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## eSubmission Cover Letter

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**From:** Patricia Duclos-Miller  
**E-mail:** [pduclos@bristolhospital.org](mailto:pduclos@bristolhospital.org)  
**Phone Number:** 860-585-3818  
**Company Name:** Bristol Hospital  
**Principal Investigator:**  
**IRB Tracking Number:** 20170730  
**Submission Notes:** There was a typo on page 5 of the WIRB document. In the section that describes the secondary rescue maneuver we mention sat> 94% which should be 90% instead as illustrated in attachments A (page 9) and B (pages 10).  
 This did not affect the results of our trial as none of our patients needed to have a secondary rescue maneuver.  
**Sponsor Name:** Bristol Hospital

**Submitted Files:**

File	Type
corrected wirb research proposal bh use of non invasive positive pressure ventilation in obese pts undergoing upper gi endoscopy procedures final 3 23 17.docx.pdf	Protocol/Grant
corrected wirb research proposal bh use of non invasive positive pressure ventilation in obese pts undergoing upper gi endoscopy procedures final 3 23 17.docx.pdf	Miscellaneous

**BRISTOL HOSPITAL**

**Protocol Title: Use of Non-invasive Positive Pressure Ventilation for Obese Patients Undergoing Upper  
GI Endoscopy Procedures**

**Corrected and most recent version on 4-23-19**

Makram Gedeon, MD, Primary Investigator

Research Site

Bristol Hospital  
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Bristol, CT 06010  
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BRISTOL HOSPITAL

**Protocol Title: Use of Non-invasive Positive Pressure Ventilation for Obese Patients Undergoing Upper GI Endoscopy Procedures**

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## **Use of Non-invasive Positive Pressure Ventilation for Obese Patients Undergoing Upper GI Endoscopy Procedures**

### **ii. Purpose of the study:**

The aim of our study is to evaluate the effect of non-invasive positive pressure ventilation (BiPAP) in severely obese patients undergoing upper endoscopy both as an adjunct to sedation to decrease the incidence of hypoxic episodes, and as a rescue maneuver in case a hypoxic episode occurs.

Hypothesis: Use of non-invasive positive pressure ventilation in morbidly obese patients (BMI >40) will improve oxygen saturation during upper GI endoscopy procedures.

**Background:** Current estimates of the prevalence of severe obesity are 5.5 % in males and 9.9% in females. Obesity constitutes a major health problem and bariatric surgery is currently the most effective and sustainable treatment option especially for patient with severe obesity (BMI >40). (Flegal, 2016)

Many patients being evaluated for bariatric surgery undergo screening upper endoscopy, although this practice has been challenged recently. Our center has adopted a universal screening policy in the evaluation of patients undergoing bariatric surgery.

Sedation is widely performed during endoscopy to decrease patient anxiety, discomfort and pain. Obesity has been identified as an independent risk factor for sedation-related adverse events, such as hypoxia and need for airway maneuvers, in patients undergoing endoscopy. Non-invasive positive pressure ventilation is commonly used in hospitals to supplement oxygenation and ventilation, especially in the morbidly obese patients. Our hypothesis is that use of non-invasive positive pressure ventilation in morbidly obese patients (BMI>40) will improve oxygen saturation during upper GI endoscopy procedures.

### **iii. Criteria for Subject Selection**

**Title:** Use of Non-invasive Positive Pressure Ventilation for Obese Patients Undergoing Upper GI Endoscopy Procedures

**Number of participants:** 88

**Gender of Subjects:** Male; female

**Age of Subjects:** 18-65 years of age

**Racial and Ethnic Origin:** No race or ethnic origin restrictions

**Inclusion Criteria:**

The following patients will be included in this research study:

- Patients undergoing screening upper endoscopy prior to weight loss surgery
- BMI 40-60

**Exclusion Criteria:**

The following patients will be excluded from this research study:

- Pregnant patients
- Previous weight loss surgery or stomach surgery

- BMI > 60 and BMI < 40
- Active smokers
- Patients with a history of recent URTI (Upper Respiratory Tract Infection) within the preceding 2 weeks
- Lung disease, COPD asthma, cystic fibrosis, sarcoidosis
- Baseline O2 saturation less than or equal to 94%
- Exclude substance abusers (active alcohol abuse, benzodiazepine abuse, active illicit drug use)

#### **iv. Methods and Procedures.**

This study is an Effectiveness trial.

#### **End points to be measured with definitions**

Monitoring vital signs every 2-3 minutes unless there is an event:

1. O2 saturation
  - Desaturation defined as O2 sat  $\leq$  94%
  - Desaturation requiring intervention O2 sat < 90 %
2. Heart rate
3. Blood pressure
4. Respiratory rate:
  - In the control group this will be obtained from the ETCO2 monitor
  - In the treatment group this will be measured by the BiPAP machine
5. Procedure times
  - Time of start of sedation (time 0/start time)
  - Time of scope in patient
  - Time of scope out of patient
  - Time to patient opens eyes to verbal stimuli (end time) as end of procedure
6. Number of endoscope withdrawing events during procedure
7. Number of procedure cancellations after induction with propofol
8. Measure age, sex, neck circumferences, ASA score, Mallampati score, BMI and end points
9. Total dose of propofol per patient

#### **BiPAP settings:**

-IPAP 12 cm H<sub>2</sub>O/EPAP 6 cm H<sub>2</sub>O with maximum IPAP 18 cm H<sub>2</sub>O /8 cm H<sub>2</sub>O on 100% FiO<sub>2</sub> and for a tidal volume of 300-800 mL (target is 450-500)

-If TV are more or less than the 300 to 800 mL range the pressure will be adjusted by 1-2 cm H<sub>2</sub>O accordingly

CO2 upper endoscopy

Propofol used: divided doses of 50 mg each until loss of eyelash reflex; continual doses as needed until loss of gag reflex

Recording to be done by independent third person

#### **Control group: nasal cannula + BiPAP mask, not connected to machine**

- Nasal cannula set at 6L/min flow rate
- if desaturation below 90 % move to primary rescue maneuver started (nasal cannula removed and BIPAP mask connected to machine)
- If BiPAP rescue maneuvers attempted (adjustments in pressure) and O2 sat is not above 90 % within 3 min of starting BiPAP, secondary rescue maneuver started and scope removed

- Secondary rescue maneuvers performed at the discretion of the anesthesiologist (chin lift, oral airway, bag mask, nasal trumpet, LMA, intubation)
- If sat > 90 % with secondary rescue maneuvers, resumption of scope exam to the discretion of anesthesia
- If sat does not increase > 90 % with secondary rescue maneuvers, scope exam to be cancelled and patient care per anesthesiologist

**Experimental group: BiPAP mask, will connect to machine once sedated**

- If desaturation below 90 % on BiPAP despite increased BiPAP pressures secondary rescue maneuver started and scope removed
- Secondary rescue maneuvers at the discretion of the anesthesiologist (chin lift, oral airway, bag mask, nasal trumpet, LMA, intubation)
- If sat > 90 % with secondary rescue maneuvers, resumption of scope exam at the discretion of anesthesia
- If sat does not increase > 90 % with secondary rescue maneuvers, scope exam to be cancelled and patient care per anesthesiologist

**Definitions:**

**OSA:**

Negative OSA: Patient tested and negative study obtained or Low Risk STOP BANG Assessment

Positive OSA: Patient has STOP BANG Assessment with "High Risk" result (no testing done yet)

Positive OSA: Patient tested by PSG or HST and has a positive study result of either mild, moderate, or severe OSA

**Data Analysis and Data Monitoring.**

Statistical power was calculated to detect a significant treatment effect for the desaturation primary outcome based on a chi-square goodness of fit test for the difference between the treatment and control group in the likelihood of a desaturation event. Assuming a moderate effect size for the difference between the two groups in the probability of a desaturation event (Cohen's  $w=.30$ ), a total of  $N=88$  participants ( $N=44$  per study arm) are required to achieve acceptable statistical power of 0.80 for a two-tailed test with  $\alpha=0.05$ .

**Data Storage and Confidentiality**

During and after the research study the participants data will be housed in the investigator's office in a locked file cabinet and locked office after office hours. Further security will be ensured by only allowing the investigator, sub-investigator, data collection analysis, statistician and research coordinator who will have access.

**V. Risk/Benefit Assessment**

**Risk Category.** Minimal Risk

**Potential Risk.**

Risks for BiPAP use

BiPAP is commonly used and is safe. Most problems from BiPAP involve the facemask. The mask will be close fitting to allow for an air seal. Some other risks include:

- Local skin damage from the mask
- Mild stomach bloating
- Dry mouth
- Leaking from the mask, causing less pressure to be delivered
- Eye irritation
- Sinus pain or sinus congestion

Risks may differ depending on age, the amount of time BiPAP is needed, and participant medical problems.

**Alternatives to Participation.**

The participant who does not want to participate in the research study will receive the same level of care as there will be no change in the endoscopic procedure.

**vi. Subject Identification, Recruitment And Consent/Assent**

**Method of Subject Identification and Recruitment**

The prospective subjects will be identified based on the inclusion criteria and from the physician practices of Gedeon, MD and Adra, MD. The primary physician will not discuss the research or attend to recruit patients into the study. The nurse will interview, conduct patient education and obtain the consent for participation in the research study.

**Process of Consent.** Karen Roy, RN will obtain consent for the prospective patients. The description of the research study as stated on the consent form will be discussed with any patient who meets the inclusion criteria in the office. K. Roy, RN will be responsible for ensuring that valid consent is obtained and documented for all subjects. Documentation of Consent forms will be entered in a tracking log and maintained in a secure area of the principal investigator's office.

**Subject Capacity.** Only patients capable of understanding and giving consent to be a participant in the research study will be included.

**Consent Form.**

**Attachment C**

**Costs to the Subject.** There is no cost to the subject for participating in this study.

## References

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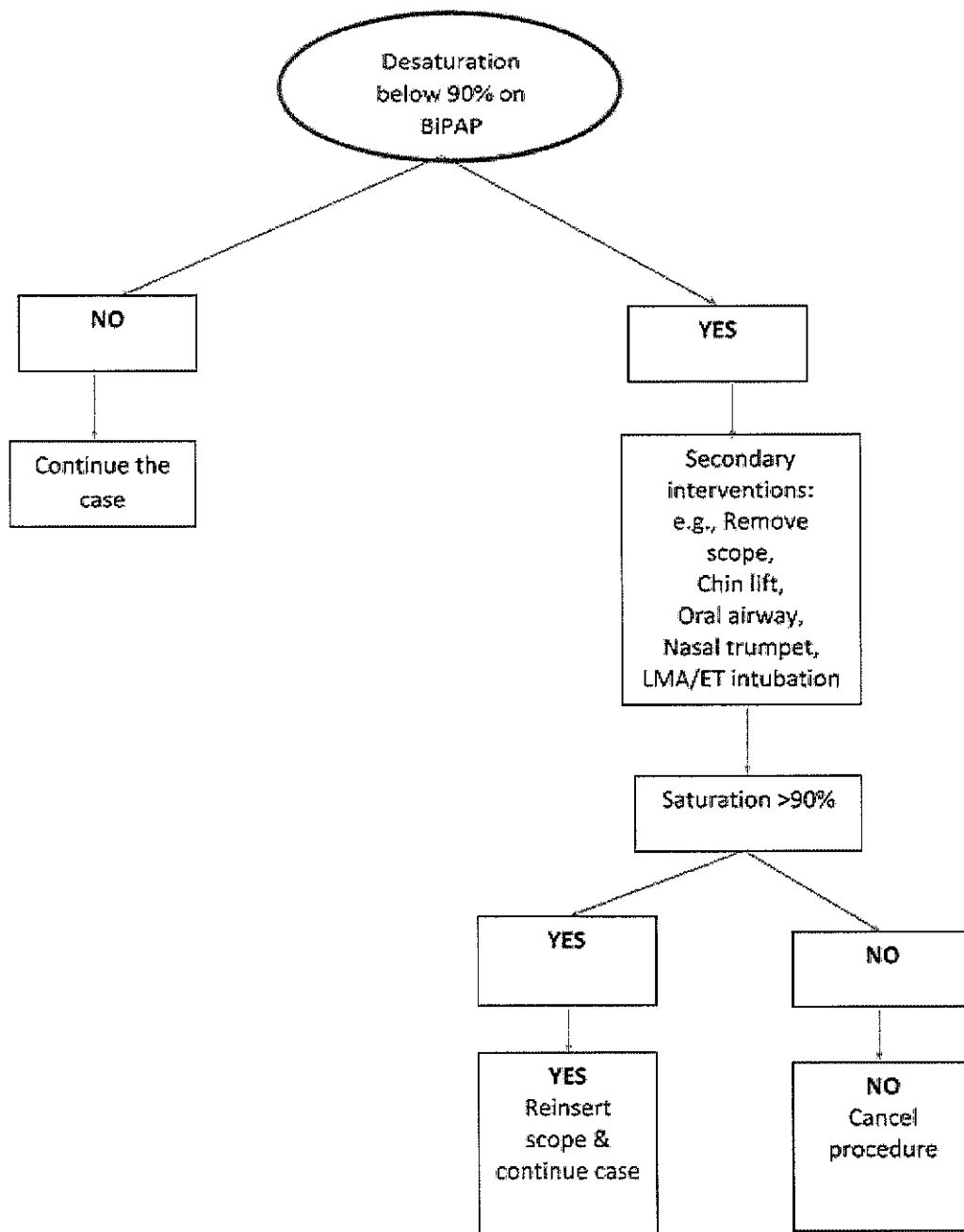
Wani, S., Azar, R., Hovis, CE., Hovis, RM., Cote, GA., Hall, M., Waldbaum, L., Kushnir, V., Early, D., Mullady, DK., Murad, F., Edmundowicz, SA., Jonnalagadda, SS. (2011). Obesity as a risk factor for sedation-related complications during propofol-mediated sedation for advanced endoscopic procedures. *Gastrointest Endosc*, 74(6):1238-47. doi: 10.1016/j.gie.2011.09.006.

**Attachment A**

DECISION TREE FOR RESEARCH STUDY

BIPAP USE DURING ENDOSCOPY

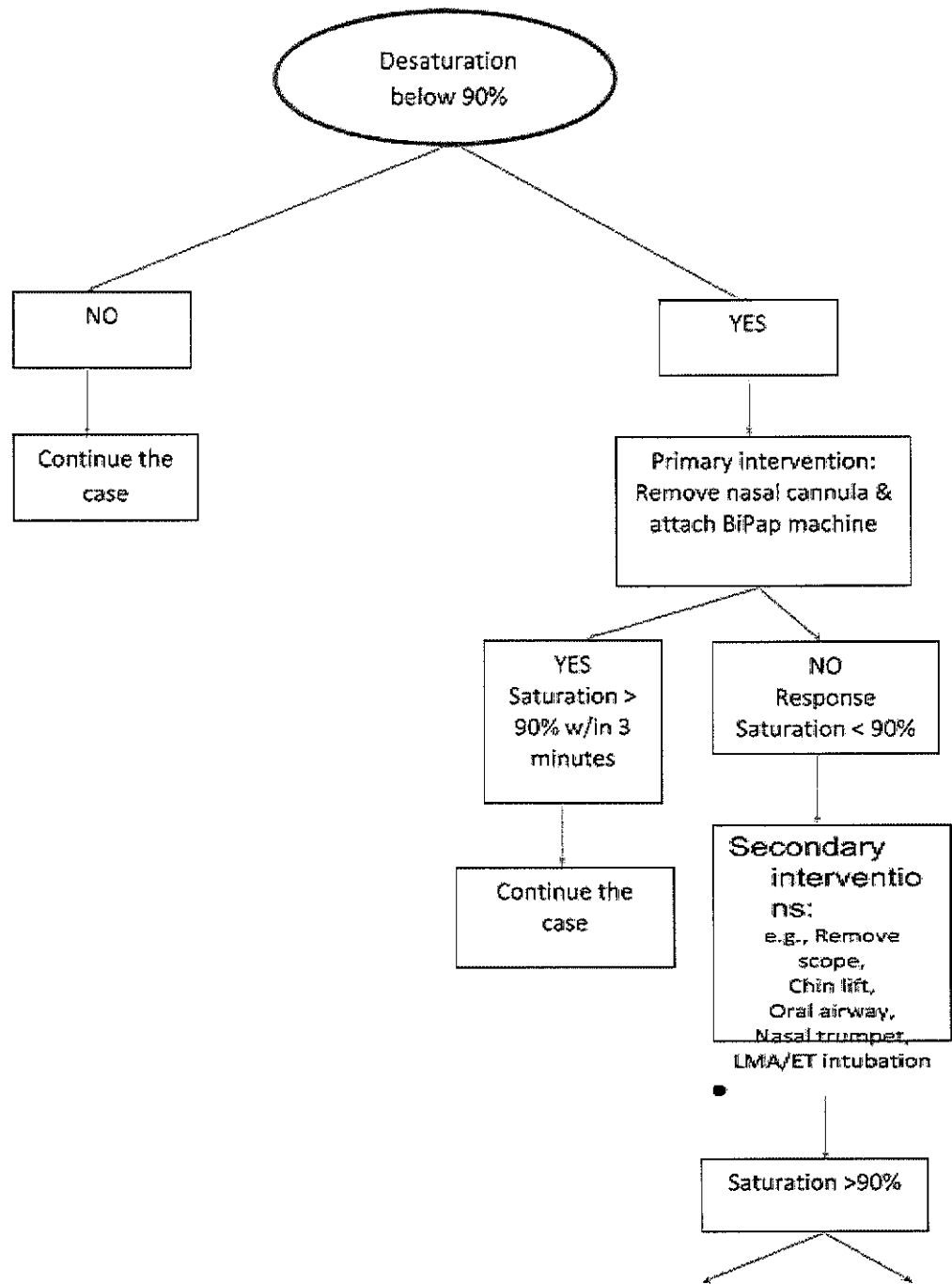
EXPERIMENTAL GROUP



DECISION TREE FOR RESEARCH STUDY

BIPAP USE DURING ENDOSCOPY

CONTROL GROUP



**Attachment C**

Reinsert  
scope

Cancel  
procedure

**RESEARCH SUBJECT INFORMATION AND CONSENT**

**TITLE: Use of Non-invasive Positive Pressure Ventilation for Obese Patients Undergoing Upper GI Endoscopy Procedures**

**PROTOCOL NO.:**

**SPONSOR:** Bristol Hospital  
**INVESTIGATOR:** Makram Gedeon, MD  
Bristol Hospital  
41 Brewster Road  
Bristol, CT 06010 USA

**STUDY-RELATED PHONE NUMBER(S):**

Makram Gedeon, MD Phone: 860-585-1560  
Sheldon Gomes, MD Pager: 860-842-9274 (Leave a call back phone number)

**SUMMARY**

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

*Things to know before deciding to take part in a research study:*

- The main goal of a research study is to learn things to help patients in the future.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study will involve standard medical care. (Standard care is the treatment normally given for a certain condition or illness).
- Other parts of this study may involve experimental (investigational) procedures that are being tested for a certain condition or illness.
- Your medical records may become part of the research record. If that happens, your medical records will be looked at by the members of the research study.

**PURPOSE OF THE STUDY**

The purpose of this study is to see whether BiPAP (non-invasive positive pressure) benefits the patient during upper GI endoscopy procedures. Some of the patients will have BiPAP (non-invasive positive pressure) during upper GI endoscopy procedures. Patients will be selected on a random basis.

**PROCEDURES**

- The patients will be selected at random.

- If you are selected for the study you may or may not have BiPAP (non-invasive positive pressure).
- All procedures for your upper GI endoscopy will be the standard of care regardless of your participation in the research study.

## **RISKS AND DISCOMFORTS**

*The side effects for the use of the BiPAP may be:*

- Most common: dry mouth, leaking from mask, eye irritation
- Less common: local skin damage, mild stomach bloating, sinus congestion
- Rare: nausea and vomiting

## **BENEFITS**

There may be a potential decrease in the number of times your oxygen levels go down. However, it cannot be promised that you will receive any medical other benefits from being in this study.

## **COSTS**

Bristol Hospital will provide the study device (BiPAP) free of charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You or your insurance company may be billed for:

- Any standard medical care given during this research study.

## **PAYMENT FOR PARTICIPATION**

You will not be paid for being in this study.

## **ALTERNATIVE TREATMENT**

This is not a treatment study. Your alternative is not to be in this study.

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

### **What information may be used and given to others?**

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

### **Who may use and give out information about you?**

The study doctor and the staff working with the doctor; Bristol Hospital; Western Institutional Review Board® (WIRB®).

### **Why will this information be used and/or given to others?**

- The information is used to do the research and to study the results.

**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

**May I review or copy my information?**

Yes, but only after the research is over.

**May I withdraw or cancel my permission?**

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor prior to your scheduled procedure. If you withdraw your permission, you will not be able to stay in this study.

**Is my health information protected after it has been given to others?**

Your information will be locked in a secure location and not available to anyone else except the research team.

**COMPENSATION FOR INJURY**

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest
- if the oxygen saturation level remains at 90% or below for 3 minutes and the patient does not respond to secondary interventions

**SOURCE OF FUNDING FOR THE STUDY**

The Bristol Hospital will pay for this research study.

**QUESTIONS**

Call Dr. Gedeon at 860-585-1560 for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)  
1019 39th Avenue SE Suite 120 1  
Puyallup, Washington 98374-2115  
Telephone: 1-800-562-4789 or 360-252-2500 1  
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

### **CONSENT**

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study. By signing this consent form, I have not given up any of my legal rights.

### ***Signature:***

\_\_\_\_\_  
Participant Name (printed)

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

**Your Participation in a Bristol Hospital Research Study**

**Purpose of the Study:**

The aim of our study is to study the effect of using **BiPAP** also called non-invasive positive pressure ventilation in selected patients undergoing upper endoscopy while under sedation. The research study is looking to see if **BiPAP** helps with a patient's oxygen level during an endoscopic procedure.

**What does this mean for me?**

1. You will have your endoscopy procedure performed by your doctor as you would if you were not participating in this study. The endoscopy procedure will not change due to the study.
2. Your anesthesia will not be changed due to the study.
3. All patients will receive the necessary oxygen devices routinely utilized while under anesthesia for an endoscopy procedure.
4. You may be one of the patients who will receive **BiPAP** (non-invasive positive pressure ventilation).

**Who is eligible to participate in the study?**

1. Patients undergoing endoscopy procedure under the care of Dr. Gedeon or Dr. Adra.
2. Patients who have a BMI between 40-60.
3. Patients who are non-smokers.
4. Patients who have not had prior weight loss surgery or stomach surgery.
5. Patients who have no history of recent respiratory tract infections, lung disease, COPD, cystic fibrosis, or sarcoidosis.
6. Patients who are not pregnant.
7. Patients who are between the ages of 18-65 years of age.
8. Patients with a baseline oxygen saturation of 94% or greater before the procedure.
9. Patients who are not substance abusers (no active alcohol abuse, benzodiazepine abuse, or active illicit drug use).

**Will my name or medical information be released outside of Bristol Hospital?**

No, we will remove your identification for any of the medical data used for the research study.

**What are the potential risks?**

1. Those risks normally associated with any endoscopic procedure. Your surgeon will review the risks of the endoscopic procedure with you.
2. **BiPAP** is usually very safe.
3. Most problems from **BiPAP** involve the facemask. It may fit too tightly or loosely.
4. Some other risks can include: local skin irritation from the mask, mild stomach bloating, dry mouth, air leaking around the mask can cause less pressure to be delivered, eye irritation, and sinus pain or sinus congestion.

**Please call 860.585.1560 if you have any questions or concerns**



