INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY: Maggie Jeffries, MD

PROTOCOL NUMBER AND TITLE OF STUDY: ANES001

NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR): Maggie Jeffries, MD

TELEPHONE NUMBER(S): 832-390-4477

INTRODUCTION

You are being invited to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

The investigator is the sponsor and is paying for this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate which combination of anesthesia medications that our patients prefer for cataract surgery. We would also like eliminate the need for IVs in certain patient populations with the use of oral medications.

Your participation in this study is in addition to your regular medical care. Your regular doctor(s) will continue to make decisions about what treatments are best for you. Your participation in this study will not affect or replace your regular medical care.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last about 1 year. About 600 men and women over the age of 18 are expected to be in this study.

TO BE IN THIS STUDY

You can participate in this study if you are having cataract surgery. You cannot be in this study if you are cane/walker/wheelchair dependent, allergic to our medications, unable to consent for yourself, or under the age of 18.

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing to answer survey questions the day after your surgery via telephone
- Ask questions as you think of them

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to sign this consent form. All patients scheduled for cataract surgery will be included in the study unless exclusion criteria are met.

Study Procedures:

You will arrive for surgery at Kirby Glen Surgery Center on the day of your cataract surgery and all processes that normally take place will occur. Consents for the study, surgery and anesthesia will be signed. You will meet with your anesthesiologist who will complete your anesthetic evaluation, determine suitability for anesthesia and write the order for you to receive medications. The nurse will choose at random which combination of anesthesia medications you are to receive and those medications will be administered. Additional medications will be administered as needed throughout your surgery as needed. No medications will be withheld.

Before you leave the surgery center and the day after, a nurse will ask you questions about your experience. Data will be collected regarding your opinions as well as demographics and medications received.

Storage and Disposition of Research Data About You

The data collected about you will be stripped of identifying information and entered into a database at the anesthesia office on a password protected computer.

If you decide to withdraw from this study, the data collected prior to your leaving the study will remain in the study database and continue to be used; however, no new information will be collected.

POSSIBLE RISKS OR DISCOMFORTS

There are no additional risks or side effects associated with participation in the study. The risks of anesthesia are in the anesthesia consent and do not differ from what you would experience should you not participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from this study, however you may receive a chance to be in a research study that may help others.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator(s)
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

No form of compensation is offered.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Maggie Jeffries, MD
832-390-4477
avalonanesthesia@gmail.com

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
MJ: 4/3/17

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Employees of the investigator/sponsor are excluded

The investigator, the sponsor company, IntegReview, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not answer the survey questions
- If we find out you should not be in the study
- If the study is stopped

If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

SUBJECT'S BILL OF RIGHTS

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

CONSENT FOR SUBJECTS WHO CANNOT READ
The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information provided to the subject.

The signature lines below are required for subjects that are visually impaired.
The study subject has indicated that he/she is visually impaired. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____
Signature of Impartial Witness* Date

*The impartial witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

You will receive a signed and dated copy of this consent form to keep.