APPENDIX O

CASE REPORT FORM - DATA SHEET

A- PARTICIPANT REGISTRATION

Centre Name: ____

Centre Code: ☐☐☐ Study Number: ☐☐☐☐

Title: ________ First name(s): ______________________________

Surname: ____

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Hospital Number / identifier: ______________________________

Age at study entry: ☐☐

DATE OF ENROLMENT ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Please tick ONE box only
Genetic testing has shown that the subject:

☐ Has tested POSITIVE for the familial *BRCA1* mutation

☐ Has tested POSITIVE for the familial *BRCA2* mutation

☐ Has tested NEGATIVE for the familial *BRCA1* mutation

☐ Has tested NEGATIVE for the familial *BRCA2* mutation

Please specify the mutation position that is present in this family as written on the gene report: ☐

B – INCLUSION AND EXCLUSION CRITERIA

Centre Code: ☐☐☐	Study Number: ☐☐ ☐☐
Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)	Initials: ☐☐☐☐

INCLUSION CRITERIA: Answers to questions 1-4 must be YES

1. Is the subject aged 40 – 69 years? ☐ Yes ☐ No
2. Has the subject tested positive or negative for a mutation in *BRCA1* or *BRCA2* that is known to be present in their family? ☐ Yes ☐ No
3. Has the subject read the patient information sheet and had had the opportunity to ask questions? ☐ Yes ☐ No
4. Has the subject been fully informed about the study and signed the consent form? ☐ Yes ☐ No

Date consent form signed ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

EXCLUSION CRITERIA: Answers to questions 5 and 6 must be NO

5. Has the subject had prostate cancer? ☐ Yes ☐ No
6. Has the subject been affected by cancer with a terminal prognosis of less than 5 years? ☐ Yes ☐ No

C – YEAR 1: STUDY ENTRY

Centre Code: ☐☐☐ Study Number: ☐☐☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Initials: ☐☐☐☐

Date of Visit 1: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

☐ Meets eligibility criteria

☐ Has copy of patient information sheet

☐ Written consent gained
- ☐ Copy to patient
- ☐ Copy in notes
- ☐ Copy in research file

☐ Permission to contact GP

☐ Letter sent to GP

☐ FHQ completed / Gained from genetics notes. Details ______________________________

☐ Medical Questionnaire completed

☐ Copy of genetic test report obtained

☐ Urine sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time urine sample spun ☐☐: ☐☐ (Hour Mins)

☐ Blood sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time blood sample spun ☐☐: ☐☐ (Hour Mins)

☐ PSA result ☐ Further Action required ☐ Yes ☐ No

☐ If applicable to your centre please record the following

Free:Total PSA: ☐ Testosterone: ☐ Sex Hormone Binding Globulin: ☐

Completed By:

______________________________ ______________ ______________________________

Print Name Date Signature

YEAR 1: Biopsy / Treatment Checklist (If applicable)

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year) Initials: ☐☐☐☐

☐ Date of biopsy ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year)

Hospital____

☐ Copy of histopathology form received
- ☐ Benign, returned to annual PSA testing
- ☐ To be repeated after 6 weeks (eg BPH /inconclusive result)
- ☐ To be repeated immediately (egASAP)
- ☐ Malignant

☐ Date of REPEAT biopsy (if applicable) ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year)

Hospital___________________________

☐ Copy of histopathology form received

☐ Treatment Questionnaire completed:

At diagnosis	☐
Year 1	☐
Year 2	☐
Year 3	☐
Year 4	☐
Year 5	☐
Year 6	☐
Year 7	☐
Year 8	☐
Year 9	☐
Year 10	☐

Contact details of Oncologist:

Name:___________________________

Hospital:____

Address____

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Phone Number: ____________________

Fax Number: ______________________

SECTION C. YEAR 2

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Initials: ☐☐☐☐

Date of Visit 2: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

☐ Contact details checked

☐ Family History updated

☐ Medical Questionnaire updated

☐ Urine sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time urine sample spun ☐☐: ☐☐ (Hour Mins)

☐ Blood sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time blood sample spun ☐☐: ☐☐ (Hour Mins)

☐ PSA result ☐ Further Action required ☐ Yes ☐ No

☐ If applicable to your centre please record the following

Free:Total PSA: ☐ Testosterone: ☐ Sex Hormone Binding Globulin: ☐

Completed By:

Print Name	Date	Signature

YEAR 2: Biopsy / Treatment Checklist (If applicable)

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year) Initials: ☐☐☐☐

☐ Date of biopsy ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year)

Hospital____

☐ Copy of histopathology form received
- ☐ Benign, returned to annual PSA testing
- ☐ To be repeated after 6 weeks (eg BPH inconclusive result)
- ☐ To be repeated immediately (egASAP)
- ☐ Malignant

☐ Date of REPEAT biopsy (if applicable) ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year)

Hospital___________________________

☐ Copy of histopathology form received

☐ Treatment Questionnaire completed:
- At diagnosis ☐
- Year 1 ☐
- Year 2 ☐
- Year 3 ☐
- Year 4 ☐
- Year 5 ☐
- Year 6 ☐
- Year 7 ☐
- Year 8 ☐
- Year 9 ☐
- Year 10 ☐

Contact details of Oncologist:

Name:___________________________

Hospital:____

Address____

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Phone Number: ____________________

Fax Number: ______________________

SECTION D. YEAR 3

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Initials: ☐☐☐☐

Date of Visit 3: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

☐ Contact details checked

☐ Family History updated

☐ Medical Questionnaire updated

☐ Urine sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time urine sample spun ☐☐: ☐☐ (Hour Mins)

☐ Blood sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time blood sample spun ☐☐: ☐☐ (Hour Mins)

☐ PSA result ☐ Further Action required ☐ Yes ☐ No

☐ If applicable to your centre please record the following

Free:Total PSA: ☐ Testosterone: ☐ Sex Hormone Binding Globulin: ☐

Completed By:

____________________ __________ ____________________

Print Name Date Signature

YEAR 3: Biopsy / Treatment Checklist (If applicable)

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Initials: ☐☐☐☐

☐ Date of biopsy ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

Hospital____

☐ Copy of histopathology form received
- ☐ Benign, returned to annual PSA testing
- ☐ To be repeated after 6 weeks (eg BPH inconclusive result)
- ☐ To be repeated immediately (egASAP)
- ☐ Malignant

☐ Date of REPEAT biopsy (if applicable) ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

Hospital___________________________

☐ Copy of histopathology form received

☐ Treatment Questionnaire completed:
- At diagnosis ☐
- Year 1 ☐
- Year 2 ☐
- Year 3 ☐
- Year 4 ☐
- Year 5 ☐
- Year 6 ☐
- Year 7 ☐
- Year 8 ☐
- Year 9 ☐
- Year 10 ☐

Contact details of Oncologist:

Name:__________________________

Hospital:____

Address____

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Phone Number: ____________________

Fax Number: ______________________

SECTION E. YEAR 4

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year) Initials: ☐☐☐☐

Date of Visit 4: ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year)

☐ Contact details checked

☐ Family History updated

☐ Medical Questionnaire updated

☐ Urine sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year) Time ☐☐:☐☐ (Hour, Mins)

☐ Time urine sample spun ☐☐: ☐☐ (Hour, Mins)

☐ Blood sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day, Month, Year) Time ☐☐:☐☐ (Hour, Mins)

☐ Time blood sample spun ☐☐: ☐☐ (Hour, Mins)

☐ PSA result ☐ Further Action required ☐ Yes ☐ No

☐ If applicable to your centre please record the following

Free:Total PSA: ☐ Testosterone: ☐ Sex Hormone Binding Globulin: ☐

Completed By:

Print Name ________ Date ________ Signature ________

YEAR 4: Biopsy / Treatment Checklist (If applicable)

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Initials: ☐☐☐☐
Day Month Year

☐ Date of biopsy ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Hospital______________________________________

☐ Copy of histopathology form received
- ☐ Benign, returned to annual PSA testing
- ☐ To be repeated after 6 weeks (eg BPH /inconclusive result)
- ☐ To be repeated immediately(eg ASAP)
- ☐ Malignant

☐ Date of REPEAT biopsy (if applicable) ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Hospital__________________________

☐ Copy of histopathology form received

☐ Treatment Questionnaire completed:
- At diagnosis ☐
- Year 1 ☐
- Year 2 ☐
- Year 3 ☐
- Year 4 ☐
- Year 5 ☐
- Year 6 ☐
- Year 7 ☐
- Year 8 ☐
- Year 9 ☐
- Year 10 ☐

Contact details of Oncologist:

Name:_________________________

Hopsital:____

Address____

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Phone Number: ___________________

Fax Number: _____________________

SECTION F. YEAR 5

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Initials: ☐☐☐☐

Date of Visit 5: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)

☐ Contact details checked

☐ Family History updated

☐ Medical Questionnaire updated

☐ Urine sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time urine sample spun ☐☐: ☐☐ (Hour Mins)

☐ Blood sample obtained ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year) Time ☐☐:☐☐ (Hour Mins)

☐ Time blood sample spun ☐☐: ☐☐ (Hour Mins)

☐ PSA result ☐ Further Action required ☐ Yes ☐ No

☐ If applicable to your centre please record the following

Free:Total PSA: ☐ Testosterone: ☐ Sex Hormone Binding Globulin: ☐

Completed By:

Print Name ________ Date ________ Signature ________

YEAR 5: Biopsy / Treatment Checklist (If applicable)

Centre Code: ☐☐☐ Study Number: ☐☐ ☐☐

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Initials: ☐☐☐☐
Day Month Year

☐ Date of biopsy ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Hospital____

☐ Copy of histopathology form received
- ☐ Benign, returned to annual PSA testing
- ☐ To be repeated after 6 weeks (eg BPH inconclusive result)
- ☐ To be repeated immediately (egASAP)
- ☐ Malignant

☐ Date of REPEAT biopsy (if applicable) ☐☐ - ☐☐ - ☐☐☐☐
Day Month Year

Hospital___________________________

☐ Copy of histopathology form received

☐ Treatment Questionnaire completed:
- At diagnosis ☐
- Year 1 ☐
- Year 2 ☐
- Year 3 ☐
- Year 4 ☐
- Year 5 ☐
- Year 6 ☐
- Year 7 ☐
- Year 8 ☐
- Year 9 ☐
- Year 10 ☐

Contact details of Oncologist:

Name:___________________________

Hospital:____

Address____

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Phone Number: ____________________

Fax Number: ______________________

SECTION G: DISCONTINUATION / COMPLETION FORM

Centre Code: ☐☐☐	Study Number: ☐☐ ☐☐
Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ (Day Month Year)	Initials: ☐☐☐☐

Did participant complete 5 year study?

☐ Yes

☐ No

If **No** please state reason:-

☐	Tumour occurrence	(If Yes, please complete histology & treatment sheets)
☐	Personal Choice	Comment ____________________
☐	Lost to follow up	Comment ____________________
☐	Adverse Event	(If Yes, please complete Adverse Event form)
☐	Death	Date of Death ____________________
		Cause ____________________
☐	Other	Specify ____________________

Completed By:

____________________	____________	____________________
Print Name	Date	Signature