I1 Radiation Therapy Oncology Group
Phase II Study of IMRT with Concurrent Systemic Therapy Followed with Chemotherapy for Post-op Endometrial Cancer
Initial Evaluation Form

RTOG Study 0921 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

AMENDED DATA ☐

INSTRUCTIONS: All questions must be answered per code table and/or instructions. Record dates as mm-dd-yyyy unless otherwise specified.

1 ☐☐ **PATIENT AGE**(1)

2 ☐ **ZUBROD PERFORMANCE STATUS**(2)

3 ☐ **SURGICAL PROCEDURE**(3)
- 1 TAH
- 2 Vaginal hysterectomy
- 3 Radical hysterectomy
- 4 Laparoscopic assisted vaginal hysterectomy
- 5 Robotic-assisted hysterectomy

4 **DATE OF SURGICAL PROCEDURE**____-_____-_____(4)

5 **TUMOR STAGING CRITERIA**
- 1 No
- 2 Yes

☐ Grade 3 carcinoma with greater than 50% myometrial invasion; all papillary serous and clear cell carcinoma will be considered grade 3(5)

☐ Grade 2 or 3 carcinoma with any cervical stromal invasion(6)

☐ Known extra-uterine disease confined to the pelvis, any grade.(7)

6 ☐ **WAS BILATERAL SALPINGO-OOPHORECTOMY PERFORMED?** (8)
- 1 No
- 2 Yes

7 ☐ **HISTOLOGY**(9)
- 1 Endometrioid Endometrial Adenocarcinoma
- 2 Clear cell carcinoma
- 3 Papillary serous Adenocarcinoma
- 4 Adenosquamous carcinoma
- 5 Other adenocarcinoma variant, specify_____(10)
- 6 Carcinosarcoma

8 **DATE OF HISTORY / PHYSICAL / NORMAL POST-OP EXAM** _____-_____-_____(11)

9 **DATE OF CHEST XRAY OR CHEST CT OR PET/CT**

_____-_____-_____(12)

10 **DATE OF CT OR PET-CT OF ABDOMEN AND PELVIS**

_____-_____-_____(13)

11 **BASELINE LABS (Please report in specified units)**

ANC ☐☐☐☐ **mm³**(14)

DATE ____-____-_____(15)

PLATELETS ☐☐☐, ☐☐☐ **mm³**(16)

DATE ____-____-_____(17)

HEMOGLOBIN ☐☐.☐ **g/dL**(18)

DATE ____-____-_____(19)

SERUM CREATININE ☐☐.☐ **mg/dl**(20)

DATE ____-____-_____(21)

SERUM CREATININE ULN ☐☐.☐ **mg/dl**(22)

TOTAL BILIRUBIN ☐☐.☐ **mg/dl**(23)

DATE ____-____-_____(24)

BILIRUBIN ULN ☐☐.☐ **mg/dl**(25)

SGOT (AST) ☐☐.☐ **IU/L**(26)

DATE ____-____-_____(27)

SGOT (AST) ULN ☐☐.☐ **IU/L**(28)

SGPT (ALT) ☐☐.☐ **IU/L**(29)

DATE ____-____-_____(30)

SGPT (ALT) ULN ☐☐.☐ **IU/L**(31)

12 ☐ **HAS PATIENT RECEIVED WARFARIN WITHIN 14 DAYS PRIOR TO STUDY ENTRY?**(32)
- 1 No
- 2 Yes

☐ **If yes, was INR < 1.5**(33)
- 1 No
- 2 Yes

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13 ☐ **PRE STUDY URINE PROTEIN SCREENED BY URINE PROTEIN RATIO (UPC)?**(34)

1 < 1.0
2 ≥ 1.0

DATE _____-_____-_____(35)

14 **ADDITIONAL LABS**

ALK PHOS	**DATE** _____-_____-_____(38)
MG	**DATE** _____-_____-_____(39)
BUN	**DATE** _____-_____-_____(40)
SODIUM	**DATE** _____-_____-_____(41)
POTASSIUM	**DATE** _____-_____-_____(85)
CHLORIDE	**DATE** _____-_____-_____(86)
BICARBONATE(HCO_3)	**DATE** _____-_____-_____(87)

15 **GENERAL CONDITIONS**

1 No
2 Yes

☐ Prior systemic chemotherapy for uterine cancer ?(42)

☐ Prior invasive malignancy?(43)
If yes, date eradicated ____-____-____(44)

☐ Prior chemo for other malignancy (45)
If yes, date of completion _____-_____-_____(46)
Agent _____ (47)

☐ Prior chemo for a non-malignant condition? (48)
If yes:
Condition _____ (49)
Date of completion_____-_____-_____(50)
Agent(s) _____ (51)

☐ Prior radiation therapy to the pelvis resulting in overlapping of radiation therapy fields?(52)

☐ Active inflammatory bowel disease?(53)

☐ Transmural myocardial infarction within last 12 months?(54)

☐ Acute bacterial or fungal infection requiring intravenous antibiotics at the time of study entry?(55)

☐ COPD exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of study entry?(56)

☐ Hepatic insufficiency resulting in clinical jaundice and/or coagulation defects? (57)

☐ Acquired Immune Deficiency Syndrome based upon current CDC definition?(58)

☐ Ototoxicity > CTCAE grade 2 at time of study entry?(59)

☐ Neuropathy >CTCAE grade 1 at time of study entry?(60)

☐ Metastatic extrauterine disease, gross disease, residual disease, (not including pelvic nodal disease) or distant metastases?(61)

☐ Unstable angina and/or congestive heart failure (NYHA ≥ grade II) requiring hospitalization within the last 12 months?(62)

☐ GI ulcers, GI bleeding, or inflammatory bowel disease, or GI obstruction?(63)

☐ Inadequately controlled hypertension defined as systolic >150 and diastolic > 90 on hypertensive medications?(64)

☐ Significant vascular disease including aortic aneurysm or aortic dissection or arteriovenous malformation, within 12 months?(65)

☐ Serious cardiac arrhythmia on medication (well-controlled atrial fibrillation on medication is allowed)?(66)

☐ Serious non-healing wound, ulcer or bone fracture?(67)

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___ History of arterial thromboembolic events, including transient ischemic attack (TIA), or clinically symptomatic peripheral artery disease within 12 months of study entry?(68)

___ Major surgical procedure requiring open biopsy incision or significant trauma within 28 days prior to study entry or anticipation of need of any surgical activity during the course of the study excluding vascular access to device placement or procedures that do not require significant incision?(69)

___ History of abdominal fistula, GI perforation or intra abdominal abscess within 6 months prior to study entry?(70)

___ History of an organ transplant?(71)

___ Any history of hypertensive crisis or hypertensive encephalopathy?(72)

___ History of stroke/cerebrovascular event (CVA) within 6 months of study entry?(73)

___ Known hypersensitivity to Chinese hamster ovary cell products or other recombinant human antibodies?(74)

___ Mental status changes or bladder problems that make patient unable to comply with bladder filling instructions?(75)

___ Mental or psychiatric illness that would prevent informed consent?(76)

___ Prior allergic reaction to Bevacizumab, Cisplatin, Carboplatin or Paclitaxel?(77)

___ Does the patient require > 1mg/day of Warfarin(78)

___ Positive common iliac or positive para-aortic nodal disease (radiologically LN$\geq$2cm in any dimension or biopsy proven)(79)

___ Prior therapy with Anti-VEGF compounds?(80)

___ Is the patient currently breast feeding? (81)

COMMENTS_____

_____(82)

The reported case report information has been reviewed and confirmed by the principal investigator.

_____(83)
Investigator Signature

_____-_____-_____(84)
Date