|  |
| --- |
| [insert institutions’ logos] |
| **PARTICIPANT INFORMATION STATEMENT [Optical Services]** |
| Optical services  [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 error care in [*location*].You have been invited because you run an optical service providing refractive error care to the general public. Your contact details were obtained from [*describe who and how*].

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 include optical services who meet the following criteria:

An optical service located in[*location*]

Your optical service does eye tests and dispenses glasses.

1. **Do I have to take part in this research study?**

If you do not want to participate in this research study you will need to opt-out. This means that if your service is selected by the researchers, and you do not formally withdraw your participation, your service will take part in this research. If you do not want to take part, you do not have to - please complete the ‘Form for Withdrawal from Participation’ provided at the end of this document. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you do not pass the criteria above, please complete the ‘Form for Withdrawal from Participation’ provided at the end of this document.

1. **What does participation in this research require, and are there any risks involved?**

If you decide you want to take part in the research study, you will be asked to:

* + Read the information carefully
  + Keep a copy of this form with you
  + Contact us if you would like to receive feedback on the study

If you decide to take part in the research study, we will ask you to just go about your daily business. Up to [*number*] people posing as patients might attend your optical service for an eye examination and buy glasses. If you have been chosen, the patients will attend at random times. The patients will observe your standard practices and the research team will assess the quality of the glasses dispensed to the patients.

We don’t expect the visits from patients to cause any harm, however 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.

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

If you decide to participate in this research, we will buy glasses from your store. We hope to use information we get from this research study to update evidence on the quality of refractive error care that will allow more targeted planning for improving eye care services in [*location*].

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

By **not** signing the withdrawal form, you consent to the research team collecting and using information about you for the research study. Your data will be kept for a minimum of [*number*] years after the project’s completion. Your information will be kept confidential and stored in a safe place where access is only available to the people on the project. In any reports that are made, your information will not be identifiable. This includes any reports that will be made to health departments.

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 [*institutions involved in the research*]*.*

If you decide to leave the research project, the researchers will not collect additional information from you, although 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 type of 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 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 [*position*]:

Complaints Contact Details

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

#### **Participant Details Form**

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;

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Optical Service Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Participant Signature

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

The section for Participant Details should be forwarded to:

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

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

Declaration by the participant

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

I wish to WITHDRAW my consent to participate in the research described above because (tick one):

I do not wish to participate

I do not provide eye tests AND do not dispense glasses

I understand that such withdrawal WILL NOT affect my relationship with [*institutions involved in this research*]

Participant Signature

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

The section for Withdrawal of Participation should be forwarded to:

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