Family recruitment No 011D

1. Introduction

All potential subjects for the study will be recruited from Medical Research Council (MRC) General Practitioner (GP) framework practices where possible. It is important to get as much information as possible from prospective subjects from the posted questionnaire and subsequent follow up telephone calls, so that visit appointments are made only for suitable candidates. In order to obtain the maximum and most reliable information it is necessary that all nurses follow the same screening procedure and ask all the same open and non-leading questions documented in the screening questionnaire booklet.

2. Responsibilities

Research nurses trained in the method are responsible for recruiting suitable families and ensuring subject documentation is completed thoroughly. It is the responsibility of the Nurse Co-ordinator to ensure that all research nurses are familiar with the study procedures and equipment, and adhere to the guidelines set out in the standard operating procedures.

3. Equipment

It is the responsibility of each nurse to ensure that they always have the relevant paperwork and equipment available at all times

4. Method

All research nurses involved with the study should be familiar with the study protocol and should be aware of the inclusion/exclusion criteria before attempting to recruit potential subjects.

The BP monitor should have the charged batteries already installed; the guidelines for this procedure can be observed in the Omron manual. Additional batteries should also be available to protect against battery failure. The monitor should also be programmed with the correct date & time and printer paper. Any alterations required with the monitor's set up can be achieved by reading the guidelines from the manufacturer.

4.1 Return of initial questionnaire

- After the return of a questionnaire the guidelines laid down in SOP 013 should be followed.

- Subjects should only be recruited to the study if they fit the inclusion/exclusion criteria.

4.2 Telephone contact

- Ensure that the subject understands the study and what will be required of them.

- Obtain the subject's family details and ensure that they correspond with the study protocol.

- Ensure that there is a sibling pair willing to take part.

- Arrange a visit time suitable to the subject.

4.3 Visit

- Provide the subject with further information about the study, pitched at their level of understanding.

- Record phenotypic data and ensure that they correspond with the inclusion/exclusion criteria.

4.4 After visit

- Providing a family meets all the inclusion criteria, place the subject's documentation details in the appropriate family file. The family file will be the only documentation by which a subject can be traced, all further details will use a unique identification number. Only staff directly involved with the study may consult the family file.

- Allocate the family a unique identification number. The first two letters should represent your centre name, e.g. LN for London. The following five numbers will be unique to the family and your centre number allocation, e.g. 00001 to 00200 for London. The final numbers will depict which member of the family the subject represents, e.g. 001 for father and 002 for mother.

- Every subject's identity is maintained by the allocation of the unique identification number, it is completely unrelated to their name. This ID number will be the only reference used for the subject after they are entered into the study. All subject details stored on the computer database will use this identification number.

- Enter the subject's details into the study database.

- Ensure the bloods and urine are sent to the appropriate laboratories (guidelines in SOP 009).

- Arrange a follow up visit or phone call for any missing details, if necessary.

- Provide the subject's GP with the medical results obtained. However, due to ethical constraints, genetic details will not be issued to either the GP or the subject. If several subjects are seen at the same practice, several results can be issued together.

- Store details in the correct files for subjects not meeting all the study requirements and those withdrawing from the study due to personal/health reasons,

- Thank the subject(s) for their time and assistance with the study. Subjects requesting results should be encouraged to visit their surgery after the results have been sent to their GP.

5. Additional Information

- It is essential that subject confidentiality is maintained at all times. Families may be unaware of their relatives' medical history and so individual subject confidentiality should be paramount.

- It is vital that subjects are fully aware of all aspects of the study. A written consent should be signed by the subject before any phenotypic, medical or personal details are taken.

6. Reference Documents

Refer to the other standard operating procedure for guidelines.