JACOBI MEDICAL CENTER (JMC)
NORTH CENTRAL BRONX HOSPITAL (NCB)

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant (you or your child); "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called **Comparison of Two Drug Combinations for Ambulatory Oral & Maxillofacial Surgery.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Stephen Gelfman, DDS, MD. You can reach **Dr. Gelfman** at:

Jacobi Medical Center
1400 Pelham Parkway South #3NE-1
Bronx, N.Y. 10461
Telephone #: 718-918-3419

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg Room 1002
Bronx, New York 10461

Why is this study being done?

The goal of this study is to compare two drug combinations that are commonly used during dental surgery sedations at Jacobi Medical Center and North Central Bronx Hospital. The drugs are: ketamine/fentanyl/midazolam/nitrous oxide and propofol/fentanyl/midazolam/nitrous oxide. We want to determine if the patients or the surgeons prefer one combination over the other.

Ketamine/propofol/fentanyl/midazolam/nitrous oxide have all been approved by the U.S. Food and Drug Administration (FDA) to be used as part of an intravenous sedation.

Why am I being asked to participate?

You are being asked to participate in this study because you need your wisdom teeth removed to maintain your dental health and you have requested sedation for your surgery. You are being included because you are in good health and are a good candidate for this sedation.

How many people will take part in the research study?

We expect to enroll 100 patients who will be treated at JMC/NCB.

How long will I take part in this research?

It will take you 2 surgical and 2 post-operative visits to our clinic to complete this research study. This is the same number of visits it would require if you do not participate in the study.

What will happen if I participate in the study?

The Screening Visit will take about 15 minutes. During this visit, we will do some tests and non-dental procedures to see if you are eligible to take part in this research study. This may include a dental exam and x-rays. All dental patients at our clinic have routine x-rays. If you are a new patient you will have your x-rays taken at the screening visit. The study doctor will review the results of these tests and procedures. If you aren't eligible, the study doctor will tell you why. At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Test your urine for pregnancy (at the surgical appointments), if you are a female and able to become pregnant. Pregnant women cannot take part in this research.

If you are eligible for the study, we will assign you by chance (like a coin toss) to one of the drug groups for your first surgery and the other drug group for your second surgery. Group 1 will receive one of our usual intravenous drug combinations which is midazolam, fentanyl, ketamine and nitrous oxide and Group 2 will receive our other usual intravenous drug combination of midazolam, fentanyl, propofol and nitrous oxide. At your second surgery you will receive the drug combination you did not have first. You and the study doctor cannot choose your order of study group. You will have an equal chance of being assigned to either group first.

Surgical visit one will take about two hours. Surgical visit two will also take about two hours. At these visits we will:

- Check your vital signs
- Ask you for a urine sample (females only)
- Give you some questionnaires to fill out
- Proceed with your sedation and surgery as we usually do
- Give you some paper and pencil tests after your surgery to judge your recovery
- Give you some paper and pencil questionnaires to rate the experience

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. You and/or your insurance company will have to pay for any costs that are part of your regular dental care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical/dental treatment, as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Victor Badner, DMD, MPH at 718-918-3419

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.***
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Are there any risks to me?

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them

- groups that review research (the Einstein IRB, the Office for Human Research Protections, and the Food and Drug Administration)

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Risks of Intravenous Sedation
The study medications (ketamine/fentanyl/midazolam/nitrous oxide and propofol/fentanyl/midazolam/nitrous oxide) are to be used in the same manner as if you were not in the study. Therefore, the side effects from these drugs are the same as if you were not in this study.
Anytime intravenous sedation is administered using these combinations you may experience:

- slow recovery and prolonged feeling of tiredness
- nausea
- dreaming during your surgery
- bruising at site of needle insertion
- changes in blood pressure and heart rate

Risks to Women Who Are or May Become Pregnant
The effect of the drugs used in this study may have an effect on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

Taking Study Drug with Other Medications
For your safety during this study, call your study doctor BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplement

Allergic Reaction to Study Drug
Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

Unknown Risks
We have described all the risks we know. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. We hope you will participate because the study will generate important information about which drug combination is preferred by either the patient or surgeon.

What choices do I have other than participating in this study?
You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you. You can have your wisdom teeth removed with IV sedation without being enrolled in this study.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason.

Can the study end my participation early?
If this form of routine treatment is not the best for you, we may change your treatment and the study will end for you. In addition, your participation will end if the investigator stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed Name of Guardian or Family Member (when applicable)	Signature of Guardian or Family Member (when applicable)	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time