ARISTOTLE

Trial Number: A R I — ☐☐☐ **Patient Initials:** ☐☐☐

SUSPECTED RESIDUAL DISEASE OR RECURRENCE FORM

***NB** All dates should be in DD-MM-YYYY format*

INSTRUCTIONS:

Complete this form if the patient has suspected residual disease or recurrence.

Suspected residual disease is defined as incomplete resection of tumour after CRT without biopsy proof of residual disease.

A **suspected recurrence** includes:

- Elevated CEA but without definitive evidence of loco-regional or metastatic disease
- Appearance of equivocal findings on CT or pelvic MRI scanning
- In CEA non-secretors:
  - Enlarging or new mass indicative of locoregional recurrence without biopsy confirmation
  - Evidence of distant metastases without biopsy confrimation

Once a suspected recurrence is reported, **the case must be reviewed by the MDT 6 months later** and a Confirmation of Residual Disease or Recurrence (CRDR) Form submitted

(NB: A CRDR Form must be submitted in ALL cases. If the suspected disease is not confirmed after 6 months, this can be recorded on the CRDR Form)

1. Residual disease following CRT

A) Does the patient have suspected residual disease? ☐ Yes ☐ No

2. Elevated CEA

A) Does the patient have suspected recurrence based on elevated CEA? ☐ Yes ☐ No

If yes, i) Date of blood sample: ☐☐ / ☐☐ / ☐☐☐☐

ii) CEA value (μg/mL): ☐☐☐☐

3. Loco-regional recurrence in CEA non-secretors *(Biopsy confirmation contraindicated or not feasible)*

A) Does the patient have a new mass? ☐ Yes ☐ No

B) Does the patient have an enlarging mass? ☐ Yes ☐ No

C) If yes to A or B,

i) Date of scan identifying new or enlarging mass: ☐☐ / ☐☐ / ☐☐☐☐

ii) Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

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4. Metastatic disease in CEA non-secretors *(Biopsy confirmation contraindicated or not feasible)*

A) Does the patient have evidence of metastatic disease? ☐ Yes ☐ No

If yes, i) Date of scan identifying metastases: ☐☐ / ☐☐ / ☐☐☐☐

ii) Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

iii) Site(s) of metastatic disease:
- ☐ Liver
- ☐ Lung
- ☐ Lymph nodes
- ☐ Peritoneum
- ☐ Bone
- ☐ Brain
- ☐ Other *(specify)* _____

5. Equivocal findings on imaging

A) Is the suspected recurrence based on equivocal findings on imaging? ☐ Yes ☐ No

If yes, i) Date of scan: ☐☐ / ☐☐ / ☐☐☐☐

ii) Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

iii) Findings:
- ☐ Evidence of loco-regional recurrence
- ☐ Evidence of distant metastases

iii) Site(s) of metastatic disease:
- ☐ Liver
- ☐ Lung
- ☐ Lymph nodes
- ☐ Peritoneum
- ☐ Bone
- ☐ Brain
- ☐ Other *(specify)* _____

Completed by (print name):	**Signature:**	**Date Completed:**
		☐☐ ☐☐ ☐☐☐☐

Site:

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____