Cancer Molecular Diagnostics, LabMed Directorate, St. James's Hospital, Dublin 8
Tel: 01-4103575 01-4162353
Email: cmd@stjames.ie

BRCA/HRD TEST REQUEST AND CONSENT FORM FOR PARP INHIBITOR SELECTION

Surname:	**First Name:**	
Date of Birth	**MRN/Hospital Number**	**Gender:**
Residential Address:		
Requesting Medical Oncologist (first name, surname, department and hospital):		
Clinical Team Email Address:	**Pathology Email Address:**	
CURRENT DIAGNOSIS (tick one):	**DETAILS OF TEST REQUESTED:**	
□ Fallopian tube cancer □ Primary peritoneal cancer □ High grade epithelial ovarian cancer (other) Please specify type: …… □ High grade serous ovarian cancer	□ HRD and Tumour BRCA only (FFPE tumour block >30% NCC) - **NCCP funded** □ Germline BRCA only (EDTA blood only)	
□ HER2 negative locally advanced or metastatic breast cancer (germline BRCA test only) □ HER2-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy	□ Germline BRCA only (EDTA blood only)	
□ Metastatic adenocarcinoma of the pancreas being considered for platinum treatment	□ Germline BRCA only (EDTA blood only)	
□ Metastatic Prostate Cancer	□ Germline BRCA only (EDTA blood only) □ Combined Tumour and Germline BRCA* (EDTA blood & FFPE tumour block)	

*For germline and tumour requests complete the form in full and include a copy of the form with the blood sample and send a photocopy to histopathology to include with block referral

CLINICAL INFORMATION:

□ Patient is being considered for maintenance PARP inhibitor treatment of a platinum-sensitive relapsed tumour
□ Patient is being considered for adjuvant treatment of HER2-negative high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy
□ Patient is being considered for PARP inhibitor treatment of HER2-negative locally advanced or metastatic breast cancer.
□ Patient is being considered for PARP inhibitor treatment of mCRPC
□ Patient is being considered for maintenance treatment with olaparib for metastatic adenocarcinoma of the pancreas.

To be completed by patient – Please read the below statement and intial the box on the right to indicate understanding.

Statement	Please Initial Every Box
I have read the written information given to me, understand the implications and limitations of the test, have discussed it with my doctor and consent to HRD analysis and/or BRCA gene testing of my blood and/or tissue sample	
I consent that DNA/RNA from my blood and/or tissue sample will be stored in the CMD laboratory as standard practice, unless I request its disposal.	
I consent that my genetic test result can be made available for use in counselling other family members.	
I consent for this sample to be used for quality assurance and audit purposes .	

- If I am unable to receive the results of the test, I would like the result to be given to the following person(s):

Name: …… Relationship: ..... Contact no:.....

Signed (Patient): ..... **Date:** .....

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For **completion by referring doctor:**

- I have discussed this test with my patient and they understand the implications of the test and the potential need for referral to the cancer genetics service.

Signature..... Name (block capitals) .....

Contact Number..... Medical Council Registration Number: .....

Sample Details (complete as appropriate)	
Germline (blood) samples	**Tumour/FFPE samples**
□ Blood Sample (>3ml EDTA) □ Tube labelled with patient name, DOB and MRN Sample Taken by (Full Name): ..... Date Taken: ..... Signature:	**Ovarian** □ Pre-chemotherapy biopsy sample (preferred) □ Post-chemotherapy biopsy sample □ Pathology report attached (required) **Prostate** □ Pre-chemotherapy biopsy sample (preferred) □ Post-chemotherapy biopsy sample □ Pathology report attached (required) to include age of sample Pathologist Name (Full Name): ..... Hospital Name: ..... Case Number: ..... Signature: .....

For Germline BRCA testing only:

- Sample required is 3-5ml of venous blood in EDTA anticoagulant. Send at room temperature by courier to: Cancer Molecular Diagnostics, St James's Hospital, James's Street, Dublin 8, D08 RX0X. Refrigerate if there will be more than a 24 hr delay before posting. DO NOT FREEZE.
- Note the minimum identification requirements for genetic testing are:
  a) patient's forename & surname and date of birth or medical record number.
  b) these identifiers must be present on the sample tube and the genetic test request form and must match exactly.

For HRD and/or BRCA tumour testing only:

- Complete form and forward to the histopathology laboratory for block selection. A pathologist will review the available material and select the most appropriate block for testing.
- This block will be sent to the Cancer Molecular Diagnostics (CMD) laboratory and a report issued.
- A copy of the tumour report will also be sent to the histopathology laboratory for their records.

For combined HRD and/or BRCA tumour and germline testing:

- Complete form and photocopy.
- Include one copy of the form with the blood sample. See germline testing sample requirements above.
- Forward a second copy of the form to the histopathology laboratory for block selection.

Information for Pathologists:

- Please indicate if it is a pre-chemotherapy or a post-chemotherapy biopsy sample as this may impact testing outcome
- Please select the block with the largest tumour content (ideally >50% high grade serous carcinoma tumour nuclei content, with minimal necrosis for ovarian samples and block with highest tumour cellularity available for prostate samples), however please note this will be re-assessed at the reference lab also. A minimum of 30% neoplastic cell content is required for HRD analysis.
- Please include a representative H&E slide with the block. If minimal material is present in the block, the tissue may be exhausted during processing.
- Send the sample with a copy of the histopathology report by courier to: Cancer Molecular Diagnostics, St James's Hospital, James's Street, Dublin 8, D08 RX0X.

Queries regarding the sample, sample identification requirements or transport should be directed to cmd@stjames.ie or 01-416 3575.