiotics; **Moderate** - Oxygen support; **Severe** - Ventilation/intensive care)				
Urine infection	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - First line antibiotics; **Moderate** - Second line antibiotic; **Severe** - Pyelonephritis)				
Intra-abdominal infection	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Antibiotics; **Moderate** - Interventional radiology; **Severe** - Laparotomy)				
Infection at stoma site	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Antibiotics; **Moderate** - Interventional radiology; **Severe** - Laparotomy)				
Infection at other incisional site	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Antibiotics; **Moderate** - Interventional radiology; **Severe** - Laparotomy)				
Wound dehiscence	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Superficial (skin); **Moderate** - Deep (fascia); **Severe** - Return to theatre)				
If yes, specify location:				**Port site** ☐ **Midline** ☐ **Extraction site** ☐ **Perineal** ☐
Wound seroma	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Drain on ward (aspirate) **Moderate** - Interventional radiology drain; **Severe** - Return to theatre))				

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

POST OPERATIVE GENERAL SURGICAL COMPLICATIONS continued...

	Yes	*No*	If yes, date started	Select Severity for all complications
Wound haematoma	☐	☐	__ __/__ __/__ __ __ __ (*d d m m y y y y*)	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Drain on ward (remove wound clips); **Moderate** - Antibiotics; **Severe** - Return to theatre)				
Incisional hernia	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - <4cm in size; **Moderate** - ≥4 and <10cm in size; **Severe** - ≥10cm in size)				
If yes, specify location:			**Port site** ☐ **Midline** ☐ **Extraction site** ☐ **Perineal** ☐	
Ileus	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - <5 days; **Moderate** - ≥5 days, no IV feeding; **Severe** - IV feeding)				
Deep vein thrombosis	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Below the knee; **Moderate** - Above the knee; **Severe** - Above the knee and in the vena cava)				
Pulmonary embolism	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Diagnosed radiologically, no effect on patient (except anticoagulant); **Moderate** - Endovascular intervention;				
Myocardial infarction	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Pharmacological treatment; **Moderate** - Cath lab intervention (PCI); **Severe** - ICU management)				
Delirium	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Occurs at night time only; **Moderate** - Occurs at all hours; **Severe** - Psychiatric input required				
Kidney failure	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - IV fluid; **Moderate** - Dialysis outside ICU; **Severe** - Dialysis in ICU)				
Pressure sore	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐
(Definitions: **Mild** - Grade 1 & 2; **Moderate** - Grade 3/4; **Severe** - Surgical intervention)				
Permanent stroke	☐	☐	__ __/__ __/__ __ __ __	
Return to theatre	☐	☐	__ __/__ __/__ __ __ __	
Death	☐	☐	__ __/__ __/__ __ __ __	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

COLORECTAL SURGERY SPECIFIC COMPLICATIONS

	Yes	No	If yes, date started	Select Severity for all complications
Anastomotic leak	☐	☐	__ __/__ __/__ __ __ __ (d d m m y y y y)	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Antibiotics; **Moderate** - Radiological intervention; **Severe** - Return to theatre)

Anal/rectal stump dehiscence	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Antibiotics; **Moderate** - Radiological intervention; **Severe** - Return to theatre)

STOMA SURGERY SPECIFIC COMPLICATIONS

	Yes	No	If yes, date started	Select Severity for all complications
Mucotaneous dehiscence	☐	☐	__ __/__ __/__ __ __ __ (d d m m y y y y)	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Superficial separation at the mucotaneous junction (MCJ), either partial or circumferential;

Moderate - Involvement of dermis layer leading to increase in width or depth of separation, partial or circumferential;

Stenosis	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Tightening/narrowing of the stoma orifice, no dilation required; **Moderate** - Ability to dilate, functioning ribbon like stool; **Severe** - Non-functioning, unable to dilate)

Prolapse	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Variation in night and day length; **Moderate** - Persistent increase in length, functioning; **Severe** - Persistent increase in length, non functioning)

Retraction	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Stoma partially retracted below skin level but manageable with stoma appliance; **Moderate** - Stoma mucosa below skin level, managed with stoma appliance/accessory; **Severe** - Stoma below skin level, unable to manage with ostomy products)

Ischaemia/necrosis	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - Dark areas on stoma; **Moderate** - Partial tissue death; **Severe** - Entire stoma cold and black (necrotic))

Peristomal skin problems	☐	☐	__ __/__ __/__ __ __ __	**Mild** ☐ **Moderate** ☐ **Severe** ☐

(Definitions: **Mild** - <25% affected area; **Moderate** - ≥25% and <50% affected area; **Severe** - ≥50% affected area)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

PRE-DISCHARGE WOUND QUESTIONNAIRE:

The following questions ask about how the patient's wound(s) has(have) healed since having surgery. Please tick the box that is most relevant to your experience. If the patient has more than one wound, please answer the questions **thinking about just one inci-**

		Not at all	A little	Quite a bit	A lot
1.	Was there redness spreading away from the wound? (erythema/cellulitis)	☐	☐	☐	☐
2.	Was the area around the wound warmer than the surrounding skin?	☐	☐	☐	☐
3.	Has any part of the wound leaked clear fluid? (serous exudate)	☐	☐	☐	☐
4.	Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	☐	☐	☐	☐
5.	Has any part of the wound leaked thick and yellow/green fluid? (pus/purulent exudate)	☐	☐	☐	☐
6.	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	☐	☐	☐	☐
	a) Did the deeper tissue separate?	☐	☐	☐	☐
7.	Has the area around the wound become swollen?	☐	☐	☐	☐
8.	Has the wound been smelly?	☐	☐	☐	☐
9.	Has the wound been painful to touch?	☐	☐	☐	☐
10.	Has the patient had, or felt like they have had, a raised temperature or fever? (fever >38°C)	☐	☐	☐	☐

		Yes	No
11.	Has the patient sought advice because of a problem with their wound?	☐	☐
12.	Has anything been put on the skin to cover the wound? (dressing)	☐	☐
13.	Has the patient been given antibiotics for a problem with their wound?	☐	☐
14.	Have the edges of the wound been deliberately separated by a doctor or nurse?	☐	☐
15.	Has the wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	☐	☐
16.	Has the wound been drained on the ward? (drainage of pus /abscess)	☐	☐
17.	Has the patient had an operation under general anaesthetic for treatment of a problem with their wound?	☐	☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

CT Scans

Has the patient had a CT scan since their surgery? *Yes* ☐ *No* ☐

If **YES**, please enter date:

CT Scan 1 __ __/__ __/__ __ __ __ (*d d m m y y y y*)

CT Scan 2 __ __/__ __/__ __ __ __ (*d d m m y y y y*)

CT Scan 3 __ __/__ __/__ __ __ __ (*d d m m y y y y*)

CT Scan 4 __ __/__ __/__ __ __ __ (*d d m m y y y y*)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

FOLLOW UP DATA

Is the patient still in hospital 6 weeks after surgery?

Yes ☐ → ***If YES**, do not complete this page. Please complete the 6 week questionnaire pack with the patient. This would usually be sent to the patient at home.*

No ☐ → ***If NO**, please complete the rest of this page.*

Date of 6-week follow up: __ __/__ __/__ __ __ __ (d d m m y y y y)

How many SCN appointments has the patient had since discharge? ☐☐

Has the patient been admitted to hospital since discharge? Yes ☐ No ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had a CT scan since discharge? Yes ☐ No ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient experienced any major surgical complications since discharge (e.g. deep vein thrombosis, stroke)? Yes ☐ No ☐

There is no need to record stoma specific complications (e.g. leakage or skin problems) as these will be recorded in the stoma questionnaire.

If yes, please specify:

Has the patient had their stoma closed since discharge? Yes ☐ No ☐

If **YES**,

Date of closure: __ __/__ __/__ __ __ __

Does the patient have a parastomal hernia or did the patient have one at the time of closure? Yes ☐ No ☐ Don't know ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

6-MONTH FOLLOW UP

D²

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

FOLLOW UP DATA

Date of 6-month follow up: __ __/__ __/__ __ __ __ (d d m m y y y y)

How many SCN appointments has the patient had since their 6-week follow up? ☐☐

Has the patient been admitted to hospital since their 6-week follow up? *Yes* ☐ *No* ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had a CT scan since their 6-week follow up? *Yes* ☐ *No* ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient experienced any major surgical complications since discharge (e.g. deep vein thrombosis, stroke)? *Yes* ☐ *No* ☐

There is no need to record stoma specific complications (e.g leakage or skin problems) as these will be recorded in the stoma questionnaire.

If yes, please specify:

Has the patient had their stoma closed since their 6-week follow up? *Yes* ☐ *No* ☐

If **YES**,

Date of closure: __ __/__ __/__ __ __ __

Does the patient have a parastomal hernia or did the patient have one at the time of closure? *Yes* ☐ *No* ☐ *Don't know* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

FOLLOW UP DATA

Date of 12-month follow up: __ __/__ __/__ __ __ __ (d d m m y y y y)

How many SCN appointments has the patient had since their 6-month follow up? ☐☐

Has the patient been admitted to hospital since their 6-month follow up? *Yes* ☐ *No* ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had a CT scan since their 6-month follow up? *Yes* ☐ *No* ☐

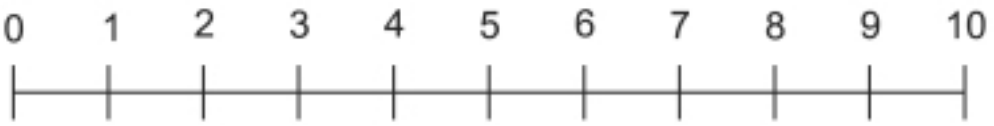
If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Using the scale below, please mark with a circle how well you think the patient is coping with their stoma.



Is not managing at Could not be man-

Has the patient had their stoma closed since their 6-month follow up? *Yes* ☐ *No* ☐

If **YES**,

Date of closure: __ __/__ __/__ __ __ __

Does the patient have a parastomal hernia or did the patient have one at the time of closure? *Yes* ☐ *No* ☐ *Don't know* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

FOLLOW UP DATA

Date of 18-month follow up: __ __/__ __/__ __ __ __ (d d m m y y y y)

How many SCN appointments has the patient had since their 12-month follow up? ☐☐

Has the patient been admitted to hospital since their 12-month follow up? *Yes* ☐ *No* ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had a CT scan since their 12-month follow up? *Yes* ☐ *No* ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had their stoma closed since their 12-month follow up? *Yes* ☐ *No* ☐

If **YES**,

Date of closure: __ __/__ __/__ __ __ __

Does the patient have a parastomal hernia or did the patient have one at the time of closure? *Yes* ☐ *No* ☐ *Don't know* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

24-MONTH FOLLOW UP

D5

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

FOLLOW UP DATA

Date of 24-month follow up: __ __/__ __/__ __ __ __ (d d m m y y y y)

How many SCN appointments has the patient had since their 18-month follow up? ☐☐

Has the patient been admitted to hospital since their 18-month follow up? Yes ☐ No ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had a CT scan since their 18-month follow up? Yes ☐ No ☐

If **YES**, date*: __ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

__ __/__ __/__ __ __ __ (d d m m y y y y) Name of hospital: _____

*The date can be approximate

Has the patient had their stoma closed since their 18-month follow up? Yes ☐ No ☐

If **YES**,

Date of closure: __ __/__ __/__ __ __ __

Does the patient have a parastomal hernia or did the patient have one at the time of closure? Yes ☐ No ☐ Don't know ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CIPHER STUDY

The CIPHER Study

WITHDRAWAL / DISCONTINUATION FORM

W1

Patient Initials: ☐☐☐

CIPHER STUDY ID: ☐☐☐-☐☐☐☐

If the patient has died, only complete Part B.

PART A: WITHDRAWAL DATA

Date of withdrawal from study: __ __/__ __/__ __ __ __ (d d / m m / y y y y)

REASON FOR WITHDRAWAL

	Yes	No
Patient choice	☐	☐

If **YES**, specify reason:

- Patient changed their mind about the study ☐
- Patient no longer wants to complete questionnaires ☐
- No reason given ☐
- Other ☐

If **OTHER**, specify reason: _____

	Yes	No
Clinician choice	☐	☐

If **YES**, specify reason:

- Patient no longer having a stoma formed ☐
- Change to planned surgery making patient ineligible ☐

Specify reason for ineligibility _____

- Clinician decision to withdraw patient ☐
- Other ☐

If **OTHER**, specify reason: _____

ADDITIONAL QUESTION

IMPORTANT: In line with new GDPR guidance, please <u>DO NOT</u> ask patients the question below. Only tick 'NO' if the patient has made a specific request, otherwise tick 'YES':

	Yes	No
Is the patient willing for data routinely collected about them by the NHS to continue to be used in this study?	☐	☐

If the patient withdraws from the study, a photocopy of the completed withdrawal form should be stapled to the front of the copy of the Patient Consent Form in the patient's notes.

Additional information (only complete if relevant)

PART B: PATIENT DEATH

Date of death: __ __/__ __/__ __ __ __ (d d / m m / y y y y)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

FOLLOW UP QUESTIONS

Please complete the following questions:

	Yes	*No*
Have you been admitted to hospital since your surgery?	☐	☐

If **YES**, please complete the date of admission and name of hospital for each admission.
Date of admission can be approximate.

Date: _____ Name of hospital: _____

Date: _____ Name of hospital: _____

Date: _____ Name of hospital: _____

	Yes	*No*
Have you had a CT scan since your surgery?	☐	☐

If **YES**, please complete the date of scan and name of hospital at which the scan took place.
Date of scan can be approximate.

Date: _____ Name of hospital: _____

Date: _____ Name of hospital: _____

Date: _____ Name of hospital: _____

	Yes	*No*
Have you abstained from heavy lifting?	☐	☐
Have you used a support garment?	☐	☐
Do you currently exercise?	☐	☐

If yes, at what level?

Gentle; walking (5-10mins), gentle abdominal exercise, gentle pilates, leisurely swim, yoga ☐

Moderate; aqua aerobics, gardening, brisk walking (30-45 min), golf ☐

Rigorous; football, tennis, gym, skiing, hill climbing, jogging, squash, cycling ☐

	Yes	*No*
Have you been performing abdominal strengthening exercises?	☐	☐

Any other comments:

FOLLOW UP QUESTIONS

Community-Based Health Care Questions

We would like you to answer some questions about the community-based health care you have had as a result of **your bowel disease or stoma in the last 6 months**. We only want you to include health care you had as an NHS patient. We use hospital records to identify care that you received at the time of your surgery and other hospital admissions and outpatient appointments, so in this questionnaire we only ask about care you have received in the community.

It is important for us to find out what health care you have and have not used, so please answer all of the questions, even if your answer is zero. If you are unsure of an answer, please write your best

1. How many times have you visited a doctor (GP) at a GP surgery or health clinic for your bowel disease or stoma? ☐☐

2. How many times have you visited another health care professional (e.g. a nurse or physiotherapist) at a GP surgery or health clinic for your bowel disease or stoma? ☐☐

3. How many times has a doctor (GP) visited you at your home for your bowel disease or stoma? ☐☐

4. How many times has another health care professional (e.g. a stoma nurse, community nurse or health visitor) visited you at your home for your bowel disease or stoma? ☐☐

EQ-5D-5L QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN/DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

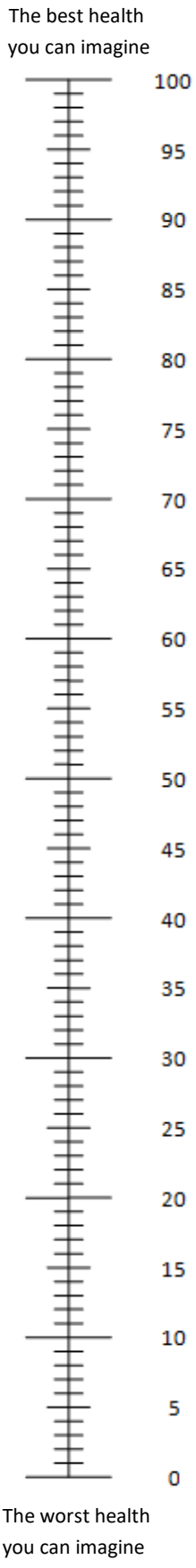
I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

EQ-5D-5L QUESTIONNAIRE

- **We would like to know how good or bad your health is TODAY.**
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.

  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



SF-12 QUESTIONNAIRE

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
b) Climbing <u>several</u> flights of stairs	☐	☐	☐

3. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) <u>Accomplished less</u> than you would like	☐	☐	☐	☐	☐
b) Were limited in the <u>kind</u> of work or other activities	☐	☐	☐	☐	☐

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) <u>Accomplished less</u> than you would like	☐	☐	☐	☐	☐
b) Did work or other activities <u>less carefully than usual</u>	☐	☐	☐	☐	☐

SF-12 QUESTIONNAIRE

5. During the <u>past 4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

6. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐	☐	☐	☐	☐
b) Did you have a lot of energy?	☐	☐	☐	☐	☐
c) Have you felt downhearted and low?	☐	☐	☐	☐	☐

7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

(IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

STOMA QUESTIONNAIRE

Depending on the type of stoma you have had, it is possible your stoma has been closed. Please indicate below if you have had your stoma closed.

☐ **Yes, I have had my stoma closed.**
If this is the case, please leave this questionnaire blank.

☐ **No, I have not had my stoma closed.**
If you currently have a stoma, we are interested in knowing how your stoma has been over the last 3 months. Please complete this short questionnaire yourself. It is fine to ask someone else to write the answers for you or help answer some of the questions, for example if you have not been able to care for your stoma yourself.

1. Have you been told by a nurse or doctor that you have a parastomal hernia?

Yes	**No**	**Unsure**
☐	☐	☐

Over the last THREE months…

	Not at all	**A little**	**Quite a bit**	**A lot**
<u>The appearance of your stoma</u>				
2a. Is there a bulge or lump of any size, around or under your stoma?	☐	☐	☐	☐
	↓ If "**Not at all**", go to question 3			
2b. Has the bulge/lump affected your overall satisfaction with your body's appearance (body image)?	☐	☐	☐	☐
3. Have you experienced irritation of the skin around your stoma?	☐	☐	☐	☐
<u>Pain or discomfort</u>				
4. Have you experienced discomfort due to problems with the stoma or bulge around the stoma?	☐	☐	☐	☐
5a. Have you experienced pain due to problems with the stoma or bulge around the stoma?	☐	☐	☐	☐
	↓ If "**Not at all**", go to question 6			

	Yes	**No**
5b. If yes, has the pain required you to seek help from a healthcare professional (e.g. stoma care nurse, doctor, emergency services)?	☐	☐

STOMA QUESTIONNAIRE

Over the last THREE months…

	Not at all	A little	Quite a bit	A lot
Stomach problems				
6. Have you felt nauseated or vomited due to a problem with the stoma or bulge around your stoma?	☐	☐	☐	☐
7. Have you experienced the sensation of feeling bloated due to a problem with the stoma or bulge around your stoma (distension)?	☐	☐	☐	☐
Your stoma bag (stoma appliance)				
8. Have you had difficulty fitting the stoma bag (stoma appliance)?	☐	☐	☐	☐
9. Have you had problems with keeping the stoma bag (stoma appliance) secure to the skin?	☐	☐	☐	☐
10. Have you experienced leaks of fluid or faeces from the stoma bag (stoma appliance)?	☐	☐	☐	☐
11. Have concerns over leaks or bag fitting stopped you from doing what you want do? E.g. being out of the home, being social or active?	☐	☐	☐	☐
12. Have you had your stoma bag (stoma appliance) modified or swapped with a different appliance because of leaks or difficulty attaching the bag?	☐	☐	☐	☐
13. Have you required help from a healthcare professional (e.g. stoma care nurse, doctor, emergency services) due to difficulty managing your stoma bag (stoma appliance)?	☐	☐	☐	☐
14. Have you been worried by bad smells (odour) from your stoma, other than when emptying the bag?	☐	☐	☐	☐

15. Is there anything else you would like to tell us about problems with your stoma or bulge around your stoma?

_____

_____

QUESTIONNAIRE ABOUT LIVING WITH A STOMA

Depending on the type of stoma you have had, it is possible your stoma has been closed. Please indicate below if you have had your stoma closed.

☐ **Yes, I have had my stoma closed.**
If this is the case, please leave this questionnaire blank. There are no further questionnaires for you to complete in this pack.

☐ **No, I have not had my stoma closed.**
If you currently have a stoma, we are interested in how you have been managing and adapting to having a stoma in the last year. These are standard questions (not specifically tailored to having a stoma) which will allow us to interpret your responses in a recognised and established method.

Please indicate, as best you can, how much you think you have been using the strategy described to adapt to having a stoma.

		I haven't been doing this at all	I've been doing this a little bit	I've been doing this quite a lot	I've been doing this a lot
1.	I've been turning to work or other activities to take my mind off things.	☐	☐	☐	☐
2.	I've been concentrating my efforts on doing something about the situation I'm in.	☐	☐	☐	☐
3.	I've been saying to myself "this isn't real."	☐	☐	☐	☐
4.	I've been using alcohol or other drugs to make myself feel better.	☐	☐	☐	☐
5.	I've been getting emotional support from others.	☐	☐	☐	☐
6.	I've been giving up trying to deal with it.	☐	☐	☐	☐
7.	I've been taking action to try to make the situation better.	☐	☐	☐	☐
8.	I've been refusing to believe that it has happened.	☐	☐	☐	☐
9.	I've been saying things to let my unpleasant feelings escape.	☐	☐	☐	☐
10.	I've been getting help and advice from other people.	☐	☐	☐	☐
11.	I've been using alcohol or other drugs to help me get through it.	☐	☐	☐	☐

QUESTIONNAIRE ABOUT LIVING WITH A STOMA

		I haven't been doing this at all	I've been doing this a little bit	I've been doing this quite a lot	I've been doing this a lot
12.	I've been trying to see it in a different light, to make it seem more positive.	☐	☐	☐	☐
13.	I've been criticizing myself.	☐	☐	☐	☐
14.	I've been trying to come up with a strategy about what to do.	☐	☐	☐	☐
15.	I've been getting comfort and understanding from someone.	☐	☐	☐	☐
16.	I've been giving up the attempt to cope.	☐	☐	☐	☐
17.	I've been looking for something good in what is happening.	☐	☐	☐	☐
18.	I've been making jokes about it.	☐	☐	☐	☐
19.	I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	☐	☐	☐	☐
20.	I've been accepting the reality of the fact that it has happened.	☐	☐	☐	☐
21.	I've been expressing my negative feelings.	☐	☐	☐	☐
22.	I've been trying to find comfort in my religion or spiritual beliefs.	☐	☐	☐	☐
23.	I've been trying to get advice or help from other people about what to do.	☐	☐	☐	☐
24.	I've been learning to live with it.	☐	☐	☐	☐
25.	I've been thinking hard about what steps to take.	☐	☐	☐	☐
26.	I've been blaming myself for things that happened.	☐	☐	☐	☐
27.	I've been praying or meditating.	☐	☐	☐	☐
28.	I've been making fun of the situation.	☐	☐	☐	☐

WOUND QUESTIONNAIRE

A. Your wound

The following questions ask about how your wound(s) has(have) healed since you left hospital after having surgery. It includes some problems that may occur with wound healing. Please note these are only possibilities and do not occur for many people. The words in brackets are the medical terminology. Next to each questions, please tick the box that is most relevant to your experience. If you have more than one wound, please answer the questions **thinking about just one wound** — not including the stoma wound.

Since you left hospital after having surgery….

	Not at all	A little	Quite a bit	A lot
1. Was there redness spreading away from the wound? (erythema/ cellulitis)	☐	☐	☐	☐
2. Was the area around the wound warmer than the surrounding skin?	☐	☐	☐	☐
3. Has any part of the wound leaked clear fluid? (serous exudate)	☐	☐	☐	☐
4. Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	☐	☐	☐	☐
5. Has any part of the wound leaked thick and yellow/green fluid (pus/ purulent exudate)	☐	☐	☐	☐
6. Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	☐	☐	☐	☐
	↓ If "**Not at all**", go to question 7			
a) Did the deeper tissue separate?	☐	☐	☐	☐
7. Has the area around the wound become swollen?	☐	☐	☐	☐
8. Has the wound been smelly?	☐	☐	☐	☐
9. Has the wound been painful to touch?	☐	☐	☐	☐
10. Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	☐	☐	☐	☐

WOUND QUESTIONNAIRE

B. Wound care since your surgery

This section includes questions about wound care following your surgery. Please remember these are only possibilities and do not occur for many people. Please tick the box that is most relevant to your experience or write your answers where requested.

Since you left hospital after having surgery….

	Yes	No
11. Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	☐	☐
12. Has anything been put on the skin to cover the wound? (dressing)	☐	☐
13. Have you been back into hospital for treatment of a problem with your wound?	☐	☐
14. Have you been given antibiotics for a problem with your wound?	☐	☐
15. Have the edges of your wound been deliberately separated by a doctor or nurse?	☐	☐
16. Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	☐	☐
17. Has your wound been drained? (drainage of pus /abscess)	☐	☐
18. Have you had an operation under general anaesthetic for treatment of a problem with your wound?	☐	☐

Do you have any other comments to tell us about the healing of your wound?

DATA ITEMS FOR CT SCAN ASSESSMENT

	Data item / question	Data type	Response options	Comment	Level of agreement with 'experts'
1.	What is the body position for scanning?	Categorical	Supine, Prone, Decubitus	Mutually exclusive options	100%
2.	Is there a parastomal hernia?[1]	Categorical	Yes, No	Mutually exclusive options	90%
2a.	If yes, what kind of tissue has herniated? Fat / omentum Bowel Other	 Categorical Categorical Categorical	 Yes, No Yes, No Yes, No	Separate responses for each. (Multiple types of tissue may have herniated.)	90%
3.	Is there an anterior abdominal wall incisional hernia? [2]	Categorical	Yes, No	Mutually exclusive options	90%
3a.	If yes, what kind of tissue has herniated? Fat / omentum Bowel Other	 Categorical Categorical Categorical	 Yes, No Yes, No Yes, No	Mutually exclusive options for each. But multiple types of tissue may have herniated.	90%
4.	Is there a syphon loop?[3]	Categorical	Yes, No	Mutually exclusive options	90%
5.	Transverse/axial trephine diameter	Continuous	Millimetres – unlikely to be <15mm, possibly up to >100mm	Nearest whole mm. 10% measurement error expected	Within ±10% of measurement 90% of the time
5a.	What is the image slice number from which the measurements were taken?	Continuous	Integer	Not applicable	Not applicable
6.	Transverse/axial parastomal hernia sack diameter ***(conditional on answering 'yes' to question 2)***	Continuous	Millimetres – unlikely to be <30mm, possibly up to >300mm	Nearest whole mm. 10% measurement error expected	Within ±10% of measurement 90% of the time

DATA ITEMS FOR CT SCAN ASSESSMENT

	Data item / question	Data type	Response options	Comment	Level of agreement with 'experts'
7.	Cranio-caudal trephine diameter	Continuous	Millimetres – unlikely to be <15mm, possibly up to >100mm	Nearest whole mm. 10% measurement error expected	Within ±10% of measurement 90% of the time
8.	Cranio-caudal parastomal hernia sack diameter ***(conditional on answering 'yes' to question 2)***	Continuous	Millimetres – unlikely to be <30mm, possibly up to >300mm	Nearest whole mm. 10% measurement error expected	Within ±10% of measurement 90% of the time
9.	Is there an external prolapse of the stoma?	Categorical	Yes, No	Mutually exclusive options	
10.	How difficult was it to make the measurements on the scans?	Categorical	Easy, moderate, difficult	Mutually exclusive options	
10a.	If difficult, please explain.	Free text			
11.	How difficult was it to decide on the presence of a PSH?	Categorical	Easy, moderate, difficult	Mutually exclusive options	
11a.	If difficult, please explain.	Free text			

[1] Parastomal hernia: tissue herniating through the abdominal wall adjacent to the trephine for stomal limb of the bowel.

[2] Incisional hernia: tissue herniating through the abdominal wall at the site of a surgical incision (midline or transverse laparoscopic port site).

[3] Syphon loop: (a) sigmoid shape (two bends) of the stomal limb of the bowel, ***and*** (b) subdermal prolapse, ***and*** (c) deviation of the stomal limb of the bowel by more than one bowel diameter.