Partial prostate Ablation versus Radical prosTatectomy

# PART STUDY

## A randomised controlled trial of *P*artial prostate *A*blation versus *R*adical pros*T*atectomy (PART)

## PART Histopathology
## Trial Specific Information (TSI)

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| **Relates to OCTRU SOP:** | **N/A** |
| **Version Number:** | **1.0** |
| **Name of Authors:** | **Steffi le Conte & Clare Verrill** |
| **Date Finalised:** | **04Sep2015** |

**PURPOSE:**

This Trial Specific Instruction (TSI) details general comments about histopathological reporting of biopsy and radical prostatectomy specimens.

**INSTRUCTIONS:**

- Biopsies and radical prostatectomy specimens are reported at the local trial sites to the requirements of the RCPath 'Dataset for Histopathology Reports for Prostatic Carcinoma. 2nd ed. 2009'[1].
- Gleason Grading is undertaken using the 2005 ISUP modified Gleason grading system[2].
- pTNM staging is undertaken using the UICC TNM 7th edition[3].

**Biopsy reporting:**

Biopsies are reported by consultant pathologists locally at each site. Biopsies are not routinely double reported or reviewed. However, the follow up biopsies following ablation therapy may be reviewed for academic interest by the pathology working group (using scanned images).

Biopsy data (at baseline and post-procedurally) should be completed by the research team.

**Radical prostatectomy reporting:**

Radical prostatectomy specimens are reported in the local sites by the local pathologists. All slides are scanned and centrally reviewed in Oxford by Clare Verrill, not for double reporting purposes, but to record additional parameters that would not otherwise have been routinely reported and allow close correlation of tumour topography with the imaging. Additional parameters to be recorded are: the diagnosis within each of 12 PiRADs zones A-L (benign, malignant, atypical), Gleason grade grouping[4] and whether there is inflammation or fibrosis present. If any histological parameters cannot be filled in from the local report as particular features have not been reported, this can be filled in on central review. Also, the tumour location category will be double checked on central review and amended if necessary with or without referral to the pathology working group.

The "Radical Prostatectomy Pathology Report Worksheet" is filled in at the local site by the **study PI, Co-investigator or pathologist**. If the pathologist fills it in, the 'M' staging and PART study randomisation number should already have been filled in (can be done by the Research Nurse) and the pathologist will need to know what the histology/pathology number is in order to review the case.

Tumour location on the radical prostatectomy is defined as:

- ✓ Unilateral clinically intermediate risk (Gleason 7 [3+4 or 4+3] or High volume Gleason 6 [any tumour dimension ≥4mm])
- ✓ Dominant* unilateral clinically significant intermediate risk & small contralateral low-risk disease (Dominant Gleason score 7 [3+4/4+3]
- ✓ Bilateral and/ or high risk disease (Bilateral is Gleason 7 [3+4/4+3] on dominant side and Gleason 7 [3+4/4+3] or high volume Gleason 6 on contralateral side (any tumour dimension >4mm). High risk is Gleason score 8 and above.
- ✓ Uncertain – to be completed post central review.

**Dominant defined as the largest tumour, which is usually the tumour with the highest stage and grade[2].*

Cases diagnosed as showing bilateral or high risk disease should be centrally reviewed in Oxford in the first instance and then anonymised images shared and discussed by the pathology working group to reach a consensus on the contralateral Gleason Score in bilateral cases to ensure it is definitely 3+4 or above and consensus on the Gleason Score in the high risk cases.

**Central Review**

To enable central review in Oxford, the RP slides should be requested and sent to Clare Verrill in Oxford. After randomisation, the PART Trial Office will send a letter to the lead site pathologist and request the RP slide(s). The slides should be anonymised before sending to Oxford with only the PART ID number listed. If this has not happened, they will be anonymised in Oxford by OCHRe. The anonymous slides will then be scanned in Oxford and images will be saved on an external hard drive. One external hard drive will be kept securely with Clare Verrill in her NHS office, and another by the Trial Office, again in a secure location. Cases that

need central review by the Pathology Working Group will be saved on the web microscope for sharing.

Sites that wish to do their own scanning and uploading onto in-house hosting websites should discuss this in advance with either Clare Verrill or the PART Office (full contact details below).

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**References:**

1. Dataset for Histopathology Reports for Prostatic Carcinoma. 2nd Ed. RCPath, London. 2009.
2. Epstein J, Allsbrook WC jr, Amin MB et al. The 2005 ISUP consensus conference on Gleason Grading of Prostatic Carcinoma. Am J Surg Pathol 2005; 29: 1228-42.
3. TNM classification of malignant tumours. 7th ed. UICC.
4. Pierorazio PM, Walsh PC, Partin AW, Epstein JE. Prognostic Gleason grade grouping: based on the modified Gleason scoring system. BJU Int 2013; 111: 753-760.

**HISTORY:**

| **Version number Date** | **Significant changes from previous version** |
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| V1.0_04Sep2015 | Not applicable as this is the 1st issue |