PARTICIPANT INFORMATION SHEET 參與者資料小冊子

1. Study Information
1. 研究資料

Protocol Title: 方案題目

An investigation of the effectiveness of Paul Glaucoma Implant (PGI) – a pilot study

Paul Glaucoma Implant (PGI) 有效性的調查試驗研究

Hong Kong Principal Investigator & Contact Details:
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眼科及視覺科學學系 香港中文大學眼科中心

You are invited to participate in a collaborated research study with National University of Singapore (NUS). NUS is our collaborator. You are invited because examination showed that you have glaucoma that is not controlled with your existing medicines effectively. In this case, surgery is needed in order to control your eye pressure. Please read this information sheet with care and ask any questions you may have about this study. Your questions will be answered. You may consult your family members, friends or family doctor if necessary. If you have any questions or would like to have more information, please consult investigators of this research and decide your participation afterwards. Also, you will be given a signed copy of the consent form and participant information sheet for retention.

我們誠邀您參加一項與新加坡國立大學合作的研究。新加坡國立大學是我們的合作伙伴。我們誠邀您參加是因為檢查顯示您的青光眼未能被您現有的藥物所有效控制。在這種情況下，需要用手術來控制你的眼壓。以下內容告訴您有關此研究。請小心閱讀此資料頁及提出有關於這項研究的任何問題。您的問題將被回答。如有必要，請您和您的家人、朋友及您的家庭醫生討論。若您有任何疑問，或想知道更多的資料，請向負責這項研究的人員詢問，然後決定是否參與。此外，您將獲得已簽署的同意書副本及參與者資料小冊子作保存。

2. Purpose of the Research Study
2. 研究目的

This study is carried out to determine the safety and efficacy of a new shunt that has been developed to eliminate some of the disadvantages of current shunts in the treatment of refractory/severe and moderate glaucoma. This new device was developed and invented by one of the glaucoma surgeons (Associate Professor Paul Chew) of the National University of Singapore. However, this new implant has been extensively tested in animal experiments prior to the current research study. **In this research study, the implant will be used for the first time in human eyes.** Starting from 7 September 2017, this new implant is allowed to use in human eyes in United Kingdom and Germany.

這研究旨在確定新分流手術的安全性和有效性，以消除目前分流手術在治療難治性/重度和中度青光眼中的一些缺點。這新裝置是由新加坡國立大學其中一位青光眼外科醫生（副教授 Paul Chew）所開發和發明。然而，在目前的研究之前，這新的植入物已經在動物實驗中廣泛地進行測試。**在這項研究中，植入物將首次在人眼中使用**。在 2017 年 9 月 7 日開始，這新裝置已容許於英國和德國的人眼中使用。

This study will recruit 6 participants with glaucoma from Hong Kong Eye Hospital from 24 November 2017 to 29 December 2017.

這研究將會在 2017 年 11 月 24 日至 2017 年 12 月 29 日於香港眼科醫院中招募 6 名患有青光眼的參與者。

3. What procedures will be followed in this study
3. 有什麼程序將會於研究中進行

If you take part in this study, you will undergo an eye operation using the glaucoma drainage implant. Post-operatively, you will be asked to return to the outpatient eye clinic for review based on a fixed schedule (as shown below).

如果您參加這研究，您將會接受使用青光眼引流植入物的眼科手術。手術後，您將被要求根據固定時間表返回眼科門診診所檢查（如下圖所示）。

Your participation in the study will last 12 months from the date of procedure. You will be followed up for 12 months. You will need to visit the clinic 8 times (including day of procedure) in the course of the study. Each study visit takes around 4 hours.

您參加該研究將持續自手術日起的 12 個月。您將被跟進 12 個月。在研究過程中，您需要到診所 8 次（包括手術日）。每次隨訪需時約 4 小時。

If you agree to take part in this study, you will receive the following assessments:

如果您同意參加這研究，您將會接受下列檢查：

Refraction: a method of measuring the refractive power of the eye.

屈光度: 一個測量眼睛屈光度的方法。

Visual acuity (Snellen) : using a chart to grade the best vision using the best corrected power from refraction

視力(斯內倫) : 使用一個圖表記錄最佳屈光後的視力

Slit lamp examination: using a clinic microscope to check the anterior & posterior parts of the eye.

裂隙燈檢查：使用臨床顯微鏡檢查眼睛的前房和後房。

Goldmann Applanation Tonometry: is a method of measuring the eye pressure.

戈德曼壓平眼壓計: 一個測量眼壓的方法。

Indentation gonioscopy: examination of the anterior part of the eye focusing more on the angles.

前房角鏡: 在多角度上集中的眼睛前房的檢查。

Dilated fundus examination: examination of the back of the eye (retina, optic nerve) after putting an eye drop (Tropicamide) to dilate the pupils.

散瞳眼底檢查: 在滴眼液（托吡卡胺）放大瞳孔後，檢查眼睛後房（視網膜，視神經）。

Pachymetry: a method of measuring the thickness of the cornea.

測厚儀: 一個測量角膜厚度的方法。

Specular microscopy: a microscopic imaging of the inner layer of the cornea.

	Preop 手術前	**1 Day** 第一日	**1 Week** 第一星期	**1 Mon.** 第一個月	**3 Mos** 第三個月	**6 Mos** 第六個月	**12 Mos** 第十二個月
Refraction 屈光度	X					X	X
Visual Acuity 視力	X	X	X	X	X	X	X
Slit Lamp examination 裂隙燈檢查	X	X	X	X	X	X	X
Goldmann Applanation Tonometry* 戈德曼壓平眼壓計*	X	X	X	X	X	X	X
Indentation gonioscopy 前房角鏡	X						X
Dilated fundus examination 散瞳眼底檢查	X			X	X	X	X
Pachymetry 測厚儀	X						X
Specular microscopy 鏡面顯微鏡	X						X
Ocular motility Evaluation 眼球能動性評估	X					X	X

鏡面顯微鏡：一個在角膜內層的顯微鏡成像。

Ocular motility evaluation: checking the movements of the eye in all directions.

眼球能動性評估：檢查眼睛在各個方向的運動。

* If unable to use Goldmann applanation tonometer, a tonopen will serve as the substitute.
*如果未能使用戈德曼壓平眼壓計，手持式眼壓儀將會是代替品。

When your participation in the study ends, you will resume your routine glaucoma care in the eye clinic at Hong Kong Eye Hospital.

當您參與的研究結束時，你將恢復您於香港眼科醫院眼科診所中的常規青光眼護理。

4. Your Responsibilities in This Study
4. 您在研究中的責任

If you agree to participate in this study, you should follow the advice given to you by the study team. You will visit the hospital 8 times and undergo all the procedures that are outlined above, including the day of surgery.

如果您同意參與這研究，您將要跟隨研究小組給您的建議。你將會回 8 次醫院去接受上述的所有程序，包括手術日。

5. What Is Not Standard Care or is Experimental in This Study
5. 什麼不是標準護理或在這項研究中是試驗性

The study is being conducted because this new glaucoma implant is not yet proven to be a standard treatment in subjects who have glaucoma. We hope that your participation will help us to determine whether it is effective and safe. The standard care and experimental treatment are listed under Part 8 in this participant information sheet.

研究將會進行是因為這種嶄新青光眼植入物尚未被證實是患有青光眼的受試者的標準治療。我們希望您的參與能夠幫助我們確定是否有效和安全。標準護理和試驗治療在參與者資料小冊子的第 8 部分。

6. Possible Risks and Side Effects
6. 可能的風險和副作用

A. Intra-operative risks include risks of general anesthesia. Regarding the eye, bleeding can be a potential risk.

A. 手術中風險包括全身麻醉的風險。關於眼睛，出血可能是潛在的風險。

B. Post-operative complications including:
B. 手術後併發症包括:

a. Ocular pain (Eye pain): You may experience post-operative pain on the first day after the procedure. This is usually adequately controlled with oral analgesia such as paracetamol or Nonsteroidal anti-inflammatory drugs (NSAIDs).

a. 眼痛 (眼痛): 你在程序後的第一天可能會出現手術後疼痛。這通常透過口服止痛是足夠地適當控制，例如撲熱息痛或非類固醇消炎藥。

b. Anterior chamber inflammation (swelling in the front part of the eye): The anterior chamber inflammation is expected to be mild to moderate and this will be controlled with topical steriods after the procedure

b. 眼睛前房炎症(眼睛前面腫脹)：眼睛前房炎症預計為輕度至中度，並且在程序後，將會用局部使用類固醇來控制。

c. Anterior part of the eye may become flat or shallow.

c. 眼睛前房可能變得平坦或淺薄

d. Bleeding in the anterior &/or posterior parts of the eye

d. 在眼睛的前房和/或後房出血

e. Cornea damage: The cornea is the clear and transparent front part of the eye. The cornea can potentially be swollen after the surgery. We will be monitoring this possible complication with slit lamp examination and provide the necessary treatment to treat the swelling post operatively.

e. 角膜損傷：角膜是指清澈和透明的眼睛前房。手術後，角膜可能會腫脹。我們將利用裂隙燈檢查來監測這種可能的併發症，和提供必需的治療來治療手術後的腫脹。

f. Reduction in visual acuity: Your vision may be temporarily or permanently affected due to any of the aforementioned side effects of the treatment. We will monitor your vision closely after the procedure and provide the necessary treatment.

f. 視力下降：由於任何上述治療的副作用，您的視力可能會有暫時或永久性影響。 我們將在手術後密切監視您的視力和提供必要的治療。

C. Patients would be followed-up regular as per protocol. We would also educate the patients about the symptoms of complications (e.g. Hypotony, elevated IOP, enophthalmitis).

C. 患者將會按照方案進行定期隨訪。 我們還會教育患者併發症的症狀(例如低血壓，高眼壓，眼球炎)。

This new design of glaucoma drainage implant is still being tested; therefore, you may experience other side effects that have not yet been reported. However, you will be kept informed of any significant new findings that may relate to your willingness to continue to take part in this study.

這種嶄新設計的青光眼引流植入物仍然在測試中; 因此，您可能會遇到其他尚未報告的副作用。但是，您將會被通知任何重要的新發現，當中或會與您是否願意繼續參與這研究有關。

If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.

如果您經歷任何新的症狀，您應該盡快與您的醫生或首席研究者聯絡。

There is no assurance you will benefit from participation in this study. However, the new design of the glaucoma drainage implant is meant to decrease your eye pressure better and to prevent the complications encountered in the existing/conventional glaucoma drainage implants.

我們無法保證您參與本研究將會有所得益。 但是，嶄新設計的青光眼引流植入物目的是更好地降低眼壓和防止在現有/常規的青光眼引流植入物中遇到的併發症。

7. Important Information for Women Subjects
7. 女性受試者重要的信息

The effect the implant on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study.

植入物對嬰兒發育的影響是未知。 因此，懷孕和喂哺母乳婦女不可以參加這項研究。

8. Alternatives to Participation
8. 其他治療方法

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this could be any of the following: the use of existing/conventional glaucoma drainage implants or performing other glaucoma filtering surgery (e.g. trabeculectomy, a procedure that shunts aqueous from inside the eye to underneath the conjunctiva without the use of implant) or laser surgery (e.g. diode cyclophotocoagulation).

如果您選擇不參加本研究，您將接受符合您情況的標準護理。在我們的機構中，這可能是以下任何一種：使用現有/常規青光眼引流植入物或進行其他青光眼濾過手術（例如小梁切除術，一種將眼睛內部的水分分流到結膜下方而不使用植入物的程序）或鐳射手術（例如二極體光凝術）。

9. Study Termination
9. 終止研究

We reserve the right to terminate your participation in the research project. In the event that any safety concerns are raised during the study or interim results from the study show no

further samples are needed, your participation will no longer be required. If you are unable to return for the follow up visits, your participation will be terminated.

我們保留終止您參與本次研究的權利。在出於對您安全的考慮或研究中期相關結果顯示您不再需要繼續本研究時，我們將終止您的研究。如果您未能回來隨訪，您的參與將會被終止。

10. Costs & Payments if Participating in the Study
10. 參與研究的收費和報酬

If you agree to take part in this research study, you are not required to pay extra fees and will not receive any reward. However, you are still responsible for paying for the follow-up care and surgical expenses. The cost of follow-up care includes consultation fee for each Hong Kong Eye Hospital clinic visit, charges for dressing care and medicine.

當您同意參與這研究，您不需要支付額外費用，也不會收到任何報酬。然而，您仍需要支付覆診及手術費用，覆診的費用包括每次在香港眼科醫院門診諮詢費、傷口護理的費用和藥費。

11. Voluntary Participation
11. 自願參與

Your participation in this study is entirely voluntary. You will be updated of new information that may be relevant to your willingness to continue participation in the study. You are allowed as much time as you need to consider participation in this study, or to discuss with your relatives prior to signing the consent. You can call us via the contact telephone number provided on this participant information sheet when you would like to get more information. You also can express your wish to participate during future routine clinic visits. You have the right to refuse participation or to withdraw from this study at any time, with no prejudice towards your present or future medical treatments at the Chinese University of Hong Kong or any of the hospitals involved. After signing the informed consent form, a participant information sheet and a copy of signed informed consent form will be given. Even after signing the informed consent form, you are free to withdraw your consent and discontinue your participation in the study at any time. Once you request to withdraw, all clinical data arising from study investigations will be deleted. The clinical data in the medical records will, however, be retained for future clinical management.

您參與這項研究是完全自願的。您將收到更新的訊息去決定是否繼續參與這項研究。您會給予足夠的時間去考慮是否參與這項研究。在簽署知情同意書前，您亦可與親戚一起討論。當您需要獲得更多信息時，您可以撥打我們在參與者資料小冊子提供的聯絡電話號碼。在日後覆診時，您也可表達您是否繼續參與這項研究。在任何時候，您有權拒絕參與或退出本研究。退出本研究不會影響現在或將來您於香港中文大學或任何參與醫院的治療。簽署知情同意書後，您會獲得一份參與者資料小冊子及已簽署的知情同意書副本。即使已簽署知情同意書，您可以在任何時候改變您參與這項研究的意願及退出此計劃。一旦您要求退出，所有的臨床研究數據將被刪除。但是臨床醫療記錄將被保留作日後臨床治療用途。

12. Compensation for Injury
12. 賠償創傷

If you are injured during your participation in this study, the investigator will provide medical treatment to you or refer you to other treatment. You are not giving up any of your legal rights by signing the informed consent form. It is important that you follow carefully all the instructions given by the Study Doctor and his/her staff regarding this study. The reasonable costs of such treatment beyond that provided by your insurance will be covered by the collaborator. If you have any queries related to the insurance coverage from your own insurer(s) for your participation in the study, please discuss with your insurance consultant. The insurance provided by our collaborator will cover the participants whom do not have any

insurance coverage.

若您因參與本研究而引致任何身體損傷，研究負責人將會為您進行治療或轉介您接受治療。您不會因為簽署本知情同意書而放棄任何法律權利。您小心遵從研究醫生及工作人員對本研究的所有指示是很重要的。治療的合理費用，假如超出您所投保的保單覆蓋範圍，餘下部分將由合作伙伴支付。假如您有任何關於其保險公司對您參加這項研究的承保範圍方面的疑問，請與您的保險顧問討論。我們的合作伙伴提供的保險將覆蓋沒有購買保險的參與者。

13. Confidentiality of Study and Medical Records
13. 研究和醫療記錄的保密

Electronic data will be only saved in physically-secured and password-protected computers in our research office. Information from this study will be submitted to the Department of Ophthalmology and Visual Sciences, Chinese University of Hong Kong for statistical analysis. Only the overall result will be published and your identity will remain confidential. Records and results of all study investigations can be destroyed on your request in future. By signing a written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

電子數據將只在我們安全的研究室電腦內保存，並受到密碼保護。這項研究的資料將給予香港中文大學眼科及視覺科學學系進行統計分析。您的身份將受嚴格保密，只有整體的結果將被公佈。於任何時間，您可要求消毀所有相關的研究結果和記錄 。簽署知情同意書的同時，亦表示您允許臨床研究倫理委員會及有關法定機構在合適的條例及法例容許下及在不侵犯您的私隱情況中，直接翻查您的病歷記錄正本以核實臨床研究計劃之程序和/或數據。

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

根據香港法律規定（特別是第 486 章《個人資料（私隱）條例》），您享有或可享有確保您的個人資料保密的權利，例如在或為本研究中有關收集、監管、保留、管理、控制、使用（包括分析或比較）、轉進或轉出香港、不披露、清除和／或以任何方式處理或棄置的權利。如有任何問題，請您咨詢個人資料私隱專員或其職員（電話號碼：2827 2827），以瞭解妥善監控或監管您的個人資料保護之事宜，以確保您完整掌握和瞭解遵守規管個人資料私隱的法律之重要性。

14. Who To Contact if You Have Questions

14. 如果您有疑問可以聯絡

In case of any injuries during the course of study or you have questions about this research study, you may contact the Principal Investigator.

如果在本研究過程中遇到任何損傷，或您對這研究計劃有疑問，您可以聯絡首席研究者。

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Tel: 3943 5818 / 3943 5825/ 3943 5845/ 3943 5869

電話: 3943 5818 / 3943 5825/ 3943 5845/ 3943 5869

If you have any questions about your rights as a participant, you may contact Research Ethics Committee (Kowloon Central / Kowloon East)

Telephone no. : 35068888

Address : Block S, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon

若您對作為研究參與者權利有任何疑問，您可以聯絡九龍中及九龍東聯網臨床研究倫理委員會

電話 : 3506 8888

地址 : 九龍加士居道 30 號伊利沙伯醫院 S 座

INFORMED CONSENT FORM　知情同意書

Protocol Title: 方案題目:

An investigation of the effectiveness of Paul Glaucoma Implant (PGI) – a pilot study

Paul Glaucoma Implant (PGI) 有效性的調查試驗研究

I _____hereby consent to participate in the research study of "**An investigation of the effectiveness of Paul Glaucoma Implant (PGI) – a pilot study**".

本人 _____茲同意參與「**Paul Glaucoma Implant (PGI) 有效性的調查試驗研究**」。

I have read the **PARTICIPANT INFORMATION SHEET** and **INFORMED CONSENT FORM**. The study has been explained to me by investigator. I understood all the benefits and the risks associated with this study. I am not giving up any of my legal rights by signing this informed consent form. I have opportunities to ask questions to investigator and all my questions have been satisfactorily answered. I have received enough information about the study.
本人已細讀**參與者資料小冊子**及**知情同意書**。研究員已向本人詳細解釋研究的細節。本人明白所有有關本研究的好處及風險。本人沒有因簽署這知情同意書而放棄了任何法律權益。本人有機會向研究員提出疑問，而亦已完滿地解答本人的疑問。對於此研究，本人已獲得足夠的資料。

If the result of my participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer me for treatment.

若本人因參與本研究而引致任何身體不適或情緒上的波動，研究員將會為本人進行治療或轉介本人接受治療。

By signing this informed consent form, I certify that all information provided is true and correct. I consent to participate in this study and understand that my participation is voluntary and I have the right to withdraw at any time without having to give a reason for withdrawing and the withdrawal will not affect my present and future medical care.

因為簽署此知情同意書，証明本人提供的所有資料均為正確無誤。本人同意參與這項研究，本人的參與是自願的，本人有權在任何時間退出，而無須給予理由，同時不影響本人現在或日後所獲得的治療。

I ☐ agree / ☐ disagree to be contacted via phone or email to see my interest in participating relevant studies in future.

本人 ☐ 同意 / ☐ 不同意 就今後諮詢參與相關研究的興趣，以電話或電郵方式再進一步聯絡本人。

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my original research data for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

本人明白，本人之身份將獲得保密處理。本人亦允許臨床研究倫理委員會及有關法定機構在合適的條例及法例容許下及在不侵犯本人的私隱情況中，直接翻查本人的研究數據正本以核實臨床研究計劃之程式和/或資料。

Name of Participant （in BLOCK Letters） 參與者姓名（正楷）	Signature 簽署	Date 日期

Name of Impartial Witness （If applicable） （in BLOCK Letters） 公正見證人姓名（若適用） （正楷）	Signature 簽署	Date 日期

If participant is not able to read and write, signature of impartial witness is mandatory.
如果參與者沒有能力閱讀或寫字, 必須有公正見證人的簽署。

Name of investigator （in BLOCK Letters） 研究員姓名（正楷）	Signature 簽署	Date 日期

I will be given a participant information sheet and a signed copy of this informed consent form.

本人將會獲得一份參與者資料小冊子及這份已簽署的知情同意書副本。