ACRIN 6664

NATIONAL CT COLONOGRAPHY TRIAL
Case Report Form Set

American College of Radiology Imaging Network
CT Colonography
Forms Index

ACRIN Study 6664
CT Colonography
Case # : _____

		Version Date	Submission Date
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See next page for Cost Effectiveness Forms

1 The "person responsible for the data" refers to the individual who has collated the data on this specific data form.

2 The "person entering data" is the individual who enters the data from the specific form into the web data form.

3 The "data form completed" is the date the worksheet, 'paper' CRF, etc. is completed, not the date it is entered into the web form. However, in most instances, the date form completed will be the same as the date of web data entry.

***** Submission date" - This column is intended as a tracking tool for forms submission on individual cases. It is recommended that the RA maintain a printed copy within each case file as a tool to document form submission.

American College of Radiology Imaging Network
CT Colonography
Forms Index

ACRIN Study 6664
CT Colonography
Case # : _____

Cost Effectiveness

		Version Date	Submission Date
CS	Coversheet for PQ Form	09-02-05	
ES	Participant Coversheet for PQ Form	01-26-05	
PQ	Patient Cost and Acceptability Form	01-26-05	
TM	Time / Motion Form	01-26-05	
T2	Time / Motion Form	01-26-05	

Image Quality Control

DP	Imaging Transmittal Form Worksheet	03-17-05	
QA	CT Quality Assessment Form	07-12-05	

APPENDIX II
Eligibility Checklist

ACRIN Institution # _____

ACRIN 6664 Case#_____

ELIGIBILITY CHECK

Eligibility Requirements: Inclusion Criteria (a response coded other than that prompted renders a participant ineligible for enrollment).

_____ (Y) 1. Participant is scheduled for a screening colonoscopy exam.

___/___/_____ 2. Scheduled date of Colonoscopy exam.
mm/ dd / yyyy

_____(Y) 3. Participant is aged 50 years or older.

Eligibility Requirements: Exclusion Criteria (a response coded other than that prompted renders a participant ineligible for enrollment).

_____(N) 4. Serious medical condition that would increase the risk associated with colonoscopy or is so severe that screening would not benefit the participant.

_____ (N) 5. Lower GI Symptoms related to melanotic stools and or hematochezia (on more than one occasion within previous 6 months)

_____(N) 6. Lower abdominal pain requiring medical intervention.

_____(N) 7. Personal history (participant) of adenomatous familial polyposis (genetic syndrome).

_____(N) 8. Personal (participant) history of inflammatory bowel disease.

_____(N) 9. Pregnancy.

_____ (N) 10. Anemia (hemoglobin less than 10gm/dl).

_____ (N) 11. Prior colonoscopy in the past 5 years.

_____ (N) 12. Positive fecal occult blood test (FOBT).

The following questions will be asked at Study Registration:

_____ 1. Name of institutional person registering this case?

_____(Y) 2. Has the Eligibility Checklist (above) been completed?

_____(Y) 3. Is the participant eligible for this study?

___/___/____ 4. Date the study-specific Consent Form was signed? (must be signed prior to any study procedure)

mm / dd / yyyy

_____ 5. Participant's Initials (Last, First) (L, F)(numerics may be used other than the case number, NNNN)

_____ 6. Verifying Physician

_____ 7. Participant ID # (optional: this is an institution's method of internally tracking a participant to a protocol case number; may code a series of 9s)

_____ 8. Date of Birth (mm/dd/yyyy)

_____ 9. Ethnicity

- 1 Hispanic or Latino
- 2 Not Hispanic or Latino
- 9 Unknown

10. Race (check all that apply)

- ❑ American Indian or Alaskan Native
- ❑ Asian
- ❑ Black or African American
- ❑ Native Hawaiian or other Pacific Islander
- ❑ White
- ❑ Unknown

_____ 11. Gender

- 1 Male
- 2 Female

_____ 12. Participant's Country of Residence (if country of residence is other, complete Q18)

- 1 United States
- 2 Canada
- 3 Other
- 9 unknown

_____ 18. Other country, specify (completed only if Q12 is coded **other**)

__ __ __ __ __ 13. Zip Code (5 digit code, US residents only)

_____ 14. Participant's Insurance Status

- 0 Other
- 1 Private insurance
- 2 Medicare
- 3 Medicare and Private insurance
- 4 Medicaid
- 5 Medicaid and Medicare
- 6 Military or Veteran Administration
- 7 Self-pay
- 8 No means of payment
- 9 Unknown/declined to answer

_____ 15. Will any component of the participant's care be given at a military or VA facility?

1 No
2 Yes
9 Unknown

____/____/_____ 16. Scheduled date of CTC exam (mm/dd/yyyy)

_____ 17. Registration Date

Completed by _____ Date form completed: __/___/____

Participant signature: _____
(If information is obtained through direct interview with the participant, participant signature and date MUST appear on document)

_____
Signature of person entering data onto the web

I1 ACRIN 6664
CT Colonography On-Study Evaluation/Medical History Data

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, indicate by checking box. ☐

Instructions: The on study and medical history data is completed and submitted to the ACR via the web within 1 week of registration. Information may be obtained from clinical charts, specific questionnaire or directly from the participant via interview. If any portion of the data is supported by participant interview, the form must be signed and dated by the participant.

I. GENERAL (Colonoscopy must take place within 30 days after CTC)

1. Date of Screening Colonoscopy exam

_____-_____-_____
mm dd yyyy

2. Date of CTC exam _____-_____-_____
mm dd yyyy

II. LOWER GI TRACT MEDICAL HISTORY (participant history)

3. Indication(s) prompting colonoscopy exam:
(Check all that apply)

- ☐ Screening, no symptoms
- ☐ Follow-up to test(s)
  - ☐ FOBT
  - ☐ Barium enema
  - ☐ Proctosigmoidoscopy
  - ☐ Colonoscopy, Date of last exam_____-_____ mm-yyyy
    (If date is unknown, code as 12-2100)
- ☐ Personal history of polyps or cancer
- ☐ Irritable bowel syndrome
- ☐ Family history of colon cancer
  - ☐ Mother
  - ☐ Father
  - ☐ Sister(s)
  - ☐ Brother(s)
  - ☐ Other, specify: _____

III. BOWEL PREPARATION ASSESSMENT

4. Type of colon preparation utilized (check one)

- o Go-Lytely lavage preparation plus bisacodyl tablets
- o Phosphosoda, plus bisacodyl tablets
- o Magnesium citrate, plus bisacodyl tablets
- o Other, specify: _____

5. Was the cathartic laxative (Go-Lytely, Phosphoda or Magnesium Citrate) taken as directed

- o No (Answer Q5a, and continue with form)
- o Yes (Continue with form)

5a. ____ % provide percent consumed

6. Were 10mg (2 tablets) of bisacodyl taken?

- o No (Answer Q6a, and continue with form)
- o Yes (Continue with form)

6a. ____ number of tablets taken

7. Was the barium sulfate taken as directed?

- o No (Answer Q7a and Q7b, then continue with form)
- o Yes (Continue with form)

7a. ____ % estimate percentage consumed

7b. Specify when barium sulfate was consumed
(A check ☑ equals a "yes" response)

- ☐ Breakfast
- ☐ Lunch
- ☐ Dinner

8. Was the iodinated oral contrast taken as directed?

- o No (Answer Q8a and Q8b, then continue with form)
- o Yes (Continue with form)

8a. ____ % estimate percentage consumed

8b. Specify when iodinated oral contrast was consumed
(A check ☑ equals a "yes" response)

- ☐ Bed time
- ☐ Morning of exam

IV. Medical History

9. Other known medical conditions? (record only "yes" responses from the participant completed questionnaire.)

- o No (sign and date form)
- o Yes (proceed to Q9a and Q9b)
- o Unknown (sign and date form)

Continued on page 2

I1 **Revision** ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

9a. Check all applicable medical history events:

(A ☑ equals a yes response)

- ☐ Lung cancer or nodule
- ☐ Kidney cancer or cyst
- ☐ Kidney stones
- ☐ Abdominal Aortic Aneurysm
- ☐ Liver disease/Cirrhosis
- ☐ Hernia
- ☐ Gallbladder disease (not including cholecystectomy)
- ☐ Cyst or cancer of the ovary

9b. List any other significant abdominal medical problems:

1. _____
2. _____
3. _____
4. _____
5. _____

If information reported directly on the form has been obtained through participant interview only, signature of the participant must appear below.

_____ _____-_____-_____

Participant's signature Date

COMMENTS: _____

_____

_____

_____ _____-_____-_____

Name of person responsible for data [1] Date form completed

_____

Name of person entering data into web [2]

TA

ACRIN 6664

CT Colonography
Local CTC Acquisition Form

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, indicate by checking box. ☐

Instructions: This form is completed by the Research Associate or Technologist and submitted via the ACRIN web. Report all data on the actual conditions under which the CTC exam was performed.

I. General

1. **Date of CTC exam** _____-_____-_____ mm-dd-yyyy

2. **Person performing colon insufflation** (check one)
   - o Research associate
   - o Technologist
   - o Nurse
   - o Physician
   - o Other _____

   2a. Was a physician immediately available during exam? **(e.g. adjacent room or within radiology department)**
   - o No
   - o Yes
   - o Unknown

   2b. Record time patient enters room ☐☐☐☐ **(military time; e.g. 9am = 0900, 3pm = 1500)**

   2c. Record time patient leaves room ☐☐☐☐ **(military time; e.g. 9am = 0900, 3pm = 1500)**

II. Procedure Preparation

3. **Method performed for insufflation of colon** (check one)
   - o Mechanical insufflation
   - o Manual insufflation
   - o Mechanical and manual insufflation

4. **Gas used for insufflation** (check one)
   - o Room air
   - o CO_2
   - o Room air and CO_2
   - o Venting to room air
   - o Other, specify _____

5. **Glucagon administered** (check one)
   - o No (complete Q5a only)
   - o Yes (complete Q5b, 5c, and 5d)

   5a. If glucagon not administered: check one
   - o Brittle diabetic
   - o Pheochromocytoma
   - o Patient request
   - o Other, specify _____

   5b. If glucagon administered: route of administration
   - o Subcutaneous
   - o Other, specify _____

   5c. ☐☐☐ **mg/ml**

   5d. Elapsed time from glucagon injection to beginning of insufflation ☐☐☐ **(minutes)**

6. **Are there any reportable complications / adverse events per protocol Sec. 17.4?**
   - o No
   - o Yes, Complete Adverse Event Reporting Form (AE)

III. CT Acquistion Parameters

7. **Specify scanner type** (check one and complete Q7a)
   - o GE (complete chart 1)
   - o Siemens (complete chart 2)
   - o Philips (complete chart 3)
   - o Toshiba (complete chart 4)

TA

Revision ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

7a. Complete parameters based on Scanner type used:

#1

GE	
Algorithm	
Thickness (mm)	☐☐.☐☐
Interval (mm)	☐☐.☐
Rotation Time (s)	☐.☐☐
Detector Configuration	☐☐ x ☐.☐☐
Pitch	☐.☐☐☐
kVp	☐☐☐
mA	☐☐☐
Feed (mm/rot)	☐☐.☐☐
DFOV (cm)	☐☐
CTDI mGy	☐.☐

#2

SIEMENS	
Kernel	
Width (mm)	☐.☐☐
Interval (mm)	☐.☐
Rotation Time (s)	☐.☐☐
Collimation	☐☐ x ☐.☐☐
Pitch	☐.☐☐☐
kVp	☐☐☐
Effective mAs	☐☐☐
Feed (mm/rot)	☐☐.☐☐
DFOV (cm)	☐☐
CTDI mGy	☐.☐

#3

PHILIPS	
Algorithm	
Thickness (mm)	☐.☐☐
Interval (mm)	☐.☐
Rotation Time(s)	☐.☐☐
Detector Configuration	☐☐ x ☐.☐☐
Pitch	☐.☐☐☐
kVp	☐☐☐
mAs/slice	☐☐☐
Feed (mm/rot)	☐☐.☐☐
DFOV (cm)	☐☐
CTDI mGy	☐.☐

#4

TOSHIBA	
Algorithm	
Thickness (mm)	☐.☐☐
Interval (mm)	☐.☐
Rotation Time(s)	☐.☐☐
Detector Configuration	☐☐ x ☐.☐☐
Pitch	☐.☐☐☐
kVp	☐☐☐
mA	☐☐☐
Feed (mm/rot)	☐☐.☐☐
DFOV (cm)	☐☐
CTDI mGy	☐.☐

Comments: _____

_____

_____

_____

Name of person completing the form[1]

_____

Name of person entering data into web[2]

_____-_____-_____

Date form completed (mm-dd-yyyy)

C2 ACRIN 6664 CT Colonography Local CTC Interpretation

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the Radiologist interpreting the exam. The completed form is submitted via the ACRIN web site. The images are reviewed using the primary image review method assigned at registration. **This form must be completed while blinded to the colonoscopy results and prior to completing the PL Form.**

I. GENERAL INFORMATION

1. Did study commence?
- o No* (complete Q1a)
- o Yes (proceed to Q2)

1a. *If no, give reason (then skip to Signature Page) [In all instances other than patient refusal, the exam should be rescheduled]
- o Scheduling problems
- o Equipment failure
- o Patient refusal
- o Medical reasons
- o Other, specify _____
- o Unknown

2. Study completed?
- o No* (complete Q2a and Q3, then sign and date form)
- o Yes (proceed to Q3)

2a. *Reason not completed (check one) [In all instances other than patient refusal, the exam should be rescheduled]
- o Equipment failure
- o Patient refusal
- o Medical reasons
- o Other, specify _____
- o Unknown

3. Date of CTC exam ____-____-_____ (mm-dd-yyyy)

4. Date of CTC interpretation ____-____-_____ (mm-dd-yyyy)

5. Reader ID # |_|_|_|_|_|_|_|

5a. Primary image review method: (primary image review method is designated at time of participant registration)
- o 2D conventional (with 3D problem solving)
- o 3D endoluminal fly-through (with 2D problem solving)

6. Machine Software:
- o Siemens
- o GE
- o Philips
- o Viatronix
- o Vital Images
- o Other, specify _____

C2

Revision ☐

ACRIN Study 6664 Case #
PLACE LABEL HERE
Institution _____ Institution No. _____
Patient's Name _____ Patient's I.D. No. _____

II. COLONOGRAPHY PREPARATION ASSESSMENT

7. ____ Interpretation start time
(military time, e.g. 9:00 a.m. = 0900, 3:00 p.m. = 1500)

8. ____ Interpretation end time
(military time, e.g. 9:00 a.m. = 0900, 3:00 p.m. = 1500)

9. Colon Assessment:

Segment	Preparation Assessment				≥ 5 mm	≥ 10 mm
	Residual Fluid	Residual Stool	Bowel Distention	Breathhold Artifacts	Confidence of polyp	Confidence of polyp
	1 No luminal fluid present **0%** 2 Minimal fluid present **1-25%** 3 Moderate amount **25-50%** 4 More than **50%** full	1 No stool 2 Small particles present (did not compromise study) 3 Moderate amount of solid stool, diagnostic 4 Lumen full of liquid stool, non-diagnostic	1 Entire segment visualized and well distended 2 Entire segment visualized but under distended 3 Poorly visualized 4 Collapsed	1 No breathhold artifacts 2 Moderate 3 Severe, non-diagnostic	0 No lesions identified of the designated size 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	
Rectum	☐	☐	☐	☐	☐	☐
Sigmoid	☐	☐	☐	☐	☐	☐
Descending	☐	☐	☐	☐	☐	☐
Transverse	☐	☐	☐	☐	☐	☐
Ascending	☐	☐	☐	☐	☐	☐
Cecum	☐	☐	☐	☐	☐	☐

10. Does this patient have any significant findings ≥ 5 mm in largest diameter?
- o No (proceed to Q12)
- o Yes (complete Q10a and 10b and continue with form)

10a. What is your confidence that this patient has at least one lesion ≥ 5 mm in largest diameter that would be classified as a polyp? (check one)
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

10b. ____ % **What is the estimated probability that at least one finding ≥ 5 mm is a polyp?** (0-100%)

11. Does this patient have any significant findings ≥ 10 mm in largest diameter?
- o No (proceed to Q12)
- o Yes (complete Q11a and Q11b and continue with form)

11a. What is your confidence that this patient has at least one lesion ≥ 10 mm in largest diameter that would be classified as a polyp? (check one)
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

11b. ____ % **What is the estimated probability that at least one finding ≥ 10 mm is a polyp?** (0-100%)

12. Are there any Extracolonic findings to report?
- o No
- o Yes (complete form FX-Extracolonic Findings)

COMMENTS: _____

_____

_____ ____-____-_____
Name of person responsible for data [1] Date form completed

_____
Name of person entering data into web [2]

WX ACRIN 6664 CT Colonography Local CTC Interpretation Worksheet

If this is a revised or corrected form, indicate by checking box ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.**_____

Participant Initials_____ **Case No.**_____

Instructions: This form is completed by the Radiologist. **This form must be completed while blinded to the colonoscopy results and prior to completing the PL Form. A completed form is submitted to ACRIN via the website.** A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN Data Management.

I. General Information:

1. **Date of CTC exam** _____ - _____ - _____
   mm dd yyyy

2. **Date of interpretation** _____ - _____ - _____
   mm dd yyyy

3. **Reader ID #** |_|_|_|_|_|_|_|

4. **Machine Software** **Software Version**
   - o Siemens _____
   - o GE _____
   - o Philips _____
   - o Viatronix _____
   - o Vital Images _____
   - o Other, specify: _____ _____

II. CTC Interpretation:

5. |_|_|_|_| **Interpretation start time** [Exclude load time] (military time, e.g., 9:00a.m.=0900,3:00p.m. =1500)

6. |_|_|_|_| **Interpretation end time**

7. **Are there any colonic findings to report?**
   - o No (proceed to comments, page 3)
   - o Yes (continue with form, pages 2 and 3)

Continued on page 2

WX

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

8. Colon Assessment: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**
- ◆ For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column* *y=row* *z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column* *y=row* *z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
1				x _____ y _____ z _____		x _____ y _____ z _____							
2				x _____ y _____ z _____		x _____ y _____ z _____							
3				x _____ y _____ z _____		x _____ y _____ z _____							
4				x _____ y _____ z _____		x _____ y _____ z _____							
5				x _____ y _____ z _____		x _____ y _____ z _____							

Continued on page 3

WX

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

9. <u>Colon Assessment continued</u>: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

- For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column* *y=row* *z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column* *y=row* *z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
6				x _____ y _____ z _____		x _____ y _____ z _____							
7				x _____ y _____ z _____		x _____ y _____ z _____							
8				x _____ y _____ z _____		x _____ y _____ z _____							
9				x _____ y _____ z _____		x _____ y _____ z _____							
10				x _____ y _____ z _____		x _____ y _____ z _____							

Comments: _____

_____

_____ _____ _____ - _____ - _____

Name of person responsible for data[1] Name of person entering data into web[2] Date form completed (mm-dd-yyyy)

W1

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet (Lesions 11-20)

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, indicate by checking box ☐

Instructions: This form is completed by the Radiologist. A completed form is submitted to ACRIN via the website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN Data Management.

I. General Information:

1. **Date of CTC exam** _____ - _____ - _____
   mm dd yyyy

2. **Date of interpretation** _____ - _____ - _____
   mm dd yyyy

3. **Reader ID #** |_|_|_|_|_|_|_|

4. **Machine Software** **Software Version**
   - o Siemens _____
   - o GE _____
   - o Philips _____
   - o Viatronix _____
   - o Vital Images _____
   - o Other, specify: _____ _____

II. CTC Interpretation:

5. |_|_|_|_| **Interpretation start time** [Exclude load time] (military time, e.g., 9:00a.m.=0900,3:00p.m. =1500)

6. |_|_|_|_| **Interpretation end time**

7. **Are there any colonic findings to report?**
   - o No (proceed to comments, page 3)
   - o Yes (continue with form, pages 2 and 3)

Continued on page 2

W1

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet (Lesions 11-20)

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Revision ☐

8. Colon Assessment: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**
◆ For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column y=row z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column y=row z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
11				x _____ y _____ z _____		x _____ y _____ z _____							
12				x _____ y _____ z _____		x _____ y _____ z _____							
13				x _____ y _____ z _____		x _____ y _____ z _____							
14				x _____ y _____ z _____		x _____ y _____ z _____							
15				x _____ y _____ z _____		x _____ y _____ z _____							

Continued on page 3

W1

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet (Lesions 11-20)

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

9. Colon Assessment continued: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

- For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column y=row z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column y=row z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
16				x _____ y _____ z _____		x _____ y _____ z _____							
17				x _____ y _____ z _____		x _____ y _____ z _____							
18				x _____ y _____ z _____		x _____ y _____ z _____							
19				x _____ y _____ z _____		x _____ y _____ z _____							
20				x _____ y _____ z _____		x _____ y _____ z _____							

Comments: _____

_____

_____ Name of person responsible for data[1]

_____ Name of person entering data into web[2]

_____ - _____ - _____ Date form completed (mm-dd-yyyy)

PL

ACRIN 6664
CT Colonography
Local Colonoscopy/Pathology Form

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the participating (6664 Radiologist), based on the Local Colonoscopy and Pathology interpretations. **The radiologist must complete Forms C2 and WX while blinded to the colonoscopy results and prior to completing the PL Form.** Record the time the PL Form is started in military format. The form is submitted via the ACRIN website. Only submit forms to ACRIN for revisions - corrections. If submitted to ACRIN, Mail or Fax to (215-717-0936).

NOTE: On page 2 (question 7) Lesion size(s): ONLY LESION(s) 5mm or greater will need pathology submission to the central pathology laboratory at the Mayo Clinic. The following forms, reports will be sent: (P4 with the left half completed by the RA, PC, P1, C3, and S2 if applicable) - See protocol for descriptions.

Enter time form is started here ☐☐ : ☐☐

I. Colonoscopy

1. Was colonoscopy completed or attempted?

- o No, exam not attempted (Complete Q1a, sign and date form)
- o No, exam not completed, no findings (Complete Q1a, Q2, Q3, and Q5, then proceed to comments and sign and date form)
- o Yes (Proceed to Q2)
- o Yes, No findings to report (Answer Q2, Q3, Q4, Q5, Q6, then proceed to comments and sign and date form)
- o Incomplete exam with findings (Complete Q1a, Q2, Q3, Q4, Q5 and Q6)

1a.
- o Contraindications
- o Scheduling problem
- o Equipment failure
- o Patient refusal
- o Medical reason
- o Other, specify _____
- o Unknown

2. Date of colonoscopy exam _____-_____-_____
mm dd yyyy

3. Segment to which colonscopy reached:

- o Rectum
- o Sigmoid
- o Descending
- o Transverse
- o Ascending
- o Cecum

4. Is there indication of prior colon resection?

- o No (Proceed to Q5)
- o Yes (Complete Q4a, and continue)

4a. Indicate most proximal section remaining:
- o Rectum
- o Sigmoid
- o Descending
- o Transverse
- o Ascending
- o Cecum

5. Are there any reportable complications / adverse events from Colonoscopy per protocol Sec. 17.4?

- o No
- o Yes, [Complete Adverse Event Reporting Form (AE)]

II. Surgery

6. Was surgery performed post colonoscopy?

- o No (continue with form)
- o Yes (Provide date of surgery in Q6a, and continue)
- o Unknown

6a. Date of surgery _____-_____-_____
mm dd yyyy

PL

Revision ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

7. Colonoscopy/Pathology Results. *Record lesion size based on pathology for all instances except when the lesion is removed in pieces; if lesion is removed in pieces, record the estimated size from the colonoscopy report.

Lesion #	**Segment** (1-6)	**Size** (mm) e.g. xx	***Size source** 1=Colonoscopy 2=Pathology	**Specimen removed in pieces** ☑	**Histology** (1-17, 88, 98)	****Other Histology Specified (write in)**	**Morphology** (1-4, 8)	*****Other Morphology Specified (write in)**	**Treatment** (0-4)	**Additional Findings** 1 No 2 Yes
1				☐						
2				☐						
3				☐						
4				☐						
5				☐						
6				☐						
7				☐						
8				☐						
9				☐						
10				☐						
11				☐						
12				☐						
13				☐						
14				☐						
15				☐						
16				☐						
17				☐						
18				☐						
19				☐						
20				☐						

Segment:
1 Rectum
2 Sigmoid
3 Descending
4 Transverse
5 Ascending
6 Cecum

Histology:
1 Adenocarcinoma
2 Medullary carcinoma
3 Mucinous carcinoma (colloid type) (greater than 50% mucinous carcinoma)
4 Signet ring cell carcinoma (greater than 50% signet ring cell)
5 Squamous cell (epidermoid) carcinoma
6 Adenosquamous carcinoma
7 Small cell carcinoma
8 Undifferentiated carcinoma
9 Carcinoma, NOS
10 Hyperplastic
11 Lipomatous

Histology continued:
12 Adenomatous
13 Tubular adenoma
14 Tubulovillous adenoma
15 Villous adenoma
16 Tubulovillous adenoma with dysplasia
17 Normal mucosa
88 Other, specify**
98 Not applicable

Morphology:
1 Sessile
2 Pendunculated
3 Flat[2] (colonoscopy)
4 No comment
8 Other***

Treatment:
0 Not detected, at colonoscopy
1 Detected, no RX, not removed
2 Biopsy removal
3 Fulguration (burnt off)
4 Surgical removal

[2]**Note:** "Flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.

PL

Revision ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

III. TNM Stage [AJCC Cancer Staging Manual, 6th edition]

8. Has specimen histology yielded a diagnosis of cancer? (stage is based on worst finding)

- o No (sign and date form)
- o Yes (complete Q8a, 8b, and 8c)

8a. Primary Tumor (T)

- o **TX** Primary tumor cannot be assessed
- o **T0** No evidence of primary tumor
- o **Tis** Carcinoma in situ: intraepithelial or invasion of lamina propria
- o **T1** Tumor invades submucosa
- o **T2** Tumor invades muscularis propria
- o **T3** Tumor invades through the muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
- o **T4** Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

8b. Regional Lymph Nodes (N)

- o **NX** Regional lymph nodes cannot be assessed
- o **N0** No regional lymph node metastasis
- o **N1** Metastasis in 1 to 3 regional lymph nodes
- o **N2** Metastasis in 4 or more regional lymph nodes

8c. Distant Metastasis (M)

- o **MX** Distant metastasis cannot be assessed
- o **M0** No distant metastasis
- o **M1** Distant metastasis

Comments: _____

_____

_____

_____

_____

Name of person responsible for data[1]

_____

Name of person entering data into web[2]

_____-_____-_____

Date form completed (mm-dd-yyyy)

B1 ACRIN 6664 CT Colonography Lesion Photograph Transmittal

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is used to submit photographs of all lesions removed during colonoscopy as well as a photograph documenting the completed colon examination (either the appendiceal orifice or ileocecal valve). Label photograph underneath image if not labeled on image already. Use as many pages as necessary to submit all photographs.

Total # of images _____ **Total # of pages** _____

_____ _____-_____-_____

Name of individual submitting photographs Date (mm - dd - yyyy)

_____

Name of person submitting form

P4 ACRIN 6664 CT Colonography Core Colonoscopy/Pathology Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: Part A is to be completed by the Research Associate. After completion of Part A, the form is sent to the Core Pathologist for completion of Part B. Part B will be completed by the Core Pathologist based on the pathologic material available. Part C will be completed by the Alternate Core Pathologist if a second opinion is needed. At the time of slide submission a copy of the PC form, the P4 form and the P1 (pathology report) should be mailed to ACRIN 6664 Data Management, 1818 Market Street, Suite 16, Philadelphia, PA 19103. **A separate form is submitted for each lesion.**

Part A (completed by site Research Associate)

1. **Date of procedure** _____-_____-_____ (mm-dd-yyyy)

2. **Date specimen sent to core lab**

   _____-_____-_____ (mm-dd-yyyy)

3. ☐ **Number of slides submitted on this specimen**

4. **Finding # _____ of # _____ as identified on Colonoscopy. To maintain consistency in reporting of lesions, the "Finding #" is column 1 on the PL form.**

5. **Segment** (check one)
   - o Rectum
   - o Sigmoid
   - o Descending
   - o Transverse
   - o Ascending
   - o Cecum

Completed by (Site RA) _____

Part B (completed by Core Pathologist)

1. ☐ **Core Pathology Reviewer**
   - 1 Lawrence Burgart M.D.
   - 2 Other _____

2. **Histology of Index Lesion**
   (Check all that apply; A ☑ indicates a "yes" response)

Histopathological Type
- ☐ Adenocarcinoma
- ☐ Medullary carcinoma
- ☐ Mucinous carcinoma (colloid type) (greater than 50% mucinous carcinoma)
- ☐ Signet ring cell carcinoma (greater than 50% signet ring cell)
- ☐ Squamous cell (epidermoid) carcinoma
- ☐ Adenosquamous carcinoma
- ☐ Small cell carcinoma
- ☐ Undifferentiated carcinoma
- ☐ Carcinoma, NOS
- ☐ Other, specify _____

Benign
- ☐ Hyperplastic
- ☐ Lipomatous
- ☐ Adenomatous
  - ☐ Tubular adenoma
  - ☐ Tubulovillous adenoma
  - ☐ Villous adenoma
  - ☐ Tubulovillous adenoma with dysplasia
- ☐ Normal mucosa
- ☐ Other, specify _____

3. **Specimen size** (largest diameter in mm) ☐☐☐ mm

4. ☐ **Histologic grade (G)**
   - 1 GX Grade cannot be assessed
   - 2 G1 Well differentiated
   - 3 G2 Moderately differentiated
   - 4 G3 Poorly differentiated
   - 5 G4 Undifferentiated

Histologic grade (G)

5. ☐ **Adenomas**
   - 1 G1A low grade
   - 2 G2A high grade
   - 3 Not applicable

P4 If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part B (continued)

Complete Q6, Q7 and Q8 if histology of index lesion (Q2) is not benign. If histology of index lesion is benign proceed to Q9.

6. ☐ **Primary Tumor (T)**

1	TX	Primary tumor cannot be assessed
2	T0	No evidence of primary tumor
3	Tis	Carcinoma in *situ:* intraepithelial or invasion of lamina propria
4	T1	Tumor invades submucosa
5	T2	Tumor invades muscularis propria
6	T3	Tumor invades through muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
7	T4	Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

7. ☐ **Regional Lymph Nodes (N)**

1	NX	Regional lymph nodes cannot be assessed
2	N0	No regional lymph nodes metastasis
3	N1	Metastasis in 1 to 3 regional lymph nodes
4	N2	Metastasis in 4 or more regional lymph nodes

8. ☐ **Distant Metastasis (M)**

1	MX	Distant metastasis cannot be assessed
2	M0	No distant metastasis
3	M1	Distant metastasis

9. Agree with local diagnosis
- o No (complete 9a)
- o Yes

9a. Second opinion needed
(If Core Pathologist disagrees with local read)
- o No
- o Yes

Part C (completed by the Alternate Core Pathologist)

1. Agree with
- o Local diagnosis
- o Core Pathologist

_____
Name of Pathologist completing Section C

_____-_____-_____
Date of second opinion (mm-dd-yyyy)

Comments: _____

_____

_____

_____

_____
Name of Pathologist completing the form

_____-_____-_____
Date form completed (mm-dd-yyyy)

PC **ACRIN 6664**
Pathology Submission Form

Study # 6664 **Case # _____**

If this is a revised or corrected form, please ✓ box. ☐

Institution | **Institution #**

Participant | **Participant I.D.**

INSTRUCTIONS: This form must be completed and mailed with the Pathology Specimens whenever slides are sent. All **slides** must be sent with the **Pathology Transmittal Form (PC)**. At the time of shipment, a copy of the **PC and P4** forms and the **P1** (pathology report) should also be **mailed** to **ACRIN 6664 Data Management Associate at 1818 Market Street, Suite 16, Philadelphia, PA 19103**. Refer to Pathology Section of protocol. *Specimens need to be labeled with the **ACRIN Study and Case Number**.

Lesion Number As defined on PL Form	Procedure Date	Number of Slides	Slide ID	Pathology Specimen #
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			

REQUIRED ENCLOSURES:

_____ **Pathology Report(s) (to ACR)**

_____ **Slides (see Protocol Sec. 13)**

*** Fax to ACR copy of this form and Pathology reports.**

SUBMITTED BY: _____

DATE: _____ - _____ - _____

TELEPHONE NO: (_____) _____

SEND TO:
Rebecca Chavez
Mayo Clinic
Department of Pathology
Hilton 11
200 First Street, S.W.
Rochester, MN 55905

FX ACRIN 6664 CT Colonography Extracolonic Findings

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the Radiologist who interprets the CTC exam. Report all extracolonic findings found at the time of CTC exam. Submit this form via the ACRIN website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN: Data Management.

Note: Check all findings that apply within an overall location. Each checked location requires at least one diagnosis code. If a code (067) "other" or code (076) "Hernia (list type)" is used, detail in question 6.

Location	Diagnosis Code		
Part I			
1. GI			
☐ Liver			
☐ Bile Duct			
☐ Gall Bladder			
☐ Pancreas			
☐ Stomach			
☐ Small Bowel			
☐ Colon			
☐ Appendix			
☐ Spleen			
☐ Peritoneum/ Mesentery			
☐ Retroperitoneum			
Part II			
2. Chest			
☐ Lung Parenchyma			
☐ Pleura			
☐ Chest Wall			
☐ Mediastinum			
Part III			
3. GU			
☐ Adrenal			
☐ Kidney			
☐ Ureter			
☐ Bladder			
☐ Prostate			
☐ Uterus			
☐ Ovary/Adnexal			

KEY DIAGNOSIS CODES

Congenital	
Absence	011
Normal variant	012
Anomaly	013
Inflammatory/Parenchyma	
Inflammation	021
Infection (including Diverticulitis)	022
Abscess	023
Granuloma	024
Indeterminate Mass/Nodule	030
Benign Mass	
Simple cyst	310
Fibroid	311
Lipoma	312
Adenoma	313
Hemangioma	314
Other Benign Tumor	315
Malignant Mass	
Malignant Tumor	320
Lymphoma	321
Metastases	330
Vascular	
Aneurysm	050
Atherosclerosis/Vascular	051
Ca++	052
Thrombosis	053
Fluid	
Effusion/Ascites	060
Miscellaneous	
Calcification	071
Stone	072
Degenerative	073
Diverticulum (osis)	074
Dilatation/Obstruction	075
Hernia (list type)	076
Parenchymal Disease	
Atrophy	061
Focal Scarring/Infarct	062
Cirrhosis	063
Fibrosis	064
Emphysema	065
Organomegaly	066
Other	067

FX **Revision** ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV

4. Vascular

☐ Aorta |_|_|_| Aneurysm max size |_|_|.|_| cm Location |_____|

☐ Heart/Pericardium |_|_|_| |_|_|_|

☐ Other artery |_|_|_| |_|_|_| Location |_____|

☐ Vein |_|_|_| |_|_|_| Location |_____|

5. Musculoskeletal

☐ Bones |_|_|_| |_|_|_| Location |_____|

☐ Joint |_|_|_| |_|_|_| Location |_____|

Code Table to Complete Question 6 (Location)

1 Liver	15 Mediastinum
2 Bile Duct	16 Adrenal
3 Gall Bladder	17 Kidney
4 Pancreas	18 Ureter
5 Stomach	19 Bladder
6 Small Bowel	20 Prostate
7 Colon	21 Uterus
8 Appendix	22 Ovary/Adnexal
9 Spleen	23 Aorta
10 Peritoneum/Mesentery	24 Heart/Pericardium
11 Retroperitoneum	25 Other Artery
12 Lung Parenchyma	26 Vein
13 Pleura	27 Bones
14 Chest Wall	28 Joint

6. Other (detail): (Question 6 is completed only if a code "067" or "076" is used in Q1-5: The location coded in 6a - 6c is at location from Q1-5 coding "067" or "076").

6a. Location |_____| description: _____

6b. Location |_____| description: _____

6c. Location |_____| description: _____

7. In your practice, would you recommend additional evaluation of findings?

o No (proceed to Q8)
o Yes (complete Q7a)

7a. Code findings for follow-up: |_|_|_| |_|_|_| |_|_|_| |_|_|_|

8. In clinical practice, would you recommend urgent care regarding highly significant clinical findings?

o No (form complete, Sign and date)
o Yes (complete Q8a)

8a. Code findings requiring urgent treatment: |_|_|_| |_|_|_| |_|_|_| |_|_|_|

COMMENTS: _____

_____

_____

_____

_____ ____-____-_____

Name of person responsible for data[1] Date form completed

_____

Name of person entering data into web[2]

CX ACRIN 6664 CT Colonography Secondary Reader CTC Interpretation

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the Radiologist interpreting the Re-Reader exam. The completed form is submitted via the ACRIN web site.

I. GENERAL INFORMATION

1. **Date of CTC exam** ____-____-_____ (mm-dd-yyyy)
2. **Date of CTC interpretation** ____-____-_____ (mm-dd-yyyy)
3. **Reader ID #** |_|_|_|_|_|_|_|

3a. Primary image review method: (as assigned for the case by ACRIN)
- o 2D conventional (with 3D problem solving)
- o 3D endoluminal fly-through (with 2D problem solving)

4. **Machine Software:** **Software Version**
- o Siemens _____
- o GE _____
- o Philips _____
- o Viatronix _____
- o Vital Images _____
- o Other, specify _____ _____

II. COLONOGRAPHY ASSESSMENT

5. **Does this patient have any significant findings ≥ 5 mm in largest diameter?**
- o No (proceed to comments, then sign and date form)
- o Yes (complete Q5a and 5b and continue with form)

5a. What is your confidence that this patient has at least one lesion ≥ 5 mm in largest diameter that would be classified as a polyp?
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

5b. |_____| % What is the estimated probability that at least one finding ≥ 5 mm is a polyp? (0-100%)

6. **Does this patient have any significant findings ≥ 10 mm in largest diameter?**
- o No (proceed to comments then sign and date form)
- o Yes (complete Q6a and Q6b)

6a. What is your confidence that this patient has at least one lesion ≥ 10 mm in largest diameter that would be classified as a polyp?
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

6b. |_____| % What is the estimated probability that at least one finding ≥ 10 mm is a polyp? (0-100%)

COMMENTS: _____

_____

_____ ____-____-_____

Name of person responsible for data [1] Date form completed

_____

Name of person entering data into web [2]

W2

ACRIN 6664
CT Colonography
Secondary Reader CTC Interpretation Worksheet

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, indicate by checking box ☐

Instructions: This form is completed by the Radiologist performing the secondary read. A completed form is submitted to ACRIN via the website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN Data Management.

I. General Information:

1. **Date of CTC exam** _____ - _____ - _____
   mm dd yyyy

2. **Date of interpretation** _____ - _____ - _____
   mm dd yyyy

3. **Reader ID #** |_|_|_|_|_|_|_|

4. **Machine Software** **Software Version**
   - o Siemens _____
   - o GE _____
   - o Philips _____
   - o Viatronix _____
   - o Vital Images _____
   - o Other, specify: _____ _____

II. CTC Interpretation:

5. |_|_|_|_| **Interpretation start time** [Exclude load time] (military time, e.g., 9:00a.m.=0900,3:00p.m. =1500)

6. |_|_|_|_| **Interpretation end time**

7. **Are there any colonic findings to report?**
   - o No (proceed to comments, page 3)
   - o Yes (continue with form, pages 2 and 3)

Continued on page 2

W2

ACRIN 6664
CT Colonography
Secondary Reader CTC Interpretation Worksheet

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

8. Colon Assessment: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**
◆ For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column y=row z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column y=row z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
1				x _____ y _____ z _____		x _____ y _____ z _____							
2				x _____ y _____ z _____		x _____ y _____ z _____							
3				x _____ y _____ z _____		x _____ y _____ z _____							
4				x _____ y _____ z _____		x _____ y _____ z _____							
5				x _____ y _____ z _____		x _____ y _____ z _____							

Continued on page 3

W2

ACRIN 6664
CT Colonography
Secondary Reader CTC Interpretation Worksheet

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

9. Colon Assessment continued: Complete all columns associated with each finding ≥5mm in diameter.
****Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

- ◆ For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

CTC Findings #	Segment 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	Seen on: 1 Supine only 2 Prone only 3 Both supine and prone	Supine Axial Slice #	◆X,Y,Z Coordinate Supine # *x=column y=row z=slice #*	Prone Axial Slice #	◆X,Y,Z Coordinate Prone # *x=column y=row z=slice #*	**CTC Size (mm)	Confidence level that finding identified is a polyp: 0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence	Polyp Morphology 1 Polypoid 2 Flat* *A "flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.	Polyp location 1 Between folds 2 On folds	Orientation of colon at polyp site: 1 Straight 2 Bend	Location of polyp relative to colonic bend 1 Inside curve 2 Outside curve	Additional findings 1 No 2 Yes *If yes complete next row
6				x _____ y _____ z _____		x _____ y _____ z _____							
7				x _____ y _____ z _____		x _____ y _____ z _____							
8				x _____ y _____ z _____		x _____ y _____ z _____							
9				x _____ y _____ z _____		x _____ y _____ z _____							
10				x _____ y _____ z _____		x _____ y _____ z _____							

Comments: _____

_____

_____ _____ _____ - _____ - _____

Name of person responsible for data[1] | Name of person entering data into web[2] | Date form completed (mm-dd-yyyy)

P4 ACRIN 6664 CT Colonography Core Colonoscopy/Pathology Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: Part A is to be completed by the Research Associate. After completion of Part A, the form is sent to the Core Pathologist for completion of Part B. Part B will be completed by the Core Pathologist based on the pathologic material available. Part C will be completed by the Alternate Core Pathologist if a second opinion is needed. At the time of slide submission a copy of the PC form, the P4 form and the P1 (pathology report) should be mailed to ACRIN 6664 Data Management, 1818 Market Street, Suite 16, Philadelphia, PA 19103. **A separate form is submitted for each lesion.**

Part A (completed by site Research Associate)

1. **Date of procedure** _____-_____-_____ (mm-dd-yyyy)

2. **Date specimen sent to core lab**

   _____-_____-_____ (mm-dd-yyyy)

3. ☐ **Number of slides submitted on this specimen**

4. **Finding # _____ of # _____ as identified on Colonoscopy. To maintain consistency in reporting of lesions, the "Finding #" is column 1 on the PL form.**

5. **Segment** (check one)
   - o Rectum
   - o Sigmoid
   - o Descending
   - o Transverse
   - o Ascending
   - o Cecum

Completed by (Site RA) _____

Part B (completed by Core Pathologist)

1. ☐ **Core Pathology Reviewer**
   - 1 Lawrence Burgart M.D.
   - 2 Other _____

2. **Histology of Index Lesion**
   (Check all that apply; A ☑ indicates a "yes" response)

Histopathological Type
- ☐ Adenocarcinoma
- ☐ Medullary carcinoma
- ☐ Mucinous carcinoma (colloid type) (greater than 50% mucinous carcinoma)
- ☐ Signet ring cell carcinoma (greater than 50% signet ring cell)
- ☐ Squamous cell (epidermoid) carcinoma
- ☐ Adenosquamous carcinoma
- ☐ Small cell carcinoma
- ☐ Undifferentiated carcinoma
- ☐ Carcinoma, NOS
- ☐ Other, specify _____

Benign
- ☐ Hyperplastic
- ☐ Lipomatous
- ☐ Adenomatous
  - ☐ Tubular adenoma
  - ☐ Tubulovillous adenoma
  - ☐ Villous adenoma
  - ☐ Tubulovillous adenoma with dysplasia
- ☐ Normal mucosa
- ☐ Other, specify _____

3. **Specimen size** (largest diameter in mm) ☐☐☐ mm

4. ☐ **Histologic grade (G)**
   - 1 GX Grade cannot be assessed
   - 2 G1 Well differentiated
   - 3 G2 Moderately differentiated
   - 4 G3 Poorly differentiated
   - 5 G4 Undifferentiated

Histologic grade (G)

5. ☐ **Adenomas**
   - 1 G1A low grade
   - 2 G2A high grade
   - 3 Not applicable

P4 If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part B (continued)

Complete Q6, Q7 and Q8 if histology of index lesion (Q2) is not benign. If histology of index lesion is benign proceed to Q9.

6. ☐ **Primary Tumor (T)**

1	TX	Primary tumor cannot be assessed
2	T0	No evidence of primary tumor
3	Tis	Carcinoma in *situ:* intraepithelial or invasion of lamina propria
4	T1	Tumor invades submucosa
5	T2	Tumor invades muscularis propria
6	T3	Tumor invades through muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
7	T4	Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

7. ☐ **Regional Lymph Nodes (N)**

1	NX	Regional lymph nodes cannot be assessed
2	N0	No regional lymph nodes metastasis
3	N1	Metastasis in 1 to 3 regional lymph nodes
4	N2	Metastasis in 4 or more regional lymph nodes

8. ☐ **Distant Metastasis (M)**

1	MX	Distant metastasis cannot be assessed
2	M0	No distant metastasis
3	M1	Distant metastasis

9. Agree with local diagnosis
- o No (complete 9a)
- o Yes

9a. Second opinion needed
(If Core Pathologist disagrees with local read)
- o No
- o Yes

Part C (completed by the Alternate Core Pathologist)

1. Agree with
- o Local diagnosis
- o Core Pathologist

_____
Name of Pathologist completing Section C

_____-_____-_____
Date of second opinion (mm-dd-yyyy)

Comments: _____

_____

_____

_____

_____
Name of Pathologist completing the form

_____-_____-_____
Date form completed (mm-dd-yyyy)

PC **ACRIN 6664**
Pathology Submission Form

Study # 6664 **Case # _____**

If this is a revised or corrected form, please ✓ box. ☐

Institution | **Institution #**

Participant | **Participant I.D.**

INSTRUCTIONS: This form must be completed and mailed with the Pathology Specimens whenever slides are sent. All **slides** must be sent with the **Pathology Transmittal Form (PC)**. At the time of shipment, a copy of the **PC and P4** forms and the **P1** (pathology report) should also be **mailed** to **ACRIN 6664 Data Management Associate at 1818 Market Street, Suite 16, Philadelphia, PA 19103**. Refer to Pathology Section of protocol. *Specimens need to be labeled with the **ACRIN Study and Case Number**.

Lesion Number As defined on PL Form	Procedure Date	Number of Slides	Slide ID	Pathology Specimen #
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			
	____ - ____ - ____			

REQUIRED ENCLOSURES:

_____ **Pathology Report(s) (to ACR)**

_____ **Slides (see Protocol Sec. 13)**

*** Fax to ACR copy of this form and Pathology reports.**

SUBMITTED BY: _____

DATE: _____ - _____ - _____

TELEPHONE NO: (_____) _____

SEND TO:
Rebecca Chavez
Mayo Clinic
Department of Pathology
Hilton 11
200 First Street, S.W.
Rochester, MN 55905

FX ACRIN 6664 CT Colonography Extracolonic Findings

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the Radiologist who interprets the CTC exam. Report all extracolonic findings found at the time of CTC exam. Submit this form via the ACRIN website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN: Data Management.

Note: Check all findings that apply within an overall location. Each checked location requires at least one diagnosis code. If a code (067) "other" or code (076) "Hernia (list type)" is used, detail in question 6.

Location	Diagnosis Code		
Part I			
1. GI			
☐ Liver			
☐ Bile Duct			
☐ Gall Bladder			
☐ Pancreas			
☐ Stomach			
☐ Small Bowel			
☐ Colon			
☐ Appendix			
☐ Spleen			
☐ Peritoneum/ Mesentery			
☐ Retroperitoneum			
Part II			
2. Chest			
☐ Lung Parenchyma			
☐ Pleura			
☐ Chest Wall			
☐ Mediastinum			
Part III			
3. GU			
☐ Adrenal			
☐ Kidney			
☐ Ureter			
☐ Bladder			
☐ Prostate			
☐ Uterus			
☐ Ovary/Adnexal			

KEY DIAGNOSIS CODES

Congenital	
Absence	011
Normal variant	012
Anomaly	013
Inflammatory/Parenchyma	
Inflammation	021
Infection (including Diverticulitis)	022
Abscess	023
Granuloma	024
Indeterminate Mass/Nodule	030
Benign Mass	
Simple cyst	310
Fibroid	311
Lipoma	312
Adenoma	313
Hemangioma	314
Other Benign Tumor	315
Malignant Mass	
Malignant Tumor	320
Lymphoma	321
Metastases	330
Vascular	
Aneurysm	050
Atherosclerosis/Vascular	051
Ca++	052
Thrombosis	053
Fluid	
Effusion/Ascites	060
Miscellaneous	
Calcification	071
Stone	072
Degenerative	073
Diverticulum (osis)	074
Dilatation/Obstruction	075
Hernia (list type)	076
Parenchymal Disease	
Atrophy	061
Focal Scarring/Infarct	062
Cirrhosis	063
Fibrosis	064
Emphysema	065
Organomegaly	066
Other	067

FX **Revision** ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV

4. Vascular

☐ Aorta |_|_|_| Aneurysm max size |_|_|.|_| cm Location |_____|

☐ Heart/Pericardium |_|_|_| |_|_|_|

☐ Other artery |_|_|_| |_|_|_| Location |_____|

☐ Vein |_|_|_| |_|_|_| Location |_____|

5. Musculoskeletal

☐ Bones |_|_|_| |_|_|_| Location |_____|

☐ Joint |_|_|_| |_|_|_| Location |_____|

Code Table to Complete Question 6 (Location)

1 Liver	15 Mediastinum
2 Bile Duct	16 Adrenal
3 Gall Bladder	17 Kidney
4 Pancreas	18 Ureter
5 Stomach	19 Bladder
6 Small Bowel	20 Prostate
7 Colon	21 Uterus
8 Appendix	22 Ovary/Adnexal
9 Spleen	23 Aorta
10 Peritoneum/Mesentery	24 Heart/Pericardium
11 Retroperitoneum	25 Other Artery
12 Lung Parenchyma	26 Vein
13 Pleura	27 Bones
14 Chest Wall	28 Joint

6. Other (detail): (Question 6 is completed only if a code "067" or "076" is used in Q1-5: The location coded in 6a - 6c is at location from Q1-5 coding "067" or "076").

6a. Location |_____| description: _____

6b. Location |_____| description: _____

6c. Location |_____| description: _____

7. In your practice, would you recommend additional evaluation of findings?

o No (proceed to Q8)
o Yes (complete Q7a)

7a. Code findings for follow-up: |_|_|_| |_|_|_| |_|_|_| |_|_|_|

8. In clinical practice, would you recommend urgent care regarding highly significant clinical findings?

o No (form complete, Sign and date)
o Yes (complete Q8a)

8a. Code findings requiring urgent treatment: |_|_|_| |_|_|_| |_|_|_| |_|_|_|

COMMENTS: _____

_____

_____

_____

_____ ____-____-_____

Name of person responsible for data[1] Date form completed

_____

Name of person entering data into web[2]

CX ACRIN 6664 CT Colonography Secondary Reader CTC Interpretation

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is completed by the Radiologist interpreting the Re-Reader exam. The completed form is submitted via the ACRIN web site.

I. GENERAL INFORMATION

1. **Date of CTC exam** ____-____-_____ (mm-dd-yyyy)
2. **Date of CTC interpretation** ____-____-_____ (mm-dd-yyyy)
3. **Reader ID #** |_|_|_|_|_|_|_|

3a. Primary image review method: (as assigned for the case by ACRIN)
- o 2D conventional (with 3D problem solving)
- o 3D endoluminal fly-through (with 2D problem solving)

4. **Machine Software:** **Software Version**
- o Siemens _____
- o GE _____
- o Philips _____
- o Viatronix _____
- o Vital Images _____
- o Other, specify _____ _____

II. COLONOGRAPHY ASSESSMENT

5. **Does this patient have any significant findings ≥ 5 mm in largest diameter?**
- o No (proceed to comments, then sign and date form)
- o Yes (complete Q5a and 5b and continue with form)

5a. What is your confidence that this patient has at least one lesion ≥ 5 mm in largest diameter that would be classified as a polyp?
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

5b. |_____| % What is the estimated probability that at least one finding ≥ 5 mm is a polyp? (0-100%)

6. **Does this patient have any significant findings ≥ 10 mm in largest diameter?**
- o No (proceed to comments then sign and date form)
- o Yes (complete Q6a and Q6b)

6a. What is your confidence that this patient has at least one lesion ≥ 10 mm in largest diameter that would be classified as a polyp?
- o Low confidence
- o Possible
- o Indeterminate
- o Probable
- o High confidence

6b. |_____| % What is the estimated probability that at least one finding ≥ 10 mm is a polyp? (0-100%)

COMMENTS: _____

_____

_____ ____-____-_____

Name of person responsible for data [1] Date form completed

_____

Name of person entering data into web [2]

PR

ACRIN 6664
Protocol Variation Form

If this is a revised or corrected form, indicate by checking box ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for **each case** and for **each event**. Retain the form in the case study file and enter via the ACRIN web site. ***Incomplete forms will be returned for resolution of blank data fields***.

1. Check The Protocol Event Being Reported (report only one per form)
Provide a description of the event (see page 2)

- ☐ Inclusion/exclusion criteria not met at time of registration/randomization **(complete 1a)**
- ☐ Imaging-related deviation **(complete 1b)**
- ☐ Duplicate case registration, duplicate case # ☐☐☐☐
- ☐ Unapproved radiologist read CTC exam
- ☐ Assigned 2D/3D reading did not follow randomization
- ☐ CTC workstation not per protocol requirements
- ☐ Lesion pathology unavailable/lost, other issue
- ☐ Lesion photographs lost/unavailable
- ☐ Participant cost and acceptance questionnaire not completed
- ☐ Colonoscopy occurred greater than 30 days from CT Colonography
- ☐ No Follow-up colonoscopy performed within 90 days for false positives greater than 1cm
- ☐ Participant rescheduled due to poor prep
- ☐ Colonoscopy incomplete
- ☐ Incorrect bowel prep/non-protocol approved bowel prep
- ☐ Colonoscopy performed by Fellow
  - O Colonoscopy was performed with limited or no oversight by a GI physician
  - O Colonoscopy was performed with close oversight by a GI physician
- ☐ Other, specify: _____

1a. Inclusion/exclusion criteria not met:

- ☐ Aged 50 years or older (at study entry)
- ☐ Inflammatory bowel disease and/or familial polyposis syndrome (Personal history)
- ☐ Pregnancy
- ☐ Previous colonoscopy within the past five years
- ☐ Anemia (hemoglobin less than 10 gm/dl)
- ☐ Positive fecal occult blood test (FOBT)
- ☐ Melanotic stools and/or hematochezia on more than one occasion in the previous six months
- ☐ Lower abdominal pain that would normally require medical evaluation
- ☐ Serious medical conditions that would increase risk associated with colonoscopy or are so severe that screening would have no benefit
- ☐ Other, specify: _____

PR

If this is a revised or corrected form, please check box ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1b. Imaging Deviation

- ☐ CTC Images lost, unable to archive
- ☐ Image data not available for CAD database
- ☐ CT Scanner used was not per protocol
- ☐ Supine image data set not performed
- ☐ Prone image data set not performed
- ☐ Incorrect KV utilized
- ☐ Incorrect Gantry Rotation Time utilized
- ☐ Incorrect MA utilized
- ☐ Incorrect Reconstructed Slice Width utilized
- ☐ Incorrect Reconstructed Interval utilized
- ☐ Incorrect Reconstructed Algorithm utilized
- ☐ Incorrect Number of Slices for a specific Algorithm
- ☐ Incorrect Pitch utilized
- ☐ Incorrect DFOV utilized
- ☐ Other, specify: _____

2. Date Protocol Deviation Occurred: _____-_____-_____ (mm-dd-yyyy)

3. Date Protocol Deviation Was Discovered: _____-_____-_____ (mm-dd-yyyy)

4. Describe the Protocol Deviation:

_____

_____

_____

_____

5. What was done to rectify the situation and/or prevent future occurrence:

_____

_____

_____

_____

_____
Person responsible for data (RA, study staff)

_____-_____-**20**_____
Date form completed (mm-dd-yyyy)

_____
Investigator Signature

SX **ACRIN**
Screening CT Colonography Software Questionnaire

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, indicate by checking box. ☐

Instructions: Form to be completed by Radiologist at study activation, at 6 months from study activation and at close of study. Mail completed forms to: ***ACRIN Data Management****, 1818 Market Street, Floor 16, Philadelphia, PA 19103.*

I. GENERAL REVIEWER/SOFTWARE INFORMATION:

Date of review ____-_____-_____ (mm/dd/yyyy)

1. **Reader I.D.#** ☐☐☐☐☐☐☐

1a. Reviewer Name: _____

2. **Reviewer ACRIN Institution #** : _____

2a. Institution Name: _____

3. ☐ **No change in my evaluation method since the previous questionnaire.**
(Check box if there are no changes since completion of previous form, then skip to page 4, sign and date form).

4. **Reviewer experience** (approximate number of CTC exams with colonoscopy correlation evaluated):
   - ○ < 50
   - ○ 50-100
   - ○ 100-200
   - ○ >200

5. **Specify CT scanner type used for (CTC) exams** (check one)
   - ○ GE
   - ○ Toshiba
   - ○ Philips
   - ○ Siemens
   - ○ Other _____

5a. Number of detectors ☐☐

6. **CTC software type** (check one)
   - ○ Siemens
   - ○ GE
   - ○ Philips
   - ○ Viatronix
   - ○ Vital images
   - ○ Other, specify _____

7. **CTC workstation version #:** _____

8. **Monitor size:** (check one)
   - ○ 17 inch
   - ○ 20 inch
   - ○ 25 inch
   - ○ Other, specify _____

9. ☐ **# of Monitors:** (e.g., 1, 2)

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

10. When doing clinical CTC cases (non-study) do you prefer:

- ○ Primary 2D Evaluation
- ○ Primary 3D Evaluation
- ○ Both - Complete 2D *and* 3D Evaluation
- ○ Other, specify: _____

II. <u>WHEN EVALUATING AXIAL IMAGES FOR POLYPS</u>

11. Do you evaluate the axial images for polyps so that the axial image is the only one displayed on your monitor? (see image A, page 4)

- ○ No (proceed to Q12)
- ○ Yes (complete Q11A)

11a. If <u>yes</u>, select one of the following responses:

○ Do you evaluate the axial images using the large field of view (FOV) (see image A, page 4)

OR

○ Do you decrease the FOV (i.e., zoom) on a specific colon segment (see image B, page 4)

12. Do you evaluate the axial images for polyps when the axial image is displayed with coronal/sagittal images on the same monitor (see image C, page 4)

- ○ No (proceed Q13)
- ○ Yes (complete Q12A)

12a. If <u>yes</u>, select one of the following responses:

○ Do you evaluate the axial images using the large FOV (see image C, page 4)

OR

○ Do you decrease the field of view (FOV, i.e., zoom) on a specific colon segment (see image D, page 4)

13. How do you evaluate **SUPINE** images: (<u>select one</u> of the following responses)

○ Axial supine: rectum to cecum (or vice-versa) and reverse

OR

○ Axial supine: rectum to cecum (or vice-versa) only

OR

○ Other specify, _____

14. How do you evaluate **PRONE** images: (<u>select one</u> of the following responses)

○ Axial prone: only used to confirm supine findings

OR

○ Axial prone: rectum to cecum (or vice-versa) and reverse

OR

○ Axial prone: rectum to cecum (or vice-versa) only

OR

○ Other specify, _____

15. SUPINE AND PRONE IMAGES:
(select one of the following responses)

○ Synchronized supine and prone images on different monitors
OR
○ Synchronized supine and prone images on same monitor
OR
○ Non-Synchronized supine and prone images on different monitors
OR
○ Non-Synchronized supine and prone images on same monitor
OR
○ Other specify, _____

16. EVALUATION OF ABNORMAL INTRACOLONIC FINDINGS: (select one of the following responses)

○ Evaluate each abnormal axial finding immediately with multiplanar and/or 3D imaging
OR
○ Evaluate the entire colon, mark abnormal findings and evaluate lesions after completely evaluating the colon
OR
○ Other specify, _____

III. REVIEW ORIENTATION / SETTINGS

17. MULTIPLANAR 2D IMAGES: (check all that apply)

☐ Used only to further evaluate abnormalities on axial CT
☐ Reformatted coronal images evaluated routinely
☐ Reformatted sagittal images evaluated routinely
☐ Other specify, _____

18. WINDOW SETTINGS: (check all that apply)

☐ Soft tissue window settings: routinely used to evaluate the colon
☐ Soft tissue window settings: routinely used for extracolonic findings
☐ Soft tissue window settings: routinely used to evaluate colonic polyps/masses
☐ Other specify, _____

COMMENTS: _____

_____

_____

_____
Name of person responsible for data [1]

____-____-_____
Date form completed
(mm-dd-yyyy)

_____
Name of person entering data into web [2]

SX

Revision ☐

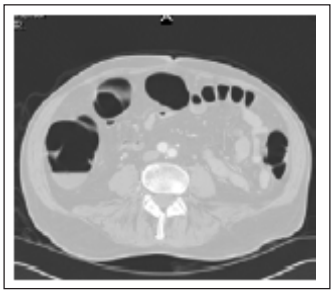
ACRIN Study 6664

PLACE LABEL HERE

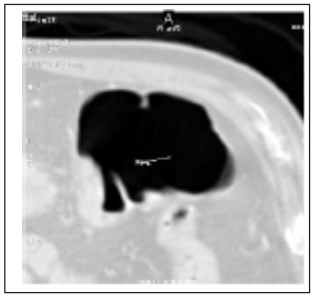
Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

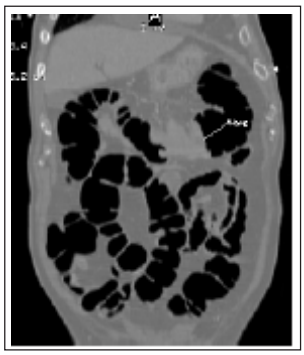
Images for reference when completing Section II

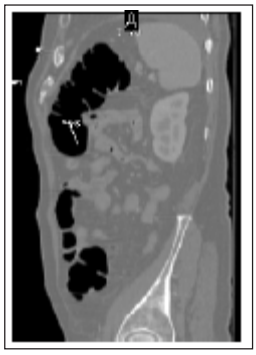


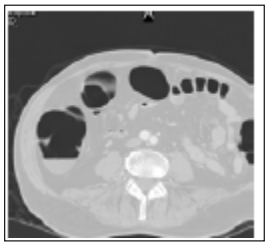
A. Large FOV axial image
(occupies entire monitor)



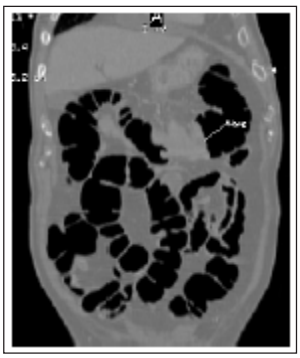
B. Small FOV axial image
(occupies entire monitor)

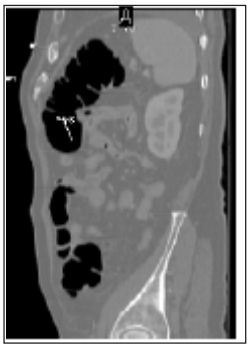


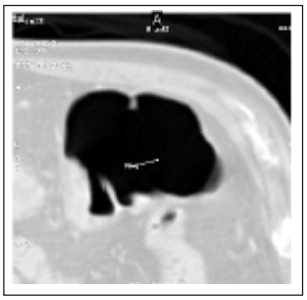




C. Multiplanar 2D images all on one monitor with LARGE FOV axial







D. Multiplanar 2D images on one monitor with SMALL FOV axial

CS ACRIN 6664 Coversheet for PQ Cost and Acceptability Form

Revised or corrected form, check box and fax to 215-717-0936. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This coversheet represents the first page of the Cost and Acceptance questionnaire. This form is not sent to the Participant. It is completed by the RA who administers the PQ. This form is submitted via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

Questionnaire Compliance

1. ☐ **Did participant answer any questionnaire items?**

1 No (complete Q2, Sign and date form)
2 Yes, date questionnaire completed:

☐☐-☐☐-2 0 0☐ Skip to Q3

2. ☐ **If no, please state reason:**

1 Participant refused
2 Participant ill or hospitalized
3 Participant deceased
4 Participant out of the country
5 Incorrect contact information
6 Telephone disconnected
7 Participant unable to be contacted
8 Other, specify: _____

3. ☐ **Specify method of completion:**

1 At appointment
2 By mail (include mailed questionnaire brought to the site completed)
3 By telephone
99 Unknown

COMMENTS: _____

_____

_____

_____ ____-____-_____

Name of person responsible for data [1] Date form completed

_____

Name of person entering data into web [2]

ES

ACRIN 6664
Participant Cover Sheet for PQ Cost and Acceptability Form

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, indicate by checking box. ☐

Instructions: Thank you for completing the PQ Cost and Acceptance questionnaire. We would now like to ask you some questions to help us understand when and how people get the results of their colon screening test, and to understand whether someone helped you with completing these forms. Your cooperation in providing this additional information is very important to the success of this trial and we appreciate your time.

1. Have you received both the CT Colonography and colonoscopy screening tests?

- ☐ No (go to Q4)
- ☐ Yes (complete Q2)
- ☐ Not sure

2. Have you received any results from your screening test?

- ☐ No (go to Q4)
- ☐ Yes (complete Q2a)

2a. If yes, do you remember the date on which you first received these results?

- ☐ No
- ☐ Yes - Date you received the results: _____-_____- **20** _____(mm-dd-yy)

3. How were the results first given to you?

- ☐ Phone call from doctor's office
- ☐ Letter from doctor's office
- ☐ Nurse told me during office visit
- ☐ Doctor's told me during office visit
- ☐ Other (please tell us how): _____

4. Did you require any assistance to complete the PQ Cost and Acceptance Questionnaire?

- ☐ No (go to signature and date)
- ☐ Yes (complete Q4a and Q4b)

4a. Please specify the person who assisted you in completing PQ Cost and Acceptance Questionnaire

- ☐ Family
- ☐ Friend
- ☐ Other, specify _____

4b. What assistance did this person provide to you?

- ☐ Read items to you
- ☐ Marked items on the questionnaire in the way that you asked them to
- ☐ Interpreted items into another language for you
- ☐ Helped explain items in English for you

Participant: Please Initial _____ **Today's date:** _____-_____- **20**____(mm-dd-yy)

Thank You!

TM

ACRIN 6664
Time-Motion Study Form

If this is a revised or corrected form, indicate by checking box ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Reader I.D. No. |_|_|_|_|_|_|_|

Task No.	Start Military Time	Stop Military Time	Skipped	Task Description (☑ If present during task)	CT Tech #1	CT Tech #2	CT Tech Asst	Res/Fellow	Radiologist	RN	LPN	Nurs. Asst.	Transport	Other
1				**Patient Arrival and Preparation** Note: Begins when patient leaves changing area and ends when patient sits on exam table.										
2				**Glucagon Administration** Note: May begin and/or end within task 1.										
3				**Pre-Examination Room Preparation** Note: May begin and/or end within task 1 or 2.										
4				**1st Image Acquisition (Circle: Supine Prone Other)** Note: Begins when patient sits on exam table and ends when final image acquisition and image checking is complete. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition.										
5				**2nd Image Acquisition (Circle: Supine Prone Other)** Note: Begins when patient is repositioned from first acquisition and ends when final image acquisition and image checking is complete. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition.										
6				**Administration of IV Contrast (if necessary)** Note: Begins with ordering of IV contrast and ends when patient is ready for scans to resume.										
7				**Further Image Acquisition (Circle: Supine Prone Other)** Note: Begins when patient is repositioned from second acquisition and ends when all additional images are acquired. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition.										
8				**Post-Examination Patient Care** Note: Begins when enema tip is withdrawn and ends when patient is returned to changing area.										
9				**Post-Examination Room Cleanup** Note: Begins when patient returns to changing area and ends when room is ready to be prepared for next patient. *Do not include activities also included in Task 3 for the next patient.*										

List Other Personnel Present and Associated Task Number

_____ |_____| _____ |_____|

Balloon Enema Tip? Check if yes ☐

_____ Signature of person responsible for the data [1]

_____ Signature of person entering data onto the web [2]

_____-_____-_____ Date form completed[3] (mm-dd-yyyy)

T2 ACRIN 6664 Time-Motion Study Form

If this is a revised or corrected form, indicate by checking box ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: This form is to be filled out by trained site RAs. Please complete the form following the stopwatch method and count any significant delays in the interruption check box at the bottom of the form.

1. ☐☐☐☐☐☐☐ **Reader ID**

2. This read was:

☐ Primary 2D with 3D Problem Solving

☐ Primary 3D with 2D Problem Solving

3. ☐☐:☐☐ **Time Radiologist begins to prepare workspace and loads images** (record in military time)

4. ☐☐:☐☐ **Time Interpretation stops** (Read completed) (record in military time)

5. ☐☐ **hours** ☐☐ **minutes** **Stopwatch Time** (Time on task)

Interruption checkbox:

6. _____ **Number of Interruptions**

7. Is the Radiologist completing ACRIN Forms during the interpretation time?

☐ No
☐ Yes

8. Radiologist used digital subtraction on this case?

☐ No
☐ Yes

_____ Signature of person responsible for data [1]

____-____-_____ Date form completed

_____ Signature of person entering data onto the web[2]

DP

ACRIN 6664
CTC Colonography
Imaging Transmittal Form Worksheet

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If a revised or corrected form, indicate by checking box. ☐

INSTRUCTIONS: As a note to the RA: Please attach this worksheet to the Radiology Requisition. This worksheet is to be completed by the CT Technologist at the same time of the scan. The completed form is to be submitted to the Imaging Management Center (IMC), by faxing it to 215-923-1737, at the same time the images are being sent from the ACRIN PC to ACRIN HQ.

1. Date of study _____-_____-_____ (mm-dd-yyyy)

2. Technical Parameter Checklist for **Supine** series

Parameter	Inspection findings
Slice collimation	
Pitch	
MA or Effective mAs	
Recon interval	
Rotation time	
DFOV	

3. Technical Parameter Checklist for **Prone** series

Parameter	Inspection findings
Slice collimation	
Pitch	
MA or Effective mAs	
Recon interval	
Rotation time	
DFOV	

4. Indicated data sets sent

	# Images sent	# Images received
Supine		
Prone		

5. ☐ **Scanner type**

1 GE
2 Siemens
3 Other _____

Contact Person completing form

Name: _____

Phone: _____

COMMENTS: _____

_____

_____

_____

_____
Signature of person responsible for the data [1]

Date form completed[3] ____-____-_____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

QA ACRIN 6664 CTC Colonography CT Quality Assessment Form

If a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

INSTRUCTIONS: This form is completed by the Quality Control Reviewer. The completed form is submitted to the ACR data center. Dates are reported MM/DD/YYYY. Studies that do not meet quality standards will result in notification of the site PI.

1. Technical Parameter Checklist

Parameter	Required	Inspection findings
Slice collimation	1.0 - 1.25	
Pitch	.9 - 1.4	
MA or Effective mAs	50 - 140	
Recon interval	0.8	
Rotation time	≤ 0.5	
DFOV	To fit patient	

2. ☐ Does imaging parameters meet protocol specification of:

1 No*
2 Yes

* If no, provide explanation _____

3. ☐ Is the entire colon included on both the prone and supine images?

1 No
2 Yes

4. ☐ Supine and prone series present?

1 No
2 Yes

5. Indicated data sets sent and received

	# Images sent	# Images received
Supine		
Prone		

6. ☐ Overall Images Quality

1 Excellent
2 Good
3 Average
4 Below average, acceptable
5 Unacceptable

7. ☐ Are there substantial artifacts (motion, barium, metallic) that degrade image quality?

1 No
2 Yes

QA Revision ☐

ACRIN Study **6664**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

8. Reason unacceptable or below average
(check all that apply)

- ☐ 1 Incorrect Algorithm
- ☐ 2 Incorrect Slice Thickness
- ☐ 3 Incorrect Slice Interval
- ☐ 4 Incorrect Pitch
- ☐ 5 Incorrect KVp
- ☐ 6 Incorrect Effective mAs
- ☐ 7 Incorrect DFOV
- ☐ 8 Other _____

9. ☐ Imaging Site Contacted?

1 No
2 Yes

10. Contact Date _____-_____-_____ (mm-dd-yyyy)

11. Imaging site contact person: _____

12. Reader ID# ☐☐☐☐☐☐☐

13. Date of study _____-_____-_____ (mm-dd-yyyy)

14. ☐ Scanner Type

1 GE
2 Siemens
3 Toshiba
4 Other _____

15. ☐ Is there adequate destination with minimal stool?

1 No
2 Yes

COMMENTS: _____

_____

_____

_____
Signature of person responsible for the data [1]

Date form completed[3] ____-____-_____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

LE

ACRIN 6664
National CT Colonography
Lesion Matching Form

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, indicate by checking box ☐

Instructions: The appointed Radiologist will review the colonoscopy and pathology reports for each individual case and match the lesions reported within the reports with findings from CTC using the algorithm included within this form on page 5. For a lesion to be considered a match, the lesion must be reported at colonoscopy and CTC to be within the same or adjacent segment. If the lesion matches by location then it will be assessed by size. If the lesion is reported to be within 50% in diameter of the size at colonoscopy and CTC will be considered a match. If the lesion does not match by location but is within two colon segments the colonoscopic photograph will be compared with its CTC image. If the lesion size reported is variant greater than 50% or if the lesion location is more than 2 segments apart, matching will be determined by consensus. Lesions that match by morphology and by their position on a haustral fold or colon wall will be considered to be a match. Lesions matching by location but not by size will be reviewed in a similar manner. A ***False positive*** is a "finding" seen on CTC but not seen on Pathology and a ***False negative*** is a "finding" seen on Pathology but not found on CTC.

- Column I: record the Lesion # on the WX form (column I) matching the Lesion # from the PL form. All unmatched lesions found on either CTC or Pathology are to be recorded within the form and identified as "88".
- Column II: the lesion # is abstracted from the case specific PL form (column I) for consistent numbering of identified lesions.
- Column III and V: completed from data abstracted from the colonoscopy and pathology reports (reference standard).
- Column IV and VI: completed from data abstracted from the CTC report.
- Column I-VII: completed for all findings.
- Column VII-VIII: completed in the instance when lesion matching will be determined by consensus: a size variance of more than 50% or more than 2 segments apart in location
- Column IX: completed for all findings.
- Column X: completed for all unmatched lesions recorded in Column I or Column II.
- The CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm may be referenced on page 5 of this form.

1. **Date of lesion matching review** _____ - _____ - _____
   mm dd yyyy

2. **Reviewer ID:** |_|_|_|_|_|_|_|

3. **Name of reviewer** _____

LE

ACRIN 6664
National CT Colonography
Lesion Matching Form

Revision ☐

ACRIN Study **6664**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. Lesion Matching

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the WX form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Nagative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
1											x _____ y _____ z _____
2											x _____ y _____ z _____
3											x _____ y _____ z _____
4											x _____ y _____ z _____
5											x _____ y _____ z _____
6											x _____ y _____ z _____
7											x _____ y _____ z _____

LE

ACRIN 6664
CT Colonography
Local CTC Interpretation Worksheet

Revision ☐

ACRIN Study **6664**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. Lesion Matching (continued)

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the WX form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Nagative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
8											x _____ y _____ z _____
9											x _____ y _____ z _____
10											x _____ y _____ z _____
11											x _____ y _____ z _____
12											x _____ y _____ z _____
13											x _____ y _____ z _____
14											x _____ y _____ z _____

LE

ACRIN 6664
National CT Colonography
Lesion Matching Form

Revision ☐

ACRIN Study **6664**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. Lesion Matching (continued)

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the WX form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Negative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
15											x _____ y _____ z _____
16											x _____ y _____ z _____
17											x _____ y _____ z _____
18											x _____ y _____ z _____
19											x _____ y _____ z _____
20											x _____ y _____ z _____
21											x _____ y _____ z _____

LE **ACRIN 6664**
National CT Colonography
Lesion Matching Form

Revision ☐

ACRIN Study 6664
PLACE LABEL HERE

Institution _____ **Institution No.** _____

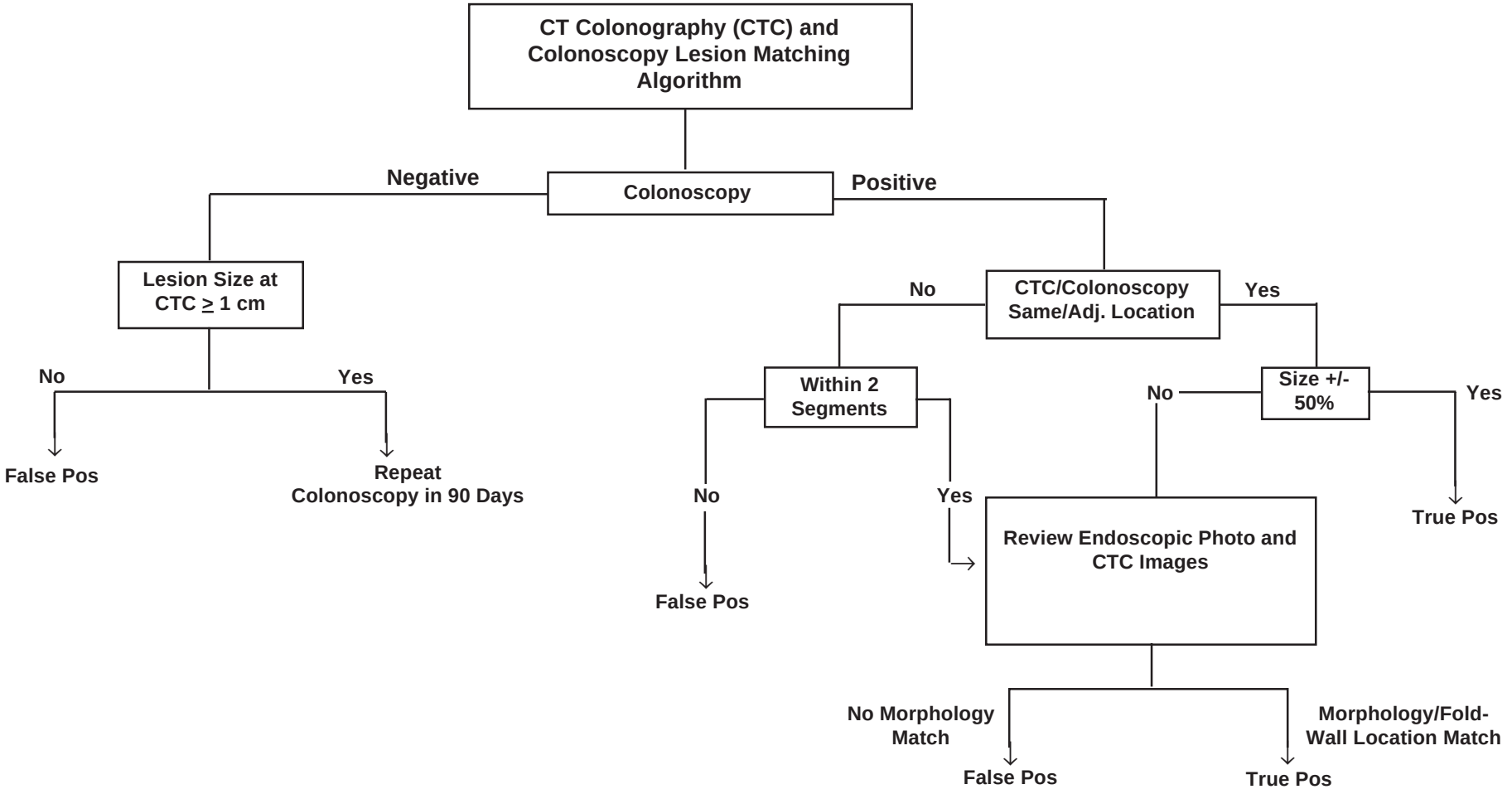
Participant Initials _____ **Case No.** _____

5. **Name of First Consensus Reviewer** _____ **(completed only if 2 member consensus review is required)**

6. **Date of First Consensus Review** _____ - _____ - _____
mm dd yyyy

7. **Name of Consensus Gastroenterologist** _____ **(completed only if 3 member consensus review is required)**

8. **Date of Gastroenterologist Consensus review** _____ - _____ - _____
mm dd yyyy



LX ACRIN 6664 National CT Colonography Lesion Matching Form for Re-Read Cases

ACRIN Study 6664

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √box. ☐

Instructions: The appointed Radiologist will review the colonoscopy and pathology reports for each individual case and match the lesions reported within the reports with findings from CTC using the algorithm included within this form on page 5. For a lesion to be considered a match, the lesion must be reported at colonoscopy and CTC to be within the same or adjacent segment. If the lesion matches by location then it will be assessed by size. If the lesion is reported to be within 50% in diameter of the size at colonoscopy and CTC will be considered a match. If the lesion does not match by location but is within two colon segments the colonoscopic photograph will be compared with its CTC image. If the lesion size reported is variant greater than 50% or if the lesion location is more than 2 segments apart, matching will be determined by consensus. Lesions that match by morphology and by their position on a haustral fold or colon wall will be considered to be a match. Lesions matching by location but not by size will be reviewed in a similar manner. A ***False positive*** is a "finding" seen on CTC but not seen on Pathology and a ***False negative*** is a "finding" seen on Pathology but not found on CTC.

- Column I: record the Lesion # on the W2 form (column I) matching the Lesion # from the PL form. All unmatched lesions found on either CTC or Pathology are to be recorded within the form and identified as "88".
- Column II: the lesion # is abstracted from the case specific PL form (column I) for consistent numbering of identified lesions.
- Column III and V: completed from data abstracted from the colonoscopy and pathology reports (reference standard).
- Column IV and VI: completed from data abstracted from the CTC report.
- Column I-VII: completed for all findings.
- Column VII-VIII: completed in the instance when lesion matching will be determined by consensus: a size variance of more than 50% or more than 2 segments apart in location
- Column IX: completed for all findings.
- Column X: completed for all unmatched lesions recorded in Column I or Column II.
- The CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm may be referenced on page 5 of this form.

1. **Date of lesion matching review** _____ - _____ - _____ [1]
   mm dd yyyy

2. **Reviewer ID:** |_|_|_|_|_|_|_| [2]

3. **Name of reviewer** _____ [3]

4. **Re-read Institution** [281]

o 4204 Clinical Radiologists S.C.
o 4205 Washington University Medical
o 4214 UT M.D. Anderson Cancer Center
o 4218 Mayo Clinic
o 4240 UCSD Medical Center
o 4277 VCU Health System
o 4303 Scottsdale Medical Imaging, LTD
o 4320 Radiology Imaging Associates
o 4342 Mayo Clinic Arizona
o 4470 Yale University-New Haven Hospital
o 4486 SF VA
o 4487 BI Medical Center
o 4492 University of Chicago
o 4494 UCLA Medical Center
o 4499 John Hopkins University

LX

ACRIN 6664
National CT Colonography
Lesion Matching Form for Re-Read Cases

Revision ☐

ACRIN Study **6664**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

5. Lesion Matching

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the W2 form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Nagative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
1	[4]	[5]	[6]	[7]	[8]	[9]	[10]	[11]	[12]	[13]	x _____ [14] y _____ [15] z _____ [16]
2	[17]	[18]	[19]	[20]	[21]	[22]	[23]	[24]	[25]	[26]	x _____ [27] y _____ [28] z _____ [29]
3	[30]	[31]	[32]	[33]	[34]	[35]	[36]	[37]	[38]	[39]	x _____ [40] y _____ [41] z _____ [42]
4	[43]	[44]	[45]	[46]	[47]	[48]	[49]	[50]	[51]	[52]	x _____ [53] y _____ [54] z _____ [55]
5	[56]	[57]	[58]	[59]	[60]	[61]	[62]	[63]	[64]	[65]	x _____ [66] y _____ [67] z _____ [68]
6	[69]	[70]	[71]	[72]	[73]	[74]	[75]	[76]	[77]	[78]	x _____ [79] y _____ [80] z _____ [81]
7	[82]	[83]	[84]	[85]	[86]	[87]	[88]	[89]	[90]	[91]	x _____ [92] y _____ [93] z _____ [94]

LX

ACRIN 6664
National CT Colonography
Lesion Matching Form for Re-Read Cases

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

5. Lesion Matching (continued)

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the W2 form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Nagative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
8	[95]	[96]	[97]	[98]	[99]	[100]	[101]	[102]	[103]	[104]	x [105] y [106] z [107]
9	[108]	[109]	[110]	[111]	[112]	[113]	[114]	[115]	[116]	[117]	x [118] y [119] z [120]
10	[121]	[122]	[123]	[124]	[125]	[126]	[127]	[128]	[129]	[130]	x [131] y [132] z [133]
11	[134]	[135]	[136]	[137]	[138]	[139]	[140]	[141]	[142]	[143]	x [144] y [145] z [146]
12	[147]	[148]	[149]	[150]	[151]	[152]	[153]	[154]	[155]	[156]	x [157] y [158] z [159]
13	[160]	[161]	[162]	[163]	[164]	[165]	[166]	[167]	[168]	[169]	x [170] y [171] z [172]
14	[173]	[174]	[175]	[176]	[177]	[178]	[179]	[180]	[181]	[182]	x [183] y [184] z [185]

LX

ACRIN 6664
National CT Colonography
Lesion Matching Form for Re-Read Cases

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

5. Lesion Matching (continued)

	Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII	Column VIII	Column IX	Column X	Column XI
	Lesion # (from the W2 form)	**Lesion # (from the PL form)**	**Colonoscopy/ Pathology (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**CTC Segment (1-6)** 1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum	**Colonoscopy/ Pathology Size (mm)**	**CTC Size (mm)**	**2 member team review (0-2)** 0 not required 1 performed with consensus 2 performed without consensus	**3 Member team review** 0 not required 3 performed with 2 to 1 vote	**Match Status (0-2)** 0 false negative 1 true positive 2 false positive	**False Negative (1-4)** 1 seen retrospectively on 2D 2 seen retrospectively on 3D 3 seen on both 2D and 3D 4 not seen in retrospect on 2D or 3D	**Missed lesion coordinates**
15	[186]	[187]	[188]	[189]	[190]	[191]	[192]	[193]	[194]	[195]	x [196] y [197] z [198]
16	[199]	[200]	[201]	[202]	[203]	[204]	[205]	[206]	[207]	[208]	x [209] y [210] z [211]
17	[212]	[213]	[214]	[215]	[216]	[217]	[218]	[219]	[220]	[221]	x [222] y [223] z [224]
18	[225]	[226]	[227]	[228]	[229]	[230]	[231]	[232]	[233]	[234]	x [235] y [236] z [237]
19	[238]	[239]	[240]	[241]	[242]	[243]	[244]	[245]	[246]	[247]	x [248] y [249] z [250]
20	[251]	[252]	[253]	[254]	[255]	[256]	[257]	[258]	[259]	[260]	x [261] y [262] z [263]
21	[264]	[265]	[266]	[267]	[268]	[269]	[270]	[271]	[272]	[273]	x [274] y [275] z [276]

LX

ACRIN 6664
National CT Colonography
Lesion Matching Form for Re-Read Cases

Revision ☐

ACRIN Study **6664**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

6. **Name of First Consensus Reviewer** _____ [277] **(completed only if 2 member consensus review is required)**

7. **Date of First Consensus Review** _____ - _____ - _____ [280]
mm dd yyyy

8. **Name of Second Consensus Reviewer** _____ [278] **(completed only if 3 member consensus review is required)**

9. **Date of Second Consensus review** _____ - _____ - _____ [279]
mm dd yyyy