# UNSW Human Research Ethics Application Form

More than Low Risk OR Low Risk Research Applications

**Project: Behavioural habits of contact lens wearers**

## 1. Lay Summary & Aims

Earlier research on the aetiology of contact lens (CL) related diseases shows that inappropriate water exposure can add to microbial contamination of the ocular environment. Using tap water for cleaning CL storage case or handling lenses with wet hands can directly transfer water-borne microorganisms to the lens and ultimately the ocular tissue. Use of domestic tap water can cause Acanthamoeba keratitis in people who demonstrate non-compliant behaviour towards water use including exposure of the CL or case to tap water, inappropriate hand washing, showering and swimming while wearing CL without any protective goggles. Despite the association of water and CL with severe corneal infection, many CL wearers continue to place themselves at risk for example by showering in lenses, handling lenses following not drying hands after washing them and rinsing CL storage cases in tap water. Anecdotally lens wearers report ignorance of this risk.

**Aims of the project**

In this study we propose to investigate the impact of CL packaging displaying a 'no water' logo graphic and evaluate whether this affects wearers' behaviours and attitudes to CL care/ wear. Our secondary aim is to determine the effect of behaviour change on microbial contamination of the CL storage case.

**Importance of the study**

Inappropriate exposure to water of wearers can lead to the direct transfer of water borne microorganisms into the eye. With representations of water displayed on numerous CL packaging and promotional materials and the FDA not mandating a change in gas permeable (GP) CL solution packaging to remove the instruction to rinse with tap water, it can be seen how wearers may receive mixed messages, even if their practitioner alerts them to this risk. A universal "no water" logo for CL packaging is a simple visual cue to avoid tap water that transcends language barriers. It is particularly pertinent in a culture where online purchase of lenses is common and in an expanding market that includes myopia control for young wearers and a greater range of CL correction options for presbyopes.

## Background Literature Review

Representations of water, indicating comfortable lens wear and freedom from dryness symptoms, are extensively used in CL marketing strategies. Freedom from spectacles means that CL wearers are able to participate in activities such as swimming and showering while wearing lenses. These behaviours are well established risk factors for corneal infection, particularly Acanthamoeba keratitis[1] yet water contact is often not discussed with CL wearers.

Acanthamoeba keratitis is rare, but is one of the most severe forms of infection of the cornea with 85% of cases occurring in CL wearers[2] It is a chronic disease lasting 1-3 years in 50% of patients. Lifelong disabling vision loss occurs in a third of patients and corneal transplantation is required in around 25%.[3]

While Acanthamoeba Keratitis can occur in non-lens wearers and daily disposable users, it is predominantly a disease of re-usable daily wear CLs, involving use of a CL storage case. The causative organism is frequently isolated from the storage case and storage cases are often heavily contaminated with environmental organisms that are used as a food source for Acanthamoeba. There is also evidence that such co-contamination not only confers a survival advantage to the organisms but increases the resistance of Acanthamoeba to antimicrobials.[1]

Ms Irenie Ekkeshis, who has had Acanthamoeba Keratitis for over 3 years, was so motivated by this general lack of knowledge amongst CL wearers, that she designed a "No water" logo graphic for CL and paraphernalia packaging. The graphic has been endorsed by the British Contact Lens Association and is available for purchase by BCLA members and has been adopted by other organisations including the Cornea, Contact Lens and Refractive Technology Section of the American Academy of Optometry and more recently the Cornea and Contact Lens Association of Australia.

A recent study[4] established behaviour related risk factors in CL case contamination in asymptomatic wearers, however there is limited data on the impact of the change in water contact behaviour on storage case contamination and disease.

This study aims to assess attitudes and behavioural changes of CL wearers and case contamination rates in terms of lens aftercare compliance including case hygiene, hand washing, avoiding overnight wear, discarding of used disinfecting solution and recommended replacement frequency of CL/care products, when a "no water" graphic is added to CL packaging.

Better understanding of those behaviours specifically associated with the use of contemporary CL types and enhanced surveillance capacity for ocular complications is needed to develop health promotion activities that can encourage CL wearers to improve their hygiene behaviour. Associations between CL user's hygiene profile and CL case contamination can help to identify key factors in reducing the microbial burden, which is a major risk factor for microbial keratitis,[5] including Acanthamoeba keratitis.[6]

### References

**1.** Carnt N, Stapleton F. Strategies for the prevention of contact lens-related Acanthamoeba keratitis: a review. Ophthalmic Physiol Opt 2015.

**2.** Dart JK, Saw VP, Kilvington S. Acanthamoeba keratitis: diagnosis and treatment update 2009. Am J Ophthalmol 2009; 48(4): 487-99 e 2.

**3.** Robaei D, Carnt N, Minassian DC, Dart JK. The impact of topical corticosteroid use before diagnosis on the outcome of Acanthamoeba keratitis. Ophthalmology 2014;121(7):1383-8.

**4.** Wu YT, Willcox MD, Stapleton F. The effect of contact lens hygiene behavior on lens case contamination. Optom Vis Sci 2015;92(2):167-74.

**5.** Stapleton F, Edwards K, Keay L, et al. Risk factors for moderate and severe microbial keratitis in daily wear contact lens users. Ophtalmology 2012;119(8):1516-21.

**6.** Radford CF, Minassian D, Dart JKG. Acanthamoeba keratitis in England and Wales: incidence, outcome and risk factors. Br J Ophthalmol 2002;86:536-42.

**7.** Wu YT, Zhu H, Willcox M, Stapleton F. The effectiveness of various cleaning regimens and current guidelines in contact lens case biofilm removal. Invest Ophthalmol Vis Sci 2011;52(8):5287-92.

**8.** Legarreta JE, Nau AC, Dhaliwal DK. Acanthamoeba keratitis associated with tap water use during contact lens cleaning: manufacturer guidelines need to change. Eye Contact Lens 2013;39(2):158-61.

**9.** Dart JK, Radford CF, Minassian D, et al. Risk factors for microbial keratitis with contemporary contact lenses: a case-control study. Ophthalmology 2008;115(10):1647-54, 54.e1-3.

**10.** Stapleton F, Keay L, Edwards K, et al. The incidence of contact lens-related microbial keratitis in Australia. Ophthalmology 2008;115(10):1655-62.

## 2. Research Design and Methodology

**Research Design:**

- This will be a prospective randomized controlled study.

**Study timeline:**

- Overall duration of study: 12 months
- Estimated start date: 27th October 2016 (after Ethics approval has been received)

**Data collection methods:**

1. Enrollment: Two hundred (200) established CL wearers will be randomly selected to either receive packaging with the "No water" graphic (test group) or without (control group). The test group will receive general written instructions on safe CL wear with the "no water" graphic while the control group will receive the general written instructions on safe CL wear only.
2. Completion of Questionnaire: The participants will complete a survey on attitudes to lens care/wear prior to being randomized (baseline) and at 6 weeks (follow up) interval. Six weeks after enrolment, participants will have to complete the questionnaire and return the used trial CL case to the research investigator. They will receive a replacement of CL case at each visit.
3. General clinical examination: The participants will undergo a brief slit lamp examination at both visits to determine status of ocular health with CL wear.
4. Disposal of trial CL case + Written instruction package: At baseline visit after being randomized, each research participant will receive a package which includes a pamphlet containing general instructions on safe CL use and one new CL case with or without a "No water" graphic sticker. The written instructions pamphlet has already been used in various publicity and awareness campaigns of School of Optometry and Vision Science, UNSW (and is enclosed for review and approval). The stickers will be attached on the top surface of the lid of CL storage case. Pre made packs- some with stickers and some without will be given out randomly according to a randomization sequence from sealed envelope, an online randomization generator. (https://www.sealedenvelope.com/simple-randomiser/v1/lists
5. Microbiological analysis of CL case contamination: All collected CL cases will be transferred to the microbiological laboratory at level 2, SOVS to perform microbiological analysis within 2 hours of collection. Microbial load of CL cases will be measured with the MTT assay.[7] A comparative analysis of CL case contamination between baseline and the follow up visit will be conducted for the magnitude of change from baseline between two groups and correlated with behaviour change at the 6 week time point.

6. Subject compliance:
   There will be a two weeks window for participants to complete the surveys. Three reminders by phone or email will be administered in this time. Should participants not complete the surveys within the two week window, they will be withdrawn from the study
7. Data Analysis:
   A general compliance score will be calculated out of a maximum of 40 (Lens disinfection 20, Hand hygiene 8, Case replacement 6, Case hygiene 6), based on previous study methodology.[9,10] A water awareness score (maximum 15) and a water behaviour score (maximum 30) will also be generated.
   Our primary endpoint is "Water behaviour" at the 6 week time point and we will perform an ANCOVA to determine changes from baseline (non-normal data will be log transformed). "General compliance" and "water awareness" change from baseline at 6 weeks will be secondary measures.

**Sample Size**

Two hundred CL wearers will be randomized to either receive packaging with the 'No water' graphic or without.
It is known that rinsing of the storage case with tap water is a common source of exposure to Acanthamoeba spp. among even compliant contact lens wearers. Patients are attempting to "clean" their lens cases, but in doing so, they risk contamination with pathogens.[7] Recent data suggests that around a third of asymptomatic CL wearers rinse their storage cases in tap water (35%).[4] We assume that if behaviours such as showering in CL are included in this estimate, we would expect around 50% of asymptomatic lens wearers to have some contact with tap water. To detect a minimum odds ratio of 0.5x (relative precision of 30%), with α=0.05 and power of 80%, we would therefore require a sample size of 100 per group, i.e. 200 wearers in total (G*Power 3.1.9.2).

## 3. Research Participants

**Participant Selection:**
Two hundred daily wear CL users will be recruited as study participants. Participants will be randomized to two groups, test and control. Test group will include those who will receive written instructions + "no water" graphic while control group will receive written instructions only. CL wearers who have consented to be contacted for research purposes will be invited via email to participate in this study.

**Inclusion Criteria:**
CL wearers who are 18 years of age or older.

**Exclusion Criteria:**
There are no specific exclusion criteria.

**Recruitment of participants**

Trial participants will be recruited from the local population at the investigational site (University of New South Wales). The approved study advertisement will be circulated to all SOVS staff, the Brien Holden Vision Institute, the Centre for Eye Health, SOVS post-graduate students, UNSW administrative staff and previous study participants who have indicated their willingness to be contacted to participate in future research studies. Advertisements may also be posted in University newsletters, notice boards, websites, local newspapers, social media (e.g. Facebook), on the SOVS clinic TV screen and other local advertising and community websites. Anyone who responds to the advertisement will be invited to attend the UNSW Optometry Clinic for assessment and collection of cases. Those who indicate a willingness to participate will be identified on eligibility criteria and written informed consent will be obtained from all participants.

**Consent**

For interested participants who are attending the UNSW Optometry Clinic, an investigator will provide the

participants with a copy of the Participant Information Statement and Consent Form (PISCF) and allow them sufficient and undisturbed time to read through the form and will be advised that they are free to ask any questions or seek clarification about the content of the form. Once the participant has read through the PISCF and the key points including the purpose of the study, the study design and visit schedule, how confidentiality will be maintained throughout the study and in any reporting have been explained, the participant will be given the opportunity to ask any questions they may have and to make a decision as to whether or not they wish to participate in the study. If they do not agree to participate, they will be assured that their decision has no impact on the care that they receive at the School of Optometry and Vision Science clinic both now and in the future, and they will be free to leave.

For interested participants who respond to the study advertisement, a copy of the PISCF will either be emailed or posted to the potential participants in advance. They will be encouraged to ask any questions they may have about the study in advance prior to attending the UNSW Optometry Clinic for the baseline visit. The same procedure as outlined above for participants now in attendance at the UNSW Optometry Clinic will then be followed.

Participation in the study is entirely voluntary. Potential participants will not be directly approached by the Investigators and/or coerced into participating in the study at any time. Recruitment will be conducted at arm's length via e-mail invitations sent by a non-investigator of the study and through advertisements which may be posted in University newsletters, notice boards, websites and local newspapers.

Study participants may be known to the investigators as friends, family members, class mates or staff. However, subjects will not be coerced to participate and may refuse to participate without their decision having any impact on their relationship with The University of New South Wales or the School of Optometry and Vision science. This is clearly stated within the Participant information and Consent form, and will be emphasized during the consent process.

## 4. Reimbursement of Expenses or Incentives to Participate

In this study, participants' CL cases will be collected. Therefore, a replacement CL case will be provided at each visit. All participants will receive a $20 gift voucher following successful completion of the two time points, at baseline and at 6 weeks.

## 5. Risks to participants

There are no risks involved in participating in this research.

## Privacy and Confidentiality

All participants will be given a unique study identification code. Data will be de-identified (re-identifiable by only study team) at the time of collection such that only patient initials and a study identity number will be used to identify the data for each patient. Although the sample will be linked to information identifying participants, all aspects of this study will be kept confidential and only those conducting and monitoring the study will have access to the results. The sample will be stored as a re-identifiable sample. This means that sample will be identified by a code but will have all identifiers (e.g. name and personal details) removed. It will be possible to re-identify the sample by using the code, even though there is no identifiable information stored with the sample. All case report forms (paper and electronic) will be kept secure under lock and key in locked cabinets or computer storage with access limited to key personnel requiring access codes. The study database will be password protected and only accessed by personnel associated with the study.

Any data included in reports, publications or presented at meetings will be provided in the form of group responses, 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.

## 6. Publications and Dissemination of Results

A short summary of the results will be provided to the participants, should they indicate a desire to receive feedback on the study, once the study findings have been published. Participants who wish to receive feedback will notify the investigator by checking the tick box at the end of the informed consent.
Data from the study will be published in peer reviewed journals and presented at international and /or local scientific conferences. The results of the study will also be published in newsletters and official website of the School of Optometry and Vision Science. Privacy and confidentiality of information about each participant will be preserved in the reports and any publication of the data.
Any data included in reports or publications or presented at meetings will be provided in the form of group responses only, such that the participants cannot be identified.