Royal Victoria Eye & Ear Hospital
Adelaide Road
Dublin 2

Ethics & Medical Research Committee
**Integrated Patient Information leaflet & Consent form**

# Patient Information Leaflet

### Preparing a Patient Information Leaflet

The patient information leaflet is an important essential component of the proposed research study. It forms the foundations of the consent process and represents the best opportunity to explain the research study to the potential respondents/participants. Essentially, the participant/respondent information sheet should be simple, use plain English with explanations where necessary (it should also be translated into other language groups when appropriate). The following structure is suggested:

**The Study Title:**

The Title should be self-explanatory to a lay reader. It may be necessary to include a more simplified Sub-Title.

**A Paragraph of Invitation to the Participants/Respondents:**

Individuals should be invited to participate in your study. The following is an example:

*"You are being invited to take part in a research experiment (or study). However, before you decide whether or not to take part, it is important that you fully understand what the research is about and what you will be asked to do. It is important that you read the following information in order to make an informed decision and if you have any questions about any aspects of the study that are not clear to you do not hesitate to ask me. Please make sure that you are satisfied before you decide to take part or not. Thank you for your time and consideration of this invitation".*

**Purpose of the Research Study**

The background to the Research Study and its aims should be set out in clear concise language. It would be advisable to include a short description of the area of interest, the procedure and aims/hypotheses of what is going to be studied.

Why as a Participant/Respondent have I been asked to take part in this study?

You should explain to the person why they were chosen and if requested provide a rough estimate of total numbers.

Participation:

It should be made clear that participation in this research study is entirely voluntary and that the participant has the complete freedom to withdraw at any time (prior to publication/ anonymisation) with no compromise in treatment. An example for your information sheet could be phrased like this:

*"Taking part in this research study is entirely up to you and if you do decide to take part you will be provided with an information leaflet to take with you. Additionally, you will be required to sign a consent form. However, if you do not wish to take part and if you change your mind at any time (prior to publication), you can withdraw from the Research Study without giving a reason".*

**During the Study**

It is important for the respondent/participant that they know where they have to go, at what time, the duration of the study, how many times they will have to come back and in general what will happen during the study itself. It is also suggested that the respondent/participant be notified who (one researcher or several) will be present and what to bring along with them. Importantly, studies which include interventions should be clearly detailed.

**Risks**

It is important that you mention and explain clearly any potential risks and restrictions. Additionally, it is important to explain clearly any possible side effects that may occur either at a psychological or physiological level. It is necessary to provide the contact details and telephone number if the respondent/participant needs to make further enquiries and/or emergency numbers should be provided in case they are needed. Furthermore it is important to consider the medical condition of those taking part in your study.

**Potential Benefits/Lack of Benefit**

If no potential benefits are going to be experienced by those taking part, it should be mentioned.

**At the End of the Study**

It is important to explain to the participant/respondent what will happen at the end of the Research Study. More so, if an intervention is needed or if the study itself is longitudinal and additional further contact may be required in the future.

**Confidentiality**

It should be clearly stated that the information/data will be kept at all times in a secure location. Additionally it should be mentioned that any information, which could identify anyone taking part, would be removed before publication/presentation. It should also be stated who is funding the research.

**Specifics**

The Patient Information Leaflet should be on Hospital Headed Paper with the Chief Researchers contact details. Details of what is involved in participation in the study should be outlined and what will happen if a problem is detected during this study. Data collected should be anonymised. The database should be password protected to ensure access only by the study investigators. Furthermore it should be mentioned that:

Example:

The study team may require access to your medical records and those of your baby. The study is not compulsory and refusing to participate will not affect care in any way.
Participants are free to withdraw from the study at any stage and will not have to justify this decision to anyone.

The Study details will be kept for up to two years (for example, once the study ends, if the Research Group wants to perform another study they may wish to contact the participant during that period).

Details of any funding obtained should be listed with the application.

**Contact Details:**

It is important that you provide contact details for those respondents/participants who wish to obtain further information about your research study.

**Consent Form:**

This consent form should include the following requirements:

Acknowledgement that the:

- Participant has read the Information Leaflet about the study.
- Researcher has spoken to the patient about the study and answered any questions.
- Patient has agreed to take part in this study.
- Patient has agreed to allow their medical records to be accessible to the Research Team.
- Data will be kept stored confidentially and disposed of within a specified period.

The Consent Form should be simple, without excessive medical jargon. Where necessary, an explanation of medical terms should be attached.

To expedite the approval of large or complex studies, the person or persons attending the Ethics & Medical Research meeting should have sufficient knowledge to answer questions on all aspects of the proposal so that all the questions raised by the Committee can be addressed contemporaneously.

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**CONSET BY SUBJECT OF RESEARCH**
**INVESTIGATION/EXPERIMENT/CLINICAL TRIAL**

**TITLE OF THE STUDY TO APPEAR HERE WITH INVESTIGATORS' NAMES UNDERNEATH.**

**PLEASE NOTE: A SIMPLIFIED VERSION OF THE TITLE SHOULD APPEAR HERE TO ENSURE THE PATIENTS INVOLVED FULLY UNDERSTAND THE STUDY.**

(It is important that there is one copy for the Participant and one copy for the Study Researcher.)

Respondent / Participant Number /I.D:

Title of Project (Printed):

Project Sub Title (If Appropriate):

Name of Principal Investigator:

_____

I, of

**hereby consent to participate in the research investigation entitled above to be carried out.**

I confirm that I have read and fully understood all the information provided in the accompanying patient information leaflet and each of my inquiries about the study has been answered.

YES ☐ NO ☐ Initials [ ]

I fully understand that my participation is completely voluntary and that I am free to withdraw at any given time (prior to publication) without providing a reason and it will not affect my care in any way.

YES ☐ NO ☐ Initials [ ]

I understand that the researchers involved in this study will hold in confidence and securely all collected data and other relevant information. Additionally, I understand that I will not be identified as a participant/respondent in this study (unless a legal requirement) and that the Researchers may hold my personal information for a ____ year(s) duration.

YES ☐ NO ☐ Initials [ ]

I confirm that I have full legal capacity to give consent in that I am not a minor under 18 years of age, my mental capacity is not impaired in any way and I am not suffering from any learning disability, mental illness or other illness whatsoever.

YES ☐ NO ☐ Initials [ ]

I agree to participate in the above research study.

YES ☐ NO ☐ Initials [ ]

Name of Respondent/Participant:

Printed_____Signature_____Date

Name of Person Taking Consent:

Printed_____Signature_____Date

Name of Researcher:

Printed _____Signature_____Date