國泰醫療財團法人國泰綜合醫院

CATHAY GENERAL HOSPITAL

(CATHAY MEDICAL FOUNDATION)

醫療器材臨床試驗受試者同意書

Medical Device Clinical Trial Informed Consent Form

本試驗已通過國泰綜合醫院人體試驗審查委員會審查，計畫編號：

This clinical trial has been reviewed and approved by the Institutional Review Board of Cathay General Hospital. Project Number:

計劃名稱：評估Airmod與Capnostream™35在呼吸速率監測上的非劣性與使用者經驗之臨床評估

Project Name: Evaluating the Non-Inferiority of Airmod to Capnostream™35 on Respiratory Rate Monitoring and User Experience Clinical Evaluation

計劃執行單位：

Execution Unit:

計劃贊助或委託單位：

Sponsor or Contracting Entity:

計劃主持人姓名：	職稱：	電話：
Principal Investigator Name:	Title:	Telephone:
協同主持人姓名：	職稱：	電話：
Sub-Investigator Name:	Title:	Telephone:
協同主持人姓名：	職稱：	電話：
Sub-Investigator Name:	Title:	Telephone:
研究人員姓名：	職稱：	電話：
Research Fellow Name:	Title:	Telephone:
研究人員姓名：	職稱：	電話：
Research Fellow Name:	Title:	Telephone:

研究人員姓名：　　職稱：　　電話：

Research Fellow Name:　　Title:　　Telephone:

24小時緊急聯絡電話：

24-Hour Emergency Contact Number:

受試者姓名：

Subject Name:

性別：　　出生日期：　　病歷號碼：

Sex:　　Date of Birth:　　Medical Record Number:

通信地址：

Mailing Address:

聯絡電話：

Contact Number:

法定代理人／有同意權人姓名：

Name of Legal Representative/Authorized Representative:

性別：　　出生日期：　　身分證字號：

Sex:　　Date of Birth:　　Identity Card Number:

通信地址：

Mailing Address:

聯絡電話：

Contact Number:

見證人姓名：

Name of Witness:

性別：　　出生日期：　　身分證字號：

Sex:　　Date of Birth:　　Identity Card Number:

通信地址：

Mailing Address:

聯絡電話：

Contact Number:

一、試驗用醫療器材全球上市現況簡介：

I. Overview of the Global Market Status of the Investigational Medical Device:

1. 醫療器材資料：商品名稱：「Airmod」(為尚未取得許可證之呼吸監測輔助軟體，於本研究搭配已取得衛福部上市許可(**衛部醫器製字第007347號**)之「正音電子聽診器」使用。

目前臨床常規之呼吸監測儀普遍使用於全身麻醉的病患用來監測呼吸相關參數，目前市面上之呼吸監測儀大多仰賴國外進口，本次研究使用之「Airmod」為國產之呼吸監測輔助軟體，可透過「正音電子聽診器」以蒐集與分析呼吸聲音，計算呼吸次數等來監測麻醉中病患之呼吸狀況。聿信醫療器材科技股份有限公司致力於開發重症領域與呼吸監測的醫材科技公司，希望未來可以將其產品販售至台灣本土及世界各地造福人群。

Medical Device Information:

Product Name: "Airmod" (Respiratory Monitoring Aided Software, which has not yet obtained a Medical Device License). Used in conjunction with the "AccurSound Electronic Stethoscope", which has received market approval from the Ministry of Health and Welfare (MOHW) (MOHW-MD-No.007347) for this study. The current clinical customary practice involves the widespread use of breath monitors in patients under general anesthesia to monitor respiratory-related parameters. Most of the breath monitors available in the market are imported from abroad. In this study, we are utilizing 'Airmod', a domestically developed software designed to aid in respiratory monitoring. It can collect and analyze respiratory sounds, calculate respiratory rates, and monitor the respiratory condition of patients under anesthesia using the "AccurSound Electronic Stethoscope". Heroic Faith Medical Science Co., Ltd. is committed to developing medical technology in the critical care field and respiratory monitoring. They aim to sell their products to both the domestic market in Taiwan and global populations in the future, contributing to the well-being of people worldwide.

2. 醫療器材上市狀況：

「Airmod」呼吸監測輔助軟體目前尚未在台灣及其他國家上市，而試驗過程中所搭配使用的「正音電子聽診器」(**衛部醫器製字第007347號**)以及使用之「比對品」(「美敦力凱諾辛攜帶式呼吸監測器」，衛部醫器輸字第032283號)，均為衛福部食品藥物管理署核可之醫療器材。

Market Status of the Medical Device:

The 'Airmod' respiratory monitoring aided software is currently not available on the market in Taiwan or any other country. However, the "AccurSound Electronic Stethoscope" (MOHW-MD-No.007347) used in conjunction during the trial, as well as the "Comparison Product" ("Medtronic" Capnostream 35 Portable Respiratory Monitor, WEI-BU-YI-QI-SHU-ZI-No.032283), are both approved medical devices by the Taiwan Food and Drug Administration, Ministry of Health and Welfare.

二、試驗目的：

本研究是一個台灣多中心非侵入性醫材之臨床評估研究，預計收納經麻醉前評估，適合靜脈全 身麻醉(IVG)、年齡 20 歲以上之受試者參與本臨床評估試驗研究，本院預計收案 100例，另於 行天宮醫療志業醫療財團法人恩主公醫院等試驗中心同步收案，台灣多中心收案加總合計共 300 例，並由馬偕紀念醫院麻醉部黃健中醫師擔任總計畫主持人。

II. Trial Objective:

This study is a multi-center clinical evaluation trial study of a non-invasive medical device in Taiwan. It is expected

to recruit participants who have undergone pre-anesthetic assessment, are suitable for intravenous general anesthesia (IVG), and are aged 20 years and older. The Hospital aims to enroll a total of 100 cases, with simultaneous enrollment taking place at trial centers such as En Chu Kong Hospital. In total, 300 cases will be recruited from multiple centers in Taiwan, and the project will be led by Dr. Huang Chien-Chung from the Department of Anesthesiology at Mackay Memorial Hospital, who serves as the Project Principal Investigator.

本研究的目的是驗證「Airmod」呼吸監測輔助軟體，搭配已取得衛福部上市許可之「正音電子聽診器」(**衛部醫器製字第007347號**)使用，在監測呼吸速率方面的性能整體效果是否與常規標準設備「Medtronic Capnostream 35 Portable Respiratory Monitor」(「美敦力凱諾辛攜帶式呼吸監測器」，衛部醫器輸字第032283號)，以下簡稱「比對品」，相近或更優。另為了提升照護品質確保安全，本研究亦將同步紀錄研究過程中來自「正音聽診器」的呼吸聲音與比對品的呼吸徵狀(如:哮喘音、痰音、呼吸道浸潤、積水、阻塞聲音、呼吸停止、呼吸道水腫)與生命徵象 相關事件進行後續分析，未來將應用於擴增「Airmod」之功能與提升分析準確度。

The purpose of this study is to validate the performance and overall effectiveness of the 'Airmod' respiratory monitoring aided software when used in conjunction with the 'AccurSound Electronic Stethoscope', which has obtained market approval from the Ministry of Health and Welfare (MOHW-MD-No.007347), in monitoring the respiration rate. The objective is to determine whether the performance of this combination is similar to or superior to that of the conventional standard equipment, the 'Medtronic Capnostream 35 Portable Respiratory Monitor' (referred to as the 'Comparison Product', WEI-BU-YI-QI-SHU-ZI-No.032283). To enhance the quality of care and ensure safety, this study will also concurrently record respiratory sounds from the 'AccurSound Electronic Stethoscope' and respiratory symptoms from the 'comparison product' (such as stridor, coarse rales, respiratory tract infiltrates, effusion, obstruction sound, respiratory arrest, respiratory tract edema) and vital signs-related events during the research process. These recordings will be subjected to subsequent analysis and will be applied to augment the functionality of 'Airmod' and improve the accuracy of analysis in the future.

主要目標：與「比對品」相比，評估「Airmod」測量之呼吸速率(RR)的準確性和效能。主要目標是確立相較於「比對品」之不劣性(不劣性代表不比「比對品」差，因此有可能跟比對品性能相似或是更優)。

Primary Objective: To assess the accuracy and performance of 'Airmod' in measuring Respiration Rate (airRR) compared to the 'comparison product'. The primary aim is to establish non-inferiority to the 'comparison product' (non-inferiority implies that 'Airmod' is not worse than the 'comparison product', hence, it may perform similarly or superiorly to the comparison product).

次要目標：

Secondary Objectives:

1. 在二氧化碳分析不敏感區段，與研究團隊依照紀錄收音做出之呼吸聲音畫記相比，評估 「Airmod」的準確度。

   In the CO_2 analysis insensitive section, the accuracy of 'Airmod' is evaluated by comparing it with the breathing sound recordings made by the research team, per the records.
2. 評估「Airmod」測量的呼吸速率與研究團隊在「比對品」二氧化碳圖畫記的呼吸速率的一致性。

   Evaluate the consistency between the respiration rate measured by 'Airmod' and Manual-scored Capnography (ManCRR).

3. 評估在呼吸中止狀況下實施拖顎法後，「Airmod」與「比對品」二氧化碳圖偵測到第一次呼吸的反應時間。

Evaluate the response time for detecting the first breath on both 'Airmod' and the CO_2 graph of the 'comparison product' after performing the jaw-thrust maneuver in cases of apnea.

4. 比較在不同呼吸頻率的受試者，由「Airmod」、研究團隊畫記和「比對品」所測量的呼吸速率監測的影響(以bpm為單位)。

Compare the impact on respiration rate monitoring (measured in bpm) among subjects with different respiratory frequencies, as measured by 'Airmod'(airRR), Manual-scored auscultation sound originated from AS-101(acoRR), and Machine-scored Capnography (CapRR) generated from Capnostream™35 (K150272, Medtronic).

5. 評估「Airmod」的安全性及可用性。

Evaluate the security and availability of 'Airmod'.

三、試驗之主要納入及排除條件：

3. Main Inclusion and Exclusion Criteria for the Trial:

納入條件：

Inclusion Criteria:

為了有資格參與本研究，個人必須滿足以下所有標準：

1. 提供簽署並註明日期的知情同意書。
2. 願意遵守並參與所有的研究流程。
3. 年齡須於20歲以上。
4. 經麻醉前評估，適合靜脈全身麻醉（IVG）。

To participate in this study, individuals must meet all of the following criteria:

1. Provide a signed and dated informed consent form.
2. Willingness to adhere to and participate in all research procedures.
3. Must be over the age of 20.
4. Suitable for intravenous general anesthesia (IVG) as determined by a pre-anesthetic assessment.

排除條件：

Exclusion Criteria:

1. 您存在頸部疼痛或受傷。
2. 您因醫療需求需使用高流量氧氣鼻導管。
3. 經醫師評估，您於事前或研究過程中無法佩戴「Airmod」和「比對品」設備相關配件。
4. 您因意識狀況、其他因素無法閱讀本同意書或研究人員無法確認您能充分理解本研究內容與相關風險。
5. 經醫師評估，您可能因疾病狀況或其他因素而無法完成研究程序或參與本研究可能有額外風險。

1. You currently have neck pain or injury.
2. You require the use of a High Flow Nasal Cannula (HFNC) for medical reasons.
3. A physician assesses that you are unable to wear the 'Airmod' and the 'comparison product's' related accessories during the study or beforehand.
4. You are unable to read the consent form or the research team cannot confirm your full understanding of the

study content and associated risks due to your mental state or other factors.

5. A physician assesses that you may not be able to complete the study procedures or participating in the study may pose additional risks due to your medical condition or other factors.

四、試驗方法及相關檢驗：

4. Methods and Related Procedures of This Trial:

本研究主要目的為驗證「Airmod」在監測呼吸速率方面的性能整體效果是否與常規標準設備「比對品」相近或更優，將於麻醉諮詢門診及住院病房收案，執行研究地點為手術室，於完成常規與例行之麻醉術前準備，經研究團隊確認「Airmod」及「比對品」佩戴並安裝完畢之後，由麻醉醫療團隊針對您欲進行的手術進行既定與常規例行之麻醉藥物注射，隨後由研究團隊開始監測呼吸紀錄，直至您於恢復室評估 PAR score 評估分數或 PADSS 達 9 分以上(PAR score、PADSS 均為麻醉術後評估工具的一種)，即結束監測呼吸紀錄。

The primary objective of this study is to validate the performance of 'Airmod' in monitoring respiration rate compared to the conventional standard equipment's 'comparison product'. Enrollment will occur at the Pre-Anesthesia Clinic and hospital wards, with the study being conducted in the operating room. Following the completion of routine and necessary pre-operative preparation and anesthesia, and after the research team confirms the proper placement and setup of both 'Airmod' and the 'comparison product', the anesthesiology team will carry out the established and routine injection anesthesiology for your surgery. Subsequently, the research team will begin monitoring breathing records until your assessment in the Recovery Room reaches a score of 9 or above on either the PAR score or PADSS system (both are post-anesthesia evaluation tools). At this point, the monitoring of breathing records will conclude.

試驗操作步驟：

Trial Procedures:

1. 研究團隊將於門診麻醉諮詢或住院麻醉評估時，針對符合納入排除條件之受試者向其簡介本研究並徵詢參與本研究之意願，如其有意願參與本研究，研究團隊將依據同意書內容向您進行說明，並提供您足夠的時間考慮或跟家人討論後再依您個人意願簽署受試者同意書，若諮詢當中無法完成同意書簽署，則可於手術前任一時間繳交給研究護理師，即可納入試驗，並由研究護理師填寫個案報告表。
   During the pre-anesthesia clinic consultation or anesthetic assessment for admission to a hospital ward, the research team will introduce this study to subjects who meet the inclusion and exclusion criteria, and inquire about their willingness to participate. If they are willing, the team will explain the study based on the consent form content and give them ample time to consider or discuss with their family before signing the Subject Informed Consent Form. If the consent form cannot be signed during the consultation, it can be submitted to the clinical research nurses at any time before surgery to be enrolled in the trial. The clinical research nurses will then complete the case report form (CRF).
2. 於試驗開始前在不影響原術式的流程與處置下，研究團隊須為您安裝穿戴「Airmod」及「比對品」。
   Before the start of the trial, without affecting the flow and handling of the original surgical method, the research team must install and fit you with 'Airmod' and the 'comparison product'.

「 Airmod」安裝要求為：

'Airmod' Installation Requirements:

A. 將裝有「Airmod」之Android設備與「正音電子聽診器」連接。

B. 將「正音電子聽診器」之聽診貼片放在您的頸部（左側或右側甲狀腺軟骨的平面區），用手術膠帶固定(如下方圖示)。

C. 點擊 Android 設備螢幕上的「Airmod」，進入軟體介面。當Android設備和「正音電子聽診器」正確連接後，出現指示燈，即可點擊開始按鈕開始監測。

D. 透過點擊開始/停止按鈕，立即透過揚聲器和顯示螢幕分別呈現呼吸聲和頻譜圖，如果訊號或接收不穩定，可調整聽診貼片或用手術膠帶固定改善。

A. Connect the Android device with the 'Airmod' to the 'AccurSound Electronic Stethoscope.'

B. Place the auscultation adhesive patches of the 'AccurSound Electronic Stethoscope' on your neck (either on the left or right side of the thyroid cartilage plane area) and secure it with surgical tape as shown in the diagram below.

C. Tap the 'Airmod' app on the Android device to enter the software interface. When the Android device and the 'AccurSound Electronic Stethoscope' are correctly connected, an indicator light will appear, and you can then press the start button to begin monitoring.

D. By clicking the start/stop button, the breathing sound and spectrum map will be displayed immediately through the speakers and display screen respectively. If the signal or reception is unstable, adjust the position of the auscultation adhesive patches or secure them with surgical tape to improve the connection.

「比對品」安裝要求為：

Installation Requirements for the 'Comparison Product':

A. 確認「比對品」應有足夠的電量，足以維持整個研究過程。

B. 在監測顯示螢幕上，選擇選單→操作→患者管理→插入受試者編號。

C. 將採樣線連接到監測儀上，順時針擰到不能再轉動為止並同時將採樣線連接到您的鼻孔 上，調整下帶處的鬆緊度，讓您感受到舒適與服貼(如下方圖示)。

D. 將血氧夾接頭端連接到監測儀上，同時用血氧夾夾住您的手指。

E. 連接正確後，監測儀會立即開始偵測呼吸，3.4～5.0 秒後在顯示螢幕上顯示 EtCO2值和波形及SpO2數值。

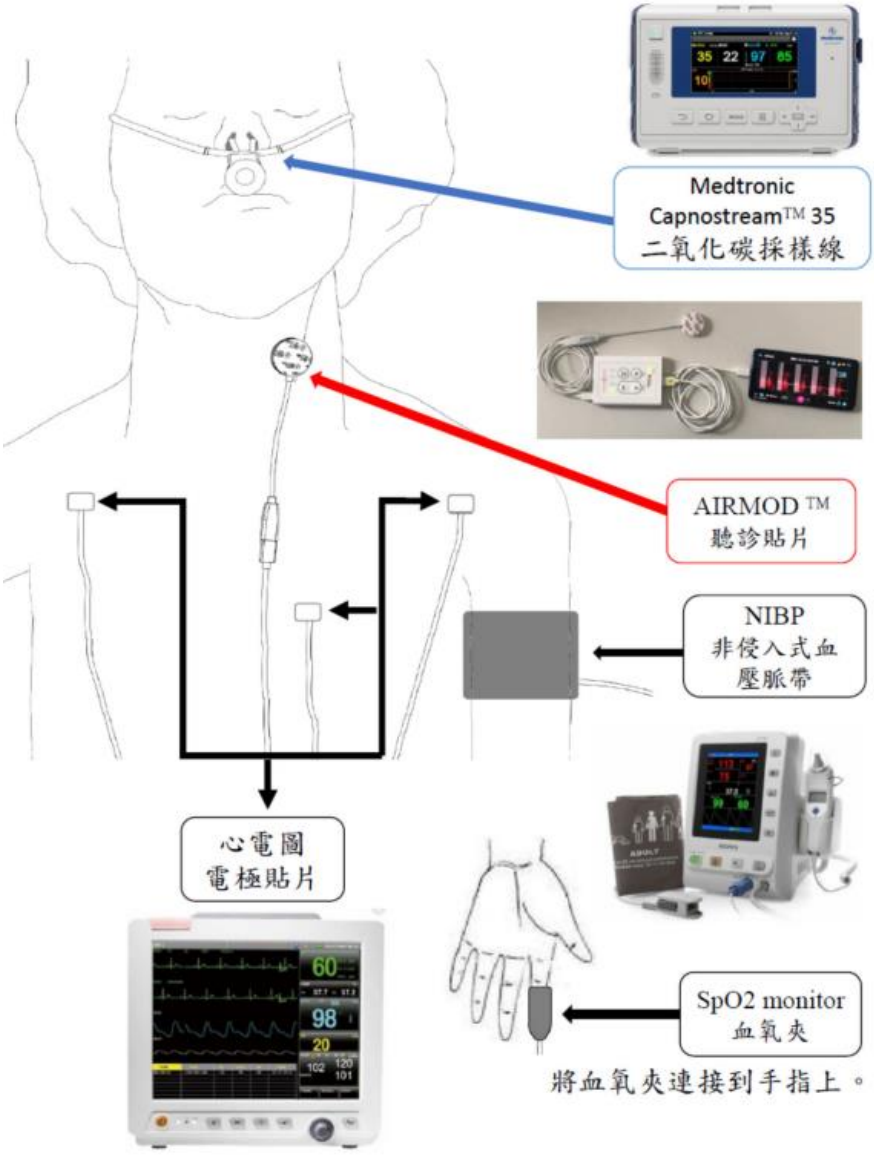
A. Ensure that the 'comparison product' has sufficient battery power to last the entire duration of the study.

B. On the display screen of the monitor, select menu → operate → patient management → insert subject number.

C. Connect the sampling line to the monitor and twist it clockwise until it can no longer be rotated. Attach the sampling line to your nostril, adjusting the tightness of the strap for comfort and a secure fit (as shown in the diagram below).

D. Connect the oximeter clips to the breath monitor and attach the clip to your finger.

E. Once correctly connected, the breath monitor will immediately start detecting breathing. After 3.4 to 5.0 seconds, the $EtCO_2$ value and waveform, as well as the SpO_2 value, will be displayed on the screen.



將採樣線連接到鼻孔上，並調整下帶處的鬆緊度。
將聽診貼片貼附於頸部（左側或右側甲狀軟骨的凹陷平坦處的平面區）

3. 研究護理師會於常規例行麻醉藥物第一輪注射後、完成麻醉誘導之時開始紀錄，直到術後跟隨您至麻醉恢復室，評估PAR score或PADSS達9分以上時，即結束紀錄。(如手術過程當中，醫師評估生命徵象不穩，須採取如LMA(laryngeal mask airway，喉罩呼吸道)或插管等緊急事件時，將會以緊急醫療需求為優先，並終止本研究，而終止前已收集取得的資訊，仍將會納入供作本研究分析之使用。
   Clinical research nurses will begin recording immediately after the first round of anesthetic injection and the completion of induced anesthesia. They will continue to follow you to the Post-Anesthesia Recovery Room and record until your PAR score or PADSS reaches 9 points or above, at which point the recording will end. If, during the surgery, the doctor assesses that your vital signs are unstable and emergency procedures such as LMA (laryngeal mask airway) or intubation are required, the study will be terminated in favor of emergency medical needs. However, any data collected before the termination will still be included for analysis in this study.
4. 研究護理師會將試驗開始到試驗結束過程監測到的各項結果填入個案報告表，而「Airmod」和「比對

品」錄製的呼吸聲及頻譜圖之電子檔案，則會儲存至加密過的SD卡或隨身硬碟中。

Clinical research nurses will fill in the results monitored from the start to the end of the trial into the case report form (CRF). The electronic files of the breathing sounds and spectrum maps recorded by 'Airmod' and the 'comparison product' will be stored on an encrypted SD card or USB flash drive.

5. 研究護理師會將個案報告表及SD卡或隨身硬碟繳交給計畫主持人檢視比對，若確認無誤，計畫主持人將會於個案報告表上簽名，並統一保存至辦公室內之上鎖的檔案櫃中。

Clinical research nurses will submit the CRF along with the SD card or USB flash drive to the Principal Investigator for review and comparison. If everything is confirmed to be correct, the Principal Investigator will sign the CRF and store it securely in a locked file cabinet in the office.

6. 研究團隊於此試驗結束後，須填寫紀錄與問卷。

After the conclusion of this trial, the research team is required to fill out records and questionnaires.

7. 本研究蒐集的呼吸監測數據分析後，測試結果僅做為本臨床評估研究之用，不做為任何診斷的依據，相關診斷與判讀之仍以本院常規之麻醉監測儀器為主。

After the analysis of the respiratory monitoring data collected in this study, the test results will only be used for this clinical evaluation research and will not serve as a basis for any diagnosis. Diagnosis and interpretation will still primarily rely on the standard anesthesia monitoring equipment used by this institution.

8. 後續數據處理：

Subsequent data handling will be as follows:

A. 本研究收集之個案報告表，將分類並保存於計畫主持人辦公室上鎖的檔案櫃中。

B. 「Airmod」和「比對品」所錄製的呼吸聲及頻譜圖之電子檔案將會儲存於加密過後的SD卡或隨身硬碟，如需開啟電子檔案，則會以加密之電腦設備開啟。

C. 參與研究之團隊成員會對您的個人健康和試驗相關資料保密。

D. 與您相關之所有紙本文件及存有電子檔案之加密SD卡或隨身硬碟，將與受試者同意書分別存放於計畫主持人辦公室上鎖的檔案櫃中，並將其保存至試驗結束且產品上市5年後銷毀。

A. The case report forms collected in this study will be categorized and stored in a locked file cabinet in the Principal Investigator's office.

B. The electronic files of the breathing sounds and spectrum maps recorded by 'Airmod' and the 'comparison product' will be stored on encrypted SD cards or USB flash drives. To access these electronic files, encrypted computer equipment will be used.

C. The research team members involved in the study will maintain confidentiality regarding your health information and trial-related data.

D. All paper documents related to you and encrypted SD cards or USB flash drives containing electronic files, along with the Subject Informed Consent Forms, will be separately stored in a locked file cabinet in the Principal Investigator's office and will be preserved until five years after the trial's completion and the product's market launch, after which they will be destroyed.

五、可能產生之副作用、發生率及處理方法：

5. Possible Side Effects and Their Incidence and Countermeasures:

1. 與試驗藥物/醫療器材相關的副作用(風險)發生率與處理方法

Side effects (risks) associated with the trial drug/medical device: Possible incidence and countermeasures

A. 「Airmod」為非侵入性之呼吸監測輔助軟體，可透過分析呼吸聲音，計算呼吸次數等來 監測麻醉中病患之呼吸狀況。「Airmod」為呼吸監測輔助軟體，不會直接與人體接觸。

'Airmod' is a non-invasive respiratory monitoring aid software, capable of analyzing breathing sounds and calculating the number of breaths to monitor the respiratory status of patients under anesthesia. As an aid software for respiratory monitoring, 'Airmod' does not come into direct contact with the human body.

B. 搭配使用之「正音電子聽診器」、手術膠帶、相關監測設備之貼片或夾點因與皮膚接觸有可能因個人體質會造成輕度皮膚刺激或不適(例如：發紅、瘙癢、皮疹、壓力或壓迫感)，若有不適，研究團隊將會依照您當下的狀況給予適當之處置，並暫停研究程序以評估您的狀況是否恢復。

The use of the 'AccurSound Electronic Stethoscope', surgical tape, adhesive patches, or fixtures from related monitoring equipment, due to skin contact, may cause mild skin irritation or discomfort in some individuals (such as skin redness, pruritus, rash, stress, or a feeling of pressure). If discomfort occurs, the research team will provide appropriate management based on your condition at the time and will temporarily suspend the research procedures to assess whether your condition has improved.

C. 「正音聽診器」與「比對品」等設備，因需以電力維持運作，因此可能有與家用電器設備相似之電性、火、電磁波等危害狀況，但醫療器材應用於醫療場域與上市前均需完成較家用產品嚴格之醫材電性安全、電磁相容性等等測試，其風險相對於家用產品較低，且研究團隊於操作前均會測試產品之功能正常，會盡力確保相關之設備之安全性，並確認有適當之備用設備與因應方案，以盡力將您的風險降低致與常規醫療風險相符。

Devices such as the 'AccurSound Electronic Stethoscope' and the 'comparison product' require electricity to operate, and therefore may pose hazards similar to household electrical appliances, including electrical properties, fire, and electromagnetic waves. However, medical devices are subjected to stricter electrical safety and electromagnetic compatibility tests than household products before they are used in medical settings and launched on the market. Thus, their risks are relatively lower compared to household products. The research team will test the functionality of these products before use to ensure their safety and will have appropriate backup equipment and contingency plans in place to minimize your risk to a level comparable with conventional medical risks.

D. 本臨床研究中使用的「比對品」是美敦力公司(Medtronic)的一款市售便攜式呼吸監測儀。上市以來，該公司並未發現該產品存在任何重大問題，在本臨床研究中，該產品均依循其原廠說明書之標準操作規範使用。

The 'comparison product' used in this clinical study is a commercially available portable breathing monitoring recorder from Medtronic. Since its launch, the company has not identified any major issues with this product. In this clinical study, the product is used under the standard operating procedures outlined in its manufacturer's instructions.

E. 此試驗不涉及、不影響受試者常規之檢查、診斷、治療與追蹤，其對病患造成之傷害風險極低。如發生故障等狀況，試驗委託者將提供備用器材取代。

This trial does not involve or affect the subjects' routine examinations, diagnoses, treatments, and follow-ups. The risk of harm to patients is extremely low. In the event of a malfunction or similar situation, the trial sponsor will provide replacement equipment.

2. 與試驗過程相關的副作用(風險)發生率與處理方法

Side Effects (Risks) Associated with the Trial Procedure, Possible Incidence and Countermeasures:

A. 在整個研究過程中，不會干涉您既有的常規麻醉程序與藥物使用，研究團隊與相關專業醫護人員會依循臨床常規完成您的麻醉過程與後續之麻醉評估，您於研究過程中遭遇之風險與不參與研究相符。

Throughout the entire research process, there will be no interference with your existing standard anesthesia procedures and medication use. The research team and relevant healthcare professionals will follow clinical protocols to complete your anesthesia process and subsequent anesthesia assessment. The risks you may encounter during the research process will not differ from those not participating in the study.

六、本疾病相關之其他替代療法及說明：

6. Alternative Treatments and Explanations Related to this Disease:

本研究為非侵入性醫材之臨床評估試驗研究，不涉及、不影響受試者常規之檢查、診斷、治療與追蹤，但您有權利不參與本研究，參加與否不會影響您的醫療照護。

This study is a Clinical Evaluation Trial Study of a non-invasive medical device. It does not involve or affect the participants' routine examinations, diagnoses, treatments, or follow-ups. However, you have the right to choose not to participate in this study, and your decision will not have any impact on your medical care.

七、試驗預期效益：

7. Anticipated Trial Benefits:

期望本研究中之目標產品「Airmod」在監測呼吸速率方面的性能整體效果能與常規標準設備「比對品」相近或更優。

The expected goal of this research is that the performance and overall effectiveness of the target product 'Airmod' in monitoring respiration rate should be comparable to or even superior to that of conventional standard equipment, which serves as the reference or 'comparison product'.

八、試驗進行中受試者之禁忌、限制與應配合之事項：

8. Contraindications, Restrictions and Requirements for Participants During the Trial:

本研究為非侵入性醫材之臨床評估研究，研究過程不影響您的治療，無禁忌、限制或應配合事項，唯因研究過程中需配戴「正音電子聽診器」與「比對品」，需要以貼片與夾點感測訊號，並以手術膠帶固定，若您屬於易過敏之體質或是曾有藥疹或異位性皮膚炎之病史，請及早告訴研究團隊，以利研究團隊與您討論後續之因應方案。

This study is a Clinical Evaluation Study of a non-invasive medical device. The research process will not affect your treatment, and there are no contraindications, restrictions, or specific requirements to adhere to. However, during the research process, you will need to wear the 'AccurSound Electronic Stethoscope' and the 'comparison product', which require the use of adhesive patches or fixtures for signal sensing, secured with surgical tape. If you have a history of being easily allergic or have had drug eruptions or atopic dermatitis, please inform the research team promptly. This will allow the research team to discuss appropriate measures for your participation.

九、機密性：

9. Confidentiality:

國泰綜合醫院將依法把任何可辨識您的身分之記錄與您的個人隱私資料視為機密來處理，不會公開。研究人員將以一個研究代碼代表您的身分，此代碼不會顯示您的姓名、國民身分證、統一編號、住址等可識別資料。如果發表試驗結果，您的身分仍將保密。您亦瞭解若簽署同意書即同意您的原始醫療紀錄可直接受監測者、稽核者、本院人體研究倫理審查委員會及主管機關檢閱，以確保臨床試驗過程與數據符合相關法律及法規要求，上述人員並承諾絕不違反您的身分之機密性。

Cathay General Hospital will abide by the law to keep the confidentiality of any record containing your

identification and your personal private information, and will not disclose it. The research staff will assign you a research code, and this code will not show any identifiable information such as your name, identification number, or address. In the event that trial results are published, your identification will continue to be kept confidential. You also understand that by signing this consent form, you are approving the direct use of your original medical records by the monitors, auditors, (the name of the hospital IRB) and the competent authorities, to ensure that the clinical trial is conducted and data are collected following applicable laws and regulations. The aforementioned personnel guarantee the confidentiality of your identity will not be violated.

十、賠償與保險：

10. Compensation and Insurance:

1. 如您參與本臨床試驗，因發生不良反應造成損害，由**聿信醫療器材科技股份有限公司**負補償責任。但本受試者同意書上所記載之可預期不良反應，不予補償。
   If you are a participant, Heroic Faith Medical Science Co., Ltd. will bear liabilities for compensation of damages caused by the adverse events resulting from following the protocol designed for this clinical trial. However, no compensation will be made concerning the expected adverse events described in this Informed Consent Form.
2. 如依本研究所訂臨床試驗計畫，因而發生不良反應或損害，本院(國泰醫院)願意提供專業醫療照顧及醫療諮詢。您不必負擔治療不良反應或損害之必要醫療費用。
   The hospital (Cathay General Hospital) will provide professional medical care and consultations for adverse events or damages resulting from following the protocol designed for this clinical trial. You will not be responsible for the necessary medical expenses concerning the treatment of the adverse events or damages.
3. 除前二項補償及醫療照顧外，本研究不提供補償。若您不願意接受這樣的風險，請勿參加試驗。
   This trial does not provide compensation in any form other than the compensation and the medical care outlined in the above 2 points. If you do not accept this level of risk, please do not participate in the trial.
4. 您不會因為簽署本同意書，而喪失在法律上的任何權利。
   You will not lose any legal rights under your signing of this Informed Consent Form.
5. 本試驗■有投保責任保險□未投保責任保險。
   This trial ■ is covered by liability insurance □ is not covered by liability insurance.

十一、受試者權利：

11. Rights and Interests of the Subject:

1. 本試驗不會向您收取試驗有關之任何費用，本試驗不在全民健康保險之給付範圍。
   This trial will not charge you any fees related to the trial, and it is not covered by the National Health Insurance.
2. 試驗過程中，與您的健康或是疾病有關，可能影響您繼續接受臨床試驗意願的任何重大發現，都將即時提供給您。
   During the trial, any significant findings related to your health or the disease that may impact your willingness to continue participating in the clinical trial will be promptly communicated to you.
3. 如果您在試驗過程中對試驗工作性質產生疑問，對身為受試者之權利有意見或懷疑因參與

研究而受害時，您可以與國泰綜合醫院人體試驗審查委員會（這是一個為保護研究受試者而成立的委員會）聯絡請求諮詢，其電話號碼為：02-27082121 轉 6984；傳真號碼為：02-66369260；e-mail：irb@cgh.org.tw。

If in the process of your participation, you have any questions or concerns about the nature of the clinical trial or if you believe that your rights as a subject are being violated, or have concerns about any harm you may have experienced due to participation in the research, you may contact the Institutional Review Board of the Cathay General Hospital (A Committee established to protect research subjects) for consultation. You can reach them at the following contact information: Phone: 02-27082121 ext. 6984; Fax: 02-66369260; Email: irb@cgh.org.tw.

4. 如果你(妳)現在或於試驗期間有任何問題或狀況，請不必客氣，可與在國泰醫院麻醉科的 XXX 醫師聯絡。(24 小時聯繫電話: 09xxxxxxxx)。

If you have any questions or concerns now or during the trial, please do not hesitate to contact Dr. XXX from the Anesthesiology Department at Cathay General Hospital. (24-hour contact number: 09xxxxxxxx).

5. 本同意書一式兩份，醫師已將同意書副本交給您，並已完整說明本研究之性質與目的。研究團隊已回答您有關醫療器材與研究的問題。

This consent form is provided in two copies. The physician has provided you with one copy of the signed consent form and has thoroughly explained the nature and objectives of this research. The research team has also addressed any questions you may have had regarding the medical device and the study.

十二、試驗之退出與終止/中止：

12. Withdrawal / Termination / Suspension of the Trial:

1. 受試者於試驗施行期間中，可隨時無條件撤回同意，退出試驗。不需任何理由，且不會引起任何不愉快或影響其日後醫師對您的醫療照護。試驗主持人或贊助廠商亦可能必要時中止/終止本試驗進行。

During the implementation of the trial, subjects have the right to unconditionally withdraw their consent and exit the trial at any time, without the need to provide any reasons. This withdrawal will not result in any discomfort or impact on their future medical care from their physician. Additionally, the Principal Investigator or the Trial Sponsor may also, if necessary, suspend or terminate the clinical trial.

2. 本試驗為觀察性試驗 無介入臨床處置，受試者退出試驗後即回歸醫療常規，並不在試驗中進行追蹤檢查。

This trial is an observational trial with no interventional clinical procedures. After a participant withdraws from the trial, he/she will return to regular medical care, and there will be no further follow-up examinations conducted as part of the trial.

3. 當受試者退出本研究或主持人判斷受試者不適合繼續參與本研究時，在退出前已得到的資料將被保存於上鎖的檔案櫃中，由試驗主持人負責保管，待試驗結束且產品上市後 5 年後銷

毀，納入分析。且受試者退出後即不再繼續收集受試者的資料。

If the subject decides to withdraw from the trial, or if the Principal Investigator determines that the subject is no longer suitable to participate in this study, the data collected before the withdrawal will be securely stored in a locked filing cabinet. The Principal Investigator will be responsible for safeguarding the data. These data will be retained for analysis until five years after the trial concludes and the product is on the market, after which they will be destroyed. Furthermore, no additional data will be collected from the subject after his/her withdrawal.

十三、簽名頁

13. Signature Page

本人 試驗主持人/協同主持人/授權之研究人員 已詳細解釋有關本臨床試驗中研究方法的性質與目的，以及可能產生的危險與利益，並且已回答受試者針對本臨床試驗所提出的問題。

The Principal Investigator/Sub-Investigator or their authorized personnel has provided a comprehensive explanation of the nature and objectives of the research method outlined in this protocol, as well as the potential risks and benefits. Additionally, any questions raised by the subjects regarding this clinical trial have been addressed.

受試者同意書解說人簽名：_____

Signature of the Person Explaining the Subject Informed Consent Form:

_____

日期：_____年___月___日

Date:_____

試驗主持人／協同主持人 簽名：_____

Signature of the Principal Investigator/Sub-Investigator: _____

日期： _____年___月___日

Date: _____

受試者已詳細瞭解本臨床試驗的研究方法，以及其所可能產生的危險與利益；此外，針對本臨床試驗所提出的問題，試驗研究人員已經詳細予以解釋。

I fully understand the research method outlined in this clinical trial, as well as the potential risks and benefits associated with it. Additionally, the trial investigators have provided comprehensive explanations in response to my questions about the clinical trial.

本人同意接受成為本臨床試驗計畫的自願受試者。

I agree to voluntarily participate as a subject in this clinical trial program.

受試者簽名：_____

Signature of the Subject: _____

日期：_____年___月___日

Date: _____

與受試者之關係（須勾選） 1.□父母 2.□監護人

Relationship with the Subject (please tick) 1.□Parents 2.□Legal Guardian

法定代理人簽名/有同意權人簽名：_____

Signature of Legal Representative/Authorized Representative: _____

日期： 年 月

Date: _____

茲見證下列事項：

□ 立同意書人無法閱讀，經解釋已確切了解本同意書內容。

Hereby witnessing the following:

☐ The person signing this consent form is unable to read, but after explanation, has fully understood the content of this consent form.

見證人簽名：_____

Signature of Witness: _____

日期：_____年____月____日

Date: _____

*接受試驗者為**限制行為能力人**，應得其本人與法定代理人同意；接受試驗者為**無行為能力人**，應得其法定代理人同意。法定代理人若簽署本文件即謂已詳細瞭解如下人體試驗管理辦法第五條（參如下）。並於簽署時，已自行確認是符合簽署次序，若不符合簽署次序而簽署者，所致同意書失效，*

應負相關法律責任。〔若您已經排除這類受試者(排除條件載明)，本項次可以自行刪除。〕
The trial participant is a person limited in disposing capacity and requires the consent of both the participant and his/her legal representative. If the trial participant is incapable of disposing, the consent of his/her legal representative is necessary. If the legal representative signs this document, it is presumed that they have thoroughly understood Article 5 of the Regulations on Human Trials (refer below). At the time of signing, the legal representative has independently confirmed that they comply with the signing order. If the signing order is not followed, and the document is signed by someone who does not meet the signing order, the consent form will be considered invalid, and the individual will bear legal responsibility accordingly. [If you have already excluded such participants (as specified in the exclusion criteria), you may delete this section as needed.]

人體試驗管理辦法第五條

Article 5 of the Regulations on Human Trials

依本法第七十九條第一項但書召募之成年或已結婚未成年之受試者，主持人應依下列順序取得其關係人之同意：

Concerning the adult or minor but married Trial Subject recruited by the proviso of Paragraph 1, Article 79 of this Act, the trial conductor shall obtain the consent of his/her interested party in the following priority order:

一、配偶。
二、父母。
三、同居之成年子女。
四、與受試者同居之祖父母。
五、與受試者同居之兄弟姊妹。
六、最近一年有同居事實之其他親屬。

1. *Spouse*
2. *Parent*
3. *Cohabiting adult child*
4. *Cohabiting grandparent*
5. *Cohabiting brother or sister*
6. *Any relative who has cohabited with the Trial Subject within the past one year*

前項關係人之同意，不得違反受試者曾表示之意思。

The consent of the interested party outlined in the preceding paragraph shall not be against the Trial Subject's will.

人體研究法第 12 條：研究對象為胎兒時，第一項同意應由其母親為之；為限制行為能力人或受輔助宣告之人時，應得其本人及法定代理人或輔助人之同意；為無行為能力人或受監護宣告之人時，應得其法定代理人或監護人之同意；為第一項但書之成年人時應依下列順序取得其關係人之同意：

一、配偶。
二、成年子女。
三、父母。

四、兄弟姊妹。

五、祖父母。

依前項關係人所為之書面同意，其書面同意，得以一人行之；關係人意思表示不一致時，依前項各款先後定其順序。前項同一順序之人，以親等近者為先，親等同者，以同居親屬為先，無同居親屬者，以年長者為先。

Article 12 of the Human Subjects Research Act: Where the research subject is a fetus, the consent specified in the first Paragraph shall be obtained from the mother; where the subject has been judicially declared to be of limited legal capacity or under assistance, consent shall be obtained from both the individual and their legal representative or assistant; where the person is incompetent or under guardianship, consent shall be obtained from their legal representative or guardian; where the proviso in the first paragraph is applicable, consent shall be obtained in the following order of precedence from an appropriate relation:

1. A spouse

2. An adult child

3. Parents

4. Siblings

5. Grandparents

Where the consent is provided in writing by a relation according to the preceding paragraph, such written consent may be sufficient where obtained from any such individual; where the express intent of such persons is not unanimous, the order of precedence above shall apply to determine the matter. In the preceding order of precedence, among the same order, closer relatives shall be accorded priority; where the relatives are of the same degree of closeness, cohabitation shall be accorded priority; and in case of non-cohabiting relatives, the elderly shall be accorded priority.

研究參與者須知

Information for Research Study Participants

親愛的病友、家屬、民眾您好：在就醫時，您有可能會被邀請參與臨床試驗/研究計畫，這封信是向您說明我們為了保障您參與的安全所做的一些努力，包括設有研究倫理委員會，專門針對臨床試驗/研究計畫進行審查，以確定計畫主持人會充分知會您有關臨床試驗/研究的過程，也會確保您參與這些臨床試驗/研究計畫的各項權 益保障，以便您在完全知情的情況下選擇參與這些臨床試驗/研究計畫。當然，在參與試驗/研究的過程中，您有任何不清楚之處，也應該隨時詢問研究人員。以下是一些本院人體試驗審查委員會進行審查的程序，提供給您參考。

Dear Patients, Family Members, and the Public

When seeking medical care, you may be invited to participate in clinical trials or research projects. This letter is to explain the efforts we undertake to ensure your safety in these endeavors. This includes the establishment of a Research Ethics Committee, which specializes in reviewing clinical trials and research projects. The committee's purpose is to ensure that project leaders fully inform you about the processes involved in clinical trials or research and safeguard your rights and interests when participating in these endeavors. This ensures that you can make an informed decision about your participation. Of course, if you have any questions or concerns during your participation in the trials or research, you should feel free to ask the research personnel. Below are some procedures that our Institutional Review Board follows during the review process, provided for your reference.

1. 國泰醫院執行的臨床試驗/研究計畫會經過審查嗎？如何審查？

Will the clinical trials/research projects conducted by Cathay General Hospital be reviewed? How is the review conducted?

(1)在國泰醫院執行的人體研究，都需要經過國泰醫院人體試驗審查委員會的審查，通過了才可執行。如果是需要政府衛生主管機關審查的人體試驗計畫，也必須通過衛生署審查才可執行。

All Human Subjects Research conducted at Cathay General Hospital requires review by the Institutional Review Board (IRB) of Cathay General Hospital before it can proceed. If the human research study requires review by government health authorities, it must also pass the review conducted by the National Health Administration before it can be carried out.

(2)國泰醫院人體試驗審查委員會由一群醫事專業人員、法律專家、社會工作人員及其他社會公正人士所組成，負責審查研究計畫是否符合倫理及法規。送到委員會的每件研究計畫，都會經由委員/專家以獨立、專業且謹慎的態度進行審查，審查內容包含試驗/研究的風險及好處、參加者的照護與隱私是否受到保護等。如果計畫的風險超過最低風險，也就是參加試驗對身體或心理造成不適的程度高於您在一般日常生活中、身體或心理的例行檢查所遇到的危險性，都需要提到委員會議上進行審查及討論，計畫須符合審查項目，才可通過執行。

The IRB of Cathay General Hospital is composed of a group of health professionals, legal experts, social workers, and other individuals committed to social justice. They are responsible for reviewing research proposals to ensure compliance with ethical and legal standards. Each research proposal submitted to the committee undergoes an independent, professional, and thorough review by committee members and experts. The review process includes evaluating the risks and benefits of the trial/research, as well as assessing the protection of participants' care and privacy. If a research project presents risks beyond minimal risk, meaning that participating in the trial involves a higher level of risk to your physical or psychological well-being compared to the risks encountered in routine physical or psychological examinations in your daily life, it will be brought to the committee for review and discussion. The project must meet the review criteria to be approved for execution.

(3)一旦試驗/研究計畫通過後，委員會也會針對通過的計畫持續監督，以確定研究團隊確實按照通過的計畫書妥適執行，為您做好參與研究權益把關的工作。

Once a trial/research project is approved, the committee also continues to monitor the approved project to ensure that the research team is effectively implementing the approved protocol, thereby safeguarding your rights and interests as a research study participant.

2. 國泰醫院人體試驗審查委員會如何審查臨床試驗/研究的潛在風險與利益？

How does the IRB of Cathay General Hospital review the potential risks and benefits of clinical trials/research studies?

(1)在進行臨床試驗/研究審查時，研究倫理委員會將評估這些試驗/研究計畫對於參與研究者可能造成的風險有哪些？有些風險是屬於身體上的疼痛、不適，有些則帶來心理上的不舒服，有些甚至對於您的社會及經濟方面造成影響，國泰醫院人體試驗審查委員會就是要去確保這些風險帶來的傷害已經盡力降到最小。

When reviewing clinical trials/research, the Research Ethics Committee assesses the potential risks that these research plans may pose to the research participants. Some of these risks may involve physical pain or discomfort, while others may cause psychological discomfort. In some cases, there could even be social and economic impacts. The primary objective of the Institutional Review Board of Cathay General Hospital is to ensure that every effort has been made to minimize the harm caused by these risks to the participants.

(2)除了風險，人體試驗審查委員會會也會去評估參與研究者從試驗/研究中預期或期望得到的好處，這項試驗可能會治癒疾病、可能不會痊癒疾病但可能改善受試者的生活品質、或對參加的人可能不會有好處，但對醫學研究的進步或對未來患有相同疾病的人發現新的治療方式而有所貢獻。委員會將綜合評估每個研究計畫的風險相對於獲得的好處是不是合理，以決定是否通過該計畫，風險大而對受試者或科學知識沒有任何好處的研究，將不會通過委員會的審查。

In addition to evaluating risks, the Institutional Review Board also assesses the potential benefits that research participants anticipate or hope to gain from the trial/research. The trial may have the potential to cure a disease, improve the quality of life, or contribute to medical research and the development of new treatments for future individuals with the same condition. The Board conducts a comprehensive assessment of whether the risks associated with each research plan are reasonable concerning the benefits expected to be gained. This evaluation helps determine whether the project is approved. Research that

carries significant risks without providing benefits to participants or contributing to scientific knowledge may not pass the Board's review.

3. 什麼是「知情同意」呢?

What is "informed consent"?

在參加任何的試驗/研究計畫前，您應該先充分的瞭解研究人員向您所說明的各項試驗相關資訊，並在完全瞭解後正式簽署一份同意書，才算在「知情同意」的情況下參與研究。以下就是「知情同意」的程序，提供您參考。

Before participating in any trial or research project, you should thoroughly understand the information provided by the researchers about the trial and formally sign a consent form only after you have fully comprehended the details. This process constitutes an "informed consent". Below are the steps involved in the “informed consent” procedure for your reference.

(1)請您在取得受試者同意書時務必詳細閱讀，並盡量向研究人員提出有關試驗/研究的疑問，確認以下幾件事情：您需要知道加入後所需配合的事項(例如：隔多久要回診一次?做什麼檢查?每次要抽多少血?不能做的事有哪些？例如不能開車、不能懷孕等)、可能的副作用與風險、以及對個人的好處及預期效果等。根據規定，這些臨床試驗/研究主持人或研究團隊成員都有責任一一回覆您所提出的各項疑問。

Please be sure to carefully read the Subject Informed Consent Form when obtaining it and make an effort to ask the researchers any questions you may have regarding the trial or research. Confirm the following aspects: You need to know what is expected of you after joining (e.g., how often you need to return for follow-up appointments, what tests will be conducted, how much blood will be drawn, and any restrictions like not driving or getting pregnant). You should also inquire about possible side effects and risks, as well as the personal benefits and expected outcomes. According to regulations, the clinical trial/research’s Principal Investigator or team members are responsible for addressing all the questions you raise.

(2)在充分了解前述資訊後，請您仔細考量後再決定是否簽署同意書。對於同意書的內容，您應獲得充分、清楚、完整的解說，並且在完全自主的情況下、在沒有勉強及壓力的情況下，審慎考慮後才完成受試者同意書 之簽署。在完成同意書的簽署後，請您務必自己保存一份，做為參考，試驗/研究計畫主持人也會保存一份。

After fully understanding the information provided above, please carefully consider whether to sign the consent form. You should receive a thorough, clear, and complete explanation of the contents of the consent form. You should only sign the Subject Informed Consent Form after thoughtful consideration, in a fully voluntary manner, without any coercion or pressure. After signing the consent form, please be sure to keep a copy for your reference, and the Principal Investigator of the trial/research project will also retain a copy.

4. 我可以退出試驗/研究嗎？需要任何理由嗎?

Can I withdraw from the trial/research, and do I need to provide a reason?

在簽署同意書後，或臨床試驗/研究進行中，可以在任何時間，主動告知研究團隊要退出試驗/研究，無需提出任何理由。您不會因退出試驗/研究而遭到任何不公平的待遇、權益受損，或影響日後就醫時的所有醫療照 護，請您放心。如您有任何參與臨床試驗/研究的疑慮，歡迎您亦可詢問人體試驗審查委員會受試者保護諮詢窗口（電

話：02-227082121 轉 6980）。

此外，如果您對本院在進行中的臨床試驗計畫有興趣，您可以在醫院的網站 https://www.cgh.org.tw/tw/content/depart/IRB/index.html，找到所有本院進行中的臨床試驗計畫，您可以直接洽詢計畫連絡人，了解該計畫相關資訊。

After signing the consent form or during the clinical trial/research, you have the right to voluntarily inform the research team of your decision to withdraw from the trial/research at any time, without the need to provide any specific reason. Your decision to withdraw will not result in any unfair treatment, harm to your rights, or affect your future medical care. Please rest assured that if you have any concerns about participating in the clinical trial/research, you are welcome to contact the Human Subjects Protection Consultation Office of the Institutional Review Board (Phone: 02-227082121 ext. 6980).

In addition, if you are interested in the ongoing clinical trial projects conducted by our hospital, you can visit the hospital's website at https://www.cgh.org.tw/tw/content/depart/IRB/index.html, where you can find information about all the ongoing clinical trial projects at our hospital. You can also directly contact the project coordinators to inquire about specific project details.