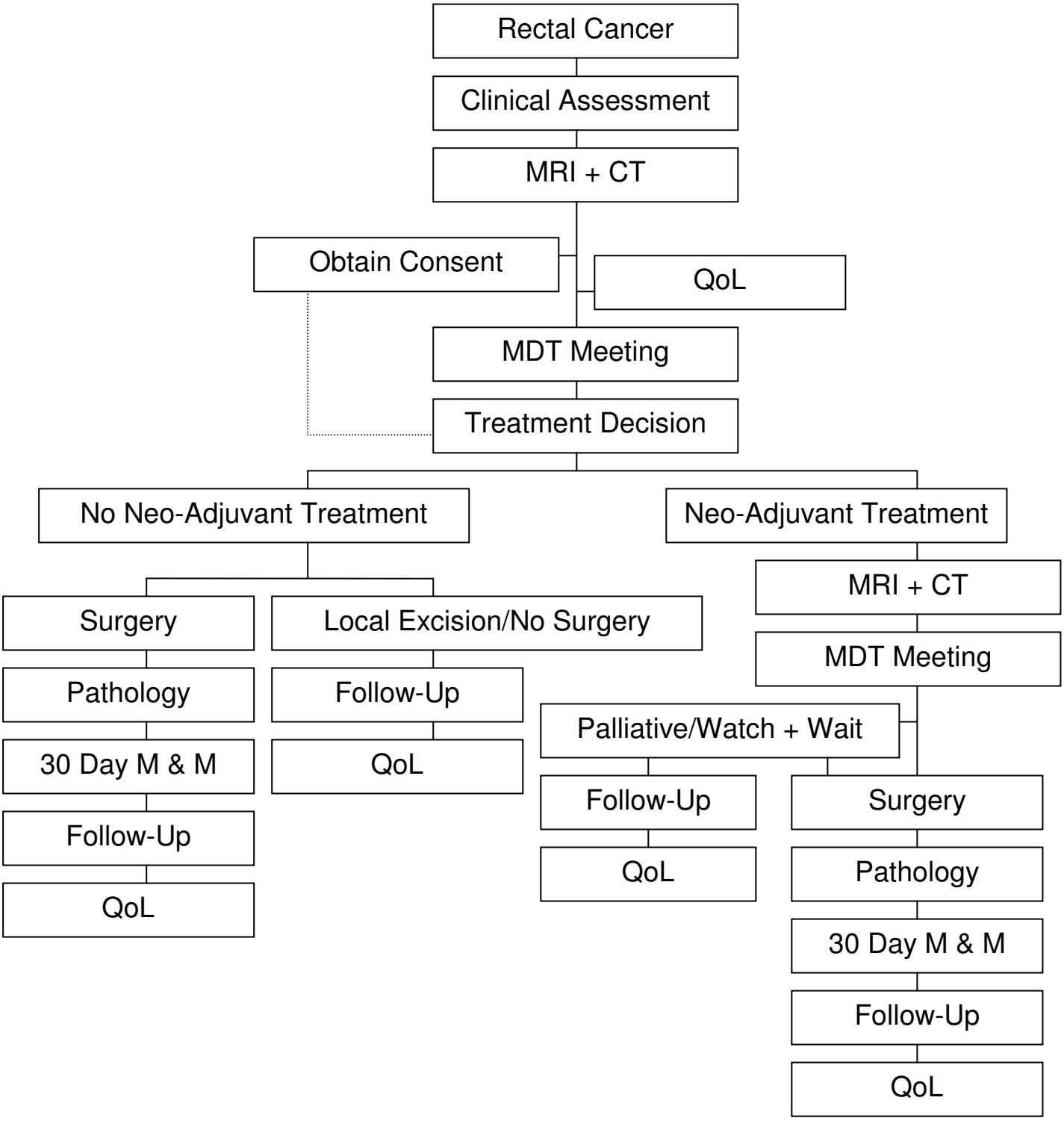
Steps of Data Collection: Mercury 2 Trial



Consent and Sample Consent Form

Informed consent will be obtained for;

1. Storage of clinical information

2. Donation of imaging data to be held in a DICOM image bank, initially from CD

3. Treatment data from outpatient, in-patient and oncology medical records.

4. Surgical and histopathological photographs

5. Regular follow-up assessment and postal/online questionnaire for QoL assessment

Sample consent form on following page

Patient Study id:		**Patient Initials:**	
Hospital id:		**Hospital:**	
Date of Birth:		**Gender:**	**M / F**

(Form to be on headed paper)

Low Rectal Cancer Study Consent Form

		Initial box
1.	I confirm that I read and understand the information sheet dated 18/02/2013 (version 1.6) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	
2.	I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected	
3.	I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the Mercury 2 research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records	
4.	I agree to my GP being informed of my participation in the study	
5.	I agree to records of my investigations, operations and tissue samples to be stored and accessed by responsible individuals from the Basingstoke & North Hampshire NHS Foundation Trust and the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research.	
6.	I agree to my tissue specimens and samples to undergo transportation and MRI scanning under the supervision of the research team, where it is relevant to my taking part in this study.	
7.	I agree to allow images of my scans to be stored on a databank. Information about my treatment, pictures of the removed cancer & images of slides to be stored on a secure database.	
8.	I consent to being contacted directly by the Mercury 2 research team so I can be sent quality of life questionnaires and study results.	
9.	I agree to take part in the above study.	

_____	_____	_____
Patient name (Print)	Date	Signature
_____	_____	_____
Person taking consent (Print)	Date	Signature
_____	_____	_____
Researcher (Print)	Date	Signature

Tissue donation for tissue based cancer research

Tissue donation consent

		Initial box
1.	I confirm that I am happy to donate a sample of the cancer tissue and a sample of normal tissue, taken at operation, for future tissue-based cancer research	
8.	I agree to take part in the above study.	

_____	_____	_____
Patient name (Print)	Date	Signature
_____	_____	_____
Person taking consent (Print)	Date	Signature
_____	_____	_____
Researcher (Print)	Date	Signature

Contact details

Please enter your contact details below:

Name:

Address:

E-mail:

MERCURY 2 STUDY SUMMARY

This study is looking at ways to improve treatment for bowel cancer that is very close to the anus.

Doctors usually treat cancer that starts in the rectum with surgery. Some people may also have radiotherapy and chemotherapy.

When you have surgery to remove cancer, the doctors want to make sure that they take out an area of tissue around the cancer that doesn't contain any cancer cells. This is what is known as a clear margin of tissue. This is important, because having a clear margin means there is less chance of the cancer coming back.

If you take part in the study, the researchers will look at your medical notes to find details of the scans, the type of operation and any other treatment you have. They will look at some of the tissue removed when you have your operation. And they will ask you to fill in a number of questionnaires.

The aims of the study are to

See if it is possible to make sure that more people get clear margins when they have cancer removed from the lowest part of the rectum

Find out how much this helps to reduce the number of cancers that come back

Look at why some cancers do come back

Learn more about side effects of treatment for rectal cancer and how this affects people's quality of life

We hope that the results of this study will improve rectal cancer treatment for people in the future.

Patient information sheet for the Lower Rectal Cancer Study (Mercury 2)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- **Part 1** tells you the purpose of this study and what will happen to you if you take part.

- **Part 2** gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part and discuss it with your family and friends and your nurse specialist if you wish.

Part 1

What is Low Rectal Cancer?

Rectal Cancer is bowel cancer that is situated in the lower part of the bowel. The focus of this study will be on cancers found in the lowest part of the rectum, whereby a low rectal cancer is defined as (which sounds complicated but is an accepted definition of this type of tumour):

- An MRI-based anatomical definition where the Mesorectum tapers at the origin of the levators. This usually corresponds to a measurement within 6 centimetres of the anal verge.

Bowel cancer remains the second largest cause of cancer death in the UK (causing 16,260 deaths in 2008). Many more patients are surviving bowel cancer. Innovations in treatment and symptom-awareness campaigns are helping to improve outcomes. However, there is more we can do to help each patient to have the best treatment for their cancer.

Over 6,000 people annually have bowel cancer very low in the bowel (rectum). These patients have previously been shown to have the worst outcomes due to the complicated anatomy in the lower pelvis. Cancers in the low rectum have the highest rate of recurrence and also the highest rates of permanent colostomy bags. Improvements in treatment, therefore, are aimed at lowering these.

What is the purpose of the study?

Currently, there is a wide variability in the way patients are treated for low rectal cancer. There have been a number of advances in how these cancers are assessed (using MRI), how the surgery is carried out and what drugs and radiation treatments can be used to improve the outcomes of treatment. These can all lead to more patients surviving their cancer diagnosis with a better quality of life.

The Mercury 2 Low Rectal Cancer Study aims to tackle these problems and issues in the treatment of very low bowel cancers. Teams of cancer specialists from hospitals around Europe will join the study and focus on the complexity of these cancers.

The aim of the study is to improve low rectal cancer treatment by limiting overtreatment whilst maximising cure rates so that clinicians can make the most appropriate treatment choice for each patient.

Why have I been chosen?

All patients diagnosed with cancer low down in the rectum are being asked to take part in our study. There are some patients who will be unable to join the study such as women who are pregnant and a small minority who are unable to have a MRI scan.

Do I have to take part?

No, you do not have to take part. If you decide not to take part, your treatment will not be affected. If you decide to take part and then later decide to withdraw, you are free to do so at any time, and do not have to give a reason.

What will happen to me if I take part?
Your treatment will be no different, whether you take part in the study or not. You will not be required to have any extra tests or undergo any different treatment. However, you will be closely monitored and your colorectal team will send us information about the quality of your imaging, surgery, pathology and oncology care as well as your quality of life. This will be measured over five years from the date that you join the study.

We will ask you to complete quality of life questionnaires to assess your quality of life. The questionnaires will ask about your general well-being, bowel or stoma function, as well as urinary and sexual function.

As part of the operation we will take out part of the bowel (specimen), and possibly scan it using magnetic resonance imaging (MRI). We will then photograph it, and prepare the specimen. This will be done in addition to standard processing techniques routinely performed on all specimens with bowel cancer.

We will also ask if you would donate some of this tissue for future studies. This will enable us to study the cancer and normal tissue to give an insight into factors that may allow us to predict how cancers will react to treatment. This will be stored in a licensed tissue bank, and this tissue will not identify you.

In summary:

· No change to your therapy, compared to if you were not to take part
· Follow-up over five years as is standard
· Quality of Life questionnaires done before surgery and each year, thereafter, for five years.
· Samples of tissue taken, possibly scanned and stored, with potential use in future studies

What do I have to do?
If you are happy to take part in the study, we will ask for your written consent to enable us to access **your medical records, examine, scan and photograph samples** of tissue taken as part of the operation and to send you questionnaires, which record details of the quality of your life related to the cancer and its treatment. In order to maximise the information from the study we will seek your permission to contact you directly for quality of life data and you will have the option of completing quality of life questionnaires online.

What is the drug, device or procedure that is being tested?
There is no new drug, device or procedure being tested. MRI scanning is a standard method of diagnosis in your hospital and we are looking to see if using MRI to direct treatment decisions for low rectal cancers helps improve patient outcomes. Your colorectal team will explain your individual treatment options to you and help you make an informed decision.

What are the alternatives for diagnosis or treatment?
This series of investigations and treatments proposed is the standard treatment for rectal cancer. Aside from surgery, there is the option to have chemo- and radiotherapy alone for

rectal cancer, but this is a very controversial area that is still undergoing close examination.

What are the side effects of any treatment received when taking part?
There are no side effects, risks or disadvantages to taking part in the study, as you will not be receiving any new or different treatments.

What are the other possible disadvantages and risks of taking part?
As part of the study, questionnaires will be produced for you to fill in. These may prove to be upsetting, as they may raise issues that you feel uncomfortable in dealing with. At all times, there will be a Nurse Specialist and Research Fellow with whom you may talk, to discuss any issues raised.

As part of the treatment there will be several types of scan used:

· MRI (Magnetic Resonance Imaging): This uses a large magnet and sensors to produce pictures of what is happening within the body.
· CT (Computerised Tomography): This uses x-ray radiation and a computer to produce pictures of what is happening within the body.
· Plain x-ray: this uses x-ray radiation to take a picture on a film of parts of your body
· Ultrasound: this uses high-frequency sound waves to produce a picture of your internal organs.

All these scans are those used in the normal management of rectal cancer, and there will be no additional scans as a result of this study.

What are the possible benefits of taking part?
There will be no direct benefits for you but the information you give us will be invaluable in helping to improve our understanding and management of low rectal cancer.

What happens when the research study stops?
You will be followed up in the normal manner for patients with rectal cancer typically over five years. The results of the study will be published over the next three years, and data from your follow-up may be used in future studies.

What if there is a problem?
Any complaints about the way you have been dealt with during the study, or any concerns over possible harm that you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details:
The doctors and nurses looking after you will be able to answer your questions about this study or, please feel free to contact Mrs Lisa Scerri (Mercury 2 Trial Coordinator) on 0208 915 6067 or by email: lisa.scerri@rmh.nhs.uk

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

Part two

What if relevant new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, but continue with your treatment as normal. Any images from scans and any information gained from pieces of tissue studied, will be removed from the study database. The scans, slides and pieces of tissue themselves will not be destroyed, as they will be important for your continued treatment.

What if there is a problem?
Complaints:
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. Please contact Mrs Lisa Scerri (Mercury 2 Trial Coordinator) on 0208 915 6067 or by email: lisa.scerri@rmh.nhs.uk. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Harm
In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Royal Marsden NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?
Yes. The information we collect will be kept strictly confidential. Access to your medical records will be by the doctors and nurses looking after you and by members of our research team. The process for the storage, handling and processing of your data will be in compliance with the Data Protection Act 1998.

Involvement of the General Practitioner/Family doctor (GP)
Permission will also be sought to inform your GP of your participation in this study and any treatment carried out within it, as would be normal for treatment for your cancer.

What will happen to any samples I give?
All tissue samples taken and analysed will be as would be done normally for an operation of this type with possible additional scanning and photography. The samples will then be stored as normal at the individual hospital sites. These samples should not leave the UK, but information about them may be shared with co-researchers in other countries. You will never be identified from the samples.

What will happen to the results of the research study?
We will be unable to contact individuals with the results of our research. We will publish the results in medical journals and provide a summary on our website (www.pelicancancer.org). You will not be identifiable in these articles, and anonymity will be preserved.

Who is organising and funding the research?
The Royal Marsden NHS Foundation Trust is sponsoring this study. The Pelican Cancer Foundation is funding it. (www.pelicancancer.org)

Who has reviewed the study?
Southampton & South West Hampshire Research Ethics Committee, on behalf of the National Research Ethics Service. The Royal Marsden Committee for Clinical Research has also reviewed this study and has allowed it to go ahead. If you are happy to take part in the study, we will ask for your written consent to enable us to access your medical records, examine samples of tissue taken as part of the operation and to send you questionnaires, which look at your quality of life.

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you very much for reading this, and for considering taking part in our study.

Clinical Assessment & registration

Date of completion ……./……/20…

Consultant Surgeon ……..… **Study Code:**

Sex	Male	[ ]	Female	[ ]				
BMI	Ht	…..cm	Wt	…..kg			BMI …..	
Faecal incontinence	Yes	[ ]	No	[ ]				
Faecal Urgency	Yes	[ ]	No	[ ]				
Ability to distinguish flatus/faeces	Yes	[ ]	No	[ ]				
Is the patient sexually active	Yes	[ ]	No	[ ]				
Urinary dysfunction	Yes	[ ]	No	[ ]				
Anal sphincter tone	Normal	[ ]	Reduced	[ ]				
Anal sphincter intact	Yes	[ ]	No	[ ]				
Would you describe the tumour as	Fixed	[ ]	Tethered	[ ]	Mobile	[ ]		
Height above the anal verge on digital rectal examination							…..cm	
Height above the anal verge on rigid sigmoidoscopy							…..cm	
Position of the tumour	Anterior	[ ]	Posterior	[ ]				
	Left Lateral	[ ]	Right Lateral	[ ]				
	Circumferential	[ ]						
Does the tumour	Invade the prostate		Yes	[ ]	No	[ ]		
	Invade the vagina		Yes	[ ]	No	[ ]		
	Invade the sphincters	Yes	[ ]	No	[ ]			

Initial surgical plan based on initial surgical assessment:

Surgery alone [ ] Pre-operative CRT [ ]

Operation plan based on initial surgical assessment:

Local Excision [ ] Extralevator AP Excision [ ]

TME Anterior Resection [ ] Exenterative Procedure [ ]

TME & Hartmanns [ ]

Intersphincteric AP Excision [ ]

TME Plane AP Excision [ ]

Specify ……

……

MDT Decision Form
Baseline

Date of MDT ……/……/20…. **Consultant Surgeon** ……

Has the patient had CRT/RT previously? Yes [ ] No [ ]

Histology Report **Adenocarcinoma** [ ] **Other……**

Evidence of metastases Yes [ ]

Liver [ ]
Lung [ ]
Peritoneal [ ]
Other …….

No [ ]

Modalities prescribed based on this assessment

SRT [ ] LRT [ ] Chemo-RT [ ]

Primary Surgery [ ] Palliative Care [ ] Neo-adjuvant Chemotherapy [ ]

Intended operation based on MDT Discussion:

Local Excision [ ]
TME Anterior Resection [ ]
TME & Hartmanns [ ]
Intersphincteric AP Excision [ ]
TME Plane AP Excision [ ]
Extralevator AP Excision [ ]
Exenterative Procedure [ ]

Specify ……

……

MDT Decision Form
Post Treatment

Date of MDT ……/……/20…. **Consultant Surgeon** ……

Has the patient had CRT/RT previously? Yes [ ] No [ ]

Histology Report **Adenocarcinoma** [ ] **Other……**

Evidence of metastases Yes [ ]

Liver [ ]
Lung [ ]
Peritoneal [ ]
Other …….

No [ ]

What treatment has the patient received?

SRT	[ ]	LRT	[ ]	Chemo-RT	[ ]
Primary Surgery	[ ]	Palliative Care	[ ]	Neo-adjuvant Chemotherapy	[ ]

Intended operation based on 2nd MDT Discussion:

Local Excision	[ ]	Extralevator AP Excision	[ ]
TME Anterior Resection	[ ]	Exenterative Procedure	[ ]
TME & Hartmanns	[ ]	Further Radiotherapy or	
Intersphincteric AP Excision	[ ]	Chemotherapy treatment	[ ]
TME Plane AP Excision	[ ]	Inoperable	[ ]

Specify ……

……

Patient Study code:

Patient MRI datasheet

Radiologist Date:

Study Code:

Patient Name:

Date of Birth:

Baseline Scan:	Yes: date / /	No
Post Pre-op Treatment Scan:	Yes: date / /	No
Tumour height from anal verge (cm.):		

MRI T-stage:	
	T1 Submucosa
	T2 muscularis
	T3a : <1mm
	T3b : 1-5mm
	T3c : 5-15mm
	T3d : >15mm
	T4a Into adjacent organs / external sphincter
	T4b perforation of visceral peritoneum

Extramural venous invasion: Yes No

If yes, score: 0 1 2 3 4
(see EMVI scoring sheet supplement)

Do involved veins threaten mesorectal fascia?
Yes No
(i.e. are they ≤ 1mm from the fascia)

Mesorectal Lymph Node Morphology:

	High resolution
No nodes visible/only high signal nodes	☐
< 4 nodes with either irregular border or mixed signal	☐
< 4 nodes with both irregular border and mixed signal	☐
> 4 nodes with irregular border or mixed signal	☐

Certainty of malignancy:
Unlikely ☐ Doubtful ☐ Definite ☐

Do any malignant nodes lie within 1mm of the CRM? **Yes** ☐ **No** ☐

Evidence of Pelvic Sidewall Lymph Nodes: (if yes, please circle and tick all that apply below)	**Yes**	**No**
Benign features only	☐	☐
Grossly disrupted with mixed signal	☐	☐

Site of node: HYPOGASTRIC/ INTERNAL ILIAC/ OBTURATOR/ EXTERNAL ILIAC/ COMMON ILIAC,/INGUINAL

Certainty of malignancy:
Unlikely ☐ Doubtful ☐ Definite ☐

Tumour is [not present] within 10mm of the top of the puborectalis sling and mesorectal margins are safe therefore distal TME plane is safe, sphincter preserving TME is possible ☐

Tumour is [present]] within 10mm of the top of the puborectalis sling at this level:
Tumour is confined to submucosa with preservation of the full thickness of muscularis propria and may be considered suitable for initial local excision ☐
[Tumour is confined to the submucosal layer/part thickness of muscularis propria indicating that the intersphincteric plane/mesorectal plane is safe and intersphincteric APE or ultra low TME is possible] ☐
[Tumour extends through the full thickness of the muscularis propria : intersphincteric plane/mesorectal plane is unsafe, Extralevator APE. is indicated for radial clearance] ☐
[Tumour extends into the intersphincteric plane : intersphincteric plane/mesorectal plane is unsafe, therefore an extralevator APE. is indicated for radial clearance] ☐
[Tumour extends into the external sphincter : intersphincteric plane/mesorectal plane is unsafe: therefore an extralevator APE. is indicated for radial clearance] ☐

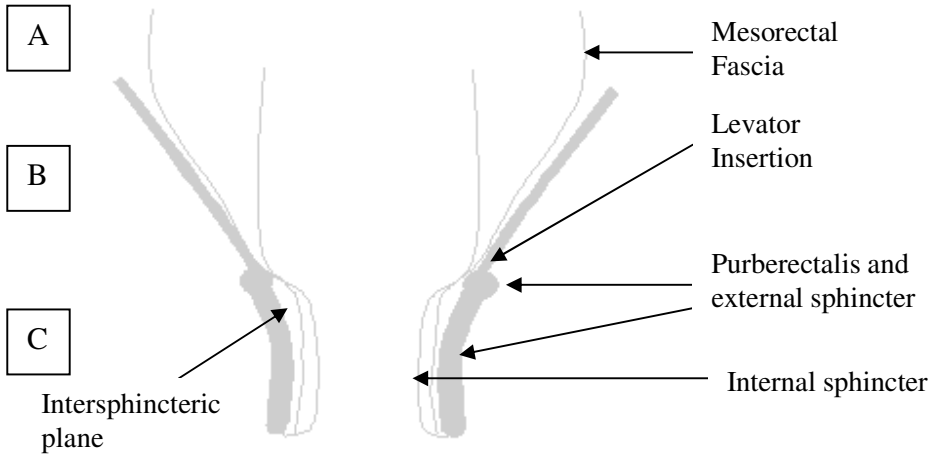
Tumour extends beyond mesorectal fascia into adjacent [prostate/vagina/bladder/sacrum/pelvic fascia and beyond : exenterative procedure will be required ☐

- Anterior Resection: >1mm from MRF & levators
- Intersphincteric APE: muscularis propria with 1mm clear margin
- Extended APE: intersphincteric plane or external sphincters
- Anterior enhanced: if en-bloc removal of prostate/vagina required
- Exenteration: Extensive T4 disease

Based on imaging the possible operations are:

a) Low anterior resection ☐
b) APE:
  a. Standard ☐
  b. Intersphincteric ☐
c) Enhanced APE
  a. Left lateral ☐
  b. Right lateral ☐
  c. Posterior ☐
d) Anteriorly enhanced APE ☐
e) Exenteration ☐

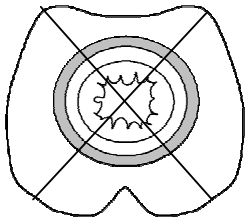
Please mark tumour position on diagram:

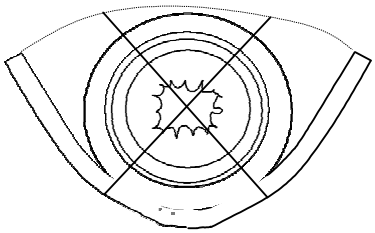


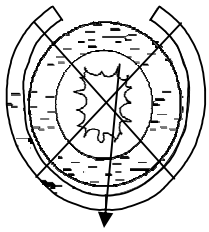
Please mark tumour position on diagram & grid:

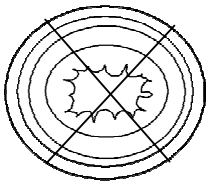
Insertion into perineal body

Right









Left

Area A (1)		
1	2	3
4	5	6
7	8	9

Radial-most extent of tumour is:
Direct spread ☐
EMV ☐
Involved node ☐
Tumour satellite ☐

Area A (2)		
1	2	3
4	5	6
7	8	9

Radial-most extent of tumour is:
Direct spread ☐
EMV ☐
Involved node ☐
Tumour satellite ☐

Puborectal Sling (3)		
1	2	3
4	5	6
7	8	9

Radial-most extent of tumour is:
Direct spread ☐
EMV ☐
Involved node ☐
Tumour satellite ☐

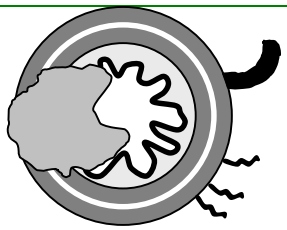
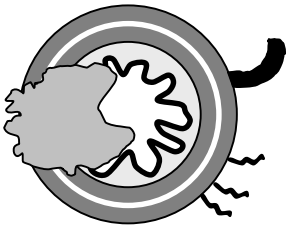
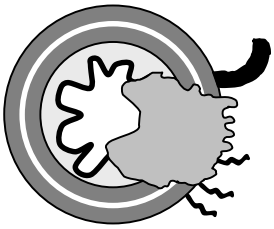
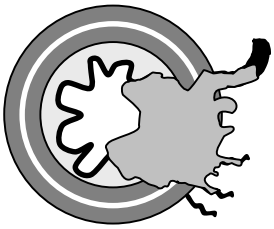
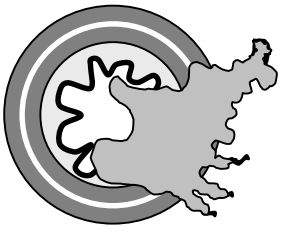
Area C (4)		
1	2	3
4	5	6
7	8	9

Radial-most extent of tumour is:
Direct spread ☐
EMV ☐
Involved node ☐
Tumour satellite ☐

Tumour regression grade scoring table

FOR ANY POST RX MRI RADIOLOGICAL TUMOUR REGRESSION GRADE Which best describes the tumour regression on MRI (please circle):	
Grade 5	No response (intermediate signal intensity, same appearances as original tumour)
Grade 4	Slight response (little areas of fibrosis or mucin but mostly tumour)
Grade 3	Moderate response (>50% fibrosis or mucin, and visible intermediate signal)
Grade 2	Good response (dense fibrosis; no obvious residual tumour, signifying minimal residual disease or no tumour)
Grade 1	Radiological complete response (rCR) (linear/crescentic 1-2mm scar in mucosa or submucosa only.)

Patient Study code:

MRI-EMVI score	Imaging features	Illustration
0		
1	Minimal extramural stranding / nodular extension seen, but not in the vicinity of any vascular structures.	
2	Stranding demonstrated in the vicinity of extramural vessels, but these vessels are of normal calibre, and there is no definite tumour signal seen within the vessel.	
3	Intermediate signal intensity apparent within vessels, although the contour and calibre of these vessels is only slightly expanded	
4	Obvious irregular vessel contour or nodular expansion of vessel by definite tumour signal.	

Form completed out by:
(Please print name)

Operation data sheet

1. Date of Operation ……/……/20.… **Consultant Surgeon……**

Operating Surgeon …… **Assisting Surgeon (grade)……**

2. A.S.A. 1 2 3 4 5

3. Has the patient undergone neoadjuvant therapy?

Yes [ ] No [ ]

Short-course radiotherapy [ ]

Long-course radiotherapy [ ]

Chemoradiotherapy [ ]

4. What was the final pre-op MRI predicted plane?

Low Anterior TME [ ]

Intersphincteric APE [ ]

ELAPE [ ]

Exenterative [ ]

5. EUA Findings:

Height above anal verge ……cm

Fixity: Mobile on muscle [ ] Tethered [ ] Fixed [ ]

Site of fixity/ tethering (Patient Lithotomy e.g. 3 – 6 o'clock):……

State if adjacent structure invasion [ ] ……

6. Tumour position: Ant. quadrant [ ] Left lateral quadrant [ ]

Circumferential [ ] Post. quadrant [ ] Right lateral quadrant [ ]

7. Actual Operation Performed

Local Excision [ ]

TME Anterior Resection [ ]

TME & Hartmanns [ ]

Intersphincteric AP Excision [ ]

TME Plane AP Excision [ ]

Extralevator AP Excision [ ]

Exenterative Procedure [ ]

Specify ……

8. Length of operation (skin incision to skin closure) ……mins

9. Blood loss …….mls

10. Was this operation: **Curative [ ]** **Palliative [ ]**
Distant metastasis [ ]
Locally residual tumour [ ]
Other ……....

11. Was there any intraoperative rectal traction injury? **Yes [ ]** **No [ ]**

Muscletube breach/ perforation **Yes [ ]** **No [ ]**

Mesorectal damage **Yes [ ]** **No [ ]**

12. Description of lateral pelvic nodal status:

Was there any visible or palpable pelvic node? **Yes [ ]** **No [ ]**

If yes, please specify where: …….

Was any node submitted for pathological examination?

Yes [ ] **No [ ]**

13. TME Status: **TME performed [ ]** **TME not performed [ ]**

14. Surgeons assessment of specimen:

Mesorectum intact [ ] **Mesorectum breached [ ]** **Obvious margin involvement [ ]**

LOW ANTERIOR RESECTION

15. Has the patient been defunctioned? **Yes [ ]** **No [ ]**
loop ileostomy [ ]
loop transverse colostomy [ ]
other ……

Splenic fixture mobilised? **Yes [ ]** **No [ ]**

Site of IMV ligation? **sigmoid mesentry [ ]**
inferior pancreatic border [ ]
other ……

Operation was: **Laparoscopic [ ]** **Open [ ]**

Type of anastomosis: **Stapled [ ]** **Hand-sewn colo-anal [ ]**

Circular stapling device used? **Yes [ ]** **No [ ]**

If yes, CDH size? …….

ABDOMINOPERINEAL EXCISION

16. Description of perineal approach to APE:

(i) Was the perineal approach done before laparotomy? Yes [ ] No [ ]

(ii) Perineum after laparotomy? Yes [ ] No [ ]

(iii) Position of patient: Prone [ ] Supine [ ]

State other ……

17. Abdominal component

Laparoscopic [ ] Open [ ]

(i) Was pelvis filled with

Small bowel [ ] Omentum [ ] Caecum [ ] Other [ ]

(ii) Did you divide the levator / puberectalis, if at all? Yes [ ] No [ ]

If yes, where?

At the pelvic side wall with en-bloc removal of the Mesorectum? [ ]

Circumferentially around muscle tube [ ]

18. Margins of excision

Anterior:	**Intersphincteric**	**[ ]**
	Outer limit of EAS	**[ ]**
	Posterior wall of vagina / prostate	**[ ]**
	Exenterative	**[ ]**
Lateral:	**Intersphincteric**	**[ ]**
	Outer limit of EAS	**[ ]**
	Inner aspect of ischial tuberosities	**[ ]**
Posterior:	**Intersphincteric**	**[ ]**
	Outer limit of EAS	**[ ]**
	Excision of coccyx	**[ ]**
	Excision of sacrum	**[ ]**

Levator present in the specimen? [ ]

19. Closure of perineal wound

Myocutaneous pedicle using:

Gluteus [ ] **Gracilis [ ]** **VRAM [ ]** **Other ……..**

Mesh [ ] **State type ……**

Simple primary closure [ ]

Plastic surgery involvement [ ]

20. Stoma construction

Simple [ ] **Biological Mesh [ ]** **Mesh [ ]**

FOR ALL OPERATIONS

21. Type of drainage

No drains used	**[ ]**		
Transabdominal	**[ ]**	**Transperineal**	**[ ]**
Active (suction)	**[ ]**	**Passive**	**[ ]**
Closed	**[ ]**	**Open**	**[ ]**

22. Other Comments ……

……

……

……

……

……

19. Closure of perineal wound

Myocutaneous pedicle using:

Gluteus [ ] Gracilis [ ] VRAM [ ] Other ……..

Mesh [ ] State type ……

Simple primary closure [ ]

Plastic surgery involvement [ ]

20. Stoma construction

Simple [ ] Biological Mesh[ ] Mesh [ ]

FOR ALL OPERATIONS

21. Type of drainage

No drains used [ ]

Transabdominal [ ] Transperineal [ ]

Active (suction) [ ] Passive [ ]

22. Other Comments …….

……

……

……

……

……

30-day morbidity & mortality form

Patient Data

Patient Study ID:		Patient name:		
Hospital ID:		Hospital:		
Date of Birth:		Sex:	M	F

Operation data

ITU/HDU post operatively?	Yes How many days?……	No
	Planned / Unplanned	

Post-operative surgical complications

Perineal wound complications	Infection	Breakdown
	Herniation	Flap Failure
Other Complications:	Anastomotic leak*	Stoma retraction
	Bleeding vessel	Visceral perforation
	Bowel ischaemia	Ureter/Organ damage
Stoma Complications	High output stoma	Retraction
	Ischaemia	Prolapse
Management of above:	Conservative	Pharmacological only
	Intervention without GA**	Intervention with GA
ITU required	No	Yes, number of days?.....

Post-operative medical complications

Respiratory	Atelectasis	Pneumonia
	Pulmonary embolus	Pulmonary oedema
	ARDS	Other……..
Gastrointestinal	Paralytic Ileus	Diarrhoea
	Obstruction	Other……..
Cardiovascular	Myocardial infarct	Heart failure
	Deep vein thrombosis	Atrial fibrillation / other arrhythmia
		Other……..
Renal	Renal failure	Other……..
Neurological	Stoke	Other……..

Outcome

Death:	Yes,	No
	Date of death …/…/…..	Date left Hospital…/…/…..

*A clinically suspected anastomotic leak, confirmed either radiologically or at relook surgery.
** Intervention includes radiological, endoscopic or surgical procedures. GA – General Anaesthetic

Please Fax to 0208 915 6067

Thank You

Amended 18/02/2013

Addressograph

Pathology Reporting Form

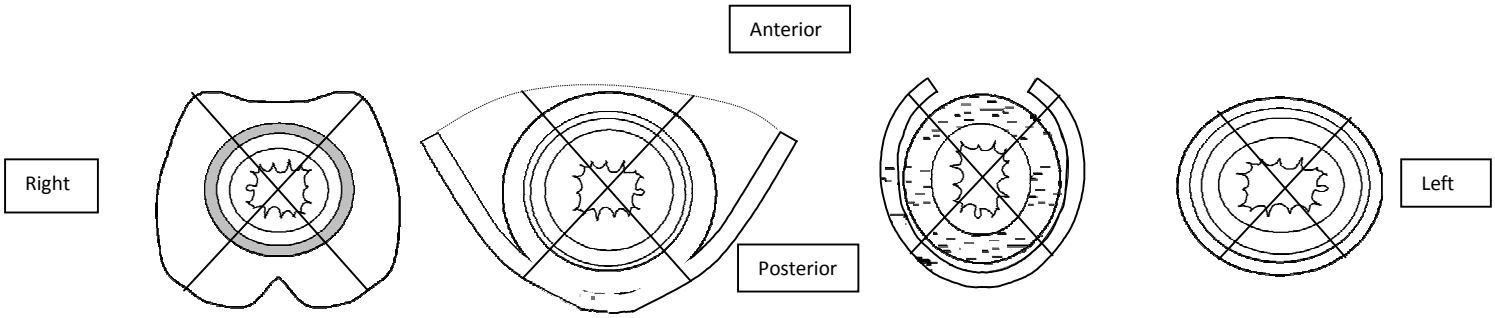
Pathologist:	Date:
Study Code:	Surgeon:
Patient initials:	Operation date …/…/20...
Date of Birth:	Sex M F

Photograph Surfaces Anterior Posterior

Tumour is above ☐ at ☐ below ☐ the peritoneal reflection

Maximum tumour diameter …..mm

Position of tumour (Please mark on diagram)



Mesorectum	Just above levator	At level of levator / puborectalis	Sphincters
1. Anterior ☐	1. Anterior ☐	1. Anterior ☐	1. Anterior ☐
2. Posterior ☐	2. Posterior ☐	2. Posterior ☐	2. Posterior ☐
3. Left Lateral ☐	3. Left Lateral ☐	3. Left Lateral ☐	3. Left Lateral ☐
4. Right Lateral ☐	4. Right Lateral ☐	4. Right Lateral ☐	4. Right Lateral ☐
5. Circumferential ☐	5. Circumferential ☐	5. Circumferential ☐	5. Circumferential ☐

Distance to distal margin …..mm

Photograph of Sequential Slices Yes ☐ No ☐

Involvement of: proximal margin Yes ☐ No ☐

distal margin Yes ☐ No ☐

Histology

Type: Adenocarcinoma Yes ☐ No ☐

Differentiation:(By predominate type) Poor ☐ Well/Mod ☐

Other tumour type (Please State) ……

Local Invasion and Perforation

Please stage the maximum extent of tumour above AND at the height of the sphincters

Above the sphincters (mesorectum)

At what distance above the top of the sphincters?

- < 1cm ☐
- Between 1 and 2 cm ☐
- > 2cm ☐

Submuscosa ☐
Inner circular layer ☐
Outer longitudinal layer ☐
Mesorectal fat ☐
Adjacent organs ☐
If so which……..

Peritoneal involvement Yes ☐ No ☐

Tumour perforation Yes ☐ No ☐

If yes: Above peritoneal reflection ☐
Below peritoneal reflection ☐

Bowel perforation Yes ☐ No ☐

If yes: Above peritoneal reflection ☐
Below peritoneal reflection ☐

At the Sphincters

Submuscosa ☐
Internal sphincter ☐
Intersphincteric space ☐
External sphincter ☐
Ischiorectal space ☐
Levator infiltration ☐
Adjacent structures ☐
If so which……..

Maximum extramural spread of tumour

- Above sphincters (from edge of muscularis propria) …..mm
- At sphincters (from edge of internal sphincter) …..mm

Minimum distance of tumour to CRM from outer edge of tumour …..mm

Is the resection complete? (>1mm to the CRM) Yes ☐ No ☐

Metastatic Spread

No of Nodes examined …….. No. of positive nodes ……..

Apical Node positive Yes ☐ No ☐

ExtramuralVascular invasion Yes ☐ No ☐

Extra – nodal deposits seen Yes ☐ No ☐

CRM Involved Yes ☐ No ☐

Maximum length of margin involvement ……mm

Mode of CRM Involvement: Direct ☐ Vascular ☐
Node ☐ Tumour Satellite ☐

Site of CRM Involvement At mesorectum ☐ Below Mesorectum (at levators/sphincters) ☐

Tissue at CRM: Normal tissue ☐ Fibrosis ☐
Tumour ☐

Distance from dentate line to lower border of Mesorectum ……..mm

Plane of resection

Mesorectum (all specimens)

Plane Muscularis propria ☐ Intramesorectal ☐ Mesorectal ☐

For Abdomino-Perineal Excision Only

Plane Perf/submucosal/in sphincter ☐ On sphincter ☐ Levators ☐

Have levators been removed en-bloc with mesorectum? Yes ☐ No ☐

Post neoadjuvant therapy tumour regression

No regression ☐ Minimal regression ☐ Moderate regression ☐

Good regression ☐ Total regression ☐

Other comments

……
……
……
……

Centre…….. **Study no**…….. **Initials**……... **Date of birth** d d / m m / y y y y

Date of follow-up d d /m m / y y y y **Months post treatment (please circle**) 12.....24....36.....60

Status on this date

Alive no disease ☐
Alive with disease ☐
Dead ☐ Date of death d d / m m / y y y y

If low anterior resection was performed, did the patient have a stoma reversal? Yes ☐ when: d d /m m / y y y y

No ☐

Recurrence

Date of recurrence d d / m m / y y y y
Site of recurrence:
Method of detection CT ☐
MRI ☐
Other ☐ Specify……

Remaining in trial

Yes ☐
No (no further follow-up) ☐ Reason for withdrawal Lost to follow-up ☐
Withdrawn consent ☐

Comment **Please give details of any important protocol deviations, serious toxicity (requiring hospitalisation), cause of death, change of doctor, etc.**

_____

_____

_____

Name of person completing form……..**Date of form completed** d d / m m / y y y y **Signature**……..…….

E-mail…….. **Telephone Number**…….. **Please fax this page to 0208 915 6721**