

The Thames Valley and South Midlands Clinical Research Network and The Centre for Research Equity, University of Oxford are working together to lead an innovative initiative to explore the development of a pharmacy workforce to aid recruitment of underserved communities to health research.

As part of this initiative, we're looking for pharmacy support within our region (Banbury, Oxford City, Reading, Slough, High Wycombe and Aylesbury) to help recruit eligible participants to the Genes and Health Study.

Genes & Health

Genes & Health: a population based DNA sequencing, medical records, and recall BioResource study of British-Bangladeshi and British-Pakistani communities

Sponsor: Queen Mary, University of London	CPMS ID: 18124
Funding body: Wellcome Trust	Trial Manager/Co-ordinator: Kamrul Islam
Chief Investigator: Prof David van Heel	
Tel.: 0207 882 2330	Tel.: 020 7882 2531
E.: d.vanheel@qmul.ac.uk	E.: k.islam@qmul.ac.uk

Aim of study:

The study has the aim of identifying new ways of improving health for Bangladeshi and Pakistani people in the UK.

Genes & Health is a not-for-profit long-term study of 100,000 people aged 16 and over with and without health problems who regard themselves as of Bangladeshi and Pakistani origin. In the UK as a whole these ethnic minority groups have five times the rates of diabetes than the rest of the population and suffer poorer health by a number of other measures including cardiovascular disease and mental health. By gaining more information on the genes involved in health and disease and by understanding the differences in their function we hope to be able to begin to cure or reduce the effect of the disease and identify better (or optimise existing) treatments to help prevent new onset of disease. Genes & Health will bring equality and the benefits of genomics in modern medicine to our currently under-research-represented local communities.

Full information can be found here: <https://www.genesandhealth.org/>

Genes and Health Study Objectives:

- To study normal variation in genes in adult Bangladeshi and Pakistani people. Knowing what is normal is important when searching for genes causing inherited childhood diseases.
- To study genes in people with very high and very low cholesterol levels, to better understand why heart disease and stroke occurs.
- To study variation in genes in healthy adults whose parents are related. These studies will tell us how genes work, and help develop new medicines.
- To study genes of people with diabetes, aiming to identify rarer types of diabetes for which more specific treatments can be used.

The volunteers will be asked to donate a small saliva (spit) sample and share their GP and hospital medical records [in strict confidence](#) with the study team. Volunteers will be asked to give their consent to be contacted again and some may be invited to participate in further health research studies on the basis of data gathered from their samples, health records and information provided.

Inclusion criteria:

- Self-described ethnicity: Bangladeshi, British-Bangladeshi, Pakistani, British-Pakistani
- Age 16 or over (no upper limit)
- Willing to give a saliva DNA sample for analysis
- Willing to grant investigators access to medical records (GP & Hospital) for the study duration
- Willing to be invited for recall (stage 2 research activity) for the duration of the study

Exclusion criteria:

- No exclusion on the basis of gender, or disease status
- Patients with mental and learning disabilities if they are not deemed competent to consent
- Patients with significant cognitive impairment

Patient involvement:

- It's a very simple study for both participants and recruiting sites - participants will be required to give consent, complete a 1 page questionnaire, provide a saliva sample and agree to be contacted with details about further potential stage 2 studies if applicable to them. This should take a max. 10-15 min to complete.

Pharmacy - Pharmacy Technician Involvement

- Attend online training:
 - NIHR Good Clinical Practice (GCP) - e-certificate (4 hrs)
 - Genes and Health Study training (1hr) - 4 dates to be provided
- Display study posters and promote on pharmacy websites or social media platforms.
- Recruit participants on site and within communities; provide a study pack, oversee participant consent and saliva sampling (10-15 min per participant).

Operational process notes:

- Sites will be provided with an Internal Site File by the study team (hard copy). This will contain the study documents such as the study protocol, PIS / VIS, delegation logs etc.
- The study team will also provide the sites with paper consent forms, questionnaires and voluntary information sheets in packs to use with the participants. Option to complete these online.
 - **Consent** - This is a voluntary consent study; therefore the participant is required to fill out the 1-page consent form themselves. The paper consent form has a carbon copy that needs to be handed over to the participant after completion along with a copy of the voluntary information sheet for them to take home.
 - **Questionnaire** - The participant will be required to complete a quick one-page questionnaire which contains basic information such as contact information, demographics and 3 health questions. Participants can complete themselves or you can complete on their behalf during the recruitment process. The study team will complete a quality check when they receive the uploads and if anything is missing e.g. NHS numbers as maybe not known at the time, they will contact the participant directly to follow up.
 - **Saliva sample** - The study team will provide kits required for sample collection and arrange a courier for the return of the samples to the sponsor. The frequency of the sample collection can be arranged directly with the study team and will be based on the amount / speed of recruitment on site.
 - Paper copies will have a barcode so that they can be scanned directly to the secure study team portal, and then stored in the site file.
- The study team will also provide translated flyers and posters that can be used for engagement purposes.
- There are no auditing requirements however there is an expectation for the sites to recruit participants, maintain records, send paperwork and samples to the Sponsor in accordance with GCP, study protocol and team instructions. Sites are expected to do routine self-monitoring of consent forms and up to date delegation log (any updates need to be sent to Sponsor or coordinating centre).

More detailed information on the process and the data flow will be provided directly by the study team during the training process.

Requirements & Remuneration:

	Overall	Per Pharmacy
Target recruitment:	100,000	Min. 38
Study recruitment period:	August 2024 - Dec 2028	

	One-off costs for training & Site Set up	Total per Site
Pharmacy Technician (£25 per hour)	GCP Training (4 hrs) Study Training (1 hr) Set up - administrative (1hr) Time for outreach planning or Informed Consent Travel (capped)	£100 £25 £25 £100 £50 (45ppm) £300

Sites will also receive £22 Service Support Costs per participant recruited (to be invoiced to the CRN)

In order to secure the funding, we require sites to identify their lead, complete the training and recruit their first participant by the 16th Sept 2024.

***Invoicing**

NIHR CRN Tracey Allen E: tracey.allen@ouh.nhs.uk
TVSM:

***Local Clinical Research Network (LCRN) Contract**

You will be required to sign an LCRN contract before any payments can be made from the Clinical Research Network (CRN). These are standard contracts which have been developed by the Department of Health and Social Care (DHSC) who have confirmed that monies cannot be paid across until contracts are in place.

To find out more or express an interest in this study, please contact mahendra.patel@phc.ox.ac.uk or [Joanne Carter](#) .