



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Behavioural habits of contact lens wearers

Dr. Jacqueline Tan-Showyin

1. What is the research study about?

You are invited to take part in this research study. This research study aims to investigate if the behavioural habits of contact lens wearers including hygiene and compliance to lens care and cleaning routine change over time. Our secondary aim is to determine if this behavior change affects the condition of the contact lens storage case. You have been invited because you currently wear contact lenses and have either responded to a study advertisement and agreed to be briefed about this study or you have previously consented to being contacted for research studies and your contact details have been obtained from the data base of the UNSW Optometry clinic.

2. Who is conducting this research?

The study is being carried out by the following researchers: Dr. Jacqueline Tan Showyin, Prof. Fiona Stapleton, Dr. Nicole Carnt and Ms. Memoona Arshad, School of Optometry and Vision Science, UNSW, telephone: +61 2 9385 6551.

3. Inclusion/Exclusion Criteria

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

- Wearing contact lenses and are 18 years of age or older

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

Participation in any research project is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

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);
- If you would like to participate, sign the consent form and;
- Take a copy of this form home with you to keep.

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

If you decide to take part in the research study, we will ask you to complete the following tasks:

- Complete two study visits at the School of optometry and Vision Science in a 6 week interval.
- At the first (Baseline) visit, you will undergo a brief slit lamp examination to determine the status of your ocular health, research team will ask you to complete a self-administered questionnaire, which will ask you questions relating to your contact lens use. We expect this activity to take approximately 30 mins to complete and then your contact lens case will be collected for laboratory analysis. You will also be provided with a package including a new contact lens storage case and a pamphlet of general instruction for "safe contact lens use"
- At the second (follow up) visit, you will undergo slit lamp examination and complete the same questionnaire as at the first visit. At the end, your contact lens storage case will be collected and you will be provided with a replacement storage case.

The light shone in the eye during slit lamp examination may cause mild discomfort/ tearing but only lasts a few seconds. We don't expect the questionnaire to cause any harm or distress however there is a small possibility that the questions that we ask you may bring about some feelings of distress. If this does occur you can let the research team know and they will provide you with assistance. There



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Behavioural habits of contact lens wearers

Dr. Jacqueline Tan-Showyin

are no risks attached in participating in this research study. You are free to withdraw from the research at any time. If you withdraw from the research, any information collected from you will not be included in the analysis.

6. What are the possible benefits to participation?

We hope to use the information we obtain from this research study to benefit those who wear contact lenses. A better understanding of the risk factors associated with contact lens complications can help in the development of new and improved contact lens education initiatives to reduce the incidence of complications related to contact lens wear

7. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about you for the research study. We will keep your data for 15 years. We will store information about you in a format that is not individually identifiable to anyone outside the study research team at UNSW Australia. Your information will only be used for the purpose of this research study. Any data included in reports, publications or presented at meetings will be provided in the form of group responses or study identity numbers, such that the participants cannot be identified. Personal and health information (either identifiable or potentially identifiable) about individuals will not be disclosed to any external parties without the individual's consent, unless required by law. The unique study identification code can be broken by the research team if required.

8. 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 and checking the tick box at the end of the consent form. We will only use these details to send you the results of the research. The results will also be made available via the schools website <http://www.optometry.unsw.edu.au/>

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

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' 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. If you decide to leave the research study, the researchers will not collect additional information from you and all the data collected up to the point of withdrawal will be excluded from the analysis. Your decision not to participate will not affect your relationship with School of Optometry and Vision Science/ UNSW Australia.

10. 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 nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following member/s of the research team:



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Behavioural habits of contact lens wearers
Dr. Jacqueline Tan-Showyin

Research Team Contact

Name	Dr. Jacqueline Tan-Showyin
Position	Research Fellow
Telepho	+61 2 9385 6551
Email	Jacqueline.tan@unsw.edu.au

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

If you have any complaints about any aspect of the project, the way it is being conducted, then you may contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC16735



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Behavioural habits of contact lens wearers
Dr. Jacqueline Tan-Showyin

Consent Form – Participant providing own consent

Declaration by the participant

- I understand I am being asked to provide consent to participate in this research project;
- I have read the Participant Information Sheet or it has been provided to me in a language that I understand.
- I understand that the research team will collect my used contact lens storage case; I provide my consent for this to happen.
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I understand that if necessary I can ask questions and the research team will respond to my questions.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the project and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- 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: _____

Address: _____

Email Address: _____

- I understand that I will be given a signed copy of this document to keep;

Participant Signature

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

Declaration by Researcher*

- I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

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



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Behavioural habits of contact lens wearers
Dr. Jacqueline Tan-Showyin

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, or the School of Optometry and Vision Sciences. In withdrawing my consent I would like any information which I have provided for the purpose of this research project withdrawn.

Participant Signature

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

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Dr. Jacqueline Tan-Showyin
Email:	Jacqueline.tan@unsw.edu.au
Phone:	+61 2 9385 6551
Postal Address:	RMB, North Wing, SOVS, UNSW