Supplementary material 1: Blank Case Report Form

HART
Hughes Abdominal Repair Trial

Swansea University
Prifysgol Abertawe

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HART Visit Schedule

Please complete the forms according to the visit schedule below
This page is not entered on the electronic database

Visit	Case Report Form
Baseline	Screening Eligibility
Baseline	Baseline
Baseline	Patient Randomisation Form
Baseline	FACT-C (To be completed prior to randomisation)
Baseline	SF-12 (To be completed prior to randomisation)
Baseline	CSRI (To be completed prior to randomisation)
Baseline	Questionnaire Compliance
Day 1	Intra-operative
Day 1	Randomisation
Up to Discharge	Reoperation
Discharge	Discharge
Up to Day 30	Patient Diary
Day 30	FACT-C
Day 30	SF-12
Day 30	Questionnaire Compliance
Day 30	Colorectal Cancer Stage Form
Unscheduled	SAE Form (Site File)
Month 6	FACT-C
Month 6	SF-12
Month 6	CSRI
Month 6	Questionnaire Compliance
Year One Visit	Year One Visit
Year One Visit	FACT-C
Year One Visit	SF-12
Year One Visit	CSRI

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Year One Visit	Questionnaire Compliance
Year One Visit	Annual Clinical Examination
Year Two Follow-Up	Year Two Visit
Year Two Follow-Up	FACT-C
Year Two Follow-Up	SF-12
Year Two Follow-Up	CSRI
Year Two Follow-Up	Questionnaire Compliance
Year Two Follow-Up	Annual Clinical Examination
Year Three Follow-Up	Year Three Visit
Year Three Follow-Up	FACT-C
Year Three Follow-Up	SF-12
Year Three Follow-Up	CSRI
Year Three Follow-Up	Questionnaire Compliance
Year Three Follow-Up	Annual Clinical Examination
Year Four Follow-Up	Year Four Visit
Year Four Follow-Up	FACT-C
Year Four Follow-Up	SF-12
Year Four Follow-Up	CSRI
Year Four Follow-Up	Questionnaire Compliance
Year Four Follow-Up	Annual Clinical Examination
Year Five Follow-Up	Year Five Visit
Year Five Follow-Up	FACT-C
Year Five Follow-Up	SF-12
Year Five Follow-Up	CSRI
Year Five Follow-Up	Questionnaire Compliance
Year Five Follow-Up	Annual Clinical Examination
Unscheduled	Abdominal Surgery Log
Unscheduled	Stitch Sinus Log
Unscheduled	Discontinuation Form

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Screening Eligibility

Please complete this form after the patient has provided written consent

Please enter patient details

Initials: ☐☐

Date of birth: D D / M M / Y Y Y Y

Gender: Male ☐ Female ☐

Please enter date of consent D D / M M / Y Y Y Y

Please enter the date of the pre-operative CT scan D D / M M / Y Y Y Y

Inclusion Criteria Patient must meet all inclusion criteria to continue in the study

	N/A	Yes	No
Age ≥18 years old		☐	☐
Able to give informed consent		☐	☐
Both standard mass closure and the Hughes repair closure are suitable closing techniques for this patient		☐	☐
Elective patient, for colorectal cancer surgery following full staging investigations including abdominal CT	☐	☐	☐
Emergency patient, strong suspicion of colorectal cancer as per CT	☐	☐	☐

Exclusion criteria Patient must meet all exclusion criteria to continue in the study

	Yes	No
Unable to provide informed consent	☐	☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Baseline Case Report Form

Please complete this form prior to surgery

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ (DD MM YYYY) **Initials:** ☐☐

Demographics

Ethnicity:

Caucasian ☐

Black ☐

Asian ☐

Other ☐

If other, please specify:_____

Height: ☐☐☐ cm **OR** ☐☐,☐☐ ft,in

Weight: ☐☐☐ kg **OR** ☐☐.☐☐ st,lb

Current Concomitant Medication

	Yes	No
On steroids / immunosuppressants	☐	☐
On antihypertensives	☐	☐
On aspirin	☐	☐
On diuretics	☐	☐

DD MM YYYY

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Specific Previous/Current Medical History

	Yes	No
Neoadjuvant Chemotherapy (for colorectal cancer)	☐	☐
Neoadjuvant Radiotherapy (for colorectal cancer)	☐	☐
If yes, please indicate length of radiotherapy course — Short course ☐ Long course ☐		
Diabetes	☐	☐
Connective Tissue Disorder (eg Ehlers Danlos/ Osteogenesis imperfect/ cutis laxa/ congenital dislocations)	☐	☐
Chronic obstructive pulmonary disease (COPD)/ Asthma or other chronic respiratory disease	☐	☐
Abdominal aortic aneurysm (AAA) (known or previous AAA surgery)	☐	☐
Congestive cardiac failure (CCF)	☐	☐
Renal failure	☐	☐
Hepatic failure	☐	☐
High alcohol use (Women> 21units/week, men >28 units/week)	☐	☐
Smoker — Yes ☐ No ☐ Ex-smoker ☐		

Other Previous/Current Medical History

	Yes	No	If yes, please provide details
Gastrointestinal:	☐	☐	
Respiratory:	☐	☐	
Cardiovascular:	☐	☐	
Genito-urinary:	☐	☐	
Haematological:	☐	☐	
Neurological:	☐	☐	
Musculoskeletal:	☐	☐	
Other:	☐	☐	

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Abdominal Surgery History

Has the patient had abdominal surgery previously? Yes ☐ No ☐

If yes, please tick procedure(s) performed. Multiple procedures allowed.

	Yes	No		Yes	No
Incisional hernia repair **(midline)**	☐	☐	Small bowel/large bowel resection	☐	☐
Incisional hernia repair **(other)**	☐	☐	Repair of perforated viscus	☐	☐
Hernia repair **(non-incisional)**	☐	☐	Diagnostic laparoscopy	☐	☐
Hysterectomy	☐	☐	Hepatic resection	☐	☐
Caesarean section	☐	☐	Pancreatic resection/ necrosectomy	☐	☐
Appendicectomy	☐	☐	Vascular procedure	☐	☐
Cholecysectomy	☐	☐	Renal procedure	☐	☐
Splenectomy	☐	☐	Other	☐	☐

If other, please specify: _____

If the patient had a previous abdominal surgery, please indicate the site of incision(s). Multiple sites allowed.

	Yes	No		Yes	No
Midline	☐	☐	Lanz	☐	☐
Subcostal	☐	☐	Flank	☐	☐
Paramedian	☐	☐	Laparoscopic port sites	☐	☐
Pfannenstiel	☐	☐	Other	☐	☐

If other, please specify: _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Current Hernia Status

Does the patient have any **non**-incisional hernias present clinically? Yes ☐ No ☐

If yes, please indicate the site(s) of the hernia(s)

	Yes	No	Bilateral		Yes	No
Spighelian	☐	☐	☐	Epigastric	☐	☐
Lumbar	☐	☐	☐	Umbilical/Paraumbilical	☐	☐
Inguinal	☐	☐	☐	Other	☐	☐
Femoral	☐	☐	☐	If other, please specify site: _____		

Does the patient have any **incisional** hernias present clinically? Yes ☐ No ☐

If yes, please indicate the site(s) of the hernia(s)

	Yes	No		Yes	No
Midline	☐	☐	Lanz	☐	☐
Subcostal	☐	☐	Flank	☐	☐
Paramedian	☐	☐	Laparoscopic port sites	☐	☐
Pfannenstiel	☐	☐	Other	☐	☐

If other, please specify site: _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Patient Randomisation Form

Patient Initials: ☐☐

In preparation for a potential randomisation, please collect the details as described below before surgery. Once you have completed randomisation, please capture the randomisation arm and number on this page and keep with the CRFs.

- Telephone the randomisation system provided by 'Sealed Envelope' on **020 8099 7784**
- The study number is **4278**

Have the closing surgeon's 3 digit investigator (PIN) number ready, but do not write it on this form.

- Patient Date of Birth DD / MM / YYYY
- Patient Gender Male ☐ Female ☐
- Consent Date DD / MM / YYYY

If consent was taken more than 6 weeks before this surgery, the patient should be approached to confirm consent is still freely given.

- Operation Type Emergency ☐ Elective ☐
- All inclusion criteria met? Yes ☐ No ☐
  - *Aged 18 years or older*
  - *Able to give informed consent*
  - *Standard mass and Hughes repair are suitable closure techniques*
  - *Elective or emergency surgical treatment for colorectal cancer*
  - *Midline abdominal incision*
  - *Incision of 5cm or more*
- Any exclusion criteria met? Yes ☐ No ☐
  - *Unable to give informed consent*
  - *Having mesh inserted as planned part of abdominal closure*
  - *Undergoing musculofascial flap closure of perineal defect in abdomino perineal wound closure*

Please document the randomisation details provided

- Randomisation Arm: Hughes ☐ Mass ☐
- Randomisation Number: ☐☐☐

Remember the patient is blinded to the suture type, and should not be informed of their randomisation.

Initials of person completing form.....Date: DD / MM / YYYY

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

PLEASE NOTE:

The following three questionnaires (SF-12, FACT-C and CSRI) have been redacted for copyright reasons

SF-12, FACT-C and CSRI questionnaires are used at multiple follow-up points. They are not reproduced here for every follow-up point. Please refer the follow-up schedule at the beginning of the supplementary material for details of when the questionnaires are used.

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

SF-12 (v2) questionnaire

To be completed by Health Care Professional. Please tick relevant time point.

☐ pre-operative (index operation)	☐12 months	☐ year 4
☐ Day 30	☐ year 2	☐ year 5
☐ 6 months	☐ year 3	

To be completed by the patient. Please complete the following details before completing the questionnaire.

Initials: ☐☐

Date of birth: _ _/ _ _/ _ _ _ _

Date questionnaire completed: _ _/ _ _/ _ _ _ _

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 question, please tick the one box that best describes your answer.

[redacted]

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

SF-12 (v2) questionnaire (cont'd)

[redacted]

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

SF-12 (v2) questionnaire (cont'd)

[redacted]

Thank you for completing these questions!

This project is funded by the National Institute for Health Research, Health Technology Assessment, 12/35/29

NHS
National Institute for
Health Research

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

FACT-C questionnaire

To be completed by Health Care Professional. Please tick relevant time point.

- ☐ pre-operative (index operation)
- ☐ Day 30
- ☐ 6 months
- ☐ 12 months
- ☐ year 2
- ☐ year 3
- ☐ year 4
- ☐ year 5

To be completed by the patient. Please complete the following details before completing the questionnaire.

Initials: ☐☐

Date of birth: __/__/____

Date questionnaire completed: __/__/____

[redacted]

This project is funded by the National Institute for Health Research, Health Technology Assessment, 12/35/29

NHS
National Institute for Health Research

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

[redacted]

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

[redacted]

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Use of health and social-service questionnaire

Client Service Receipt Inventory (CSRI)

To be completed by Health Care Professional. Please tick relevant time point.

☐ pre-operative (index operation)
☐ 6 months
☐ 12 months
☐ year 2
☐ year 3
☐ year 4
☐ year 5

To be completed by the patient. Please complete the following details before completing the questionnaire.

Initials: ☐☐

Date of birth: _ _/_ _/_ _ _ _

Date questionnaire completed: _ _/_ _/_ _ _ _

[redacted]

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

[redacted]

This project is funded by the National Institute for Health Research, Health Technology Assessment, 12/35/29

For Study Team use only

Site number: ☐☐ Patient number: ☐☐☐

Initials of person checking form:.....

NHS
National Institute for Health Research

Baseline
Questionnaire Compliance CRF

This form is intended to be completed prior to randomisation

Patient Details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Date of visit. D D / M M / Y Y Y Y

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify
_____

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify
_____

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify
_____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIA

Intra-operative Case Report Form

Please enter patient details **Date of birth:** __ / __ / ____ **Initials:** ☐☐

What was the date of the surgical procedure? __ / __ / ____

Please enter name of responsible consultant _____

	Registrar ST5 or below	SpR (ST 6-8)	Consultant
Grade of primary anesthetist	☐	☐	☐
Grade of surgeon performing index operation	☐	☐	☐
Grade of surgeon performing abdominal wall closure	☐	☐	☐
Grade of surgeon closing skin	☐	☐	☐

Please tick the proposed surgery outcome (Potentially) Curative ☐

Palliative ☐

What is the patient's ASA grade? 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Please mark which operation was performed? Please select one

APR	☐	Anterior resection	☐
Hartmanns	☐	Left hemicolectomy	☐
Right hemicolectomy	☐	Extended right hemicolocolectomy	☐
Panproctocolectomy	☐	Subtotal colectomy	☐
Sigmoid colectomy	☐	Other	☐

If other, please specify operation performed. _____

Initials of person completing form.....Date: __ / __ / ____

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ **Initials:** ☐☐

DD MM YYYY

Was a stoma formed? (Please select one)

No Stoma	☐	End ileostomy	☐	Loop ileostomy	☐
End colostomy	☐	Loop colostomy	☐	Other	☐

If other, please specify:

_____

What was the mode of the operation?

Open	☐	Laparoscopic assisted	☐
Laparoscopic	☐	Laparoscopic converted to open (midline incision)	☐

If a laparoscopic was converted to open, what was the reason?

Anatomy	☐	Adhesions	☐
Bleeding	☐	Other	☐

If other, please specify: _____

Was the colorectal cancer resected? Yes ☐ No ☐

If no, why was the cancer not resected? _____

Did the patient require an intra-operative transfusion? Yes ☐ No ☐

If yes, please indicate number of units of blood required? ☐☐

Did the patient experience any intra-operative complications? Please report any serious adverse events. Yes ☐ No ☐

DD MM YYYY

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ (DD MM YYYY) **Initials:** ☐☐

Was the wound closed as per randomisation? Yes ☐

No ☐

If the wound was not closed as per randomisation, please specify why.

Abdomen left open ☐

Used mesh (midline) ☐

Flap used (midline) ☐

Other ☐

If other, please specify why

If the wound was not closed as per randomisation, what was the closure method used?

Hughes ☐

Mass ☐

Other ☐

If other, please specify.

If HUGHES Closure

Number of interrupted 1 nylon sutures used. ☐☐

Number of continuous loop PDS sutures used ☐

If MASS Closure

Absorbable ☐ Non-absorbable ☐

Number of sutures? (Please select one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ ≥5 ☐

Suture size 2o ☐ 0 ☐ 1 ☐ 2 ☐

Was a loop suture used? Yes ☐ No ☐

Additional Closure Comments Yes ☐ No ☐

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _ (DD MM YYYY)

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** / / **Initials:** ☐☐

DD MM YYYY

Was an anti-adhesive agent (eg Seprafilm) used intra operatively? Yes ☐ No ☐

What was the final length of midline SKIN incision? ☐☐ cms

Select the **skin closure** method used Surgical clips ☐ Subcuticular absorbable suture(s) ☐

Interrupted sutures ☐ Other ☐

If other, please specify _____

What was the total time taken for the procedure? ☐☐☐ mins

What was the time taken for fascial closure? ☐☐☐ mins

What is the level of post-operative care? ITU ☐ HDU ☐ Ward/PACU ☐

If ITU or HDU, please indicate if this was planned Planned ☐ Unplanned ☐

DD MM YYYY

Initials of person completing form.....Date: __ / __ / ____

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details Date of birth: DD / MM / YYYY Initials:

POSSUM Score Please circle or mark one option for each line.

Age	<61	61-70	>70	
Cardiac	No failure	Diuretic, digoxin angina, hypertension	Peripheral oedema, warfarin, borderline cardiomyopathy	Raised JVP, cardiomegaly
Respiratory	No dyspnoea	Dyspnoea on exertion, mild COAD	Limiting dyspoena (1 flight), moderate COAD	Dyspnoea at rest (>30 RR), pulmonary fibrosis/consolidation
ECG	Normal	AF, rate 60-90	Any other abnormal rhythm, >4/min ectopics, Qwaves, ST/T changes	
Systolic BP	110-130mmHg	100-109 or 131-170mmHg	90-99 or >170mmHg	<90mmHg
Pulse	50-80bpm	40-49 or 81-100bpm	101-120 bpm	<40 or >120bpm
Haemaglobin	13-16g/dl	11.5-12.9 or 16.1-17g/dl	10-11.4 or 17.1-18g/dl	<10 or >18g/dl
WBC	4-10	10.1-20 or 3.1-4.0	>20 or<3	
Urea	<7.6mM	7.6 - 10mM	10.1 - 15mM	>15mM
Sodium	>135mM	131 - 135mM	126 - 130mM	<126mM
Potassium	3.5-5mM	3.2-3.4 or 5.1-5.3mM	2.9-3.1 or 5.4-5.9nM	<2.9 or >5.9mM
GCS	15	12-14	9-11	<9
Operation type	Minor	Moderate	Major	Complex major
No. Procedures	1	2	>2	
Operative blood loss	<100mls	101-500mls	501-999mls	>1000mls
Peritoneal contamination	None	Minor	Local pus	Free bowel content, pus or blood
Malignancy status	Benign	Primary only	Malignancy and local metastases	Malignancy and distant metastases
Mode of surgery	Elective	Urgent	Emergency within 2 hours	

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Randomisation Case Report Form

Please complete this form prior to surgery

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Randomisation Eligibility

(Randomise only if patient meets all eligibility criteria)

Inclusion Criteria Patient must meet all inclusion criteria to continue in the study

At point of surgical closure / randomisation

	Yes	No
Midline abdominal incision (open or laparoscopic assisted/converted)	☐	☐
Incision of 5 cm or more	☐	☐

Exclusion criteria Patient must meet all exclusion criteria to continue in the study

At point of surgical closure / randomisation

	Yes	No
Having a mesh inserted as planned part of the abdominal closure	☐	☐
Undergoing musculofascial flap closure of perineal defect in abdomino-perineal wound closure	☐	☐

Has the patient been randomised Yes ☐ No ☐

If no, please give reason: _____

Randomisation Result Mass Closure ☐ Hughes Closure ☐

Randomisation ID ☐☐☐

Randomisation Date D D / M M / Y Y Y Y

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Reoperation Case Report Form

Please only complete this form if the patient has had further abdominal surgery during the index admission.

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

What was the date of the (additional) surgical procedure? DD / MM / YYYY

Please enter name of responsible consultant. _____

	Registrar ST5 or below	SpR (ST 6-8)	Consultant
Grade of primary anesthetist	☐	☐	☐
Grade of surgeon performing the reoperation	☐	☐	☐
Grade of surgeon performing abdominal wall closure	☐	☐	☐
Grade of surgeon closing skin	☐	☐	☐

Please provide indication for surgery _____

What is the patient's ASA grade? 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

What was the operation performed? Please select one

Negative Procedure	☐	Washout for bleeding alone	☐
Washout for sepsis alone	☐	Defunctioning an anastomosis	☐
Take down anastomosis and formation stoma	☐	Resuture burst abdomen	☐
Small bowel obstruction	☐	Other	☐

If other please specify _____

Initials of person completing form.....Date: DD MM YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Was a stoma formed? Please select one

No stoma ☐ End ileostomy ☐ Loop ileostomy ☐

End colostomy ☐ Loop colostomy ☐ Other ☐

If other, please specify _____

What was the mode of the operation?

Open ☐ Laparoscopic assisted ☐

Laparoscopic ☐ Laparoscopic converted to open (midline incision) ☐

If the mode of operation was converted, please provide reason.

Anatomy ☐ Bleeding ☐

Adhesions ☐ Other ☐

If other, please specify why. _____

Did the patient require an intra-operative transfusion? Yes ☐ No ☐

If yes, please indicate number of units of blood required? ☐☐

What was the closure method used?

Hughes ☐

Mass ☐

Abdomen not closed ☐

Other ☐

If other, please specify _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

If **HUGHES** Closure

Number of interrupted 1 nylon sutures used? ☐☐

Number of continuous loop PDS sutures used? ☐

If **MASS** Closure

Absorbable ☐ Non-absorbable ☐

Number of sutures 1 ☐ 2 ☐ 3 ☐ 4 ☐ ≥5 ☐

Suture size 2o ☐ 0 ☐ 1 ☐ 2 ☐

Was a loop suture used? Yes ☐ No ☐

Additional Suture Comments Yes ☐ No ☐ _____

Select the **skin closure** method used.

Surgical clips ☐ Subcuticular absorbable suture(s) ☐

Interrupted sutures ☐ Other ☐

If other, please specify _____

What was the duration of the procedure? ☐☐☐ mins

What was the time taken for fascial closure? ☐☐☐ mins

What is the planned level of post-operative care? ITU ☐ HDU ☐ Ward/PACU ☐

Return to theatre requires an SAE to be completed. Has an SAE form been completed? Yes ☐ No ☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details Date of birth: __ __ / __ __ / __ __ __ __ Initials: ☐☐

POSSUM Score Please circle or mark one option for each line.

Age	<61	61-70	>70	
Cardiac	No failure	Diuretic, digoxin angina, hypertension	Peripheral oedema, warfarin, borderline cardiomyopathy	Raised JVP, cardiomegaly
Respiratory	No dyspnoea	Dyspnoea on exertion, mild COAD	Limiting dyspoena (1 flight), moderate COAD	Dyspnoea at rest (>30 RR), pulmonary fibrosis/consolidation
ECG	Normal	AF, rate 60-90	Any other abnormal rhythm, >4/min ectopics, Qwaves, ST/T changes	
Systolic BP	110-130mmHg	100-109 or 131-170mmHg	90-99 or >170mmHg	<90mmHg
Pulse	50-80bpm	40-49 or 81-100bpm	101-120 bpm	<40 or >120bpm
Haemaglobin	13-16g/dl	11.5-12.9 or 16.1-17g/dl	10-11.4 or 17.1-18g/dl	<10 or >18g/dl
WBC	4-10	10.1-20 or 3.1-4.0	>20 or<3	
Urea	<7.6mM	7.6 - 10mM	10.1 - 15mM	>15mM
Sodium	>135mM	131 - 135mM	126 - 130mM	<126mM
Potassium	3.5-5mM	3.2-3.4 or 5.1-5.3mM	2.9-3.1 or 5.4-5.9nM	<2.9 or >5.9mM
GCS	15	12-14	9-11	<9
Operation type	Minor	Moderate	Major	Complex major
No. Procedures	1	2	>2	
Operative blood	<100mls	101-500mls	501-999mls	>1000mls
Peritoneal contamination	None	Minor	Local pus	Free bowel content, pus or blood
Malignancy status	Benign	Primary only	Malignancy and local metastases	Malignancy and distant metastases
Mode of surgery	Elective	Urgent	Emergency within 2 hours	

Initials of person completing form.....Date: __ __ / __ __ / __ __ __ __

Site number: ☐☐ Patient number: ☐☐☐

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Discharge Case Report Form

Patient Details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Is the patient alive? Yes ☐ No ☐

If yes, please enter date of discharge. DD / MM / YYYY

Or, if patient has died prior to discharge, please enter date of death. DD / MM / YYYY

If patient has died, please complete as much detail as possible of this form and also complete the discontinuation form.
If death is within 30 days of index surgery or re-operation that occurs prior to discharge then please also complete an SAE form.

Did the patient require **post**operative blood transfusion? Yes ☐ No ☐

If yes, please enter number of units of blood given. ☐☐

Did the patient require postoperative feeding? Yes ☐ No ☐

If yes, please indicate number of days of NG feed. ☐☐☐

If yes, please indicate number of days of TPN. ☐☐☐

Surgical Site Infection

Has there been evidence of a Surgical Site Infection (SSI) post-operatively? Yes ☐ No ☐

If yes, please indicate severity. If there is more than one grade, please select the most severe.

	Please tick one
Superficial SSI	☐
Deep SSI	☐
Organ/ space (ie peritoneal cavity) SSI	☐

If the SSI is considered serious, please complete an SAE form as well as completing the following information.

If the patient experienced an SSI, was the SSI treated with antibiotics? Yes ☐ No ☐

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Was surgical action taken to treat the SSI Yes ☐ No ☐

If yes, please indicate surgical treatment

Wound opened on ward ☐

Percutaneous wound drain ☐

Surgical exploration and washout ☐

Other, specify _____ ☐

If the patient has undergone a surgical procedure, please complete the 'reoperation' CRF.

Burst Abdomen

Did the patient experience a postoperative burst abdomen? (ie full thickness wound dehiscence) Yes ☐

No ☐

If the patient experienced a burst abdomen, please complete an SAE form.

If the patient experienced a burst abdomen, please enter the date it occurred. D D / M M / Y Y Y Y

If the patient experienced a burst abdomen, please indicate the cause of the burst abdomen (Please tick one)

Knot slippage ☐

Sutures cut through ☐

Unclear ☐

Other, specify _____ ☐

If the patient experienced a burst abdomen, please indicate its subsequent management. (Please tick one)

Definitive closure ☐

Laparostomy ☐

Other, specify _____ ☐

If the patient has undergone surgery, please complete the 'reoperation' CRF.

Has the patient experienced any SAEs other than SSI and burst abdomen? Yes ☐ No ☐

Please note all SAEs occurring within 30 days of index surgery or re-operation must be reported on the electronic database

---

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART
Hughes Abdominal Repair Trial

Patient Diary

Patient Initials ☐☐, Patient DOB _ _/ _ _/ _ _ _ _

The day after discharge from hospital, please tick (✓) each day if you experience any of the following symptoms or activities. If you have not experienced them, then please enter a cross (x). If you missed completing parts of the form then please leave blank. Additional comments can be included at the bottom of the form if you wish. Please see reverse for a partially completed example. You will have either received an envelope to return this diary, or you can take it back at your next appointment. But please, do return this diary, even if it's not fully completed. Many thanks.

	Surgery: _ _/ _ _/ _ _ _ _	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30
Have you had oozing, leaking or discharge from the wound?																															
Have you had redness around the wound?																															
Have you noticed a smell from the wound?																															
Have you seen the district nurse or GP about problems with the wound?																															
Have you had a swab taken from the wound?																															
Have you received antibiotics for the wound?																															
Have you gone to hospital to be seen for your wound?																															

Please enter any details, with time and date, in the section below.

Date	Time	Comment	Date	Time	Comment

Site number ☐☐ Patient number ☐☐☐

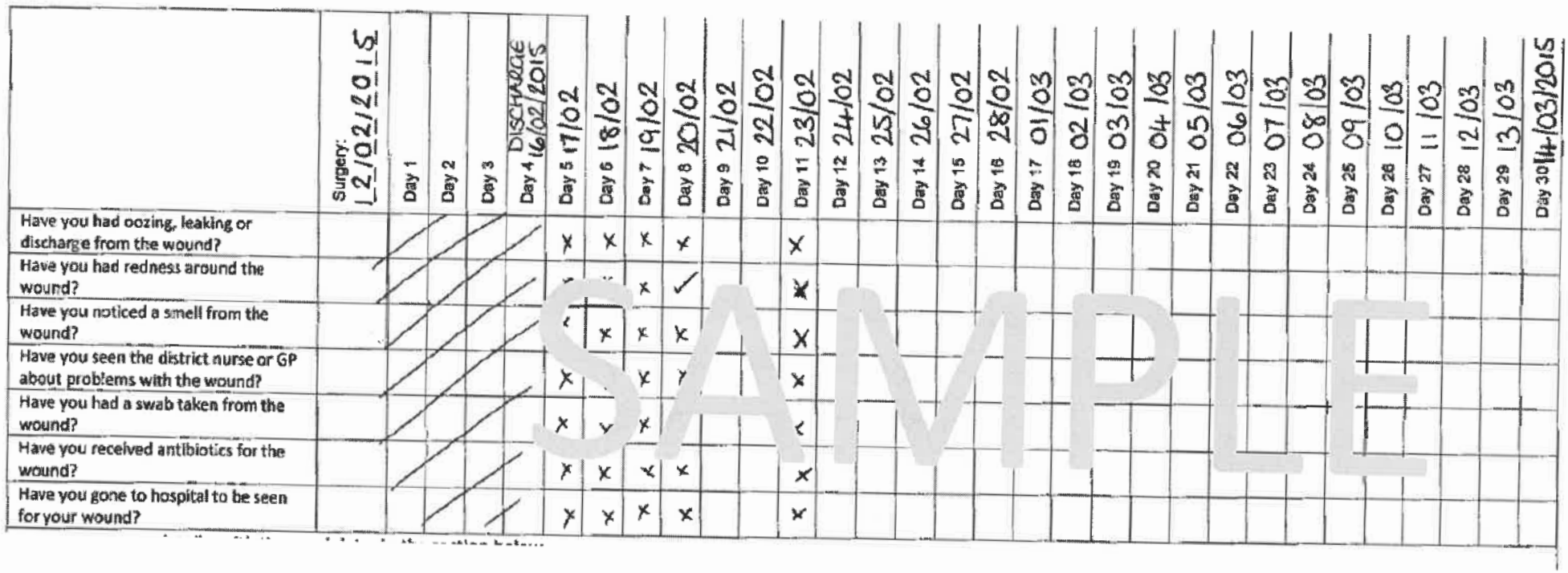
Patient Diary

Instructions for the research team

Please enter date of surgery and the date of discharge on the relevant day. Cross out all days up to discharge as data up to that point will be collected at hospital. Please enter date of day 30 to indicate when the patient can stop completing the form. If you wish, you can complete all other dates also to help the patient track days, or the patient can do this.

The patient will use a tick (✓) to answer yes to a question, a cross (x) to answer no to a question, and leave blank if the diary was not filled on that day.

Please see below for an example.



	Surgery: 12/02/2015	Day 1	Day 2	Day 3	Day 4 DISCHARGE 16/02/2015	Day 5 17/02	Day 6 18/02	Day 7 19/02	Day 8 20/02	Day 9 21/02	Day 10 22/02	Day 11 23/02	Day 12 24/02	Day 13 25/02	Day 14 26/02	Day 15 27/02	Day 16 28/02	Day 17 01/03	Day 18 02/03	Day 19 03/03	Day 20 04/03	Day 21 05/03	Day 22 06/03	Day 23 07/03	Day 24 08/03	Day 25 09/03	Day 26 10/03	Day 27 11/03	Day 28 12/03	Day 29 13/03	Day 30 14/03/2015
Have you had oozing, leaking or discharge from the wound?						x	x	x	x			x																		
Have you had redness around the wound?						x	x	x	✓			x																		
Have you noticed a smell from the wound?						x	x	x	x			x																		
Have you seen the district nurse or GP about problems with the wound?						x	x	x	x			x																		
Have you had a swab taken from the wound?						x	x	x				x																		
Have you received antibiotics for the wound?						x	x	x	x			x																		
Have you gone to hospital to be seen for your wound?						x	x	x	x			x																		

SAMPLE

This project is funded by the National Institute for Health Research, Health Technology Assessment, 12/35/29

NHS
National Institute for Health Research

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

30 Day - Questionnaire Compliance CRF

This form is to be completed 30 day ± 5 days post-index surgery. Please arrange for the questionnaires to be completed.

Patient Details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Has the patient been discharged since the index surgery? Yes ☐ No ☐

Is the patient alive? Yes ☐ No ☐

If yes, please enter date of visit. D D / M M / Y Y Y Y

Or, if patient has died, please enter date of death. D D / M M / Y Y Y Y

If patient has died, please disregard the rest of this form but complete the discontinuation form
If date of death is within 30 days post index surgery (or reoperation) then also complete an SAE form

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

Have there been any SAEs until 30 days post index surgery (or reoperation) Yes ☐ No ☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

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Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Colorectal Cancer Stage CRF

Please complete this form at day 30, or at least within 6 weeks post-index surgery

Patient Details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Was Colorectal Cancer Staging completed? Yes ☐ No ☐

If no, please provide reason _____

Please enter date of the Colorectal Cancer pathology report. DD / MM / YYYY

Please enter details of colorectal cancer staging.

TNM T ☐ N ☐ M ☐

Dukes Please tick one

A ☐ B ☐ C ☐ D ☐

Please enter total lymph node count ☐☐

Please enter positive lymph node count ☐☐

Is there evidence of lymphovascular invasion? Yes ☐ No ☐

During index surgery, were clear resection margins achieved? Yes ☐ No ☐

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Serious Adverse Event (SAE) Form

Please ensure that the SAE has been entered onto the electronic database within 24 hours of knowledge.

Please enter patient details **Date of birth**: __ / __ / ____ **Initials**: ☐☐

Is this serious adverse event reported for the first time, or is follow-up information being provided?

Initial Report ☐ **Follow-up report** ☐

Please enter date of report. If follow-up, please enter date of follow-up. __ / __ / ____

What is the serious adverse event to be reported?

Please report one serious adverse event per form

What was the start date of the serious adverse event? __ / __ / ____

Please provide further relevant details of the serious adverse event. (SAE treatment to be provided separately)

Please select seriousness criteria

Death ☐

Life-threatening ☐

Disability or incapacity ☐

Hospitalisation ☐
Needed hospital admission or extended hospital stay

Other medically important condition ☐

Initials of person completing form.....Date: __ / __ / ____

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ **Initials:** ☐☐

Is the serious adverse event related to the wound closure?

Not related ☐

Unlikely to be related ☐

Possibly related ☐

Probably related ☐

Definitely related ☐

Please describe treatment provided for the serious adverse event.

What is the outcome of the serious adverse event?

Resolved? ☐ Please enter date of resolution: _ _ / _ _ / _ _ _ _

Ongoing? ☐

Ongoing at time of death? ☐

Not yet known? ☐

Death? (only tick if death is the result of this SAE) ☐ Please enter date of death: _ _ / _ _ / _ _ _ _

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ **Initials:** ☐☐

Does the serious adverse event fall into one of the catergories below Yes ☐ No ☐
Please select

Lower Respiratory Tract Infection	☐
Urinary Tract Infection	☐
Anastomotic leak	☐
Intra-abdominal sepsis	☐
Deep Vein Thrombosis	☐
Pulmonary Embolus	☐
Wound infection	☐
Wound breakdown	☐
Surgical Site Infection	☐
Bleeding	☐
Myocardial Infarction	☐
Stoma complications – prolapsed, retraction, dehiscence or hernia	☐
Paralytic Ileus	☐

Please indicate the grade of the event as below:

Grade I complications require only medical intervention (e.g wound infections opened at the bedside, postoperative ileus)	☐
Grade II complications require pharmacological treatment	☐
Grade IIIa complications require surgical, endoscopic, or radiologic intervention, not under general anesthesia	☐
Grade IIIb complications require surgical, endoscopic, or radiologic intervention, under general anesthesia	☐
Grade IVa complications are life-threatening and require Intensive Care Unit management, single organ dysfunction	☐
Grade IVb complications are life-threatening and require Intensive Care Unit management, multi organ dysfunction	☐
Grade V complications are defined as those resulting in death	☐

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** _ _ / _ _ / _ _ _ _ **Initials:** ☐☐

Is the serious adverse event a mechanical problem of the abdominal wound? Yes ☐ No ☐

Is yes, please indicate the severity of the dehiscence.

Incisional separation of ≤ 25% of wound, no deeper than superficial fascia ☐

Incisional separation of ≥ 25% of wound with local care; asymptomatic hernia or symptomatic hernia without evidence of strangulation ☐

Fascial separation or dehiscence without evisceration, needing primary wound closure or revision by operation ☐

Mechanical problem with life threatening consequences, e.g. symptomatic hernia with evidence of strangulation, fascial disruption with evisceration, or need for major reconstruction, grafting, resection or amputation ☐

Death resulting from the mechanical problem ☐

Reporting Investigator Name: _____ Sign: _____ Date: _ _ / _ _ / _ _ _ _

Initials of person completing form.....Date: _ _ / _ _ / _ _ _ _

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

6 Month
Questionnaire Compliance CRF

This visit is intended to take place 6 months ± 1 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Has the patient been discharged since the index surgery? Yes ☐ No ☐

Is the patient alive? Yes ☐ No ☐

If yes, please enter date of visit. DD / MM / YYYY

Or, if patient has died, please enter date of death. DD / MM / YYYY

If patient has died, disregard the rest of the form but please complete the discontinuation form

---

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

One Year Post-Surgery Visit

Please complete this visit 12 months ± 2 months post-index surgery

---

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Radiology

Was a CT scan performed? Yes ☐ No ☐

If no, please provide reason? _____

If yes, please enter the date of the CT scan DD / MM / YYYY

Cancer Status and Treatment

Did the patient receive adjuvant chemotherapy following the index operation? Yes ☐ No ☐

Local recurrence

Since the surgery, has there been a local recurrence? Yes ☐ No ☐

If yes, please enter date local recurrence was diagnosed. DD / MM / YYYY

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Metastasis

Since the surgery, has the patient developed metastasis? Yes ☐ No ☐

If yes, please enter date metastasis was diagnosed. D D / M M / Y Y Y Y

If yes, please list sites of metastases?

	Yes	No
Liver	☐	☐
Lung	☐	☐
Bone	☐	☐
Brain	☐	☐
Peritoneal	☐	☐
Other	☐	☐

If other, please specify _____

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Abdominal Surgery

Has the patient had any further abdominal surgery including incisional hernia repairs since discharge? Yes ☐

If yes, please record on the abdominal surgery log No ☐

Stitch Sinus

Has the patient developed any stitch sinus since the index procedure? Yes ☐

If yes, please record on the stitch sinus log No ☐

Readmission

Has the patient been readmitted to hospital for any other wound related complication since discharge? Yes ☐ No ☐

If yes, please specify reason _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

One Year Post-Index Surgery Questionnaire Compliance CRF

This visit is intended to take place 12 months ± 2 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** DD/MM/YYYY **Initials:** ☐☐

Is the patient alive? Yes ☐ No ☐

If yes, please enter date of visit. DD/MM/YYYY

Or, if patient has died, please enter date of death. DD/MM/YYYY

If patient has died, disregard the rest of the form and please complete the discontinuation form

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other. please specify

Initials of person completing form.....Date: DD/MM/YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please Note:

The following form 'Annual Clinical Examination' is used at every annual follow-up visit but it has not been reproduced for every year in this document.

Information on how to assess the patient is reproduced from the HART Protocol and Protocol publication (REF: Cornish, J. Harries RL, Bosanquet D, Rees B, Ansell J, Frewer N. "Hughes Abdominal Repair Trial (HART) – Abdominal wall closure techniques to reduce the incidence of incisional hernias: study protocol for a randomised controlled trial." Trials 2016;17(1): 454. https://doi.org/10.1186/s13063-016-1573-0)

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES TO REDUCE THE INCIDENCE OF INCISIONAL HERNIAS

Annual Clinical Examination Case Report Form

The clinical examination must only be conducted by surgeons or colorectal cancer nurse specialists trained in the identification of hernia as outlined in the current HART protocol.

Please tick year of follow-up

Year 1 ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Please enter date of clinical examination. DD / MM / YYYY

Is a midline incisional hernia evident during clinical examination?	Yes ☐ No ☐	
If yes, please provide the length of the defect. Please measure total length if there are multiple defects.	☐☐ cm	
Please indicate number of individual hernias.	☐☐	
If there is a midline incisional hernia, how is it affecting the patient?	Please tick Yes	No
Asymptomatic	☐	☐
Cosmetic	☐	☐
Painful	☐	☐
Obstructive symptoms	☐	☐
Is the hernia irreducible?	☐	☐
Is the hernia increasing in size?	☐	☐
Have there been any skin changes?	☐	☐

The examiner will assess the patient ensuring to include the following:

With the patient in a standing position, palpate the length of the closed wound and ask the patient to cough or perform the Valsalva manoeuvre

With the patient in a supine position, palpate the length of the closed wound and ask the patient to cough or perform the Valsalva manoeuvre (Cornish et al "Hughes Abdominal Repair Trial (HART) - Abdominal wall closure techniques to reduce the incidence of incisional hernias: study protocol for a randomised controlled trial." Trials 2016;17(1): 454.)

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Year Two Annual Follow-up Visit

Please complete this visit 24 months ± 2 months post-index surgery

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Radiology

Was a CT scan performed? Yes ☐ No ☐

If no, please provide reason? _____

If yes, please enter the date of the CT scan D D / M M / Y Y Y Y

Cancer Status and Treatment

Local recurrence

Since the previous study visit, has there been a local recurrence? Yes ☐ No ☐

If yes, please enter date local recurrence was diagnosed. D D / M M / Y Y Y Y

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Metastasis

Since the previous study visit, has the patient developed metastasis? Yes ☐ No ☐

If yes, please enter date metastasis was diagnosed. D D / M M / Y Y Y Y

If yes, please list sites of metastases?

	Yes	No
Liver	☐	☐
Lung	☐	☐
Bone	☐	☐
Brain	☐	☐
Peritoneal	☐	☐
Other	☐	☐

If other, please specify _____

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Abdominal Surgery

Has the patient had any further abdominal surgery including incisional hernia repairs since the previous study visit? Yes ☐

If yes, please record on the abdominal surgery log No ☐

Stitch Sinus

Has the patient developed any stitch sinus since the previous study visit? Yes ☐

If yes, please record on the stitch sinus log No ☐

Readmission

Has the patient been readmitted to hospital for any other wound related complication since the previous study visit? Yes ☐ No ☐

If yes, please specify reason _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Year Two
Questionnaire Compliance CRF

This visit is intended to take place 24 months ± 2 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Is the patient alive? Yes ☐

No ☐

If yes, please enter date of visit. D D / M M / Y Y Y Y

Or, if patient has died, please enter date of death. D D / M M / Y Y Y Y

If patient has died, disregard the rest of the form and please complete the discontinuation form

---

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Year Three Annual Follow-up Visit

Please complete this visit 36 months ± 2 months post-index surgery

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Cancer Status and Treatment

Local recurrence

Since the previous study visit, has there been a local recurrence? Yes ☐ No ☐

If yes, please enter date local recurrence was diagnosed. DD / MM / YYYY

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Metastasis

Since the previous study visit, has the patient developed metastasis? Yes ☐ No ☐

If yes, please enter date metastasis was diagnosed. DD / MM / YYYY

If yes, please list sites of metastases?

	Yes	No
Liver	☐	☐
Lung	☐	☐
Bone	☐	☐
Brain	☐	☐
Peritoneal	☐	☐
Other	☐	☐

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

If other, please specify _____

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Abdominal Surgery

Has the patient had any further abdominal surgery including incisional hernia repair since the previous study visit? Yes ☐

If yes, please record on the abdominal surgery log No ☐

Stitch Sinus

Has the patient developed any stitch sinus since the previous study visit? Yes ☐

If yes, please record on the stitch sinus log No ☐

Readmission

Has the patient been readmitted to hospital for any other wound related complication since the previous study visit? Yes ☐ No ☐

If yes, please specify reason _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Year Three
Questionnaire Compliance CRF

This visit is intended to take place 36 months ± 2 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Is the patient alive? Yes ☐

No ☐

If yes, please enter date of visit. DD / MM / YYYY

Or, if patient has died, please enter date of death. DD / MM / YYYY

If patient has died, disregard the rest of this form and please complete the discontinuation form

---

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Year Four Annual Follow-up Visit

Please complete this visit 48 months ± 2 months post-index surgery

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Cancer Status and Treatment

Local recurrence

Since the previous study visit, has there been a local recurrence? Yes ☐ No ☐

If yes, please enter date local recurrence was diagnosed. DD / MM / YYYY

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Metastasis

Since the previous study visit, has the patient developed metastasis? Yes ☐ No ☐

If yes, please enter date metastasis was diagnosed. DD / MM / YYYY

If yes, please list sites of metastases?

	Yes	No
Liver	☐	☐
Lung	☐	☐
Bone	☐	☐
Brain	☐	☐
Peritoneal	☐	☐
Other	☐	☐

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

If other, please specify _____

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Abdominal Surgery

Has the patient had any further abdominal surgery including incisional hernia repair since the previous study visit? Yes ☐
If yes, please record on the abdominal surgery log No ☐

Stitch Sinus

Has the patient developed any stitch sinus since the previous study visit? Yes ☐
If yes, please record on the stitch sinus log No ☐

Readmission

Has the patient been readmitted to hospital for any other wound related complication since the previous study visit? Yes ☐ No ☐

If yes, please specify reason _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Year Four
Questionnaire Compliance CRF

This visit is intended to take place 48 months ± 2 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** DD/MM/YYYY **Initials:** ☐☐

Is the patient alive? Yes ☐ No ☐

If yes, please enter date of visit. DD/MM/YYYY

Or, if patient has died, please enter date of death. DD/MM/YYYY

If patient has died, disregard the rest of the form and please complete the discontinuation form

FACT-C questionnaire completed? Yes ☐ No ☐
If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify _____

SF-12 questionnaire completed? Yes ☐ No ☐
If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify _____

CSRI form completed? Yes ☐ No ☐
If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify _____

Initials of person completing form.....Date: DD/MM/YYYY

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Year Five Annual Follow-up Visit

Please complete this visit 60 months ± 2 months post-index surgery

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Cancer Status and Treatment

Local recurrence

Since the previous study visit, has there been a local recurrence? Yes ☐ No ☐

If yes, please enter date local recurrence was diagnosed. D D / M M / Y Y Y Y

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Metastasis

Since the previous study visit, has the patient developed metastasis? Yes ☐ No ☐

If yes, please enter date metastasis was diagnosed. D D / M M / Y Y Y Y

If yes, please list sites of metastases?

	Yes	No
Liver	☐	☐
Lung	☐	☐
Bone	☐	☐
Brain	☐	☐
Peritoneal	☐	☐
Other	☐	☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

If other, please specify _____

If yes, was radiotherapy administered? Yes ☐ No ☐

If yes, was chemotherapy administered? Yes ☐ No ☐

Abdominal Surgery

Has the patient had any further abdominal surgery including incisional hernia repairs since the previous study visit? Yes ☐
If yes, please record on the abdominal surgery log No ☐

Stitch Sinus

Has the patient developed any stitch sinus since the previous study visit? Yes ☐

If yes, please record on the stitch sinus log No ☐

Readmission

Has the patient been readmitted to hospital for any other wound related complication since the previous study visit? Yes ☐ No ☐

If yes, please specify reason _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART
Hughes Abdominal Repair Trial
ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Year Five
Questionnaire Compliance CRF

This visit is intended to take place 60 months ± 2 month post-index surgery. Please arrange for the questionnaires to be completed for the visit.

Patient Details **Date of birth:** DD/MM/YYYY **Initials:** ☐☐

Is the patient alive? Yes ☐

No ☐

If yes, please enter date of visit. DD/MM/YYYY

Or, if patient has died, please enter date of death. DD/MM/YYYY

If patient has died, disregard the rest of this form and please complete the discontinuation form

---

FACT-C questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

SF-12 questionnaire completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

CSRI form completed? Yes ☐ No ☐

If no, please provide reason ☐
1 = Patient did not return
2 = Patient refused
3 = Questionnaire was not administered
4 = Other
If other, please specify

_____

Initials of person completing form.....Date: DD/MM/YYYY

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial — ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Abdominal Surgery Log

Please record all abdominal surgery since discharge including incisional hernia repairs

---

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Additional Abdominal Surgery 1

Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

DD / MM / YYYY

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one

Hughes ☐ Mass ☐

Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 2

Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

DD / MM / YYYY

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one

Hughes ☐ Mass ☐

Unknown ☐ Other ☐

If other, please specify

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Additional Abdominal Surgery 3

Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery? _____

What was the procedure performed? _____

What method was used for abdominal wall closure? Please select one

Hughes ☐ Mass ☐

Unknown ☐ Other ☐

If other, please specify _____

Additional Abdominal Surgery 4

Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery? _____

What was the procedure performed? _____

What method was used for abdominal wall closure? Please select one

Hughes ☐ Mass ☐

Unknown ☐ Other ☐

If other, please specify _____

Additional Abdominal Surgery 5

Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery? _____

What was the procedure performed? _____

What method was used for abdominal wall closure? Please select one

Hughes ☐ Mass ☐

Unknown ☐ Other ☐

If other, please specify _____

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Additional Abdominal Surgery 6
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 7
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 8
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Additional Abdominal Surgery 9
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 10
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 11
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** DD / MM / YYYY **Initials:** ☐☐

Additional Abdominal Surgery 12
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

DD / MM / YYYY

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 13
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

DD / MM / YYYY

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 14
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

DD / MM / YYYY

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Initials of person completing form.....Date: DD / MM / YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Additional Abdominal Surgery 15
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 16
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Additional Abdominal Surgery 17
Was the operation through the previous midline incision? Yes ☐ No ☐

Please enter date of surgery.

D D / M M / Y Y Y Y

What was the indication for surgery?

What was the procedure performed?

What method was used for abdominal wall closure? Please select one Hughes ☐ Mass ☐ Unknown ☐ Other ☐

If other, please specify

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

HART

Hughes Abdominal Repair Trial

ABDOMINAL WALL CLOSURE TECHNIQUES to REDUCE THE INCIDENCE of INCISIONAL HERNIAS

Stitch Sinus Log

Please record all stitch sinus since the index procedure

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Stitch Sinus 1

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 2

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 3

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** DD/MM/YYYY **Initials:** ☐☐

Stitch Sinus 4

Date stitch sinus identified? DD/MM/YYYY

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. DD/MM/YYYY

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 5

Date stitch sinus identified? DD/MM/YYYY

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. DD/MM/YYYY

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 6

Date stitch sinus identified? DD/MM/YYYY

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. DD/MM/YYYY

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 7

Date stitch sinus identified? DD/MM/YYYY

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. DD/MM/YYYY

Did the procedure have successful healing? Yes ☐ No ☐

Initials of person completing form.....Date: DD/MM/YYYY

Site number: ☐☐ Patient number: ☐☐☐

Please enter patient details **Date of birth:** D D / M M / Y Y Y Y **Initials:** ☐☐

Stitch Sinus 8

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 9

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 10

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Stitch Sinus 11

Date stitch sinus identified? D D / M M / Y Y Y Y

Did this require surgery? Yes ☐ No ☐

If yes, please enter date of procedure. D D / M M / Y Y Y Y

Did the procedure have successful healing? Yes ☐ No ☐

Initials of person completing form.....Date: D D / M M / Y Y Y Y

Site number: ☐☐ Patient number: ☐☐☐