UK GENETIC PROSTATE CANCER STUDY (UKGPCS)

Recruitment SOP for recruiting hospitals

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1. Recruitment

(i) Eligibility criteria

Identify patients coming into clinic with at least one of the following criteria:

- PrCa in your patient and in their **first, second or third degree** relative where at least one person was **65 years or younger** at diagnosis
- PrCa in your patient at any age and in a cluster with **3 or more cases** on one side of the family

(ii) Recruiting patients no longer attending clinic

We prefer that patients are seen face to face in clinic. However, if an eligible patient is no longer attending clinic, they can be contacted initially using either of our ethically approved invitation letters (Invitation to patients not attending clinic no SAE.doc version 1 10/08/11, or Invitation to patients not attending clinic.doc version 2 14/06/06 if you are going to include a self-addressed envelope). These can both be downloaded from our website; please insert your hospital headers and contact information before posting and include a patient information sheet. If the patient replies to request more information about the study, please make an appointment for them to come and see you in clinic.

(iii) Keeping records of recruitment

A spreadsheet recording all subjects who have been approached about the study and with their status should be kept locally. This is to avoid re-contacting a subject who has previously declined to take part or already consented to the study.

Please keep a record of this in your study file so that all staff recruiting to UKGPCS will have access to it.

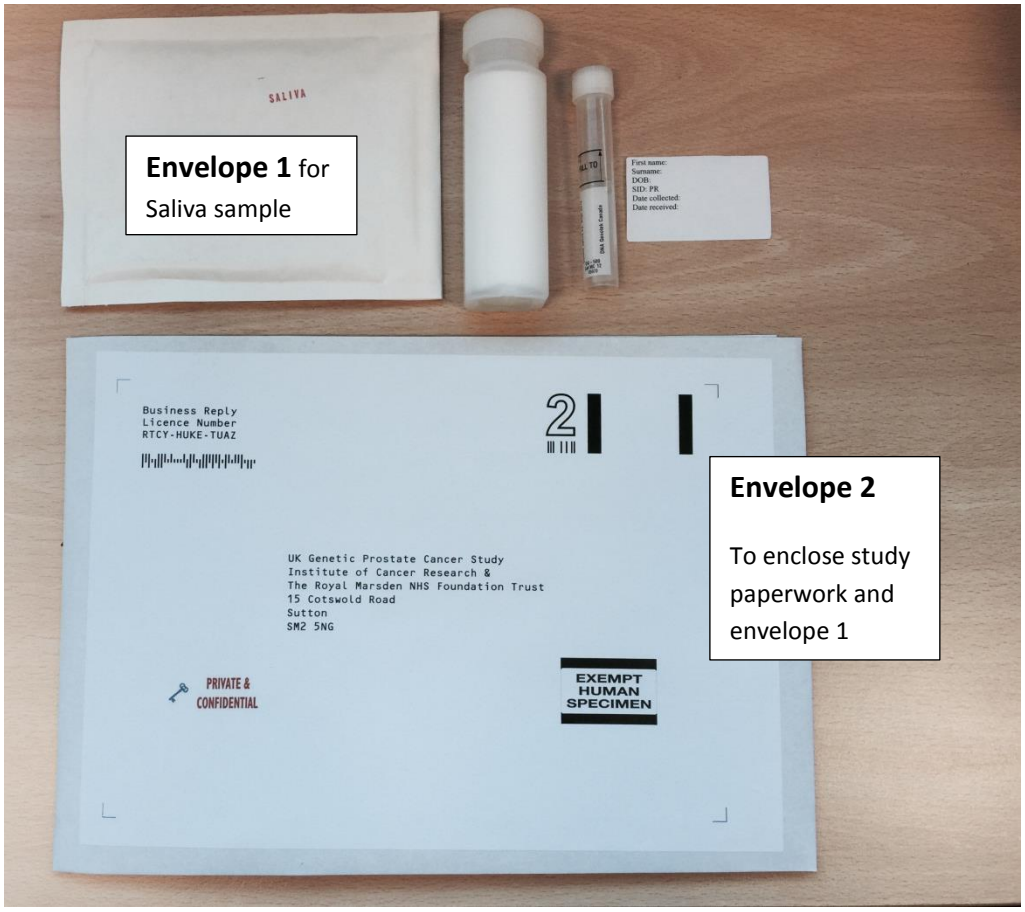
2. UKGPCS Documents

(i) Documents provided to referring sites by the UKGPCS Office

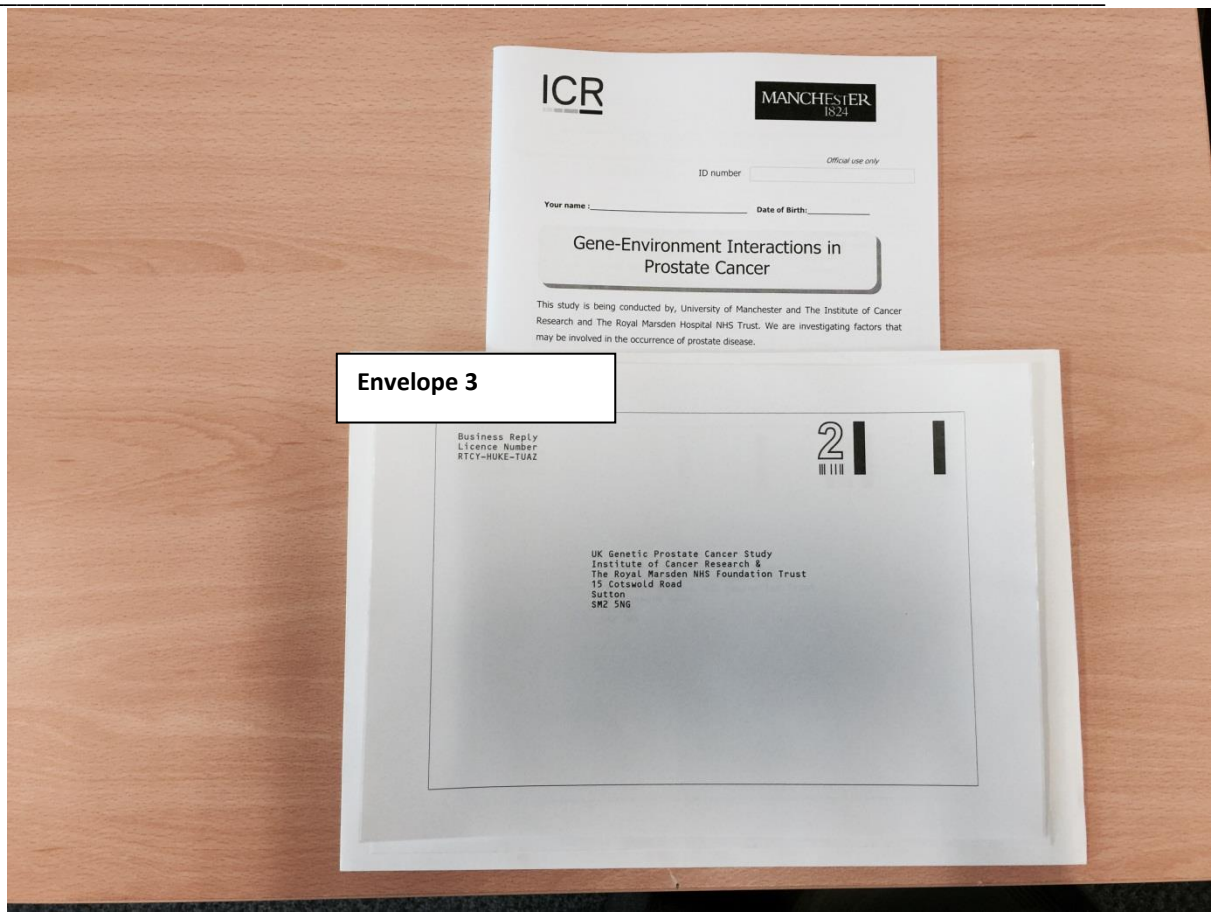
The UKGPCS Office will provide packs of the following to referring sites:

- Saliva sample collection kit containing:
  - 1x saliva collection tube
  - 1x transport tube
  - 1x sticky label for saliva tube labelling
  - 1x A6 Jiffy bag (envelope 1)

- Pre-paid, addressed padded envelope (Envelope 2) for sending the study documents to UKGPCS.



- Epidemiology questionnaire (Gene-environment Interactions in Prostate Cancer) with an A5 pre-paid, addressed envelope (Envelope 3). Please ensure this envelope is only used for this purpose; if the patient takes the questionnaire home to complete, give him one of these envelopes so he is able to return the questionnaire direct to UKGPCS.



- One-page check list for each patient v4 11/01/2017 (see Appendix I) – Please use the check list included in the kit, this will ensure you are always using the most recent version.

(ii) <u>Documents to be localised with hospital headers and printed by each hospital</u>

These documents can all be downloaded from our website at www.icr.ac.uk/ukgpcs. See the Study Documents page, using Username: ukgpcs_secure and Password: Abiraterone01.

Please put your local headers onto these documents and print them for the patients:

- Patient Information sheet (PIS)
- Original Consent form
- Personal & Medical details form
- Family History Questionnaire (FHQ)

Please do not change text on the documents apart from adding your headers.

The clinical Proforma at diagnosis form does not need your local headers. Please print this and fill it in with the clinical details for each consented patient.

The completed forms, along with the saliva sample sealed into envelope 1 should be sent to UKGPCS using Envelope 2

3. Consenting new patients

(i) Provide the patient with a copy of the Patient Information Sheet. The UKGPC study should be explained to the subject and there should be the opportunity to address all questions. The following should be explained to the patient:

- This study is looking into the possible causes of prostate cancer, in particular looking at genes that may be involved. New gene discoveries may then lead to improved screening techniques or treatments, and possibly benefit future patients.

- This is a 'one off' study and does not involve any treatment/s or new biopsy material; all that is required is a saliva sample, completed forms and previously obtained tumour tissue (only for selected pedigree, once reviewed by the study Chief Investigator, Prof Ros Eeles). Once their saliva sample and forms have been received they will have completed the study. In some rare instances we do ask patients for more saliva samples and we would come back to you if this is the case.

- We are particularly interested in patients with a family history of prostate cancer. An in-depth knowledge of their family history is not vital to a patient participating but they would need to fit in the eligibility criteria mentioned at the beginning. Any information that can be given on the Family History Questionnaire will be useful to us; especially any relative affected by cancer. The names of family members may be omitted if the patient prefers. We also recruit patients who have been adopted.

- If they are concerned about genetic testing, emphasise that only individual genes are being investigated in a research setting, and reassure that only a small number are expected to have a gene mutation. This is not genetic testing for clinical purposes and if they have any questions about genetic testing they can be referred by their GP to talk to a genetic counsellor.

- There is a moratorium on the use of genetic data obtained from research studies, and insurance companies cannot request this.

- If a patient is interested in further information about the study and what it has found so far, please direct them to the UKGPCS website (www.icr.ac.uk/ukgpcs).

(ii) When the patient feels all questions have been addressed, the consent form should be signed and dated by the patient. The ***original*** consent form should be sent to the UKGPCS office. A copy of the signed consent form should be kept by the referring hospital in your study file. If required locally, a copy of the consent form should be filed in the patient's medical notes.

(iii) The Personal & Medical details form should be completed.

(iv) The FHQ should be completed. The patient may want to take this away to complete with the help of relatives. This should then be followed up by the research nurse at their next appointment.

(v) The Epidemiological questionnaire (Gene Environment) should be given to the patient to fill in at home if they consent to this ***optional*** part of the study. The questionnaire comes with an A5 pre-paid envelope to return straight to the UKGPCS office. The patient must write their name and date of birth on the top of this form to allow us to identify them. When the form is received at the UKGPCS office, their study ID number will be written onto the front of the form, and their name and date of birth will be blanked out so that this data is not passed onto collaborators who analyse the epidemiological questionnaire.

(vi) The clinical Proforma at diagnosis form should be completed by the research nurse.

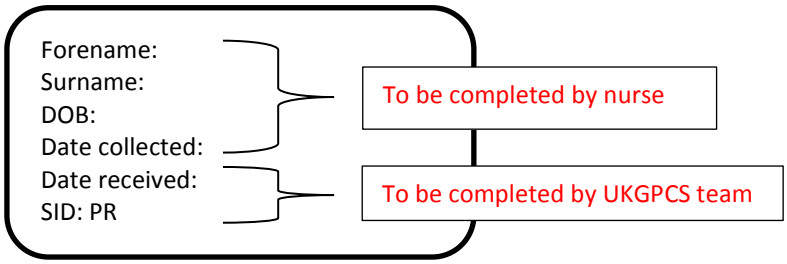
4. Patients declining study entry

(i) A database of all men approached about the study should be kept at the local centre.

(ii) No patients' details should be submitted to the data centre for patients that decline study entry.

5. Collection of saliva samples

The saliva sample should be collected in the saliva kit provided by the study team. We will provide labels which should be completed by the research nurse / study co-ordinator and stuck to the saliva tube, ensuring that a clear gap is left so that the saliva level can be read. See diagram below which explains the details required. Place the labelled saliva tube into the transport tube and then place this into the jiffy bag (envelope 1) provided and seal the envelope. The saliva sample is stored at room temperature.



6. Sending samples and documents to the UKGPCS office

Please place the A6 jiffy bag (envelope 1) containing the saliva sample into the padded envelope (envelope 2) along with the completed check list, original consent form – (copies not accepted), personal & medical details form, family history questionnaire and clinical Proforma at diagnosis along with any reports that you may have which show the reported date of diagnosis.

Please note that the saliva samples are stored at room temperature.

The epidemiological questionnaire may be returned separately (in envelope 4) by the patient or with the other completed forms in envelope 2 by the referring nurse.

NB: If a saliva sample is received without a consent form, it will have to be destroyed under the Human Tissue Act.

A patient study ID number will be allocated by the UKGPCS office when all forms and sample have been received.

7. Accruals

For a patient to be included in the accrual for your site, all of the following must be complete and received by us:

(i) Original consent form
(ii) Personal & Medical details form
(iii) Family History Questionnaire
(iv) Proforma at diagnosis
(v) 1 saliva sample

NB: If the saliva sample or any documents are missing or incomplete, then we will not be able to process a referral until we receive the sample and/or missing data.

A patient study ID number will be allocated by the UKGPCS office when all forms and sample have been received.

In the event of a patient being previously referred and consented by a different site, we will notify the new referring site that the patient is already in the study. We will keep the extra sample for these patients, and add any extra data provided to the patient file. NB: We will be unable to give the accrual points in this instance as they will already have been allocated to the original referring hospital.

To ensure that local records match those held by us, the UKGPCS office will publish the accruals on the NIHR Clinical Research Network Portfolio Database.

Accrued patients data will be sent as an uploaded file from our database of completed patients that have passed validation and added to CPMS and submitted after the end of each month between the 1st or 2nd week of the following month. All Hospitals should be able to log onto the Central Portal Management System (CPMS) to check their recruitment against their local list, please contact your R&D Department or the local Area Manager at CRN: Anna Williams, Specialty Group Facilitator | CRN: North West London | NIHR Clinical Research Network (CRN) t. 0203 313 4057 | e. anna.williams@nihr.ac.uk a. 3rd Floor

Administrative Block South, Hammersmith Hospital, Du Cane Road, London W12 OHS should you need assistance with a login for this system.

Hospitals can also retrieve the patients' study ID on the database.

Please provide us with an nhs.net email account wherever possible so that we can pass data to you in an encrypted secure format for all UKGPCS related queries.

8. Recruitment of other family members

Other family members with prostate cancer (or other cancers) will continue to be approached in writing by the UKGPCS team using information given in the Family History Questionnaire, and only with the permission of the consented relative.

You may occasionally receive a clinical Proforma' form to fill out for relative referrals if they have been diagnosed or treated at your hospital. We will include a copy of the signed consent form of permission to access the medical records of these patients. Any help that you can give us to obtain the clinical data for these relatives is very much appreciated.

APPENDIX I:

UKGPCS OFFICE ONLY: ALLOCATE NO: PR

UK Genetic Prostate Cancer Study Check List

(PLEASE COMPLETE IN CAPITAL LETTERS AND ENSURE EVERY QUESTION IS COMPLETED!)

Hospital CPMS SITE IDENTIFIER for Accrual to be given: ☐

Hospital Name and Trust :

Consultant :

Research nurse :

Telephone :

Email :

Date :

1. PATIENT DETAILS:

Forename: ☐

Surname: ☐

DOB: ☐ Patient Consent Date: ☐ Age at diagnosis: ☐

2. ELIGIBILITY (please tick relevant box):

Your patient and a 1st/2nd/3rd degree relative where one case is ≤ 65 years at diagnosis ☐

Cluster of 3 (including your patient) or more cases of PrCa on one side of the family. ☐

3. PAPERWORK ENCLOSED:

Consent signed & dated (needed to proceed) ☐

Personal & Medical Form completed ☐

Family History Questionnaire completed ☐

Sample enclosed ☐

Date sample collected ☐ / /

Proforma at diagnosis completed ☐

Epidemiology Questionnaire:

- Completed ☐
- Pt to return to UKGPCS Office ☐
- Not consented ☐

PLEASE ENCLOSE WITH THE COMPLETED PACK TO THE UKGPCS OFFICE