CLINICAL STUDY PROTOCOL

Title:	**Simulated In-Lab Usability Accessing the Use of Bleep DreamPort-Eclipse**
Protocol Number:	**BSL-SNAP-001**
Study Type:	**In-House Usability**
Date:	**07 July 2021**
Version:	**1.1**
Study Devices:	**DreamPort-Eclipse: Compact, ultra-low contact, custom fit CPAP human interface solution for obstructive sleep apnea**
Sponsor:	**Bleep, LLC** **758 The Preserve Trl** **Chapel Hill, NC 27517-7688**

07 July 2021

Sponsor – Stuart Heatherington, CEO — Date

Sponsor Contacts: **Bleep, LLCA**
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Revision History:

Protocol Version #	Protocol Date	Description of Changes
1.0	19 April 2021	Initial Protocol Version
1.1	07 July 2021	Updated adverse event description
1.2	30 June 2022	Updated Study sites

PROTOCOL SUMMARY

Title:	Simulated In-Lab Usability Accessing the Use of Bleep DreamPort-Eclipse
Design:	The study is designed to assess the usability of a novel CPAP human interface compared to a traditional nasal mask.
Objectives:	The objective of this study is to demonstrate the usability of a novel CPAP human interface compared to a traditional nasal mask in a stimulated in-lab setting.
Procedures:	Human subjects will interact with two different CPAP interfaces including a traditional CPAP mask and the 2nd generation DreamPort-Eclipse. Subjects will be requested to put on each of the different CPAP interface options a total of three times for a total of 6 trials. The order of device will be randomized.
Devices:	This comparative study design and data collection will involve the aforementioned two different CPAP interfaces: a traditional CPAP mask and the 2nd generation DreamPort-Eclipse.
Study Sites:	Three investigational sites of Sleep Centers of Middle Tennessee, Advanced Respiratory & Sleep Medicine, and Aeroflow Sleep will participate in the study.
Enrollment:	We plan to recruit 30 participants over the age of 18. We will oversample for participants who are Hispanic or African American. We will aim to recruit participants with the following racial and ethnic breakdown: 30% White; 40% Black; 10% Asian; and 20% Hispanic. We will also recruit an estimated 60% men and 40% women to reflect the OSA population, which affects more men than woman.
Eligibility Criteria:	The subject's eligibility for study enrollment will be reviewed and documented on the appropriate survey form. **Inclusion Criteria** The subject is a male or female ≥18 years old who are impacted by obstructive sleep apnea and currently are familiar with a CPAP device. **Exclusion Criteria** Subjects will be excluded if they have any medical or behavioral conditions that would compromise subject safety. Subjects under the age of 18 will be excluded from this study, as the target for this current version of the platform is the adult population.

Primary Endpoint:	**Primary Effectiveness Endpoint:** Several metrics will be recorded as part of the usability assessment. Dependent variables will include time to complete each setup, number of technical issues that occurred during the trial, and number of times subjects needed additional instructions. Subjects will also complete a survey at the end of the protocol to evaluate their experience with the different options.
Secondary Endpoints:	NA
Sample Size Estimation:	The purpose of this study is to get feedback on the usability of the device prior to clinical trials. The sample size is based on similar usability studies.
Data Collection:	All data will be acquired from the research procedures performed during usability assessments on human individuals. Data that will be collected from subjects includes demographic data and survey feedback. All subjects will be represented by subject IDs in the data in order to de-identify data. The individuals that will have the ability to access the subject IDs includes only the principal investigator and sleep center sites. The study will be conducted in accordance with applicable local regulations and national privacy laws. The clinical study will not commence at an investigational site until favorable opinion(s) from the respective Ethics Committee (EC)/ Institutional Review Board (IRB) has been received.

Investigator's Responsibility

Prior to participation in this study, the Investigator must obtain written approval from his/her Institutional Review Board (IRB). This approval must be in the Investigator's name and a copy sent to Bleep ("Sponsor") along with the IRB approved Informed Consent Form (ICF) (if applicable) prior to the start of the study. The Investigator is responsible for training all clinical staff to ensure adequate training is obtained prior to performing any data collection or study-related procedures.

The Investigator must also:

- Conduct the study in accordance with the study protocol, any modifications as requested by the IRB,
- the Declaration of Helsinki, applicable national privacy laws (e.g., Health Insurance Portability and Accountability Act (HIPAA) requirements in the U.S.), applicable Food and Drug Administration (FDA) regulations (e.g., 21 Code of Federal Regulations (CFR) Parts 50, 54, 56, and ISO 14155:2011.
- Ensure that the study does not commence until IRB approval has been obtained.
- If applicable, ensure that written informed consent is obtained from each subject prior to the conduct of any study procedure, using the current IRB-approved ICF.
- Provide all required data and reports and agree to source document verification of study data with subject's medical records.
- Allow Sponsor personnel or their designee(s), as well as regulatory agency representatives and other applicable authorities, to inspect and copy any documents pertaining to the study.
- Provide appropriate resources to ensure compliance with all study-related procedures and prompt submission of all surveys.

The Investigator retains overall responsibility for IRB approval and proper conduct of the study, including obtaining and documenting the Informed Consent process (if applicable), compliance with the study protocol, the collection of all required data, and ensuring that all study personnel have been properly trained on the protocol and have received other necessary training.

Investigator Protocol Signature Page

Site Name: _____

I have read and understand the contents of this protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the study in accordance with the study protocol, any modifications as requested by the IRB, the Declaration of Helsinki, applicable national privacy laws (e.g., HIPAA requirements in the US), GCP as well as applicable FDA regulations (21 CFR Parts 50, 54, 56) and ISO 14155:2011. I agree to participate in Sponsored training prior to performing any data collection or study-related procedures.

Stuart Heatherington
Printed Name – Principal Investigator

_____
Signature – Principal Investigator

_____
Date

Sub-Investigator Protocol Signature Page

Site Name: _____

I have read and understand the contents of this protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the study in accordance with the study protocol, any modifications as requested by the IRB, the Declaration of Helsinki, applicable national privacy laws (e.g., HIPAA requirements in the US), GCP as well as applicable FDA regulations (21 CFR Parts 50, 54, 56) and ISO 14155:2011. I agree to participate in Sponsored training prior to performing any data collection or study-related procedures.

Thomas Stern, MD
Printed Name – Co-Investigator

_____
Signature – Co-Investigator

_____
Date

CONTENTS

1. INTRODUCTION

1.1 Introduction

This Simulated In-Lab Usability Study is a multi-center study to demonstrate the usability of a novel CPAP human interface compared to a traditional nasal mask.

1.2 Device Description

Human subjects will interact with two different CPAP interfaces including a traditional CPAP mask and the next generation DreamPort-Eclipse.

2. STUDY OBJECTIVE

This minimal risk study is being conducted to collect data to compare the usability of three different CPAP modalities. Dependent variables will include time to complete each setup, number of technical issues that occurred during the trial, and number of times subjects needed additional instructions. Subjects will also complete a survey at the end of the protocol to evaluate their experience with the different options.

3. STUDY DESIGN

This multicenter study will involve recruiting 30 adult subjects who are impacted by obstructive sleep apnea and currently are familiar with a CPAP device. Clinicians will screen subjects for cognitive deficits and serious mental health or medical conditions that would compromise subject safety or accurate user feedback. Prior to data collection and study enrollment, the protocol will be explained in detail to the subjects and informed consent will be obtained.

Participants will receive and review the training materials developed in Aim 1, including written and video instructions on how to use the DreamPort-Eclipse. They will also be provided with and review instructions on the traditional nasal mask used in this study. Participants will be requested to put on each of the different CPAP interface options a total of three times for a total of six trials. The order of device trials will be randomized.

4. STUDY ENDPOINTS

4.1 Primary Effectiveness:

The primary endpoints for this study will include time to complete each setup, number of technical issues that occurred during the trial, and number of times subjects needed additional instructions. Subjects will also complete a survey at the end of the protocol to evaluate their experience with the different options.

4.2 Secondary Endpoints:

None.

5. STUDY POPULATION

5.1 Number of Subjects

Data collection will continue until 30 eligible subjects have been enrolled across our three study locations.

5.2 Eligibility Criteria

Subjects will be enrolled into the study based upon the inclusion/exclusion criteria listed below.

5.2.1 *Inclusion Criteria*

To be eligible for inclusion in this study, a subject must meet the following criteria:

The subject is a male or female ≥18 years old who is impacted by obstructive sleep apnea and currently is familiar with a CPAP device.

5.2.2 *Exclusion Criteria*

Subjects will be excluded if they have any medical or behavioral conditions that would compromise subject safety. Subjects under the age of 18 will be excluded from this study, as the target for this current version of the platform is the adult population.

6. INDEX PROCEDURE, EVALUATIONS, AND SCHEDULE

6.1 Enrollment

6.1.1 *Informed Consent and Enrollment*

Prior to data collection and study enrollment, the protocol will be explained in detail to the participants and informed consent will be obtained. All participants will provide written informed consent prior to participation. The information about the research will be provided to the participant in written form as well as read aloud to the participant.

Prior to the collection of any study-specific data or conduct of any study-specific procedures, the subject must voluntarily provide written informed consent (if needed) and comply with

applicable national privacy laws. All study procedures will be documented in the medical record and/or source document and on study case report forms (CRFs).

6.1.2 *Demographics and Medical History*

The subject's demographic information will be collected and documented on the appropriate CRFs (i.e., Age (years), sex and initials).

6.1.3 *Physical Examinations*

No physical examination will take place.

6.1.4 *Assignment of Subject Number*

A unique participant identification number (PID) will be assigned to enrolled subjects. Participant or Subject numbers will be assigned in sequential order. The Participant or Subject number will consist of six digits. The first three digits will designate the study site. The last three digits will designate the subject by number in sequential order (e.g., 210-001, 210-002…).

6.2 Index Procedure Data

6.2.1 *Index Procedure Details*

Index procedure details will be collected on all enrolled subjects. The Index procedure is defined as the SNAP CPAP usability protocol in accordance with the instructions for use (IFU). Such details related to this protocol may include, but are not limited to the following:

- Date of Usability Test
- Product Name, Catalogue Number, Lot Number
- Configuration Details
- Indication
- Accessory details
- All adverse events, device malfunction, and complications related to device or procedure

6.3 Clinical Follow-Up

There is no clinical follow-up associated with this study.

7. ASSESSMENT OF SAFETY

The Investigator is responsible for the detection and documentation of events meeting the criteria and definition of an Adverse Event (AE), Serious Adverse Event (SAE) and unanticipated Adverse Device Effects (UADE) as provided in this protocol. The occurrence of AEs should be documented in the source documents and reported using the appropriate CRF. Events that occur prior to the index-procedure should be captured within the subject's medical history.

7.1 Definition of Events

7.1.1 *Adverse Events (AE)*

An AE is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the study device [ISO14155:2011 (E)].

Abnormal laboratory results are not to be considered AEs unless the results are accompanied by clinical signs or symptoms. Preexisting conditions should be considered as part of the subject's medical history. Any medical condition that is present before the implantation procedure will be considered medical history and should not be reported as an AE. However, if the subject's condition deteriorates, or there is a substantial increase in severity or frequency of the condition (worsening of the underlying disease), which has not been attributed to natural history during the subject's clinical follow-up, it will be recorded as an AE.

7.1.2 *Serious Adverse Event (SAE)*

Each AE will be assessed to determine whether it is serious or non-serious. (Note: the term serious is not synonymous with severity, which may be used to describe the intensity of an event experienced by the subject). A SAE is an AE that:

1. Led to death: or
2. Led to serious deterioration in the health of the subject, that either resulted in:
   a. A life-threatening illness or injury;
   b. A permanent impairment of a body structure or body function:
   c. In-patient or prolonged existing hospitalization (>24 hours); or
   d. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or body function
   e. Led to fetal distress, fetal death, or a congenital abnormality or birth defect.

NOTE: Planned hospitalizations for a preexisting condition (prior to device use), or a procedure without serious deterioration in health, are not considered an SAE.

7.2 Severity of Adverse Events

Each AE should be assessed for its severity, or the intensity of an event, experienced by the subject.

1. **Mild**: Awareness of a sign or symptom that does not interfere with the subject's activity or is transient and is resolved without treatment or sequelae.
2. **Moderate**: May interfere with the subject's activity and require additional intervention and/or treatment and may have additional sequelae.
3. **Severe**: Significant discomfort to the subject and/or interferes with their activity. Additional intervention and/or treatment are necessary. Additional sequelae occur. Severe is used to describe the intensity of an event experienced by the subject.

7.3 Relationship of Adverse Event to Device/Procedure

Each AE/SAE will be assessed for its relationship to the product(s) being studied or surgical procedures as follows:

1. **Device-Related**: This category should be restricted to AEs directly attributable to the devices being studied in the study.

The following categories will be used to assign the certainty of the relationship:

1. **Definitely Related**: An AE is definitely related if the AE is known to occur with the product(s), there is a reasonable possibility that the product(s) caused the AE, or there is a temporal relationship between use of the product(s) and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the product(s) and the AE.
2. **Possibly Related**: An AE is possibly related if it is capable of being related but relatively unlikely.
2. **Not Related**: An AE is not related if it is determined that there is no reasonable possibility that the product(s) caused the event, there is no temporal relationship between the product(s) and event onset, or an alternate etiology has been established.

8. STATISTICAL CONSIDERATIONS

This section describes the planned statistical analyses for this study.

8.1 Sample Size Considerations

The purpose of this study is to get feedback on the usability of the device prior to clinical trials. The sample size is based on similar usability studies.

8.2 Data Analysis

Several metrics will be recorded as part of the usability assessment. Dependent variables will include time to complete each setup, number of technical issues that occurred during the trial, and number of times subjects needed additional instructions. Independent variables will include the subject ID and CPAP interface device. The average time to complete each trial and number of technical issues will be computed and an analysis of variance (ANOVA) completed on the data set. In general, we expect to see average trial completion times significantly less for the DreamPort-Eclipse compared to the traditional mask, and overall an average time per subject of less than 5 minutes to setup the DreamPort-Eclipse.

Additionally, we expect no more than 1 technical setup error per subject using the DreamPort-Eclipse. Subjects will also complete a usability survey to evaluate their experience. We expect average Likert scores from subjects to be greater than 3 on the System Usability Scale (SUS) (Brooke 1996). The SUS is validated (Bangor, Kortum et al. 2008), ranks scores in 1-5 responses from “Strongly Disagree” to “Strongly Agree” and integrates Usable (8 items) and Learnable (2 items) (Lewis and Sauro 2009). Additionally, we will also use a custom survey to provide targeted feedback about our specific platform features. This will include ten questions presented using a 1 to 5 Likert scale. Questions will target overall enthusiasm, if they understood how to setup the interface, comfort of wear, effectiveness of training guides, and stumbling blocks. We expect average Likert scores >3.

Finally, as part of the user feedback from this task we may further update the device input specifications and use cases. The freeform survey feedback and discussions with sleep clinicians after the usability study will inform and design modifications for continued development in this program.

9. MECHANICAL FAILURES, MALFUNCTIONS, AND DEFECTS

During the usability study, our Bleep, LLC support team will problem solve any issues that arise with the study and provide support to ensure success of the study.

10. DATA COLLECTION, QUALITY, AND RECORD RETENTION

10.1 Data Collection and Record Maintenance

The Investigator or designee is responsible for completely and accurately recording study data in the appropriate sections of the CRFs provided. The CRFs must be signed by the Investigator or by his/her documented designee.

10.2 Source Documents

Each participating site will maintain appropriate medical and research records for this study, in compliance with regulatory and institutional requirements for the protection of confidentiality of participants.

10.3 Quality Assurance and Quality Control (QC)

The Investigator is responsible for ensuring the accuracy and completeness of all study documentation. All clinical study data will be recorded in the surveys provided to the investigational site.

The investigational site will provide direct access to all study related sites, source data/documents, and reports if monitoring and auditing by the Sponsor, and inspection by local and regulatory authorities is requested. Regular monitoring and an independent audit, if conducted, will be performed according to International Council for Harmonization - Good Clinical Practice (ICH-GCP).

10.4 Record Retention

The Investigator shall retain all study records for a period of 2 years after the date on which the study is terminated or completed. The Investigator may withdraw from the responsibility to maintain records for the period required by transferring custody of the records to any other person who will accept responsibility for retaining them. Notice of a transfer shall be given to Bleep not later than 10 business days after the transfer occurs.

11. ADMINISTRATIVE REQUIREMENTS

11.1 Investigator Selection

The Investigator must be of good standing as an Investigator and knowledgeable in relevant areas of clinical research to ensure adherence to the requirements of the protocol, including the protection of human subjects. Other site personnel must have appropriate research experience and infrastructure to ensure adherence to the protocol. The curriculum vitae (CV) of the Investigator will be maintained in the Sponsor files as documentation of previous medical training, and federal databases will be searched to ensure that the Investigator and/or the site are not prohibited from engaging in federally Sponsored clinical research. The Principal Investigator will sign the signature page of this protocol, agreeing to comply with all applicable government regulations and the requirements of this study.

11.2 Communications with the Sponsor

Although the Investigator and his/her staff may have contact with other key individuals at the Sponsor throughout the course of the study, all communications regarding conduct of the study must be channeled through the Sponsor’s clinical affairs personnel or designees.

11.3 Investigator Training

Prior to the start of the study Investigators will undergo a mandatory study training that will be designed to cover all aspects of data collection and the requirements of this Clinical Protocol. The training is designed to enhance protocol adherence. All training documentation will be maintained by the Sponsor within an electronic Trial Master File and is expected to be maintained locally at participating sites in regulatory files or equivalent.

11.4 Required Documentation

An Investigator may not commence study activities until authorized to do so by the Sponsor in writing. At a minimum, the following documentation must be received by the Sponsor prior to study commencement:

1. Signed Nondisclosure Agreement by the Investigator;
2. CVs, signed and dated within 2 years of study start for the Investigator and Sub-Investigators;
3. CV for the Study Coordinator, if applicable;
4. Signed "Protocol Signature Page" by the Investigator and Sub-Investigators;
5. Study Personnel Identification List;
6. Training Log/Documentation;
7. Written approval from the IRB of the Protocol and ICF (if necessary); and
8. IRB Assurance of Compliance Form or equivalent (if applicable)

11.5 Protocol Adherence and Deviations

This study will be conducted as described in this protocol. Investigators are not permitted to deviate from this protocol except to protect subject rights. Any deviations from this protocol must be documented by the Investigator.

A protocol deviation is any noncompliance with the clinical study protocol, GCP, or SOP requirements. The noncompliance may be either on the part of the investigator, or study site staff.

All deviations must be addressed in study source documents and will be reviewed during routine monitoring visits. Investigators will be required to identify preventive and corrective actions to prevent further deviations. An Investigator may be disqualified from the study for repeated and/or egregious protocol deviations.

11.6 Publication and Data Sharing Policy

At the conclusion of the study, a multi-center article may be prepared for publication in a scientific journal. The publication of the principal results from any single-center experience within the study is not allowed until the preparation and publication of the multi-center results. Exceptions to this rule require the prior approval of Sponsor. The analysis of other

pre-specified and non-pre-specified endpoints will be performed by Sponsor or its designee. Such analyses, as well as other proposed investigations will require the approval of Sponsor. Sponsor anticipates the possibility of secondary manuscripts with principal authorship. For purposes of timely abstract presentation and publication, such secondary publications will be delegated to the appropriate principal authors, and final analyses and manuscript review for all multi-center data will require the approval of Sponsor.

All information and data sent to Sponsor or an authorized designee concerning subjects or their participation in the study will be considered confidential. All data used in the analysis and reporting of this study will be used in a manner without identifiable reference to the subject. The Investigator consents to visits by personnel of Sponsor and its affiliates or designees, as well as, FDA representatives.

The final contents of the primary manuscript will be at the discretion of the Sponsor. Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the Investigator for the purposes of performing the study, will be published or passed on to any third party without the consent of the study Sponsor. Any investigator involved with this study is obligated to provide the Investigator with complete results and all data derived from the study.

12. CLINICAL SITE MONITORING AND AUDIT

Clinical site monitoring is conducted to ensure that the rights of subjects are protected, that the reported study data are accurate, complete, and verifiable, and that the conduct of the study is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s). The PI and Co-I will monitor the site through in-person site visits and teleconference. The onsite study team will receive training on the protocol and informed consent from the PI and Co-I.

The site may be subject to a quality assurance audit by personnel of the Sponsor and/or by other Regulatory Authorities.

12.1 Site Initiation Visit

The purpose of this visit is to review with the Investigator and staff the provisions and proper conduct of the study. This includes a detail review of the protocol and surveys with instructions as to their completion, as well as reviewing regulations pertaining to the conduct of the clinical study. Arrangements for timely and accurate reporting of clinical data will be established. The following will be reviewed during the Study Initiation Visit:

1. If applicable, confirm that the ICF to be used is the one approved by IRB;
2. Verify that all essential and necessary documents are on file at the site and at Sponsor; and

3. Arrange for Electronic Data Capture/survey training

12.2 Close-Out Visit

The purpose of this visit is to collect all outstanding study data documents, confirm that the Investigator's files are accurate and complete, review the record retention requirements with the Investigator and assure that all applicable requirements for closure of the study are met. The actions and observations made at this visit will be recorded and filed.

13. REGULATORY AND ETHICAL CONSIDERATIONS

13.1 Ethical Standard

This study will be conducted in accordance with the Declaration of Helsinki, HIPAA requirements, GCP, applicable FDA regulations (21 CFR parts 50, 54, 56), and ISO14155:2011.

13.2 Institutional Review Board Approval

Before commencement of the study, the Investigator must provide Sponsor with written documentation of IRB approval. This approval must refer to the ICF (if applicable) and the study by both the title and the protocol number assigned by Sponsor. The Investigator, if a member of the IRB, is not to participate in the approval decision for this study. This non-participation should be noted in the approval letter.

The IRB must give written renewal of the original approval at least annually to continue the study. A copy of the written renewal must be provided to Sponsor.

13.3 Investigator Reports

Where applicable, the investigator should submit written summaries of the study's status to the IRB annually, or more frequently, if requested by the IRB. The investigator should promptly provide written reports to the Sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the study.

Upon completion of the study, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the study's outcome. Reporting to the regulatory authority by the Sponsor (if applicable) with any reports required.

13.4 Participant and Data Confidentiality

Subject confidentiality is strictly held in trust by the participating investigators, their staff, and the Sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the Sponsor.

The study monitor, other authorized representatives of the Sponsor, representatives of the IRB may inspect all documents and records required to be maintained by the Investigator, including but not limited to, medical records (office, clinic, or hospital) for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and applicable regulations.

13.5 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the study. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

14. PREMATURE TERMINATION OR SUSPENSION OF STUDY

The Sponsor reserves the right to temporarily suspend enrollment or terminate the study at any time. Written notice documenting the reason for study suspension or termination will be submitted to the Investigator in advance of such termination. If the study is prematurely terminated or suspended, the Investigator will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

The Sponsor may suspend enrollment or terminate the study at a specific site for reasons including, but not limited to:

1. Inadequate data collection
2. Low subject enrollment rate
3. Non-compliance with the protocol or other clinical research requirements

The study may resume once concerns about protocol compliance, and/or data quality are addressed.