**Study Agreement**

This Agreement is made effective as of date of last signature by and between The Institute of Cancer Research: Royal Cancer Hospital (“ICR”) 123 Old Brompton Road, London SW7 3RP (ICR) and (***insert name of institution***) (“Investigator Site”) ***(insert address*)**

**Project Title:** The UK Genetic Prostate Cancer Study: Epidemiology and Molecular Genetic Studies (the “Study”)

**Chief Investigator:** Prof R A Eeles

**ICR Protocol Number:** 0848

**Sponsor of the Project:** The Institute of Cancer Research: Royal Cancer Hospital

In order to ensure compliance with the Research Governance Framework for Health and Social Care 2nd Edition 2005 and the principles of good clinical practice, this Agreement makes explicit the following points of Study conduct.

By signing this Study Agreement it is accepted that:

1. The ICR and all researchers involved in the Study understand, accept and are able to discharge their duties and honour their responsibilities set out in the Research Governance Framework for Health and Social Care, Department of Health 2nd Edition 2005.
2. The Investigator Site shall procure that the principal investigator shall carry out the Study in accordance with the most recent Research Ethics Committee (“REC”) approved Study Protocol. The principal investigator is an employee of or has an honorary contract with the Investigator Site and obligations on the principal investigator are obligations on the Investigator Site.
3. Subject to clause 4, the Study can commence at the Investigator Site once REC approval is given by the relevant committee. The principal investigator shall ensure that other local Health Authority requirements are fulfilled. The principal investigator shall keep the ICR at UK Genetic Prostate Cancer Study, Institute of Cancer Research Brookes Lawley Building, 15 Cotswold Road, Sutton, Surrey, SM2 5NG**,** fully informed as to the progress of any such requests for approval and shall provide a copy of the approval letter once received.
4. The Study must be subject to local Research & Development management permission to ensure due registration and local resource decisions can be assessed. If the Investigator Site intends to send a Study patient to a centre outside of the Investigator Site’s jurisdiction, then appropriate approvals must be sought by the other NHS Trust and the ICR notified. This will only be applicable to any treatment deemed part of the Study by the Protocol.
5. To comply with relevant employee and data protection laws no member of the research team should work with patients, their tissue or data without the appropriate employment contract or honorary contract from the Investigator Site. The Investigator Site and the ICR agree to conduct the Study in accordance with the Data Protection Act 1998.
6. The Investigator Site shall ensure that procedures are in place for the collection of high quality accurate data, and for ensuring the integrity and confidentiality of data during processing and storage. Particular attention must be given to security of the systems for ensuring confidentiality of personal data.
7. The recruitment of patients including obligations for informed consent shall be carried out in accordance with the requirements as detailed in the Study Protocol.
8. The Investigator Site shall procure that the principal investigator:
   1. provides the ICR with a list of their staff members authorised to sign case report forms, together with a sample of each authorised signature:
   2. ensures that the ICR is kept informed of all staff changes and provide samples of authorised signatures for all new staff;
   3. ensures that all data collection forms are completed at the correct times and forwarded to the ICR within a reasonable time of the timing of assessment; and
   4. ensures that data collection forms are only completed by or amended by authorised signatories, that all forms are signed and dated and that all amendments are initialed and dated by authorised signatories;
9. Where the Investigator Site supplies material derived from patients or portion thereof, including information related to such material supplied by the NHS Organisation ("Material”) to ICR as part of the Study, ICR acknowledges and agrees that:
10. it shall remove Material from tumour blocks provided by the Investigator Site in accordance with the Study Protocol. For the avoidance of doubt such tumour blocks shall be returned to the Investigator Site;
11. the Material is supplied solely for the purpose of undertaking the Study in accordance with the Study Protocol, as approved by the appropriate NHS ethics committee or for the purpose of undertaking other studies as approved by an appropriate NHS ethics committee;
12. unless otherwise agreed ICR shall be the custodian of the Material and the Investigator Site shall execute any document necessary to assign custodianship to ICR or its nominee on request;
13. the Material shall not be redistributed or released to any person other than as authorised by ICR;
14. no alteration shall be made to the title or acronym of the Material;
15. the Investigator Site gives no warranty as to the fitness for purpose of the Material;
16. it shall comply with all relevant laws and regulation governing the research use of human biological material. The Investigator Site and its employees shall not be held liable for any consequences of the supply to or the use by ICR of the Material or of the supply to or the use by the any third party to whom ICR subsequently provides the Material;
17. any surplus Material shall be dealt with as waste in accordance with the Human Tissue Act 2004.
18. The Investigator Site and ICR shall both be responsible for keeping a record of the Material that has been transferred according to this Agreement.
19. The Investigator Site shall have no rights in respect to any intellectual property rights created by ICR using the Material transferred under Clause 9 if such intellectual property rights are created outside the Study Protocol.
20. The Investigator Site shall ensure that all researchers report any suspected research misconduct or fraud.
21. The Investigator Site shall ensure that individual investigators do not publish data concerning their patients that is directly relevant to the questions posed in the Study until the main results of the Study have been published and then only with prior consent from the ICR.
22. The Investigator Site shall procure that the principal investigator completes the attached Appendix 1 indicating any conflict of interest that they may have and estimated patient accrual for the Investigator Site.
23. This Agreement and any document to be entered into by the parties pursuant to this Agreement represents the entire agreement of the parties relating to the subject matter hereof and supersedes all previous agreements, arrangements and understandings between the parties in relation to the subject matter hereof.

Signed by the duly authorised representatives of the parties on the date stated at the beginning of this Agreement

# SIGNED ON BEHALF OF ICR

Signature: ………………………… Date: …………………………

Name: ………………………… Position: …………………………

# SIGNED ON BEHALF OF INVESTIGATOR SITE

Signature: ………………………… Date: …………………………

Name: ………………………… Position: …………………………

**READ AND ACKNOWLEDGED:**

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**Principal Investigator Date**

**Investigator Site**

**PRINT NAME:**

## The UK Genetic Prostate Cancer Study: Epidemiology and Molecular Genetic Studies

**Additional Information**

To be completed by the Principal investigator at the Investigator Site.

Please complete the following questions, then sign and date and return to ICR at the address below:

### 1. Conflict of interest

**No,** I have no potential conflict of interest, such as professional interest, a proprietary interest or any other conflict of interest.

**Yes,** I have a potential conflict of interest.

If yes, please specify:

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### 2. Estimated patient recruitment

I expect to recruit \_\_\_\_\_\_ patients per year.

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#### Principal Investigator Date

**Please return the form to the following address:**

**Data Manager**

**UK Genetic Prostate Cancer Study**

**The Institute of Cancer Research**

**Brookes Lawley Building**

**Cotswold Road**

**Sutton**

**Surrey**

**SM2 5NGT**