Deferral of Surgery

CASE REPORT FORMS (CRFs)

PATIENT'S INITIALS ☐☐☐

DATE OF BIRTH ☐☐ ☐☐ ☐☐☐☐
Day Month Year

HOSPITAL NUMBER ☐☐☐☐☐☐☐☐

PATIENT STUDY NUMBER ☐☐☐

Date of Registration ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Completed CRFs should be sent to:
The Deferral of Surgery Trial Coordinator
GI & Lymphoma Unit
Department of Medicine
The Royal Marsden NHS Foundation Trust
Downs Road
Sutton
Surrey SM2 5PT

Registration Fax Number:
020 8661 3610

Administration Telephone Number:
020 8661 3365

Deferral of Surgery Registration Form 1

Centre Name | Centre Number

Consultant

Person randomising

To be completed on enrolment and faxed to the RMH Trials Office: **020 86613610**

Date of study registration [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year

Date of Birth [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year Gender Male [ ] Female [ ]

Hospital Number [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Trial Study Number [ ][ ][ ]

Height [ ] . [ ][ ] m Weight: [ ][ ][ ] . [ ] kg

Consent date [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year

Consent taken by:
(Must be included on site delegation log)

Consent form: Version Date: [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year Version Number: [ ][ ]

Has the patient consented to additional blood sample and tissue collection? Yes [ ] No [ ]

If Yes, date of consent [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year

Patient information sheet Version date [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year Version Number: [ ][ ]

Protocol Version Date: [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year Version Number: [ ][ ]

Signature

Date [ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year

Received

Entered Initials

Checked Initials

Deferral of Surgery Registration Form 2

Centre Name		Centre Number	
Consultant			
Person randomising			

To be completed on enrolment and faxed to the RMH Trials Office: **020 86613610**

Performance Status 0 ☐ 1 ☐ 2 ☐ 3 ■ 4 ■

Referring Trust

Referring Clinical Oncologist

Referring Medical Oncologist

Referring Surgeon

Co-morbidities

Surgery Required APER Yes ☐ No ☐ Anterior resection Yes ☐ No ☐

Other

Clinical Stage: T ☐ T1 ☐ T2 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐ T4a ☐ T4b

N ☐ N0 ☐ N1 1-3 nodes ☐ N2 ≥4 nodes

M ☐ M0 ☐ M1 ■ **Pelvic Side-wall Nodes?** Yes ■ No ☐

Distance from anal verge: ☐☐☐ *mm* **Threatened CRM?** Yes ☐ No ☐

Signature

Date ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

Received

Entered Initials

Checked Initials

Deferral of Surgery

Registration Form 3

Centre Name		Centre Number	
Consultant			
Person randomising			

To be completed on enrolment and faxed to the RMH Trials Office: **020 86613610**

Systemic Examination Normal ☐ Abnormal ☐

If abnormal, please provide details

Clinical Trial? Yes ☐ No ☐

Radiotherapy Phase I Dose and fractionation

Radiotherapy Phase II Dose and fractionation

Induction Chemotherapy? Yes ☐ No ☐

If yes, please describe agents, doses and number of cycles

Concomittant chemotherapy? Yes ☐ No ■

Agent

Dose

Toxicities

Dose reduction? Yes ☐ No ☐

Signature

Date

Day Month Year

Received

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Initials

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Initials

Deferral of Surgery

Eligibility: Inclusion Criteria Checklist

Centre / Hospital

Patient's initials | Patient Study Number

Aged ≥18 years	Yes ☐	No ■
PS 0-2	Yes ☐	No ■
Histological confirmation of adenocarcinoma of rectum	Yes ☐	No ■
No viable disease seen at MRI performed 4-6 weeks after long-course CRT confirmed at 8 week scan Or Evidence of a good partial response of rectal tumour to pre-operative long-course CRT on 4-6 week MRI which continues to show an incremental response on 8 week MRI	Yes ☐	No ■
Locally invasive high-risk rectal adenocarcinoma as defined by the presence on MRI of at least one of the following: 1. Tumours within 1mm of mesorectal fascia 2. T3 tumours at/below levators 3. Tumours extending ≥ 5mm into peri-rectal fat 4. T4 tumours (including the involvement of bladder or vagina if surgical resection is possible with clear margins) 5. Presence of extra-mural venous invasion 6. T2 N0/½ tumours requiring Abdomino-Perineal Excision, within 1mm of mesorectal fascia ie. Circumferential resection margin threatened or involved	Yes ☐	No ■
Absence of malignant pelvic side-wall disease	Yes ☐	No ■
No evidence of metastatic disease as determined by CT scan (chest, abdomen and pelvis) or other investigations	Yes ☐	No ■
Written Informed consent	Yes ☐	No ■

Signature

Date (Day / Month / Year)

Received

Entered Initials

Checked Initials

Deferral of Surgery

Exclusion Criteria Checklist

Centre / Hospital

Patient's initials | Patient Study Number

☐ Please confirm with a tick that no exclusion criteria are present according to the current protocol.

Age <18 years	Yes ■	No ☐
Absence of concomitant chemotherapy	Yes ■	No ☐
RT dose below 50Gy	Yes ■	No ☐
Stable disease at 4-6 week MRI	Yes ■	No ☐
Disease that demonstrates a partial response at 4 week MRI but `shows no evidence of an incremental response at 8 week MRI	Yes ■	No ☐
Medical or psychiatric conditions that compromise the patient's ability to give informed consent	Yes ■	No ☐
Any contraindication to MRI scanning	Yes ■	No ☐
Tumours which are mucinous (>50% mucin seen on MRI), as these are more likely to be PET negative	Yes ■	No ☐

Written informed consent must be obtained from the patient before any study-specific procedures are performed

Signature

Date (Day / Month / Year)

Received

Entered (Initials)

Checked (Initials)

Deferral of Surgery

Pre-CRT MRI Assessment 1

Centre

Patient Study Number

Patient's initials

Date of birth (Day / Month / Year)

Date of scan (Day / Month / Year)

Sagittal Tumour Measurements

Tumour position in relation to the peritoneal reflection *At* *Above* *Below*

Distance to the dentate line from the lower edge of the tumour? *mm*

Length if tumour? *mm*

Maximum thickness of tumour? *mm*

Shortest longitudinal distance to peritoneal reflection? *mm*

Exam technically satisfactory? Yes No

If no, specify why

MRI T Stage:

- T1
- T2
- T3a
- T3b
- T3c
- T3d
- T4a
- T4b

Extramural venous invasion:

- Large vein invasion
- Minimal nodular venous invasion
- No extramural venous invasion

Nodal Spread:

- N0
- N1 1-3 nodes
- N2 ≥4 nodes

Malignant Pelvic sidewall nodes Yes No

Radiologist

Title

Signature

Date (Day / Month / Year)

Received

Entered Initials

Checked Initials

Deferral of Surgery

Pre-CRT MRI Assessment 2

Centre

Patient Study Number

Patient's initials

Date of birth (Day / Month / Year)

Date of scan (Day / Month / Year)

Mesorectal fascia and surgical margns:

Minimum distance to mesorectal fascia mm

Distance to CRM

- Involved: tumour at mesorectal margin
- At risk: tumour 1mm from margin
- Safe: clear measorectum>1mm from margin

For low tumours below the level of the levators: (Please tick)

- IS0: Tumour extends into rectal wall but does not border the interspincteric plane
- ISI: Tumour extends into rectal wall and borders the interspincteric plane
- IS2: Tumour extends into the intersphincteric plane
- IS3: Tumour extends into external sphincter

Radiologist

Title

Signature

Date (Day / Month / Year)

Received

Entered Initials

Checked Initials

For trials office use

Deferral of Surgery

Pre-CRT CT Assessment

Centre

Patient Study Number

Patient's initials

Date of birth (Day / Month / Year)

Date of scan (Day / Month / Year)

Sites Imaged ☐ Chest ☐ Abdomen ☐ Pelvis

Metastatic Lymph node involvement: Yes ☐ No ■

Distant Metastases: Yes ☐ No ■

Radiologist

Title

Signature

Date (Day / Month / Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Post-CRT CT Assessment 1

Time post CRT

☐ 1yr ☐ 2yrs ☐ 3yrs

Centre _____ Patient Study Number ☐☐☐

Patient's initials ☐☐☐ Date of birth ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Date of scan ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Sites Imaged ☐ Chest ☐ Abdomen ☐ Pelvis

Metastatic Lymph node involvement: Yes ☐ No ☐

If yes, specify site involvement:

Cervical	Yes ☐	Indeterminate ☐	No ☐
Mediastinal	Yes ☐	Indeterminate ☐	No ☐
Abdominal	Yes ☐	Indeterminate ☐	No ☐
Pelvic	Yes ☐	Indeterminate ☐	No ☐

Distant Metastases: Yes ☐ No ☐

If yes, specify site involvement:

Cervical	Yes ☐	Indeterminate ☐	No ☐	*Potentially resectable*	☐
Mediastinal	Yes ☐	Indeterminate ☐	No ☐	*Potentially resectable*	☐
Abdominal	Yes ☐	Indeterminate ☐	No ☐	*Potentially resectable*	☐
Pelvic	Yes ☐	Indeterminate ☐	No ☐	*Potentially resectable*	☐

Radiologist _____ Title _____

Signature _____ Date ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Post-CRT MRI Assessment 1/2

Time post completion of CRT:

☐ 4 weeks ☐ 8 weeks ☐ 12 wks ☐ 16 wks ☐ 6 mths ☐ 9 mths ☐ 1yr

☐ 18mths ☐ 2 yrs ☐ 3 yrs ☐ 4 yrs ☐ 5 yrs ☐ 6 yrs ☐ 7 yrs

Patient's initials ☐☐☐ Date of birth ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Centre ☐☐☐☐☐☐☐☐☐☐ Patient Study Number ☐☐☐

Date of scan ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Sagittal Tumour Measurements

Tumour position in relation to the peritoneal reflection *At* ☐ *Above* ☐ *Below* ☐

	Tumour	*Fibrosis*
Distance to the dentate line from the lower edge of the tumour?	☐☐☐ *mm*	☐☐☐ *mm*
Length if tumour?	☐☐☐ *mm*	☐☐☐ *mm*
Maximum thickness of tumour?	☐☐☐ *mm*	☐☐☐ *mm*
Shortest longitudinal distance to peritoneal reflection?	☐☐☐ *mm*	☐☐☐ *mm*

Exam technically satisfactory? Yes ☐ No ☐

If no, specify why ☐☐☐☐☐☐☐☐☐☐

yMR Tumour T Stage

☐ T0
☐ T1
☐ T2
☐ T3a
☐ T3b
☐ T3c
☐ T3d
☐ T4a
☐ T4b

Fibrosis

☐ T0
☐ T1
☐ T2
☐ T3a
☐ T3b
☐ T3c
☐ T3d
☐ T4a
☐ T4b

Extramural venous invasion:

☐ Large vein invasion
☐ Minimal nodular venous invasion
☐ No extramural venous invasion

Nodal Spread:

☐ N0
☐ N1 1-3 nodes
☐ N2 ≥4 nodes

Malignant Pelvic sidewall nodes Yes ☐ No ☐

Radiologist ☐☐☐☐☐☐☐☐☐☐ Title ☐☐☐☐☐☐☐☐☐☐

Signature ☐☐☐☐☐☐☐☐☐☐ Date ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Post-CRT MRI Assessment 2/2

Centre

Patient Study Number

Patient's initials

Date of birth (Day / Month / Year)

Date of scan (Day / Month / Year)

Mesorectal fascia and surgical margns:

	Tumour	Fibrosis
Minimum distance to mesorectal fascia	mm	mm

Distance to CRM

- ☐ Involved: tumour at mesorectal margin
- ☐ At risk: tumour 1mm from margin
- ☐ Safe: clear measorectum>1mm from margin
- ☐ Involved: fibrosis at mesorectal margin
- ☐ At risk: fibrosis 1mm from margin
- ☐ Safe: clear measorectum>1mm from margin

IS Classification: For low tumours below the level of the levators only:

	Tumour	Fibrosis
ISO : Tumour extends into rectal wall but does not border the intersphincteric plane	☐	☐
IS1 : Tumour extends into the rectal wall and borders the intersphincteric plane	☐	☐
IS2 : Tumour extends into the intersphincteric plane	☐	☐
IS3 : Tumour extends into external spincter	☐	☐

Modified Mandard Tumour Regression Grading:

- ☐ 1 Complete radiological response
- ☐ 2 Good response (dense fibrosis, no obvious tumour)
- ☐ 3 Moderate response (>50% fibrosis and visible intermediate signal)
- ☐ 4 Slight Response (mostly tumour present)
- ☐ 5 No response

Radiologist

Title

Signature

Date (Day / Month / Year)

Received

Entered (Initials)

Checked (Initials)

PET-CT scan Proforma

Deferral of Surgery

Time post completion of CRT:
☐ 8 weeks ☐ 16 weeks ☐ 1year

Centre ☐ Patient Study Number ☐☐☐☐☐☐☐☐

Patient's initials ☐☐☐ Date of birth ☐☐☐☐☐☐☐☐

Date of PET - CT ☐☐☐☐☐☐☐☐
Day Month Year

Lesion	Location	Primary lesion Y/N	SUV max	SUV mean
1				
2				
3				
4				
5				

Overall Score ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ X ☐ Y

Overall Response:
CR ☐
PR ☐
SD ☐
PD ☐

Signature ☐ Date ☐☐☐☐☐☐☐☐
Day Month Year

Received

Entered
Initials

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Initials

Deferral of Surgery

Follow-up pro-forma 1

Time post completion of CRT: ☐ 4 wks ☐ 8 wks ☐ 12 wks ☐ 16 wks ☐ 6 mths ☐ 9 mths ☐ 1 yr

☐ 15 mths ☐ 18 mths ☐ 21 mths ☐ 18 mths ☐ 21 mths ☐ 2 yrs ☐ 30 mths ☐ 3 yrs ☐ 42 mths ☐ 4 yrs

☐ 54mths ☐ 5yrs ☐ 6yrs ☐ 7yrs ☐ 8yrs ☐ 9 yrs ☐ 10 yrs

Centre / Hospital _____ Date of birth ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

Patient's initials ☐☐☐ Patient Study Number ☐☐☐☐☐☐☐☐

Date of Visit ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

CEA level ☐☐ **ug/l** **Date of Sample** ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

Disease Assessment:

Investigations completed:

DRE (please complete at each visit) Yes ☐ No ☐ If no, state reason _____

MRI
(Please complete at 4 wks, 8 wks, 12 wks, 16 wks, 6 mths, 9 mths, 12 mths, 18 mths, 2,3,4,5,6,7 year visits) Yes ☐ No ☐ If no, state reason _____

PET
(Please complete at 8 wks, 16 wks, 1yr) Yes ☐ No ☐ If no, state reason _____

Flex Sig
(Please complete at 12 wks, 6mths, 9mths, 18mths,2,3,4,6,7 year visits) Yes ☐ No ☐ If no, state reason _____

Colonoscopy
(Please complete at 1,5 and 10yr visits) Yes ☐ No ☐ If no, state reason _____

Disease Status ☐ CR ☐ PR ☐ SD ☐ Progressive disease/recurrence

If progression/recurrence: Site ☐ Local ☐ Distant

Date of progression/recurrence ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

First detected by: ☐ DRE ☐ CEA ☐ MRI ☐ PET ☐ CT ☐ Flex Sig ☐ Colonoscopy

Operable? Yes ☐ No ☐ If operable, date of operation ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

Signature _____ Date ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Follow-up pro-forma 2

Time post completion of CRT: ☐ 4 wks ☐ 8 wks ☐ 12 wks ☐ 16 wks ☐ 6 mths ☐ 9 mths ☐ 1 yr

☐ 15 mths ☐ 18 mths ☐ 21 mths ☐ 18 mths ☐ 21 mths ☐ 2 yrs ☐ 30 mths ☐ 3 yrs ☐ 42 mths ☐ 4 yrs

☐ 54mths ☐ 5yrs ☐ 6yrs ☐ 7yrs ☐ 8yrs ☐ 9 yrs ☐ 10 yrs

Centre / Hospital _____ Date of birth ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Patient's initials ☐☐☐ Patient Study Number ☐☐☐☐☐☐☐☐

Date of Visit ☐☐ ☐☐ ☐☐☐☐
Day Month Year

If operable, resection margin ☐ Positive ☐ Negative

Sphincter Preserving Yes ☐ No ☐

EORTC returned Yes ☐ No ☐

MIBDQ returned (omit for wk12, 9th, 15mth, 21mth visit) Yes ☐ No ☐

Vaizey returned (omit for wk12, 9th, 15mth, 21mth visit) Yes ☐ No ☐

LENT-SOMA returned?
(please complete for all visits except wk 8 and wk 16) Yes ☐ No ☐

Signature _____ Date ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Received

Entered
Initials

Checked
Initials

Deferral of Surgery DRE proforma

Time post completion of CRT: ☐ 4 wks ☐ 8 wks ☐ 12 wks ☐ 16 wks ☐ 6 mths ☐ 9 mths ☐ 1 yr

☐ 15 mths ☐ 18 mths ☐ 21 mths ☐ 18 mths ☐ 21 mths ☐ 2 yrs ☐ 30 mths ☐ 3 yrs ☐ 42 mths ☐ 4 yrs

☐ 54mths ☐ 5yrs ☐ 6yrs ☐ 7yrs ☐ 8yrs ☐ 9 yrs ☐ 10 yrs

Centre / Hospital _____ Date of birth ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Patient's initials ☐☐☐ Patient Study Number ☐☐☐☐☐☐☐☐

Date of Visit ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Digital Rectal Exam (DRE)

Abnormality on DRE? Yes ☐ No ☐

If this abnormality has been previously palpated, on this DRE is it:

☐ Larger ☐ Smaller ☐ Same

Distance from anal verge ☐☐ cm

Anal Tone ☐ Good ☐ Moderate ☐ Poor

Obstructing Yes ☐ No ☐

Can you get above: Yes ☐ No ☐

Blood on glove: Yes ☐ No ☐

Clock-face description _____ O'clock

Are these findings suggestive of residual disease? Yes ☐ No ☐

Are these findings suggestive of recurrentl disease? Yes ☐ No ☐

Signature _____ Date ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Received

Entered
Initials

Checked
Initials

Deferral of Surgery

Sigmoidoscopy Proforma

Time post completion of CRT:

☐ 12 wks ☐ 6 mths ☐ 9 mths

☐ 18 mths ☐ 2 yrs ☐ 3 yrs

☐ 4 yrs ☐ 6 yrs ☐ 7yrs

Centre / Hospital _____ Date of birth ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Patient's initials ☐☐☐ Patient Study Number ☐☐☐☐☐☐☐☐

Date of Visit ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Abnormality on sigmoidoscopy? Yes ☐ No ☐

Anus/anal canal? Yes ☐ No ☐

Rectum Yes ☐ No ☐

Sigmoid Yes ☐ No ☐

If this abnormality has been previously seen , on this examination is it: ☐ Larger ☐ smaller ☐ same

Distance from anal verge ☐☐ cm

Obstructing? Yes ☐ No ☐

Bleeding? Yes ☐ No ☐

Clock-face description _____ O'clock

Are these findings suggestive of residual disease? Yes ☐ No ☐

Are these findings suggestive of recurrentl disease? Yes ☐ No ☐

Signature _____ Date ☐☐ ☐☐ ☐☐☐☐ (Day / Month / Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Disease Progression Form

Centre | Patient Study Number

Patient's initials | Date of birth (Day / Month / Year)

Date Progression confirmed (Day / Month / Year)

Method of detection:
(Please tick whichever applies)

CT Scan ☐ Clinical ☐ PET ☐

MRI ☐ Endoscopy ☐ Other *(please specify)* ☐

Sites of Progression:
(Please tick all that apply)

Primary tumour ☐ Local lymph nodes ☐

Distant lymph nodes ☐ Liver ☐

Bone ☐ Brain ☐

Peritoneum ☐ Lung ☐

Other *(please specify)*

Signature | Date (Day / Month / Year)

Received | Entered (Initials) | Checked (Initials)

Deferral of Surgery

Protocol Violation Form

Centre | Patient Study Number

Patient's initials | Date of birth (Day / Month / Year)

Date of protocol violation (Day / Month / Year)

Details of violation:

- Patient has not had MRI at specified follow-up time-point ☐
- Patient has not had CT-PET at specified follow-up time-point ☐
- Patient has not had endoscopy at specified follow-up time-point ☐
- Patient has not reached MMG 1 or 2 by MRI criteria ☐
- Patient Non Compliance *(Please specify below)* ☐
- Patient has not proceeded to surgery despite evidence of disease recurrence ☐
- Other *(Please specify below)* ☐

For completion by the RMH Trials Unit Office Only

Action Taken

Signature | Date (Day / Month / Year)

Received | Entered (Initials) | Checked (Initials)

Deferral of Surgery

Study Withdrawal Form

Centre | Patient Study Number

Patient's initials | Date of birth (Day / Month / Year)

This is to be completed if patients opt to have surgery with no evidence of tumour regrowth

Date of Study Withdrawal (Day / Month / Year)

Reason for Withdrawal:

Clinician Choice ☐ Patient choice ☐

Non Compliance ☐ Other *(please specify)*

Has patient consented to continue study follow up? Yes ☐ No ☐

Signature | Date (Day / Month / Year)

Received	Entered	Checked
	Initials	Initials

Deferral of Surgery

Notification of Death or Loss to Follow-up Form

Centre | Patient Study Number

Patient's initials | Date of birth (Day / Month / Year)

Please complete if patient has died:

Date of death (Day / Month / Year)

Cause of death: Carcinoma

Other *(Specify)*

Was an autopsy performed? Yes / No

Autopsy findings?

Cause of death

Please complete if patient has been lost to follow up:

Date of last contact (Day / Month / Year)

Type of contact: Hospital visit / Telephone call to clinical team / Telephone call enquiry made to GP

Details of lost follow up:

Signature | Date (Day / Month / Year)

Received | Entered (Initials) | Checked (Initials)