

# CASE RECORD FORMS: COLOR II TRIAL

A Randomized Clinical Trial Comparing Laparoscopic and Open Surgery for Rectal Cancer

The objective of the COLOR II trial is to compare locoregional recurrence after laparoscopic and open surgery for rectal cancer. For this purpose, patients with a tumor of the rectum are randomized into either for a laparoscopic or an open resection.

- Check inclusion and exclusion criteria
- Fill out informed consent form
- You can randomize your patients:

**Internet**                      [www.color2.org](http://www.color2.org) (click “investigator” and login)

**Fax**                                +1 (902) 473 4375 (see randomization form)

- At randomization, please write down randomization number on case record and follow-up forms and fill out the first forms. Write name, patient ID and randomization number on the decoding list of patients.
- Please return completed forms to the coordinating center:

COLOR II Trial Manager  
Dalhousie University Department of Surgery  
QEII Health Sciences Centre  
Victoria Building, Room 8 - 838  
1276 South Park Street  
Halifax, Nova Scotia  
Canada B3H 2Y9

Fax: +1 (902) 473 4375

- Copies of the completed forms should be kept in the **Investigator Site File**.

## INCLUSION CRITERIA

	<u>YES</u>	<u>NO</u>
• solitary rectal cancer observed at colonoscopy or on barium enema X-ray	<input type="checkbox"/>	STOP
• no evidence for distal metastases	<input type="checkbox"/>	STOP
• distal border of the tumor within 15 cm of the anal verge at rigid rectoscopy or CT / MRI-scan (or under linea conjugate at lateral barium enema radiography)	<input type="checkbox"/>	STOP
• suitable for elective surgical resection	<input type="checkbox"/>	STOP



PLEASE FILL OUT AN EXCLUSION / NON-INCLUSION - FORM

## EXCLUSION CRITERIA (PRE-RANDOMIZATION)

	<u>YES</u>	<u>NO</u>
• T1 tumor treated by local excision	STOP	<input type="checkbox"/>
• T4 tumors	STOP	<input type="checkbox"/>
• T3 tumors with margins < 2mm to endopelvic fascia (by CTscan or MRI)	STOP	<input type="checkbox"/>
• malignancy other than adenocarcinoma at cytological / histological examination	STOP	<input type="checkbox"/>
• patients under 18 years of age	STOP	<input type="checkbox"/>
• signs of acute intestinal obstruction	STOP	<input type="checkbox"/>
• more than one colorectal tumor	STOP	<input type="checkbox"/>
• Familial Adenomatosis Polyposis Coli (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC), active Crohn's disease or active colitis ulcerosa	STOP	<input type="checkbox"/>
• scheduled need for other synchronous colon surgery	STOP	<input type="checkbox"/>
• preoperative indication of invasion of adjacent organs	STOP	<input type="checkbox"/>
• preoperative evidence of metastases (at least chest X-ray and ultrasonography of liver required to rule out metastases)	STOP	<input type="checkbox"/>
• other malignancies in medical history, except adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri	STOP	<input type="checkbox"/>
• absolute contraindication to general anesthesia or prolonged pneumoperitoneum, such as severe cardiovascular or respiratory disease (ASA class > III)	STOP	<input type="checkbox"/>
• pregnancy	STOP	<input type="checkbox"/>



PLEASE FILL OUT AN EXCLUSION / NON-INCLUSION - FORM

# RANDOMIZATION FORM: COLOR II TRIAL

Use only if internet randomization fails

Hospital / City :

Fax Number :

Location of tumor :  0 – 5 cm from anal verge  
 5 – 10 cm from anal verge  
 10 – 15 cm from anal verge

Pre-operative radiotherapy :  yes  
 no

Gender :  male  
 female

Date of birth : (dd-mm-yyyy)

Doctor to whom reply fax has to be addressed:

When completed, please fax this form to the coordinating center:  
Dalhousie University, Halifax, Canada

**Fax: +1 (902) 473 4375**

**Tel: +1 (902) 473 7489**

Randomization number and randomized procedure will be returned by fax as soon as possible

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**Date:****Procedure: LAP / OPEN****Rand nr:****Doctor:**

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**IDENTIFICATION** (no 1 - 6)*If appropriate, please encircle correct figure, more than one can be encircled per question*

1. hospital :
2. randomization no. :
3. date of birth (dd/mm/yyyy) :
4. gender : 1 male  
2 female
5. date of randomization (dd/mm/yyyy) :
6. randomized procedure : 1 laparoscopic  
2 open
- 6A. pre operative clinical TNM stage : T \_\_\_\_\_ N \_\_\_\_\_ M \_\_\_\_\_

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**Rand nr:**

**Doctor:**

**PREOPERATIVE PERIOD** < 28 days prior to surgery (no 7 - 17)

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 7. date of admission (dd/mm/yyyy) :
- 8. ASA class :
- 9. length : cm
- 10. weight : kg
- 11. no. of previous abd. operations :
- 12. date of diagnosis (dd/mm/yyyy) :
  
- 13. exact location of tumor : cm (distal border from anal verge)
  
- determined by : 1 rectoscopy  
2 colonoscopy  
3 MRI  
4 CT
  
- 14. proposed type of resection :

  - 1 Resection without TME (= Partial Mesorectal Excision)
  - 2 Resection with TME with preservation of the anus
  - 3 Resection with TME without preservation of the anus (APR)

  
- 15. previous radiotherapy of the pelvis : 0 no  
1 yes
  
- 16. preoperative radiotherapy : 0 no  
(if yes, please specify dose and duration) 1 yes ..... X ..... Gy
  
- 16a. preoperative chemotherapy : 0 no  
(if yes, please specify dose and duration) 1 yes .....
  
- 16b. Participation in Quality of Life substudy : 0 no  
1 yes

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**Date:****Procedure:** LAP / OPEN**Rand nr:****Doctor:****INTRAOPERATIVE PERIOD** (no 18 - 39)

*If appropriate, please encircle correct figure, more than one can be encircled per question*

18. name(s) of surgeon(s) :
- 18a. experience (last year) :  < 10 lap colorectal procedures  
 10 - 20 lap colorectal procedures  
 > 20 lap colorectal procedures
19. date of surgery (dd/mm/yyyy) :
20. performed operative procedure : 1 resection without TME (=Partial ME)  
 2 resection with TME and preservation of the anus  
 3 resection with TME without preservation of the anus (APR)
21. please specify level of distal transaction : cm  
*(distance between distal transaction & dentate line)*
22. ureter stent : 0 no  
 1 yes
23. presence of fibrosis considered to be due to radiation : 0 no  
 1 yes
24. macroscopic metastases : 0 no  
 1 liver  
 2 peritoneal  
 3 mesentery  
 4 other :
25. macr. invasion adj. organs : 0 no  
*(if yes, please mention which organ)* 1 yes please specify:
26. Degree of pelvic autonomic nerve preservation:  
 1. Total preservation of autonomic nervous system. (hypogastric and pelvic preservation procedure)  
 2. Bilateral preservation of parasympathetic nerve system with complete removal of the sympathetic system. (bilateral pelvic preservation procedure)  
 3. Unilateral preservation of parasympathetic nerve system with complete removal of the sympathetic system. (unilateral pelvic preservation procedure)

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27. if appropriate, reason for incomplete preservation:

1. tumor invasion
2. other :

28. length of incision : cm

29. location of incision : 0 midline  
 1 transverse right  
 2 transverse left  
 3 Pfannenstiehl  
 4 other:

30. anastomosis : 0 no (stoma)  
 1 handsewn  
 2 circular stapler; size : mm  
 3 other:

31. anastomosis configuration :

- |                |                                    |                                  |   |
|----------------|------------------------------------|----------------------------------|---|
| 0 no (stoma)   |                                    |                                  |   |
| 1 end to end   | <input type="checkbox"/> ileostomy |                                  | <input type="checkbox"/> transverse colostomy |
| 2 end to side  | <input type="checkbox"/> ileostomy |                                  | <input type="checkbox"/> transverse colostomy |
| 3 side to side | <input type="checkbox"/> ileostomy | <input type="checkbox"/> J-pouch | <input type="checkbox"/> transverse colostomy |
| 4 side to end  | <input type="checkbox"/> ileostomy | <input type="checkbox"/> J-pouch | <input type="checkbox"/> transverse colostomy |

31a. Type of stapler used to transect the rectum

- |                  |                               |                                |                      |
|------------------|-------------------------------|--------------------------------|----------------------|
| 1 Reticulator    | <input type="checkbox"/> blue | <input type="checkbox"/> green | ..... no. of firings |
| 2 Curvature      | <input type="checkbox"/> blue | <input type="checkbox"/> green | ..... no. of firings |
| 3 Linear stapler | <input type="checkbox"/> blue | <input type="checkbox"/> green | ..... no. of firings |
| 4 Other          | <input type="checkbox"/> blue | <input type="checkbox"/> green | ..... no. of firings |

32. blood loss : ml

33. skin to skin time : minutes

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**Date:****Procedure:** LAP / OPEN**Rand nr:****Doctor:**

34. complication(s) : 0 none  
 1 bleeding  
 2 fixation of the tumor  
 3 gastrointestinal perforation  
 4 adhesions  
 5 hypercapnia  
 6 anastomosis related problems  
 7 injury to ureter  
 8 nerve injury  
 9 perforation tumor  
 10 other:
35. wound protection : 0 no  
 (if yes, please mention kind of) 1 yes please specify:

**PLEASE FILL OUT NEXT QUESTIONS IN CASE OF A LAPAROSCOPIC PROCEDURE**

36. laparoscopic operative steps : 1 inspection  
 2 mobilization of bowel  
 3 ligation of main vessels  
 4 oral transection of bowel  
 5 aboral transection of bowel  
 6 resection of bowel  
 7 anastomosis
38. conversion : 0 no  
 1 yes
39. if appropriate, reason for conversion :



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**Rand nr:**  
**Doctor:**

**POSTOPERATIVE PERIOD** 1-28 days after surgery; day of operation = day 0 (no 40 - 47)

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 40. date of fluid intake > 1000 ml : (dd-mm-yyyy)
- 41. date of first passage of stool : (dd-mm-yyyy)
- 42. date of discharge from hospital : (dd-mm-yyyy)

43. if appropriate, date and nature of complication(s)

date (dd-mm-yyyy):

- 1 anastomotic leakage
- 2 cardiac complications:
- 3 respiratory complications:
- 4 abscess
- 5 ileus
- 6 other:

44. if appropriate, date and nature of re-intervention(s):

date (dd-mm-yyyy):

nature:

45. if appropriate, date and cause of death:

date (dd-mm-yyyy):

cause:

46. if appropriate, date, cause and duration of readmission:

date (dd-mm-yyyy):

cause:

readmission:

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## 47. pain medication during first 3 days

*Please mention what kind of medication, quantity (mg) and, where appropriate, speed of pump (mg/ml per hour)*

## Postoperative day 1

1 opiates :

2 non-opiates :

3 epidural :

## Postoperative day 2

1 opiates :

2 non-opiates :

3 epidural :

## Postoperative day 3

1 opiates :

2 non-opiates :

3 epidural :

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*Please add this information form for the pathologist to the resected specimen***COLOR II TRIAL**

A randomized clinical trial comparing laparoscopic and open surgery for rectal cancer

Dear colleague,

The COLOR II trial is a randomized clinical trial comparing laparoscopic and open surgery for rectal cancer. The primary endpoint is locoregional recurrence three years post-operatively. In order to assess relevant oncological parameters, the pathological examination of the specimen is of utmost importance. Below you'll find the items which will be recorded for the COLOR II trial. You are kindly asked to document these items in your examination report.

*Please provide the following data on pathology*

- Completeness of resection
  - Complete* Intact mesorectum with only minor irregularities of the mesorectal surface up to the dissection level. No defect is deeper than 5 mm. No coning towards the distal margin of the specimen. Smooth circumferential resection margin.
  - Nearly Complete* Moderate bulk to the mesorectum, no visible muscularis propria, moderate coning, irregular circumferential resection margin.
  - Incomplete* Little bulk to the mesorectum with defects down onto muscularis propria and/or very irregular circumferential resection margin, coning.
- Size of tumor
- Distance of tumor from circumferential resection margin
- Distance of tumor from proximal resection margin
- Distance of tumor from distal resection margin
- If appropriate, position of tumor with respect to peritoneal deflection
- Type and differentiation of tumor
- Tumor tissue in surgical margins (i.e. radicality)
- Number of lymph nodes harvested
- Number of lymph nodes in proximal part of mesentery, that means all lymph nodes not along resected bowel (if none, please mention)
- If appropriate, nature of metastases
- If appropriate, synchronous colorectal pathology
- pTNM classification

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**Date:****Procedure:** LAP / OPEN**Rand nr:****Doctor:****PATHOLOGY** (no 48 - 60)

*If appropriate, please encircle correct figure, more than one can be encircled per question*

48. completeness of resection

1. complete = intact mesorectum with only minor irregularities of the mesorectal surface up to the dissection level. No defect is deeper than 5 mm. No coning towards the distal margin of the specimen. Smooth circumferential resection margin on slicing.
2. nearly complete = the majority of the mesorectum has been removed, no visible muscularis propria, moderate coning, irregular circumferential resection margin.
3. incomplete = mesorectum with defects down onto muscularis propria and/or very irregular circumferential resection margin, coning.

49. size of tumor : x cm

50. distance from circumferential resection margin : cm

51. distance from proximal resection margin : cm

52. distance from distal resection margin : cm

53. ~~position of tumor with respect to peritoneal deflection : cm~~

54. type and differentiation of tumor :

55. tumor tissue in surgical margins : 0 no  
 1 oral  
 2 aboral  
 3 circumferential  
 4 other :

56. no. of lymph nodes harvested :

57. no. of lymph nodes in proximal part of mesentery :  
*(all lymph nodes **not** along resected bowel)*

58. if appropriate, nature of metastases :

59. if appropriate, nature of synchronous colorectal pathology:

60. pTNM classification : pT N M

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Date:

Procedure: **LAP / OPEN**

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 1 YEAR AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 61. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 61A pre operative clinical TNM stage : T \_\_\_\_\_ N \_\_\_\_\_ M \_\_\_\_\_
- 62. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 63. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other:
- 63a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative
- Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown
- 64. postoperative adjuvant therapy : 0 no  
1 yes please specify:
- 65. re-admissions : 0 no  
(if yes, please fill out event form) 1 yes
- 66. re-interventions : 0 no  
(if yes please fill out event form) 1 yes
- 66a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

- 66b. Specify pre-operative chemotherapy: \_\_\_\_\_
- Specify pre-operative radiotherapy: \_\_\_\_\_

*(66b not required if previously submitted)*

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Date:

Procedure: **LAP / OPEN**

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 2 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 67. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 67A. pre operative clinical TNM stage : T \_\_\_\_ N \_\_\_\_ M \_\_\_\_
- 68. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 69. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :
- 69a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative  
Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown
- 70. postoperative adjuvant therapy : 0 no  
1 yes please specify:
- 71. re-admissions : 0 no  
(if yes, please fill out event form) 1 yes
- 72. re-interventions : 0 no  
(if yes, please fill out event form) 1 yes
- 72a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

72b. Specify pre-operative chemotherapy: \_\_\_\_\_

Specify pre-operative radiotherapy: \_\_\_\_\_

*(72b not required if previously submitted)*

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Procedure: LAP / OPEN

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 3 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 73. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 73A. pre operative clinical TNM stage : T \_\_\_\_\_ N \_\_\_\_\_ M \_\_\_\_\_
- 74. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 75. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :
- 75a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative
- Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown
- 76. colon examination : 1 barium enema  
2 colonoscopy  
3 CT  
4 MRI  
5 other
- 77. result colon examination : 0 normal  
1 2<sup>nd</sup> tumor specify:  
2 stenosis specify:  
3 other specify:

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Doctor:

**FOLLOW UP FORM FOR VISIT 3 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

78. liver examination : 1 ultrasonography  
2 CT  
3 MRI  
4 other specify:

79. thorax examination : 1 X-ray  
2 CT  
3 MRI  
4 other specify:

80. recurrence : 0 no  
*(if yes, please fill out recurrence form)* 1 yes

81. re-admissions : 0 no  
*(if yes, please fill out event form)* 1 yes

82. re-interventions : 0 no  
*(if yes, please fill out event form)* 1 yes

82a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

82b. Specify pre-operative chemotherapy: \_\_\_\_\_

Specify pre-operative radiotherapy: \_\_\_\_\_

*(82b not required if previously submitted)*



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Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 4 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 83. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 83A. pre operative clinical TNM stage : T \_\_\_\_\_ N \_\_\_\_\_ M \_\_\_\_\_
- 84. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 85. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :
- 85a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative  
Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown
- 86. postoperative adjuvant therapy : 0 no  
1 yes please specify:
- 87. re-admissions : 0 no  
(if yes, please fill out event form) 1 yes
- 88. re-interventions : 0 no  
(if yes, please fill out event form) 1 yes
- 88a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

- 88b. Specify pre-operative chemotherapy: \_\_\_\_\_
- Specify pre-operative radiotherapy: \_\_\_\_\_

*(88b not required if previously submitted)*

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Date:

Procedure: **LAP / OPEN**

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 5 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 89. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 89A pre operative clinical TNM : T \_\_\_\_ N \_\_\_\_ M \_\_\_\_
- 90. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 91. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :
- 91a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative
- Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown  
4
- 92. postoperative adjuvant therapy : 0 no  
1 yes please specify:
- 93. re-admissions : 0 no  
(please fill out event form) 1 yes
- 94. re-interventions : 0 no  
(please fill out event form) 1 yes
- 94a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

94b. Specify pre-operative chemotherapy: \_\_\_\_\_

Specify pre-operative radiotherapy: \_\_\_\_\_

*(94b not required if previously submitted)*

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Date:

Procedure: **LAP / OPEN**

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 6 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

- 95. date of visit (dd/mm/yyyy) : \_\_\_\_\_
- 96. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes
- 97. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :
- 69a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative  
Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown
- 98. postoperative adjuvant therapy : 0 no  
1 yes please specify:
- 99. re-admissions : 0 no  
(if yes, please fill out event form) 1 yes
- 100. re-interventions : 0 no  
(if yes, please fill out event form) 1 yes
- 100a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

100b. Specify pre-operative chemotherapy: \_\_\_\_\_

Specify pre-operative radiotherapy: \_\_\_\_\_

(100b not required if previously submitted)

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Date:

Procedure: LAP / OPEN

Rand nr:

Doctor:

**FOLLOW UP FORM FOR VISIT 7 YEARS AFTER SURGERY**

*If appropriate, please encircle correct figure, more than one can be encircled per question*

101. date of visit (dd/mm/yyyy) : \_\_\_\_\_

102. recurrence : 0 no  
(if yes, please fill out recurrence form) 1 yes

103. complications : 0 no  
1 incisional hernia, please specify location  
(which port or incision)  
.....  
2 complaints of bowel function, other than ileus  
3 stress urinary incontinence  
4 sexual dysfunction  
5 fecal incontinence  
6 other :

69a. Bowel obstruction : 0 no  
1 yes  surgery  
 conservative

Cause of bowel obstructions : 1 benign  
2 malignant  
3 unknown

104. postoperative adjuvant therapy : 0 no  
1 yes please specify:

105. re-admissions : 0 no  
(if yes, please fill out event form) 1 yes

106. re-interventions : 0 no  
(if yes, please fill out event form) 1 yes

106a. Has ileostomy been reversed? 0 no  
1 yes

If yes: Date: \_\_\_\_\_(dd/mm/yy)

Complications: \_\_\_\_\_

106b. Specify pre-operative chemotherapy: \_\_\_\_\_

Specify pre-operative radiotherapy: \_\_\_\_\_

(106b not required if previously submitted)

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Victoria Building, Room 8 - 838  
1276 South Park Street, Halifax, Nova Scotia  
Canada B3H 2Y9  
Tel: +1 (902) 473 7489  
Fax: +1 (902) 473 4375

**Date:****Procedure:** LAP / OPEN**Rand nr:****Doctor:**

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**RECURRENCE FORM***If appropriate, please encircle correct figure, more than one can be encircled per question*

107. date of diagnosis of (re)recurrence (dd-mm-yyyy) :
108. number of recurrence (first, second, etc.) :
109. nature of recurrence : 1 locoregional  
2 liver metastasis  
3 lung metastasis  
4 trocar wound recurrence  
5 minilaparotomy wound recurrence  
6 laparotomy wound recurrence  
7 other :
110. date of cancer related death (dd-mm-yyyy) :

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Procedure: **LAP / OPEN**

Rand nr:

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**RECURRENCE FOLLOW UP FORM**

*In case of re-recurrence, please fill out a new recurrence form*

111. treatment : *(if appropriate, please describe type of procedure)*

0 no

1 curative resection :

2 palliative resection :

3 other :

112. date of cancer related death (dd/mm/yyyy) :

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**RECURRENCE FOLLOW UP FORM**

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**FORM FOR EVENTS***Please don't forget to mention randomization number in upper right corner*

113. Date of event (dd-mm-yyyy) :
114. Sort event :
115. Date of death (dd-mm-yyyy) :
116. Cause of death :
117. Cause of bowel obstruction : 0 no bowel obstruction  
 1 herniation  
 2 strangulation  
 3 non malignant stenosis  
 4 other:
118. Other complication(s) : 0 no  
 1 incisional hernia  
 2 complaints of bowel function (other than ileus)  
 3 other:
119. Date of re-operation (dd-mm-yyyy) :
120. Nature of re-operation :

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**FORM FOR EVENTS***Please don't forget to mention randomization number in upper right corner*

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