Evaluation of a Novel Positive Airway Pressure System in Volunteers

NCT07246538

Study Protocol

10/1/2025

Electronic RESEARCH INTEGRITY AND COMPLIANCE THE UNIVERSITY OF UTAH

Date: Tuesday, October 7, 2025 10:50:44 AM Print Close

IRB_00190165 **Created:** 4/8/2025 8:12 AM
PI: Kai Kuck Ph.D. **Submitted:** 4/21/2025
Title: Evaluation of a Novel PAP System in Volunteers

IRB_00190165
1. Contacts and Title

1. Study Introduction

1. **Responsible Investigator:**
Kai Kuck

Email	Training	CoI Date
kai.kuck@hsc.utah.edu	8/26/2023 MG	8/29/2025

a. **Position of the Investigator:**

- (●) **Faculty or** Non-Academic Equivalent
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

2. **Contact Persons for the Responsible Investigator:**

Name	Email	Training
Trey Blackwell	u1409868@utah.edu	5/2/2025 SMG

3. **Guests of the Responsible Investigator:**

Last Name	First Name	E-Mail

There are no items to display

4. **What type of application is being submitted?**
New Study Application (or Amendment/Continuing Review)

5. **Title Of Study:**
Evaluation of a Novel PAP System in Volunteers

6. **Study Purposes and Objectives:**

This study will evaluate the accuracy of the pressure control and respiratory monitoring capabilities of a novel system for administering positive airway pressure (PAP) therapy in healthy volunteers. The goals of the study are to evaluate how accurately the system can stabilize airway pressure to a desired level, evaluate the accuracy of the system's reported volume of each breath (tidal volume), evaluate the accuracy of the system's reported respiratory rate, evaluate the accuracy of exhaled carbon dioxide monitoring with a standard carbon dioxide monitor when the novel PAP system is used, and evaluate general comfort of the volunteers while using the system.

7. **Is this a multi-site study, where more than one site needs IRB approval?**
( ) Yes (●) **No**

8. **Background and Introduction:**

Sedation procedures involve administering drugs to patients that reduce awareness and pain without complete loss of consciousness. A common side effect of these drugs is partial or complete obstruction of the airway by the airway tissue, inhibiting the flow of oxygen to the lungs. Research has shown that this risk can be effectively reduced by administering PAP therapy during sedation, which involves directing air flow into a tight-fitting mask over the patient's nostrils and/or mouth. However, non-invasive ventilators used for administering PAP therapy are expensive and large, and often not available in areas of the hospital where sedation procedures take place.

We have developed a small and low-cost novel PAP system for use in sedation procedures that controls airway pressure to desired levels (a feature that is generally only available in larger and higher-cost devices), provides estimates for tidal volumes (generally only available with a non-invasive ventilator), provides respiratory rate estimates, and allows for more accurate monitoring of exhaled carbon dioxide with a standard carbon dioxide monitor using a novel approach that to our knowledge has not been published. The goal of our study is to demonstrate the accuracy of these features in human subjects. The system is much smaller and less expensive than a non-invasive ventilator, provides enhanced respiratory monitoring, and has the potential to be a practical alternative that would make PAP therapy during sedation much more feasible.

Our evaluation will primarily include evaluating our system's performance against an FDA cleared commercial respiratory monitor to verify accuracy. We anticipate that our system will automatically adjust oxygen flow to maintain a desired airway pressure even in the presence of variables such as mask leak and patient inhalation flow. We also anticipate that our system will provide tidal volume estimates within 15% of the respiratory monitor reference measurement, as well as respiratory rate estimates that closely match the respiratory monitor. Our system employs a method that detects when the patient exhales and removes mask pressure during exhalation, and we anticipate that this will result in improved comfort for the patient, as well as improved carbon dioxide monitoring accuracy, since removing flow during exhalation reduces dilution of the expired gas sample that is used for measuring exhaled carbon dioxide levels.

Literature review:

Fogarty et al. demonstrates the effectiveness of PAP therapy in reducing airway obstruction. This study examined oxygen desaturation and obstruction occurrences during colonoscopies and compared these when administering PAP therapy vs standard oxygen delivery through a nasal cannula.

> Fogarty M, Orr JA, Sakata D, Brewer L, Johnson K, Fang JC, Kuck K. A comparison of ventilation with a non-invasive ventilator versus standard O2 with a nasal cannula for colonoscopy with moderate sedation using propofol. J Clin Monit Comput. 2020 Dec;34(6):1215-1221. doi: 10.1007/s10877-019-00426-5. Epub 2019 Nov 23. PMID: 31760586.

Burk et al. demonstrates that oxygen flow during exhalation dilutes the exhaled carbon dioxide sample, and that removing flow during exhalation results in more accurate carbon dioxide monitoring.

> Burk KM, Sakata DJ, Kuck K, Orr JA. Comparing Nasal End-Tidal Carbon Dioxide Measurement Variation and Agreement While Delivering Pulsed and Continuous Flow Oxygen in Volunteers and Patients. Anesth Analg. 2020 Mar;130(3):715-724. doi: 10.1213/ANE.0000000000004004. PMID: 30633057.

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IRB_00190165
2. Study Location and Sponsors

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1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**

   Click the appropriate button(s) below to add locations:

	Site Name	Investigators Name	Covered Entity	Sub Sites
View	University of Utah	Kai Kuck	Yes	

2. **Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?**
   ○ Yes ● **No**

3. **Indicate the source(s) of funding obtained or applied for to support this study.**

	Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type	OrgID
View	DYNASTHETICS LLC	Industry				16800

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**
   ○ Yes ● **No**

5. **Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?**
   Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.
   ○ Yes ● **No**

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Addition of a Site

1. **Site Name:**
   University of Utah

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Kai Kuck

Email	Training	CoI Date
kai.kuck@hsc.utah.edu	8/26/2023 MG	8/29/2025

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

   b. **Will the Site PI consent participants?** ○ Yes ● **No**

3. **Site Contact Persons, if different from the Site PI:**
   ☑ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
Trey Blackwell	u1409868@utah.edu	5/2/2025 SMG

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
Trey Blackwell	u1409868@utah.edu	5/2/2025 SMG	☐	8/11/2025

5. **Site Guests:**

Name	Email	Training
There are no items to display		

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

7. **Select the study procedures that will be conducted at this site:**
   - Recruitment
   - Consent/Enrollment
   - Research observation/intervention with participants
   - Data collection
   - Data analysis

   Do you have an enrollment goal or anticipated enrollment number for this site?

   ● **Yes**
   ○ No

   Enrollment Number:
   25

8. **Select the University of Utah department responsible for this research:**
   ANESTHESIOLOGY

9. **Add any additional sites that are part of this performance group**
   There are no items to display

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IRB_00190165
IRB Smart Form

Sponsor Information

a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

● **Yes** ○ No

If yes, select the associated OSP Proposal ID/DSS through eAward to link it to the ERICA system.

You must have a fully approved Proposal ID/DSS number through eProposal which will show up in eAward after OSP has integrated the ID. To access the eAward application, use the instructions on the OSP website.

Link to a Proposal ID/DSS through eAward

Proposal ID/DSS: 10043511
PI: KUCK,KAI
Sponsor: DYNASTHETICS LLC
Prime Sponsor:
Department:
Short Title: SUPPLEMENTAL OXYGEN EVALUATION
Sponsor Award Number: IRB00094640
Type: Industry
Award Start Date: 9/29/2016
Award End Date: 9/30/2027
Prime Sponsor Type:

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IRB_00190165 3. Participants

3. Participants

1. **Ages of Participants:**
   18 and older (Consent form needed)
2. **Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**
   18+
3. **Indicate any vulnerable participant groups (other than children) included:**
   None

   If "Other", please specify:

   If "None" and no children are involved, answer the following question.
   Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
   ○ Yes ● **No**
4. **Number of participants to be included and/or enrolled in this entire study, across all study locations:** 25
5. **Characteristics of Participants/Inclusion Criteria:**

   Healthy volunteers drawn from the general public at least 18 years of age of any gender.
6. **Participant Exclusion Criteria:**

   Volunteers who report having respiratory or cardiovascular conditions will be excluded. Such conditions may include but are not limited to cold, allergies, congestion, pneumonia, lung cancer, COPD, or acute respiratory distress syndrome.
7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**
   ○ Yes ● **No**

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4. Study Information

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1. **Design of Study (select all that apply):**

   ☑ **Non-Experimental and/or Descriptive Research Design:**

   Survey/Questionnaire Research

   ☑ **Experimental and/or Interventional Research Design:**

   Prospective Biomedical Intervention or Experiment

   ☐ **Development of a research resource (repositories, databases, etc.)**

   There are no items to display

   ☐ **Other**

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:**
   6 months

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   In-person contact (e.g., patients, students, etc.)

   Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   From a database or participant pool for which participants have given prior permission to be contacted for research studies

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   Word of mouth will be used to recruit from the general public. A digital flyer will be placed on a screen at the University of Utah Pain Management Center where the study will be conducted, and printed flyers may be placed in other locations if needed to recruit additional participants. A TBD member of the Department of Anesthesiology Clinical Research Staff will contact potential participants from their database of participants that have given permission to be contacted for studies. No follow-up contact will be made with participants regarding the study, and no medical data will be used.

5. **How will consent be obtained?**

   Informed Consent Process (with or without a document)

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

   A maximum of 25 volunteers will be recruited by word of mouth from the general public.

   For this study we are focusing on English-speakers only, primarily because this is a pilot / early-phase study, primarily focused on technical feasibility and system validation rather than on generalizability to diverse populations. Inclusion of broader demographics is planned for later-phase studies. Also, participation requires real-time communication with study personnel and comprehension of complex instructions which cannot be effectively translated in real-time. To ensure participant safety and data integrity, we are limiting enrollment to English-speaking volunteers.

   After informed consent, participants will be seated in a chair and they will be fitted with an air-cushioned mask over their face, secured with an H-strap around the back of their head. A flowmeter connected to a respiratory monitor (NM3, Philips Respironics, Wallingford, CT) will be placed on the mask inlet, and then the oxygen outlet of our novel PAP system will be connected to the flowmeter. Volunteers will be informed that they can remove the mask at any time if they feel discomfort or panic. Our novel PAP system is programmed to automatically adjust air flow from an oxygen tank through a valve to maintain a desired pressure (selectable) in the mask. The system detects the volunteer's breathing and calculates respiratory rate based on the time between breaths. Tidal volume is estimated by calculating inhalation flow based on the pressure in the mask and the oxygen flow output by the system, and summing this flow throughout inhalation. The system can also be set to detect exhalation and discontinue oxygen flow during exhalation and resume flow when exhalation has ended.

   The first step of the study protocol is to characterize the mask leak on the volunteer's face. At set mask pressures of 1, 2, 5, and 10 cmH2O, each volunteer will be asked to take a deep breath and hold it for five seconds while we record the leak flow and the corresponding mask pressure so that we can account for the effects of leak on the respiratory monitor measurements in post-processing. The leak flow will be the steady-state flow measured by the flowmeter on the respiratory monitor, and this and the mask pressure will be recorded using the data logging software for the respiratory monitor running on a laptop computer. In post-processing, we will fit a curve to the leak flow vs pressure relationship recorded during the calibration to calculate the instantaneous leak flow. This instantaneous leak flow can be subtracted from the flowmeter signal recorded by the respiratory monitor logging software to obtain the instantaneous inhalation flow rate.

   After leak calibration, the PAP system will be set to control the pressure to 1 cmH2O while removing flow during exhalation. The volunteer will be asked to relax and breathe normal while they occupy themselves with their phone. While they breathe, waveforms of flow through the mask, carbon dioxide, mask pressure, and respiratory rate will be logged from the respiratory monitor. From our PAP system, waveforms of tidal volume estimates, respiratory rate, and estimated flow through the mask will be recorded continuously. After 2 and a half minutes of breathing, the PAP system will be set to deliver flow continuously during exhalation. After 2 and a a half more minutes of breathing, the set pressure will be adjusted to 5 cmH2O. After two and a half minutes more of breathing, the system will again be set to remove flow during exhalation. After two and a half more minutes of breathing, the set pressure will be adjusted to 10 cmH2O. After 30 seconds of breathing, the system will be set to deliver flow continuously during exhalation. After 30 more seconds of breathing, data collection will stop, flow from the PAP system will be discontinued, and the mask will be removed from the volunteer. The gender, age, height, and weight of each volunteer will also be collected. None of the collected information will be stored in association with the participants' identity.

   Each volunteer will then be asked if they noticed when flow was removed during exhalation as opposed to when it was given continuously, and if they did notice, to comment on whether it was more comfortable when flow was removed during exhalation or when flow was given continuously. They will also be asked if the audible noise of air flow was irritating. They will also be asked if they have ever used or if they regularly use PAP therapy. After answering these questions, the test will be complete.

   Each volunteer will use a new disposable mask, and each will be given their own disposable attachment to our PAP system that directs flow to the mask. We will have three flowmeters for the respiratory monitor available that will be cleaned with soap and warm water and disinfected after use with a single volunteer.

   After ten volunteers have been tested, the mean and standard deviation of the percent difference in tidal volume measurement between our PAP system and the respiratory monitor will be calculated. A margin of error of 3% will be

used since 3% is the reported accuracy of tidal volume measurements of the respiratory monitor. The sample size for a 95% confidence interval will be calculated as n=(1.96*SD/3)^2. If after 10 volunteers, the sample size calculation is less than the number of completed volunteers, the study will be complete. Otherwise, we will do this same check after every 5 subsequent volunteers (15, 20, etc). The PAP system was designed with a specification of less than 15% error. In the case of a 95% confidence interval where the 95% limits with a zero mean difference are at +/- 15% error, the standard deviation is approximately 7.65, which would yield a sample size of 25. We anticipate the standard deviation to be less than this, so the maximum number of participants to be enrolled will be 25.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ● **Yes** ○ No

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ● **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   End-tidal carbon dioxide measurements at 10 cmH2O of mask pressure will be compared between when the system turned off flow during exhalation and when delivering flow throughout the entire breath. We anticipate that end-tidal CO2 levels will read lower when flow is delivered continuously during exhalation because of dilution of the expired gas, and this will be demonstrated by calculating the average difference in end-tidal CO2 between these two approaches.

   The average respiratory rate reported by the respiratory monitor and rate reported by the PAP system for each volunteer will be compared to demonstrate the system's accuracy. The average difference for each volunteer will be calculated, and a 95% confidence interval will be constructed, with the ideal mean difference being zero with low variance.

   The measured pressure in the mask compared to the set pressure in the 50 milliseconds immediately preceding inhalation will be assessed for evaluating pressure control. Average differences at each set pressure will be calculated. We anticipate these numbers to be less than 1 cmH2O.

   Flow waveforms from the PAP system and the respiratory monitor will be time-aligned. Tidal volume will be calculated from the respiratory monitor by summing the flow during inhalation minus the calibrated leak flow. Tidal volumes will then be compared between the PAP system and the respiratory monitor. Differences will be analyzed using Bland-Altman statistics.

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IRB_00190165 - Consent Process

Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Study Location and Sponsors Page):**
   There are no items to display

   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).
   A TBD member of the University's Department of Anesthesiology Clinical Research Staff will obtain consent. We will not open recruitment or obtain consent until an AM has been submitted to the IRB identifying individuals who will obtain consent.

2. **Describe the location(s) where consent will be obtained.**
   Consent will be obtained at the study location, which is a study room at the University of Utah Pain Management Center (615 Arapeen Drive, #100 Salt Lake City, Utah 84108)

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
   After volunteers have been recruited and screened for eligibility, they will be given the consent form and may schedule a time to complete the study. They will have until their scheduled time to consider and may contact a member of the study staff to ask questions. Documented consent will take place at the study site immediately before the volunteer's scheduled study time, and they will have one more opportunity to ask questions in person before signing the consent form. Signed consent will then be collected immediately before beginning the protocol with a given volunteer.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
   Volunteers will be informed that participation is entirely voluntary and that they may choose to withdraw at any time before or during the study. The non conflicted TBD member of the Clinical Research Staff in the department of Anesthesiology will be obtaining informed consent.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
   Participants will be given the consent form in advance of the study and will be asked to read and ask any questions before being asked to sign.

6. **Will a legally authorized representative (LAR) be used?**
   ○ Yes ● **No**

7. **Will a language other than English be used to obtain consent?**
   ○ Yes ● **No**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
   ○ Yes ● **No**

   If yes, complete the following:

   a. **Explain why the waiver of consent documentation is being requested.**

   b. **Justification for the waiver is one of the following:**
   There are no items to display

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IRB_00190165 5. Data Monitoring

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   - Discussing the study with participants individually instead of in front of a group
   - The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected
   - Allowing for anonymous submission of surveys and questionnaires

   Other or additional details (specify):

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   - Storing research data on password protected computers or in locked cabinets or offices
   - Complete de-identification of study data
   - All data that will be transferred or transported outside of the institution will be encrypted
   - Other or additional details (specify):

   Other or additional details (specify):
   Because this study is investigating the use of a medical device, there is a possibility that the United States Food and Drug Administration (FDA) may inspect the records from this study. The FDA will only have access to the records we keep for the study, and since no identifiable information that may be linked to the volunteers may be stored, the identity of participants will remain anonymous to the FDA. Records will only include the recorded data from the respiratory monitor, recorded data from the device being assessed, de-identified demographic information, and responses to the survey. All these records will be kept on a password-protected computer and access will only be given to official representatives of the FDA at their request.

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**
   ○ Yes ● **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

   - Periodic review and confirmation of participant eligibility
   - Periodic review of informed consent documentation
   - Periodic review of the transfer/transcription of data from the original source to the research record

   Other additional details (specify):

5. **Who will be the primary monitor of the study data and documentation?**

   Select all that apply:

   - Research Assistant

   Other or additional details (specify):
   The research assistant who will be the primary monitor of the study data and documentation is Trey Blackwell, bioengineering graduate student.

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
   It is anticipated the study will be completed within three months of approval.

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6. Risks and Benefits

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1. Describe the reasonable foreseeable risks or discomforts to the participants:

The patient may experience brief discomfort from the pressure support of the PAP system or from the strap of the mask.

Another potential, but unlikely, risk is a breach of confidentiality. Many steps have been taken to make sure that the confidentiality of all data collected is protected. No identifiable information about volunteers will be collected for this study, and thus the risk is minimal.

2. Describe the potential benefits to society AND to participants (do not include compensation):

This study will benefit society by increasing our understanding of a practical and low-cost PAP system that could be feasibly used in sedation procedures to mitigate airway obstruction and will demonstrate the accuracy of the enhanced respiratory monitoring that the system provides. This may help lead to improved care for patients undergoing sedation.

There are no specific benefits to the participants.

3. Are there any costs to the participants from participation in research?

○ Yes ● **No**

If yes, specify:

4. Is there any compensation to the participants?

● **Yes** ○ No

a. If yes, answer the following:
Specify overall amount:
$50 payment processed through ADVARRA

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):
At the conclusion of their participation in the study.

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):
N/A

d. If applicable, explain plan for prorating payments if participant does not complete the study:
N/A

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7. HIPAA & the Covered Entity

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1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**
   ○ Yes ● **No**

Does this study involve any of the following:

2. **The investigational use of a drug?**
   ○ Yes ● **No**
   Mark yes, for an expanded access application.

3. **The investigational use of a medical device or humanitarian use device?**
   ● **Yes** ○ No
   Mark yes, for an expanded access application.

4. **The investigational use of a dietary supplement, food, or cosmetic?**
   ○ Yes ● **No**

5. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator'**
   ○ Yes ● **No**
   All investigator-initiated drug or device trials are required to have a full research protocol attached to the Documents and Attachments page.

6. **Will this study involve the use of an imaging modality from the department of Radiology?**
   ○ Yes ● **No**

7. **Exposure to radioisotopes or ionizing radiation?**
   ○ Yes ● **No**

8. **Genetic testing and/or analysis of genetic data?**
   ○ Yes ● **No**

9. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
   ○ Yes ● **No**

10. **Are you:**
    - **Collecting samples of blood, organs or tissues from participants for research purposes;**
    - **Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR**
    - **Introducing other biological materials (e.g. bacteria, viruses) into participants.**

    ○ Yes ● **No**

11. **Does this study involve any of the following?**
    - **Cancer Patients**
    - **Cancer Hypothesis**
    - **Cancer risk reduction**
    - **Cancer prevention**

    ○ Yes ● **No**

12. **Any component of the Clinical and Translational Science Institute (CTSI)?**
    ○ Yes ● **No**
    The Clinical Research Unit (CRU)?
    ○ Yes ● **No**

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IRB_00190165
- Investigational Use of a Device

Investigational Use of a Device

1. **What is the initial risk determination of the device study according to the investigator and/or sponsor?**

   The study is a non-significant risk (NSR) device study.

   a. **Provide IDE (or HDE) Number(s) for significant risk devices:**

IDE/HDE #	Device Name	IDE/HDE Holder

   There are no items to display

   b. **Attach verification of the IDE (or HDE) number for significant risk devices to the Documents and Attachments page. Please check the method by which you choose to verify the IDE (or HDE) number:**
   There are no items to display

2. **Describe the plan to control, store, and dispense the investigational device or humanitarian use device. This plan should ensure that the device is only used by qualified investigator(s) for the participants enrolled in this research project.**
   The device will be used only in the room where the study is being conducted. The device will be labeled in accordance with 21 CFR 812.5 by placing the following label: "CAUTION-- Investigational device. Limited by Federal (or United States) law to investigational use" followed by the investigators' names and department.

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Title: Evaluation of a Novel PAP System in Volunteers

IRB_00190165
- - Non Significant Risk Device

Non-Significant Risk Device

Review the following definition of a non-significant risk (NSR) device:

1. The medical device is not a significant risk device, because all of the following are true:
    a. The medical device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
    b. The medical device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
    c. The medical device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
    d. The medical device is does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. The medical device is not banned.

1. **Provide justification of why the investigational medical device used in this study meets the definition of a NSR device.**

a. The device to be studied under this protocol is not an implant and poses no serious risk to the health, safety, or welfare of the subjects. There is no implantable part of the device, and there is no procedure implanting anything of any kind into the volunteer.

b. The device to be studied under this protocol is not supporting or sustaining human life. In this study it will only be used on healthy volunteers that are not reliant upon any function it may provide.

c. The device to be studied is not being used to diagnose, cure, or treat any of the volunteers or otherwise to prevent impairment of their health that presents a potential for serious risk to the health, safety, or welfare of the volunteers. The device only provides support to their airway and takes measurements. There is no prescribed medical care of any kind being given to volunteers, and the intervention in no way is necessary to sustaining their life. It also poses no serious risks to the volunteers, as they are only being asked to breathe oxygen.

d. The device only provides support to the volunteer's airway and takes measurements. It does not pose any serious risk to health, safety or welfare of the subjects. The volunteers are only being asked to breathe oxygen.

In addition: The device is implemented in an FDA cleared device with only added software features. Potential adverse effects do not show potential for serious risk to participants. At any time during the study, the volunteers may remove the mask. The volunteers will not be receiving medical procedures in our study. The device is not banned. To mitigate the risk of excessive pressure from the system, a stretchy strap is used to attach the mask to the face so that the mask can move away from the face to allow air to escape if pressures begin to rise excessively. The device has a built-in 40 micron filter on the gas inlet to catch particulates from the compressed oxygen tank.

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8. Resources and Responsibilities

8. Resources and Responsibilities

1. * **State and justify the qualifications of the study staff:**

   A research assistant (graduate student) will administer the test. He has completed the University's HIPAA training and has completed CITI training.

2. * **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   Research investigator is involved in the design of the study and protocol and is familiar with the procedures.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**

   The study will utilize a tank of compressed oxygen and standard wall power. This will be conducted in a dedicated study room at the University of Utah's Pain Management Center at 615 Arapeen Drive, #100 Salt Lake City, Utah 84108.

4. * **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**

   Not applicable since risks are non-significant.

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Documents and Attachments

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
Kai Kuck, CV(0.01)	0.01	3/10/2015 2:46 PM	3/10/2015 2:46 PM	

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

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IRB_00190165 Finish

Finish Instructions

Finish Instructions

1. **To view errors, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**