|  |
| --- |
| [insert institutions’ logos] |
| **PARTICIPANT INFORMATION STATEMENT** |
| Unannounced Standardised Patients[Project Title][Principal Investigator] |

1. **What is the research study about?**

You are invited to take part in this research study. The research study aims to investigate the quality of refractive care in [location].You have been invited because you have been identified as someone who might be suitable to be a ‘standardised patient’ and data collector visiting optical services.

1. **Who is conducting this research?**

The study is being carried out by the following researchers:

*[Chief Investigator]*

*[Site Principal Investigator]*

*[Associate Investigator 1]*

*[Associate Investigator 2]*

***Research Funder:*** This research is being funded by [organisation or grant]*.*

1. **Inclusion/Exclusion Criteria**

Before you participate in this research study, we need to ensure that it is okay for you to take part. The research study is looking to recruit people who meet the following criteria:

* Adults aged 18 years or above
* Has healthy eyes
* Has the refractive error profile we are looking for (needs/does not need glasses)
* Never had refractive eye surgery
* Has not had any other eye surgery in the past 3 months
1. **Do I have to take part in this research study?**

Participation in this research study is voluntary. If you do not want to take part, you do not have to.

1. **If you decide you want to take part in the research study, you will be asked to:**
* Read the information carefully (ask questions if necessary);
* Sign and return the consent form if you decide to participate in the study;
* Take a copy of this form with you to keep.
1. **What does participation in this research require, and are there any risks involved?**
* Training to be an unannounced standardised patient
* An unannounced standardised patient (USP) is someone who attends an optical service to have an eye test while observing the activities without the staff members knowing
* We will provide a 3-day training program for you to know what you need to look for and how to record the information.
* The training program consists of understanding the project protocol, learning different types of eye tests, recording data and learning techniques on how not to be revealed as a USP.
* We will then ask you to complete an evaluation of the training program.
* Obtaining your glasses prescription
* You will have your eyes tested for glasses by three separate refractionists/optometrists
* Here they will also show you all the procedures that you have learnt during the training program
* It should take approximately 45 minutes to complete the task.

The bright lights shone at your eyes might cause some minor discomfort, however this technique will be quick and has been used on many people having an eye test without causing any damage. If you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance and discontinue you from this study.

1. **Attending optical services as an unannounced standardised patient**
* After the training program, we will advise you of all the optical stores you need to attend and which dates
* At each optical service you will be required to have an eye test, order a pair of spectacles and observe what tests the staff do. All costs of spectacles/lenses will be reimbursed.
* After the visit is complete, you will be required to record your observations onto a mobile phone survey form (or on a paper record form if the mobile phone is unavailable)
* Once the spectacles are ready, you will pick up them up and request a prescription on paper
* At your return visit, we will check how well you can see with the spectacles you ordered, check the power of the spectacles and review the quality of your data recording.
* If there are any questions regarding your observations and data recorded, we will contact you for clarification.

Each optical service visit is expected to take approximately 45 minutes. However, this depends on how busy and how quickly the service runs.

We don’t expect visiting the optical services to cause any harm. However, anxiety, exhaustion/fatigue, and physical discomfort immediately following a visit might be felt with hiding the nature of your visit to the optical service. But the literature to date appears to indicate that there are no long-lasting effects. We will provide the training required to minimise the potential discomfort experienced, this will involve role-play and test visits to ensure that you will be comfortable and well-practiced in visiting optical services. However, if you experience feelings of prolonged distress because of participation in this study you can let the research team know and they will provide you with assistance. The support service contact details are provided in the section below to assist you if necessary.

1. **What are the possible benefits to participation?**

If you decide to participate in this research, we will cover your travel, accommodation and some meal expenses during the course of the training. Then you will be employed as part of the research and compensated for your time and effort.

1. **What will happen to information about me?**

By signing the consent form, you consent to the study team collecting and using information about you for the research study. Your data will be kept for a minimum of [*number*] yearsafter the project’s completion. Your information will be kept confidential and serviced in a safe place where access is only available to the people on the project.

1. **How and when will I find out what the results of the research study are?**

The research team intend to publish and/ report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by adding your email or postal address within the details form below. We will only use these details to send you the results of the research.

1. **What if I want to withdraw from the research study?**

You may withdraw at any time. You can do so by completing the ‘‘Form for Withdrawal from Participation’’ which is provided at the end of this document. Alternatively, you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with [*institution(s) involved in the study*]*.*

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

1. **What should I do if I have further questions about my involvement in the research study?**

The person you may need to contact will depend on the question. If you require further information regarding this study or if you have any problems, which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

Support Services Contact Details

If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

|  |  |
| --- | --- |
| Name/Organisation |  |
| Position |  |
| Telephone |  |
| Email |  |

1. **What if I have a complaint or any concerns about the research study?**

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the [Name of the research ethics committee you have applied to] Human Ethics Coordinator:

Complaints Contact

|  |  |
| --- | --- |
| Position |  |
| Telephone |  |
| Email |  |
| HC Reference Number |  |

#### **Consent Form – Participant(s) providing own consent**

Declaration by the participant

[ ]  I understand I am being asked to provide consent for myself to participate in this research study;

[ ]  I have read the Participant Information Sheet or someone has read it to me in a language that I understand;

[ ]  I understand the purposes, study tasks and risks of the research described in the study;

[ ]  I provide my consent for the information collected about me to be used for the purpose of this research study only.

[ ]  I have had an opportunity to ask questions and I am satisfied with the answers I have received;

[ ]  I understand that I am free to withdraw at any time;

[ ]  I understand that I will be given a copy of this document to keep;

[ ]  I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only (OPTIONAL);

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

Researcher Signature\*

|  |  |
| --- | --- |
| Name of Researcher (please print) |  |
| Signature of Researcher  |  |
| Date |  |

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

#### **Form for Withdrawal of Participation**

Declaration by the participant

I wish to **WITHDRAW** my consent to participate as an unannounced standardised patient in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with [*the institutions involved in the project*].

Participant Signature

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

The section for Withdrawal of Participation should be forwarded to:

|  |  |
| --- | --- |
| PI Name: |  |
| Email: |  |
| Phone: |  |
| Postal Address: |  |