Participant Information Sheet

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| **Study title:** | **Cost-Effectiveness of Standalone Stents as Second-Stage Surgery Study: SUCCESSES** |
| Locality: | Capital & Coast DHB | Ethics committee ref.: | Health and Disability Ethics Committee (HDEC) |
| Lead investigators: | **Dr. Nicole Lim and** **Dr. Jesse Gale** | Contact phone number: | **02040994027****0211272979** |

You are invited to take part in a study on iStents, which are tiny stents placed in the drainage structure of the eye to lower the eye pressure.

Whether or not you take part is your choice. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page, and given a copy of this document to keep. Please make sure you have read and understood all the pages.

## What is the purpose of the study?

You have been invited to participate in this study because you have a cataract suitable for surgery and glaucoma that may benefit from further treatment. Often cataract surgery alone will improve glaucoma control, so we are studying how many people with cataracts and glaucoma would still need an iStent after cataract surgery.

**The study aims to measure the proportion of patients who would benefit from a second procedure after cataract surgery, to implant an iStent. Our aim is to determine whether this approach is more cost effective than putting an iStent in everyone with glaucoma and cataract.**

An iStent is a tiny surgical device that consists of two titanium stents (less than 0.5 mm each) that are implanted into the tissue that drains fluid out of the eye (called the trabecular meshwork). An iStent is supposed to create a channel through the blocked or dysfunctional trabecular meshwork, to allow fluid to exit the eye more easily. The iStent has been available and in general use in New Zealand since 2014.

## What will my participation in the study involve?

All participants have cataract surgery in the usual time-frame, and then have usual postoperative and glaucoma follow up visits. If you continue to have uncontrolled pressure or treatment side effects, a second procedure to implant an iStent will be offered to you. We will be recording your pressures and your quality of life and treatment side effects.

That is, you will have cataract surgery regardless of your participation in the study, and the post-operative visits and eye drops will be the same as usual. Cataract surgery by itself can lower the eye pressure very well. So, you may have much improved glaucoma control after cataract surgery alone.

You will also continue to receive your usual glaucoma care, with no change to the number of follow up visits required. The only additional testing will be a questionnaire at each visit about quality of life and treatment side effects.

If your eye pressure is higher than your target pressure more than 3 months after cataract surgery, or you have treatment side effects, you will be offered another procedure to implant an iStent (up until the completion of the study at 3 years). This is a day surgery procedure under local anaesthetic, even quicker than cataract surgery (about 10 minutes). Follow up after this procedure will be at day 1, month 1 and month 3 after iStent insertion.

## What are the possible benefits and risks of this study?

You will receive the standard of care: cataract surgery and ongoing glaucoma care. Your decision whether to have cataract surgery is not affected by your decision whether to participate in the study.

While all treatment has some risks, the risks of cataract surgery or glaucoma treatment are not altered by your participation in the study. Cataract surgery has a risk of complication of up to 5% including the possible need for more surgery to fix problems. There is a very low risk of permanent severe loss of vision, around 1 in 1000 cases.

By participating in the study, you will have greater access to the iStent surgery than the current standard of care. Some evidence indicates that iStents reduce eye pressure and reduce the number of eye drops required for glaucoma control (by one medication). iStents appear to be safe to implant, with very low risk of surgical complications around 1 in 200. These complications might include a small bleed in the eye that will usually resolve within a week, a temporary rise in pressure or inflammation, requiring further eye drops. Blockage of the stent or incorrect placement can also occur, which would simply mean they are not effective in lowering pressure. There have been no reports of any serious adverse events after iStent surgery. The device will not interfere with MRI scans or airport security scans.

If you are offered iStent surgery during the study period, you will have an opportunity to discuss the surgery further with your treating specialist.

## Who pays for the study?

There will be no cost to participate in the study. Your care is continued through the DHB as usual. Collection of data and analysis is done by the study investigators voluntarily.

## What if something goes wrong?

If you experience any problems during the study, you will immediately be cared for at the clinic. If any new health concerns are found during the study, your GP may be informed. There will be no penalty for withdrawing from the study if you wish at any stage during the study.

**Provision of compensation**

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. You are not disadvantaged from ACC cover in this study. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

## What are my rights?

You have the right to decide whether or not you take part in this study. You have the right to access your information and data collected during the study held by the research team. You also have the right to request that any information you disagree with is corrected.

During the study, you can withdraw at any time, without experiencing any disadvantage. You may withdraw your consent for the collection and use of your information, by informing your Study Doctor. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

 You can request a copy of the final report when it becomes available.

**What will happen to my information?**

To protect your privacy, we will de-identify your data when it is collected for study purposes. We will do this by assigning a study code number for you. A database will be kept linking this study code number to identifiable information (including your hospital number, name and date of birth). Only the study investigators and their trained study staff will have access to this identifiable database.

Study information that we collect (including your visual acuity, intraocular pressures, examination findings and questionnaire scores) will be kept in a separate database that is de-identified, by only using your study code number.

After data analysis, any published information will be made anonymous, by excluding the study code number or any identifiable information.

The study databases will be kept on a secure server, using the Capital & Coast District Health Board’s electronic data capture program, Redcap, with a copy kept in the Capital & Coast District Health Board’s cloud storage for security. This ensures the privacy and confidentiality of all participants. Data will be kept for a minimum of 15 years from date of study completion. After this, paper forms may be destroyed by secure document destruction services.

The extracted de-identified data will be retained indefinitely and may be made available to other researchers internationally for transparency, in order to reduce the possibility of drawing wrong conclusions or missing important details. In this situation, no linking or identifiable data would be accessible.

The Health and Disability Ethics Committee and Health, regulatory or government authorities would be granted access to identifiable data (your medical record) and de-identified coded data for audit purposes, to check the accuracy of information recorded for the study.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

**Future Research using your information**

If you agree, your coded information may be used for future research relating to glaucoma or iStents or for other medical scientific research unrelated to the current study. Consent for this optional. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies to form much larger sets of data.

You will not get reports or other information about any / some research that is done using your information. Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

## Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact the investigators:

 Dr Nicole Lim Dr Jesse Gale

Phone: 020 4099 4027 021 1272 979

Email: nicole.lim@ccdhb.org.nz jesse.gale@ccdhb.org.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Email: advocacy@advocacy.org.nz

For Maori health support please contact Whānau Care Services

Phone:  (04) 806 0948

Email:  wcs@ccdhb.org.nz

You can also contact the ethics committee that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Consent Form

**An interpreter is available on request.**

Please tick to indicate you consent to the following

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| I have read and I understand the information sheet for participants in this study, designed to test the cost effectiveness of istent implant as second-stage surgery after cataract surgery |  |  |
| I have had the opportunity to discuss this study, and I am satisfied with the answers I have been given. I have had time to consider whether to take part. I know who to contact if I have any questions about the study. |  |  |
| I have had the opportunity to use family/whanau support or a friend to help me ask questions and understand the study if desired. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care. |  |  |
| I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study. |  |  |
| I understand that as part of the study, I will be asked to complete questionnaires on my quality of life and treatment side effects. |  |  |
| I understand that my GP may be informed of any new health concerns that is found during the study. |  |  |
| I wish to receive a copy of the final report when available. | Yes □ | No □ |
| I consent to the coded information collected in this study to be used for future research related to glaucoma or iStents or an unrelated topic, which may be conducted overseas.  | Yes □ | No □ |
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Declaration by participant:

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it. I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |