

# PORTEC-4

February 2020

Randomisation Checklist

Form 1, page 1 of 2

Patient seqnr.

|\_|\_|\_|

Age at inclusion (years)

|\_|\_|\_|

Hospital:

.....

**INSTRUCTIONS:** Use this form as a checklist and randomise via TenaLea:

<https://prod.tenalea.net/iknl/dm/DELogin.aspx?refererPath=DEHome.aspx>, or complete this

form and send to **IKNL clinical research department by E-MAIL** E: [trialbureau@iknl.nl](mailto:trialbureau@iknl.nl) (in case of

questions phone: +31 88 2346500 or email [portec@iknl.nl](mailto:portec@iknl.nl))

## **STRATIFICATION:**

Histological grade (1=grade 1, 2=grade 2, 3=grade 3) ..... |\_|

Type of surgery (1=TAH-BSO or TLH-BSO without lymphadenectomy, 2= TAH-BSO or TLH-BSO with lymphadenectomy) ..... |\_|

## **INCLUSION CRITERIA:**

Histologically confirmed endometrioid type endometrial carcinoma, FIGO 2009 staging, with one of the following combinations of substage, age and grade ..... |\_|

1 = Stage IA (with invasion), grade 3 (any age, with or without LVSI)

2 = Stage IB, grade 1 or grade 2, age  $\geq$  60 years

3 = Stage IB, grade 1 or grade 2 with documented LVSI

4 = Stage IB, grade 3 without LVSI

5 = Stage II, grade 1

## **INCLUSION CRITERIA:** (0=no, 1=yes)

Surgery consisted of Total Abdominal or Laparoscopic Hysterectomy and Bilateral Salpingo-Oophorectomy (TH-BSO) with or without lymphadenectomy ..... |\_|

WHO performance status 0, 1 or 2 ..... |\_|

Written informed consent..... |\_|

Date written informed consent (dd-mm-yyyy) ..... |\_|\_||\_|\_||\_|\_|\_|\_|

Informed consent also for storage of remaining tissue for translational research..... |\_|

## **EXCLUSION CRITERIA:** (0=no, 1=yes)

Any other stage of endometrial carcinoma..... |\_|

Histological types serous or clear cell carcinoma (for mixed tumors, > 10% serous or clear cell type)..... |\_|

Uterine sarcoma (incl.carcinosarcoma)..... |\_|

History of previous malignancy within the last 5 years, except for non-melanomatous skin cancer .... |\_|

Previous pelvic radiotherapy..... |\_|

Interval between date of surgery and start of brachytherapy > 8 weeks..... |\_|

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**Hospital:**

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## PATHOLOGY:

Original Pathology Lab.....

Original Pathology Number ..... |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|

Has regional review PA been done and is the tumour tissue still at this pathology lab?(0=no, 1=yes) ..... |\_|

If yes, regional review Pathology Lab.....

If yes, regional review Pathology Number ..... |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|

## CONTACT INFORMATION RANDOMISING PHYSICIAN/RESEARCH NURSE:

Name and function.....

Telephone number .....

Email address.....

**Date:**..... **Investigator's signature:**.....

## INFORMATION GIVEN AT RANDOMIZATION:

Date of randomisation (dd-mm-yyyy) ..... |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|

Patient study number ..... |\_|\_|\_|\_|

Treatment allocation ..... |\_|

1= Standard treatment recommendation based on clinicopathological factors

2= Individual treatment recommendation based on molecular pathology

**Please do not forget to send in the pre-treatment Quality of life questionnaire and address form!**