

## APPENDIX P

### Research Agreement of Responsibilities

This agreement is made effective as of 11<sup>th</sup> August 2005 by and between The Royal Marsden NHS Foundation Trust, Fulham Road, London, SW3 6JJ (Royal Marsden), The Institute of Cancer Research (Institute) 123 Old Brompton Road, London SW7 3RP and **INSERT LOCAL DETAILS**

**Project Title:** Identification of Men with a Genetic predisposition to ProstAte Cancer: Targeted screening in BRCA1/2 mutation carriers and controls – **The IMPACT Study**

**Chief Investigator:** Dr Rosalind Eeles

**RMH Protocol Number:** CCR2598

In order to ensure compliance with the Research Governance Framework for Health and Social Care 2<sup>nd</sup> Edition 2005 and Good Clinical Practice, this agreement makes explicit the following points of study conduct.

By signing this study agreement it is accepted that:

1. The sponsor 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 2<sup>nd</sup> Edition 2005.
2. The principal investigator in the investigator site agrees to carry out the study in accordance with the most recent Research Ethics Committee approved study protocol.
3. The study can commence in the investigators hospital once Local Research Ethics Committee (LREC) approval is given by the relevant local committee. It is the principal investigators responsibility to obtain LREC approval and to ensure that other local Health Authority requirements are fulfilled. The investigator will keep the Royal Marsden fully informed as to the progress of any such requests for approval to the LREC and will 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.
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 honorary contract. The principal investigator and the Royal Marsden agree to conduct the study in accordance with the Data Protection Act 1998.
6. 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 is to be carried out in accordance with the inclusion and exclusion criteria as defined in the protocol. The principal investigator is responsible for ensuring that written informed consent is obtained for all patients prior to entering into the study.
8. The principal investigator must provide the Royal Marsden with a list of their staff members authorised to sign case report forms, together with a sample of each authorised signature. The investigator must also ensure that the Royal Marsden is kept informed of all staff changes and provide samples of authorised signatures for all new staff.
9. The investigator must ensure that all data collection forms are completed at the correct times and forwarded to the Royal Marsden within one month of the timing of assessment.

10. The principal investigator must ensure 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 initialled and dated by authorised signatories.
11. The principal investigator must ensure that any adverse incidents or suspected, unexpected serious adverse reactions (SUSARs) must be reported through the appropriate systems within the required timescales of the EU Clinical Trials Directive.
12. All researchers are required to report any suspected research misconduct or fraud.
13. Individual investigators must 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 Royal Marsden.
14. The principal investigator must complete the attached Appendix 1 indicating any conflict of interest that they may have and their estimated patient accrual.

**I hereby acknowledge that:**

- a) I have read and understood the agreement.**
- b) I agree to conform to the agreement.**

\_\_\_\_\_  
**Jane Lawrence, Clinical Research Manager**  
**The Royal Marsden NHS Trust**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Chief Investigator**  
**The Royal Marsden NHS Trust**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Director of R&D**  
**(on behalf of the other site)**

\_\_\_\_\_  
**Date**

**Identification of Men with a Genetic predisposition to Prostate Cancer: Targeted screening in BRCA1/2 mutation carriers and controls – The IMPACT Study**

To be completed by the Principal investigator at the site.

Please complete the following questions, then sign and date and return to the Royal Marsden 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.

\_\_\_\_\_  
**Principal investigator**

\_\_\_\_\_  
**Date**

**Please return the form to the Chief Investigator at the following address:**

**Dr R A Eeles MA FRCP FRCR PhD  
Reader & Honorary Consultant in Cancer Genetics & Clinical Oncology  
Institute of Cancer Research & The Royal Marsden NHS Trust  
Orchard House  
Cotswold Road  
SM2 5NG**