Comparing Two Normal Approaches to Procedural Sedation for Cataract Surgery: A Prospective, Feasibility Pilot Study (CatNAPS-1)

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MAC FEASIBILITY PILOT STUDY

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Coordinating Center:	UC San Francisco

Approval:



PI or Sponsor Signature (Name and Title)

10/27/2025

Date

This confidential information about an investigational trial is provided for the exclusive use of investigators of this study and is subject to recall at any time. The information in this document may not be disclosed unless federal or state law or regulations require such disclosure. Subject to the foregoing, this information may be disclosed only to those persons involved in the study who have a need to know, with the obligation not to further disseminate this information.

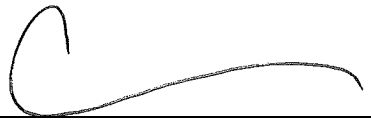
PROTOCOL AGREEMENT

I have read the protocol specified below. In my formal capacity as Investigator, my duties include ensuring the safety of the study subjects enrolled under my supervision and providing UC San Francisco with complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in accordance with accepted GCP principles and to abide by the terms of this protocol.

Protocol Number: Not yet obtained.

Protocol Title: **C**omp**A**ring **T**wo **N**ormal **A**pproaches to **P**rocedural **S**edation for Cataract Surgery (CaTNAPS-1): A Prospective, Feasibility Pilot Study

Protocol Date: 10/27/2025



10/27/2025

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LIST OF ABBREVIATIONS

AE	adverse event
BP	Blood pressure
CFR	Code of Federal Regulations
DMC	Data Monitoring Committee
DSMB	Data Safety Monitoring Board
ECog	Everyday Cognition
FRI	Functional Recovery Index
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HR	Heart Rate
ICF	informed consent form
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISAS	Iowa Satisfaction with Anesthesia Survey
MAC	Monitored Anesthesia Care
MoCA-BLIND	Montreal Cognitive Assessment. Adapted from MoCA Full.
PI	Principal Investigator
PQRS	Postoperative Quality of Recovery Scale
SAE	serious adverse experience
QoR-15	Quality-of-Recovery-15 Survey

PROTOCOL SYNOPSIS

TITLE	Comparing Two Normal Approaches to Procedural Sedation for Cataract Surgery: A Prospective, Feasibility Pilot Study (CaTNAPS-1)
SPONSOR	NIH National Institute on Aging
FUNDING ORGANIZATION	NIH National Institute on Aging University of California, San Francisco
NUMBER OF SITES	1
RATIONALE	Although the overall rate of complications from cataract surgery is extremely low, both anesthesiologists and ophthalmologists in the US have resisted the outright elimination of monitored anesthesia care (aka MAC) due to the lack of data from controlled prospective studies that demonstrate the safety and acceptability of sedation alternatives for cataract surgery. Our long-term goal is to determine whether patients will be equally satisfied with their care when undergoing cataract surgery using a less resource-intensive, but commonly used, approach to sedation. In this current study, we hope to generate the pilot data needed to lay the groundwork for a future multicenter prospective randomized controlled trial.
STUDY DESIGN	This is a single center, randomized, double-blinded, pilot clinical trial.
PRIMARY OBJECTIVE	The primary objective of this study is to assess the feasibility, completeness, and distribution of data in measuring patient satisfaction in patients undergoing two commonly used approaches to cataract surgery sedation.
SECONDARY OBJECTIVES	The secondary goals of this study are to assess success with recruitment, participant retention after interventions, adherence to the interventions, intervention fidelity, post-operative anesthesia-related complications, and quality of recovery after surgery.
NUMBER OF SUBJECTS	20
SUBJECT SELECTION CRITERIA	Patient Inclusion Criteria: 1. ≥ 60 years old 2. Capable of providing informed consent and completing the study procedures in English 3. Able to provide consent for oneself 4. Able to follow directions 5. Able to climb one flight of stairs without stopping to rest 6. Have a new diagnosis of cataract disease

	7. Plan on having cataract surgery on their eye within the next 6 months Patient Exclusion Criteria: 1. History of prior cataract surgery 2. Admission to the hospital within the past 30 days 3. Difficulty being sedated during other minor outpatient procedures or imaging studies 4. Allergy or resistance to local anesthetic agents 5. Cannot lay flat on your back without having symptoms (i.e., difficulty breathing, severe back pain, etc.) 6. History of severe anxiety requiring routine use of benzodiazepines 7. Severe valve disease (e.g., critical aortic stenosis) 8. Cardiac conditions requiring an implanted cardiac device such as a pacemaker, defibrillator, or left ventricular assist device (for arrhythmia, congestive heart failure, etc.) 9. Untreated chest pain or angina 10. Patients with movement disorders (e.g., Parkinson's Disease) 11. History of Cerebral Vascular Accident (CVA), Transient Ischemic Attack (TIA), or seizures 12. Require home oxygen (O2) at rest or with exertion 13. End-stage renal disease (ESRD) requiring dialysis 14. Morbid obesity (BMI>35) 15. Patient undergoing cataract surgery in combination with any other ophthalmologic procedure 16. Patient requiring general anesthesia during cataract surgery due to the underlying characteristics of the existing cataract and/or anticipated complexity of the planned procedure Surgeon Inclusion Criteria 1. Ophthalmologist at UCSF performing cataract surgery * There are no exclusion criteria for surgeons.
TEST INTERVENTIONS	Experimental Operative Eye o Oral Sedation (Alprazolam (0.25 - 0.5 mg)
CONTROL PRODUCT, DOSE	Control Operative Eye

AND ROUTE OF ADMINISTRATION	○ Oral placebo pill
DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	Subjects will be enrolled in the study for up to 2 months, not including time to procedure which is independent of the trial timeline. **Screening:** up to 15 days **Treatment:** up to 30 days. **Follow-up:** up to 15 days. The total duration of the study is expected to be 6 months. 2 months for subject recruitment and 4 for final subject follow-up.
CONCOMMITANT MEDICATIONS	Allowed: - **Standardized medications across both study cohorts will include topical anesthetics for analgesia,** to include but not limited to eye drops, intra-cameral, subconjunctival, and sub-Tenon blocks. - Standard therapies for monitored anesthesia care at UCSF (i.e., IV fentanyl and midazolam) will be allowed, but clinicians will be encouraged to prioritize non-pharmacological interventions (handholding, verbal reassurance, etc.), prior to resorting to these intravenous sedative medications. - Control patients are expected to require intraoperative sedative medications similar to the doses normally given during cataract surgery at UCSF, whereas intervention patients are less likely to need intravenous sedative medications since the oral alprazolam is being administered for the purpose of sedation. However, for safety and in case of emergency, both study cohorts will receive numbing eye drops, receive an intravenous line, and be monitored by an anesthesia team (either an anesthesiologist or a certified registered nurse anesthetist (CRNA)) during surgery. The anesthesia team can escalate the depth of sedation if needed, up to and including general anesthesia. In addition, an anesthesiologist will be immediately available on site to respond to any unexpected events or medical emergencies. However, conversion to general anesthesia is expected to be a very rare event given that only 3% of cataract patients receive general anesthesia for cataract surgery to begin with.
EFFICACY EVALUATIONS	N/A
PRIMARY ENDPOINT	• Ability to collect and assess patient satisfaction
SECONDARY ENDPOINTS	• Success with recruitment • Participant retention after interventions • Adherence to the interventions • Intervention fidelity

	• Post-operative anesthesia-related complications • Quality of recovery after surgery • Surgeon satisfaction
OTHER EVALUATIONS	• Feasibility of conducting preoperative cognitive function assessments using MoCA-BLIND, PQRS, and ECog surveys.
SAFETY EVALUATIONS	• Incidence of adverse events and sedation-related complications 30 days after surgery.
STATISTICS **Primary Analysis Plan**	• Primary analysis will be descriptive: o The ISAS will gather data to compute two-tailed, independent T-Tests with a Students' T-Test of patient satisfaction and Chi-Square Analysis for categorical variables* and; o Similar methodologies for FRI, PQRS, and QoR-15 surveys in analysis of secondary endpoints. • This study is not designed or powered to test any efficacy hypotheses; therefore, we will not be evaluating intervention efficacy.
Rationale for Number of Subjects	This is a pilot so the number of patients is sufficient to help plan for the larger, single-center or multicenter trial.

NOTE: Surgeons will not be given any interventions aside from the surgeon satisfaction survey

1 BACKGROUND

Cataract surgery is a common elective surgical procedure among older adults, with over 2 million cases performed annually in the United States. Due to the significant advances in modern cataract surgical techniques over the last 30 years, cataract surgery is generally accepted as a safe and effective intervention for senile cataracts, with most patients experiencing a dramatic improvement in vision and quality of life after surgery. The risk of cataract surgery is considered low enough that there are now other viable sedation alternatives to having anesthesiologists and nurse anesthetists in the operating room to provide continuous intraoperative monitoring (a.k.a., "monitored anesthesia care" or "MAC"). However, we do not know whether using a less resource-intensive, but commonly used, approach to sedation will be acceptable to patients. Therefore, the overall goal of this proposal is to assess patient satisfaction with oral sedation compared to placebo in healthy older adults undergoing cataract surgery as part of a pilot feasibility study.

1.1 Overview of Non-Clinical Studies

Ophthalmologic surgical advances over the past several decades have resulted in extremely low ophthalmologic complication rates, estimated at anywhere between 0.05% and 2.2%. Furthermore, cataract surgery in other countries with modern healthcare systems is often performed without anesthetic monitoring or sedation.[9-11] In addition, many other low-risk elective outpatient procedures, though still arguably higher risk than cataract surgery, including cardiac catheterization, gastrointestinal endoscopy, and bronchoscopy, are routinely performed in the US without the presence of an anesthesia-trained professional unless specifically requested for the procedure.

Among Medicare beneficiaries, we showed that the rate of systemic perioperative complications was similar between ophthalmologists who sometimes or always used anesthesia care compared with those who never did. Our results are consistent with other studies that show that complication rates for cataract surgery are not higher among patients who undergo cataract surgery without anesthesia care when using protocolized approaches and trained staff.[9,10,26-30]

1.2 Overview of Clinical Studies

Administration of intravenous anesthetic agents does not improve postoperative visual acuity after cataract surgery and can cause adverse effects independent of the procedure itself.[4,15,16] For example, in a cohort of 19,156 patients undergoing cataract surgery in the late 1990's, Katz and colleagues found that although the incidence of adverse events was less than 2% overall, compared to patients receiving topical anesthesia and oral sedation only, the use of any intravenous agent was associated with a 10 to 30 times increase in the odds of experiencing any perioperative adverse event, including hypertension, hypotension, arrhythmias, ischemia, and myocardial infarction.[16]

Other more recent case series have shown that cataract surgery performed with oral sedation or intravenous sedation by a sedation nurse has similar complication rates as what is reported among patients receiving monitored anesthesia care during cataract surgery.[7]

2 STUDY RATIONALE

Although the overall rate of complications from cataract surgery is extremely low, both anesthesiologists and ophthalmologists in the US have resisted the outright elimination of monitored anesthesia care (aka MAC) due to the lack of data from controlled prospective studies that demonstrate the safety and acceptability of sedation alternatives to MAC. These alternatives, which include oral sedation, have long been used at selected US institutions and in other countries with modern healthcare systems without evidence of increased rates of adverse events. Our long-term goal is to determine whether patients will be equally satisfied with their care when undergoing cataract surgery using a less resource-intensive, but commonly used, approach to sedation. In this current study, we hope to generate the pilot data needed to lay the groundwork for a future multicenter prospective randomized controlled trial.

2.1 Risk / Benefit Assessment

Risks:

1. Intravenous Line Placement Risks: There may be risks associated with IV placement, such as pain when the IV is inserted, bleeding, and bruising, as well as a rare risk of infection.

2. Sedation Risks: This study will require that patients be sedated (minimal, moderate) for research purposes. Sedation is getting medicine that makes the patient very relaxed or sleepy. Before sedation is given, the patient's overall health will be checked. The physician or nurse who will provide and monitor the patient while they are sedated has received training and certification for providing sedation. Sedation medicine can be given in such ways as through a vein or in pill form. While under sedation, the patient's vital signs and breathing will be monitored. The medical team will watch over the patients as they recover. The exact steps can vary depending on the patient's health and the type of procedure they're having.

   Specific risks of each type of sedation that could be used in the course of this study include the following:
   a. Oral: If the patient receives oral sedation (alprazolam), they may experience side effects including, but not limited to:
      i. Drowsiness, dizziness, insomnia, memory problems, poor balance or coordination, slurred speech, trouble concentrating, headache, diarrhea, constipation, nausea, vomiting, upset stomach, blurred vision, muscle weakness, dry mouth, or decreased mental alertness.
   b. Intravenous: If the patient receives intravenous sedation (midazolam and fentanyl), they may experience side effects including, but not limited to:
      i. Midazolam:

1. Hiccups, cough, nausea, drowsiness, respiratory depression, vomiting, anterograde amnesia, drowsiness, ataxia, falls confusion, thrombophlebitis, thrombosis, or pain on injection. Hypotension and tachycardia can occur with rapid intravenous administration. Paradoxical effects of midazolam are possible in people with a history of alcohol abuse and aggressive behavior, potentially leading to involuntary movements, verbalization, uncontrollable crying, and aggressive behavior.

ii. Fentanyl:

1. Euphoria, confusion, respiratory depression, drowsiness, nausea, visual disturbances, dyskinesia, hallucinations, delirium, constipation, narcotic ileus, muscle rigidity, constipation, addiction, loss of consciousness, or hypotension

c. General Anesthesia: While it is highly unlikely, if the patient is unable to tolerate cataract surgery with their sedation assignment for any reason, they may receive general anesthesia to complete cataract surgery.

i. General anesthesia is a medical state where a person is put into a deep sleep in order to undergo a surgical procedure. Before general anesthesia begins, the patient's overall health will be checked. The anesthesia team will confirm that the patient has not consumed solid or particulate foods for at least 6 hours and clear liquids for 2 hours before their surgery begins. The patient will receive IV medication that makes them fall into a deep sleep, and a special tube will be placed in their airway to help them breathe and prevent the contents of their stomach from entering their lungs. The patient won't feel pain during the procedure. A machine may assist with their breathing. The patient's vital signs will be carefully monitored. At the end of the procedure, the anesthesia is reduced, allowing the patient to wake up. The patient will then go to a recovery area for monitoring and comfort. The exact steps can vary depending on the patient's health and the type of procedure they're having.

d. If IV sedation or general anesthesia is needed, this could cause delays during surgery and increase the overall time spent in the operating room.

3. Survey/Questionnaire Risks: Although each individual survey is short, completing all the required surveys while recovering from surgery may cause physical and emotional fatigue. The surveys/questionnaires include questions about pain, anxiety, and depression that could make patients feel upset or uncomfortable, and patients may skip any questions that they do not want to answer. If their answers reveal that they are feeling very anxious or depressed, then they will be given information about mental health services. The participant's primary provider will also be notified if the participant reports a high level of anxiety or depression.

4. Placebo risks: If the patient is in a group that receives a placebo, they will not receive the study drug (i.e., alprazolam.)

5. Randomization risks: Patients might be put into a group that receives something that is not as effective as another group. Patients might have more side effects than participants in another group or people who don't join this study. Those who are randomized to the placebo may experience more anxiety than those who are randomized to the group that receives oral alprazolam.

6. Risks of Lost Time: Patients will spend additional time above and beyond the normal time to evaluate and treat cataract disease, due to the time spent on study-related activities.

7. Privacy Risks: Although the risk of breach of confidentiality and loss of privacy is small, there is a risk of inadvertent disclosure of a patient's protected health information (PHI), which can lead to breaches of patient privacy, identity theft, loss of public trust, among other serious consequences. **
8. Unknown Risks: The study drug or treatments may have side effects that no one knows about. The study team will let patients know if they learn anything that might make them change their minds about taking part in the study. **

** These risks apply to surgeon subjects.

Benefits:

There will be no direct benefit to patients or surgeons from participating in this study. The information learned from this study may help others in the future.

3 STUDY OBJECTIVES

3.1 Primary Objective

The primary objective of this study is to assess the feasibility, completeness, and distribution of data in measuring patient satisfaction in patients undergoing two commonly used approaches to cataract surgery sedation.

3.2 Secondary Objectives

The secondary goals of this study are to assess success with recruitment, participant retention after interventions, adherence to the interventions, intervention fidelity, post-operative anesthesia-related complications, surgeon satisfaction and quality of recovery after surgery.

4 STUDY DESIGN

4.1 Study Overview

This is a single-center, randomized, double-blinded, pilot clinical trial. Twenty subjects and twenty eye surgeries are planned. The participants will be randomized to receive a placebo (control group) or oral sedation (intervention group). The purpose of the placebo is to prevent participants, clinicians, and investigators from knowing whether a participant receives oral sedation or a placebo. Each subject will undergo only one surgery for their condition and enrollment in this trial. Evaluations will be made at preoperative, intraoperative, and postoperative visits.

Screening data will be reviewed to determine subject eligibility. Subjects who meet all inclusion criteria and none of the exclusion criteria will be entered into the study.

The following standard sedation approaches will be used:

- Intervention Group: Oral sedation through administration of alprazolam (0.25 - 0.5 mg) by mouth. The medication will be administered 30 – 60 minutes before the patient enters the operating room.
    - The dosing range was based on the typical starting dose range of Alprazolam when prescribed for anxiety. Other studies have used a range of 0.5 to 1.0 mg of Alprazolam for anxiolysis prior to ambulatory surgery, including cataract surgery. Since cataract patients are generally an older population, we decided to use a dose of 0.5 mg to the vast majority of patients unless there was evidence of hepatic dysfunction, for which we would offer the lower dose of 0.25 mg.
- Control Group: An oral placebo pill will be administered to patients prior to their procedure. Timing of the administration will be identical to the oral benzodiazepine (30-60 minutes before the patient enters the operating room).

Both groups will receive an IV and standard monitors, and intraoperative monitoring by the anesthesia team (a.k.a. MAC). IV sedation will not be administered prior to surgery for either the intervention or control group.

Standardized medications across both study cohorts will include topical anesthetics for analgesia, to include but not limited to eye drops, intra-cameral, subconjunctival, and sub-Tenon blocks.

Standard therapies for monitored anesthesia care at UCSF (i.e., IV fentanyl and midazolam) are allowed for both the intervention group and control group, but clinicians will be encouraged to prioritize non-pharmacological interventions (handholding, verbal reassurance, etc.), prior to resorting to these intravenous sedative medications.

Control patients are expected to require intraoperative sedative medications similar to the doses normally given during cataract surgery at UCSF, whereas intervention

patients are less likely to need intravenous sedative medications since the oral alprazolam is being administered for the purpose of sedation. However, for safety and in case of emergency, both study cohorts will receive numbing eye drops, have an intravenous line, and be monitored intraoperatively by an anesthesia team (either an anesthesiologist or a certified registered nurse anesthetist (CRNA)) during surgery. The anesthesia team can escalate the depth of sedation if needed, up to and including general anesthesia. In addition, an anesthesiologist will be immediately available on site to respond to any unexpected events or medical emergencies. Conversion to general anesthesia is expected to be a very rare event given that only 3% of cataract patients receive general anesthesia for cataract surgery to begin with.

- CRITERIA FOR EVALUATIONS

4.2 Primary Efficacy Endpoint

The primary endpoint which will be analyzed in this study is completion of assessments on patient satisfaction, presented in the aggregate for all patients. This endpoint is appropriate to monitor as the pilot study is evaluating whether a larger study would be viable. The time course of this assessment will be from patient baseline to full completion of treatment. We will assess whether demographic covariates are correlated with feasibility and acceptability measures, to determine whether additional changes in the approach are needed to meet the needs of specific demographic groups.

There will also be summary statistics calculated, Students' T-Test for continuous variables, and a Chi-Squared test for categorical variables.

4.3 Secondary Efficacy Endpoints

The secondary efficacy endpoints of this study are to assess success with recruitment, participant retention after interventions, adherence to the interventions, surgeon satisfaction and intervention fidelity. These endpoints will primarily be assessed through intraoperative monitoring by a non-operating study coordinator and postoperatively via several implemented surveys to be completed by the patient and surgeons.

These endpoints are appropriate because they support the overarching goals in determining whether the pilot study may be maintained and if future studies are appropriate.

4.4 Safety Evaluations

With the widespread adoption of phacoemulsification as the technique of choice to treat age-related cataract, modern cataract surgery has been transformed into a quick outpatient procedure performed under local or topical anesthesia, and general anesthesia is rarely required.[3,7,28]

Intraoperative analgesia is achieved using local needle-based approaches such as retrobulbar, peribulbar, subconjunctival, or sub-Tenon blocks as well as topical anesthesia. Prior studies have shown that cataract surgery can safely be performed with any of these local or topical analgesic approaches.[4,13,29-32]

Given the rarity of adverse events in anesthesia delivery per the existing literature, study personnel will not be evaluating safety to an extent beyond recording the incidence of adverse events and sedation-related complications from cataract surgery 30 days after surgery.

5 SUBJECT SELECTION

5.1 Study Population (Patients)

Subjects with a diagnosis of untreated bilateral senile cataract who meet the inclusion and exclusion criteria will be eligible for participation in this study.

The following is a list of inclusion/exclusion criteria that apply to patients:

5.2 Inclusion Criteria

1. ≥ 60 years old
2. Capable of providing informed consent and completing the study procedures in English
3. Able to provide consent for oneself
4. Able to follow directions
5. Able to climb one flight of stairs without stopping to rest
6. Have a new diagnosis of cataract disease
7. Plan on having cataract surgery on their eye within the next 6 months

5.3 Exclusion Criteria

1. History of prior cataract surgery
2. Admission to the hospital within the past 30 days
3. Difficulty being sedated during other minor outpatient procedures or imaging studies
4. Allergy or resistance to local anesthetic agents
5. Cannot lay flat on your back without having symptoms (i.e., difficulty breathing, severe back pain, etc.)
6. History of severe anxiety requiring routine use of benzodiazepines
7. Severe valve disease (e.g., critical aortic stenosis)
8. Cardiac conditions requiring an implanted cardiac device such as a pacemaker, defibrillator, or left ventricular assist device (for arrhythmia, congestive heart failure, etc.)

9. Untreated chest pain or angina
10. Patients with movement disorders (e.g., Parkinson's Disease)
11. History of Cerebral Vascular Accident (CVA), Transient Ischemic Attack (TIA) or seizures
12. Require home oxygen (O2) at rest or with exertion
13. End-stage renal disease (ESRD) requiring dialysis
14. Morbid obesity (BMI>35)
15. Patient undergoing cataract surgery in combination with any other ophthalmologic procedure
16. Patient requiring general anesthesia during cataract surgery due to the underlying characteristics of the existing cataract and/or anticipated complexity of the planned procedure

5.4 Study Population (Ophthalmologists)

Surgeons (AKA ophthalmologists) selected to participate in the study will have been in direct communication with the study PI. The study PI will ensure that surgeons are given lay information surrounding the study, patient interventions, and any additional information. Surgeons will elect to participate or not participate.

The only inclusion criterion for surgeons is that they perform cataract surgeries at the study site, are licensed ophthalmologists, and agree to participate and have their patients recruited from. There are no exclusion criteria that apply to them.

6 CONCURRENT MEDICATIONS

All subjects should be maintained on the same medications throughout the entire study period, as medically feasible, with no introduction of new chronic therapies.

6.1 Allowed Medications and Treatments

Standard therapy for monitored anesthesia care is allowed except for treatments noted in the exclusion criteria described above and as noted in the prohibited medications section below. Based on other research we are undertaking using data from the MPOG collaborative (a multicenter registry of anesthesia cases collected from over 60 member hospitals across the US), we know that approximately 70% of patients are getting a combination of IV midazolam and fentanyl for cataract sedation. This is also the typical approach to sedation for cataract patients at UCSF; therefore, these two medications were selected as the primary adjuncts if needed for escalation of sedation.

Accepted Sedation Interventions in All Groups:

- Primary Escalation Response:

  - Clinicians will be encouraged to prioritize non-pharmacologic interventions prior to resorting to these intravenous sedative medications: Handholding, reassurance, and two cc bolus of saline.

- Secondary Escalation Response:
  - Standard therapies for monitored anesthesia care at UCSF (i.e., IV fentanyl and midazolam) are acceptable. These standard therapies may be administered to patients as deemed necessary by the anesthesia team.
- Tertiary Escalation Response:
  - If operating conditions are no longer optimal, then the anesthesia team should use best clinical judgement as to the timing and administration of additional adjuncts, up to and including general anesthesia.

Prohibited Medications and Treatments

While escalation of sedation beyond fentanyl and midazolam is allowed if needed to complete cataract surgery, administration of the following medications will be considered a protocol violation for both groups:

- Anesthetic induction drugs, sedative agents, or opioids (e.g., propofol, remifentanil, ketamine, inhaled anesthetics, etc.).

7 STUDY TREATMENTS

7.1 Method of Assigning Subjects to Treatment Groups

Up to 20 eligible patients will be randomly assigned to the control group or intervention group by a computer-randomization tool.

7.2 Blinding

Patients, clinicians (operating room nurses, ophthalmologists, and anesthesia staff), and research staff responsible for data collection and analysis will be blinded to the treatment group in order to minimize bias and maximize the validity of results.

7.3 Measures of Treatment Compliance

Subjects (AKA patients) will be monitored intraoperatively by a non-participating study member to ensure fidelity and adherence to the study protocols.

7.4 Method of Intervention for Surgeons

Surgeon subjects will be given a Qualtrics-based surgeon satisfaction survey after completion of the last study subject's surgery.

8 STUDY PROCEDURES AND GUIDELINES

A Schedule of Events representing the required testing procedures to be performed for the duration of the study is diagrammed in Appendix 1.

Prior to conducting any study-related activities, written informed consent and the Health Insurance Portability and Accountability Act (HIPAA) authorization must be signed and dated by the subject. If appropriate, assent must also be obtained prior to conducting any study-related activities.

8.1 Clinical Assessments

8.1.1 Concomitant Medications

All concomitant medication and concurrent therapies will be documented at screening and when applicable. Dose, route, unit frequency of administration, and indication for administration and dates of medication will be captured.

8.1.2 Demographics

Demographic information (date of birth, gender, race) will be recorded at screening.

8.1.3 Medical History

Relevant medical history, including history of current disease, other pertinent history, and information regarding underlying diseases will be recorded at screening.

8.1.4 Physical Examination

Qualified staff (MD, NP, RN, and PA) may complete the abbreviated physical exam at Visit 2. New abnormal physical exam findings must be documented and will be followed by a physician or other qualified staff at the next scheduled visit.

8.1.5 Vital Signs

Body temperature, blood pressure, pulse and respirations will be performed preoperatively on the day of surgery to get a baseline and every 5 minutes intraoperatively between surgery start and surgery end.

8.1.6 Oximetry

Oximetry will be measured non-invasively on room air with the subject at rest on the day of surgery to get a baseline and every 5 minutes intraoperatively between surgery start and surgery end.

8.1.7 Adverse Events

Information regarding occurrence of adverse events will be captured throughout the study. Duration (start and stop dates and times), severity/grade, outcome, treatment and relation to study intervention(s) will be recorded in an electronic database.

9 EVALUATIONS BY VISIT

The following evaluations are to be conducted on a rolling basis by entry of a participant into the trial and the deemed timing of their surgery by the presiding ophthalmologist.

9.1 Baseline Visit 1 (2-4 weeks before surgery) – Zoom/Phone

1. Review the study with the subject and obtain written informed consent and HIPAA authorization and assent, if appropriate.
2. Assign the subject a unique participant ID number.
3. Record demographics data.
4. Record medical history, including a history of untreated bilateral senile cataract, diagnosis date, and prior ophthalmologic treatments.
5. Record concomitant medications.
6. Subjects will be randomly assigned to a group (intervention (oral alprazolam) or control (placebo)).
7. Administer the ECog, PQRS, and MoCA-BLIND. Record responses in the Qualtrics-based source document on a study-designated tablet.
8. Confirm date and time of cataract surgery on first eye.

9.2 Day of surgery Visit 2

9.2.1 Preoperative– In Person

1. Record any Adverse Experiences if necessary.
2. Perform abbreviated physical examination.
3. An IV will be placed in all patients.
4. Document baseline vital signs (HR and BP).
5. Document baseline oximetry (non-invasive).
6. Concomitant medications review.
7. Oversee administration of either oral placebo or alprazolam (0.25 - 0.5 mg) by nursing staff 30-60 minutes before the patient enters the operating room.

9.2.2 Intraoperative - In Person

1. Record changes to concomitant medications.
2. Document vital signs (HR and BP) every 5 minutes.
3. Document oximetry (non-invasive) every 5 minutes.
4. Perform cataract surgery per assigned intervention.
5. Record any Adverse Experiences.

9.2.3 Postoperative – In person

1. Record any Adverse Experiences.

2. Perform abbreviated physical examination (primarily assessing mental status, quality recovery from anesthesia)
3. Perform and record vital signs.
4. Administer the two surveys within 30 minutes of arrival into the PACU: PQRS and ISAS. Record responses in the Qualtrics-based source document on a study-designated tablet.

9.2.4 Post-Operative Day 1: Visit 3 – Zoom/Phone Outreach

1. Record any Adverse Experiences if necessary.
2. Administer PQRS, ISAS, FRI, and QoR-15 over the phone/zoom.

9.2.5 Post-Operative Day 7: Visit 4 – Zoom/Phone Outreach

3. Record any Adverse Experiences if necessary.
4. Administer FRI, ISAS, PQRS, and QoR-15 over the phone/zoom.
5. Record any feedback and questions before the next phase.
6. Record any necessary medical information from EHR.

9.2.6 Early Withdrawal/Discontinuation Visit

1. Record any Adverse Experiences.
2. Administer any surveys if possible and/or record reason for early withdrawal if appropriate.

9.2.7 Surgeon Satisfaction Survey

1. Administer the Qualtrics-based survey by sending a link to the surgeon's email address with a request for response.

10 DIRECTIONS FOR STAFF INVOLVED

10.1.1 Preoperative Tasks:

- Review and ensure compliance with the inclusion and exclusion criteria for patient participation in the study.
- Ensure all patients are appropriately informed about the sedation process and what to expect, adhering to the informed consent requirements.

- Verify that no new chronic therapies have been introduced and that patients maintain the same medication regimen as medically feasible throughout the study period.
- Document baseline blood pressure, pulse, and respiration rate.
- Document baseline non-invasive oximetry measurement on room air with patient at rest.
- Oversee administration of study drug (oral alprazolam 0.5mg or placebo) by nursing staff 30-60 minutes before the patient enters the operating room.

10.2 Intraoperative Tasks:

- Document blood pressure, pulse, and respiration rates at least every 5 minutes intraoperatively.
- Document non-invasive oximetry measurements at least every 5 minutes between surgery start and end.
- Monitor patients closely for any signs of discomfort or adverse events, ensuring an anesthesiologist is immediately available on-site to respond to emergencies.

10.3 Postoperative Tasks:

- Record any adverse events, documenting their duration, severity, outcome, treatment, and relation to the study intervention(s).
- Conduct an abbreviated physical examination primarily assessing mental status and quality of recovery from anesthesia.
- Administer the two surveys within 30 minutes of arrival into the PACU: ISAS and PQRS.
- Ensure patients are monitored until deemed ready to leave the hospital by the PACU nursing staff.
- Follow up with patients as required, ensuring their recovery is progressing as expected and addressing any complications or concerns that arise.

These tasks are crucial for ensuring patient safety and comfort throughout the surgical process, as well as for collecting accurate data for the study.

11 ADVERSE EXPERIENCE REPORTING AND DOCUMENTATION

11.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a clinical investigation of a patient administered a pharmaceutical product and that does not necessarily have a causal relationship with the treatment. An AE is therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated

with the administration of an investigational product, whether or not related to that investigational intervention(s). An unexpected AE is one of a type not identified in nature, severity, or frequency in the current Investigator's Brochure or of greater severity or frequency than expected based on the information in the Investigator's Brochure.

The Investigator will probe, via discussion with the subject, for the occurrence of AEs during each subject visit and record the information in the site's source documents. Adverse events will be recorded in an electronic database stored on the study drive. Adverse events will be described by duration (start and stop dates and times), severity, outcome, treatment and relation to study intervention(s), or if unrelated, the cause.

AE Severity

The National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0 should be used to assess and grade AE severity, including laboratory abnormalities judged to be clinically significant. The modified criteria can be found in the study manual. If the experience is not covered in the modified criteria, the guidelines shown in Table 1 below should be used to grade severity. It should be pointed out that the term "severe" is a measure of intensity and that a severe AE is not necessarily serious.

Table 1. AE Severity Grading

Severity (Toxicity Grade)	Description
Mild (1)	Transient or mild discomfort; no limitation in activity; no medical intervention or therapy required. The subject may be aware of the sign or symptom but tolerates it reasonably well.
Moderate (2)	Mild to moderate limitation in activity, no or minimal medical intervention/therapy required.
Severe (3)	Marked limitation in activity, medical intervention/therapy required, hospitalizations possible.
Life-threatening (4)	The subject is at risk of death due to the adverse experience as it occurred. This does not refer to an experience that hypothetically might have caused death if it were more severe.

AE Relationship to Study intervention(s)

The relationship of an AE to the study intervention(s) should be assessed using the following the guidelines in Table 2.

Table 2. AE Relationship to Study intervention(s)

Relationship to Intervention	Comment

Definitely	Previously known toxicity of intervention; or an event that follows a reasonable temporal sequence from administration of the drug intervention; that follows a known or expected response pattern to the suspected intervention; that is confirmed by stopping or reducing the dosage of the drug used during the intervention; and that is not explained by any other reasonable hypothesis.
Probably	An event that follows a reasonable temporal sequence from administration of the intervention; that follows a known or expected response pattern to the suspected intervention; that is confirmed by stopping or reducing the dosage of the drugs used during the intervention; and that is unlikely to be explained by the known characteristics of the subject's clinical state or by other interventions.
Possibly	An event that follows a reasonable temporal sequence from administration of the intervention; that follows a known or expected response pattern to that suspected intervention; but that could readily have been produced by a number of other factors.
Unrelated	An event that can be determined with certainty to have no relationship to the study intervention(s).

11.2 Serious Adverse Experiences (SAE)

An SAE is defined as any AE occurring at any dose that results in any of the following outcomes:

- death
- a life-threatening adverse experience
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant disability/incapacity

Other important medical events may also be considered an SAE when, based on appropriate medical judgment, they jeopardize the subject or require intervention to prevent one of the outcomes listed.

11.2.1 Serious Adverse Experience Reporting

Study sites will document all SAEs that occur (whether or not related to study intervention(s)) per UCSF CHR Guidelines. The collection period for all SAEs will begin after informed consent is obtained and end after procedures for the final study visit have been completed.

In accordance with the standard operating procedures and policies of the local Institutional Review Board (IRB)/Independent Ethics Committee (IEC), the site investigator will report SAEs to the IRB/IEC.

11.3 Medical Monitoring

Dr. Catherine Chen should be contacted directly to report medical concerns or questions regarding safety.

Phone: 410-868-8440

Email: catherine.chen@ucsf.edu

12 DISCONTINUATION AND REPLACEMENT OF SUBJECTS

If a subject is withdrawn from treatment due to an adverse event, the subject will be followed and treated by the Investigator until the abnormal parameter or symptom has resolved or stabilized.

All subjects who discontinue study treatment should come in for an early discontinuation visit as soon as possible and then should be encouraged to complete all remaining scheduled visits and procedures.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents Refer to Section 10 for early termination procedures.

12.1 Withdrawal of Subjects from the Study

A subject may be withdrawn from the study at any time if the subject, the investigator, or the Sponsor feels that it is not in the subject's best interest to continue.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents. As noted above, subjects who discontinue study treatment early (i.e., they withdraw prior to Visit 3) should have an early discontinuation visit. Refer to Section 10 for early termination procedures. Subjects who withdraw after the Visit 2: Post-Operative Surveys, but prior to Post-Operative Day 7: Visit 4 – Zoom/Phone Outreach should be encouraged to call in for a final visit (and the procedures to be followed would include those for their next scheduled visit).

12.0 Replacement of Subjects

Subjects who withdraw from the study treatment will be replaced by recruiting additional patients until we achieve target enrollment.

13 PROTOCOL VIOLATIONS

A protocol violation occurs when the subject, investigator, or UCSF fails to adhere to significant protocol requirements affecting the inclusion, exclusion, subject safety and

primary endpoint criteria. Protocol violations for this study include, but are not limited to, the following:

- Failure to meet inclusion/exclusion criteria.
- Use of a prohibited concomitant medication.
- Unauthorized amendment to randomization design.

Failure to comply with Good Clinical Practice (GCP) guidelines will also result in a protocol violation. The University of California, San Francisco will determine if a protocol violation will result in withdrawal of a subject.

When a protocol violation occurs, it will be discussed with the investigator and a Protocol Violation Form detailing the violation will be generated. This form will be signed by a Sponsor representative and the Investigator. A copy of the form will be filed in the site's regulatory binder and in the files of UCSF.

14 STATISTICAL METHODS AND CONSIDERATIONS

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) will be written describing all analyses that will be performed. The SAP will contain any modifications to the analysis plan described below.

14.1 Data Sets Analyzed

All eligible patients who are randomized into the study and receive the study interventions and respond to study surveys will be included in the analysis.

14.2 Demographic and Baseline Characteristics

The following demographic variables at screening will be summarized by intervention: race, gender, age, ASA physical status score.

14.3 Analysis of Primary Endpoint

Chart review following surgery will be observed after 30 days as well as the four implemented surveys: ISAS, FRI, PQRS, and QoR-15. Summary statistics will be generated with this data.

Additional methodologies will include conducting a Students' T-Test and Chi-Square (for continuous and categorical variables) analysis. Because this pilot feasibility study is not designed nor powered to test any efficacy hypotheses, analyses of intervention efficacy will not be performed. However, we will review aggregate information about adverse events in each intervention arm as well as the overall trial population, including adverse events that would require early termination from the overall study.

14.4 Analysis of Secondary Endpoints

Safety and tolerability data will be summarized by treatment and control groups. Any other secondary endpoints will be evaluated through chart review and by observation. Additional analysis will be performed by conducting Students' T-Tests and Chi-Square Analysis with the appropriate variable type for the FRI, PQRS and QoR-15.

Adverse event rates will be coded by body system and MedDra classification term. Adverse events will be tabulated by treatment group and will include the number of patients for whom the event occurred, the rate of occurrence, and the severity and relationship to study intervention(s).

14.5 Interim Analysis

There are no planned interim analysis, aside from the monitoring of AEs.

14.6 Sample Size and Randomization

There will be approximately 20 individuals enrolled in this study and it is a baseline estimate for a feasibility pilot. The number of participants here will give us the opportunity to detect attrition rates which will be incorporated as we plan for a larger trial.

15 DATA COLLECTION, RETENTION AND MONITORING

15.1 Data Collection Instruments

The Investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each subject treated with the study intervention(s). Source documents will consist of the subject's completed Qualtrics survey responses for the ISAS, FRI, QoR-15, PQRS, ECog, and MoCA-BLIND. In total, each subject will have 13 completed surveys. These surveys will be administered by study personnel in their respective visits through tablets. The study personnel will ask questions and list available responses when applicable. The study personnel will record these responses into the Qualtrics-based form for each survey, noting only the unique identifier for the Subject.

Study personnel at each site will upload data from source documents corresponding to a subject's visit into a participant-designated folder when the information corresponding to the subject when that visit is available. Subjects will not be identified by name in the study database or on any study documents to be collected by the Sponsor (or designee), but will be identified by a enrollment number, patient sex and date (the unique identifier).

Additionally, the surgeon satisfaction survey will be a Qualtrics-based form that will be sent to surgeons after completion of all patient subject surgeries. Study personnel will send a link to the surgeon emails asking for a response and send a reminder after until the surgeon responds with their answers or preference to not submit a response. Surgeons will not be identified by name on any study database. The study team will only collect their responses. No unique identifiers will be assigned to any surgeon.

The Investigator is responsible for all information collected on subjects enrolled in this study. All data collected during the course of this study must be reviewed and verified for completeness and accuracy by the Investigator.

15.2 Data Management Procedures

The data will be entered into a validated database. The Data Management group will be responsible for data processing, in accordance with procedural documentation. Database lock will occur once quality assurance procedures have been completed.

All procedures for the handling and analysis of data will be conducted using good computing practices meeting UCSF guidelines for the handling and analysis of data for clinical trials.

15.3 Data Quality Control and Reporting

After data have been entered into the study database, a system of computerized data validation checks will be implemented and applied to the database on a regular basis. The study database will be updated in accordance with the resolved queries. All changes to the study database will be documented.

15.4 Archival of Data

The database is safeguarded against unauthorized access by established security procedures; appropriate backup copies of the database and related software files will be maintained. Databases are backed up by the database administrator in conjunction with any updates or changes to the database.

At critical junctures of the protocol (e.g., production of interim reports and final reports), data for analysis is locked and cleaned per established procedures with UCSF IT assistance and University of California Research Retention policies.

15.5 Availability and Retention of Investigational Records

The Investigator must make study data accessible to the monitor, other authorized representatives of the Sponsor (or designee), IRB/IEC, and Regulatory Agency (e.g., FDA) inspectors upon request. A folder for each subject must be maintained that includes the signed Informed Consent, HIPAA Authorization and Assent Form and copies of all source documentation related to that subject. The Investigator must ensure the reliability and availability of source documents from which the information in the subject folders was derived.

All study documents (patient files, signed informed consent forms, copies of completed surveys, etc.) must be kept secured for a period of two years following completion of the trial. There may be other circumstances for which the Sponsor is required to maintain study records and, therefore, the Sponsor should be contacted prior to removing study records for any reason.

15.6 Monitoring

Monitoring visits will be conducted by representatives of the Sponsor according to the U.S. CFR Title 21 Parts 50, 56, and 312 and ICH Guidelines for GCP (E6). By signing this protocol, the Investigator grants permission to the Sponsor (or designee), and appropriate regulatory authorities to conduct on-site monitoring and/or auditing of all appropriate study documentation.

15.7 Subject Confidentiality

In order to maintain subject confidentiality, only a subject number, subject sex, and subject surgery date will identify all study subjects on any subject folders and other

documentation submitted to the Sponsor. Additional subject confidentiality issues (if applicable) are covered in the Clinical Study Agreement.

16 ADMINISTRATIVE, ETHICAL, REGULATORY CONSIDERATIONS

The study will be conducted according to the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 312).

To maintain confidentiality, all laboratory specimens, evaluation forms, reports and other records will be identified by a coded number and initials only. All study records will be kept in a locked file cabinet and code sheets linking a patient's name to a patient identification number will be stored separately in another locked file cabinet. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by the FDA. The Investigator must also comply with all applicable privacy regulations (e.g., Health Insurance Portability and Accountability Act of 1996, EU Data Protection Directive 95/46/EC).

16.1 Protocol Amendments

Any amendment to the protocol will be written by the Research Team. Protocol amendments cannot be implemented without prior written IRB/IEC approval except as necessary to eliminate immediate safety hazards to patients. A protocol amendment intended to eliminate an apparent immediate hazard to patients may be implemented immediately, provided the IRBs are notified within five working days.

16.2 Institutional Review Boards and Independent Ethics Committees

The protocol and consent form will be reviewed and approved by the IRB/IEC of each participating center prior to study initiation. Serious adverse experiences regardless of causality will be reported to the IRB/IEC in accordance with the standard operating procedures and policies of the IRB/IEC, and the Investigator will keep the IRB/IEC informed as to the progress of the study. The Investigator will obtain assurance of IRB/IEC compliance with regulations.

Any documents that the IRB/IEC may need to fulfill its responsibilities (such as protocol, protocol amendments, Investigator's Brochure, consent forms, information concerning patient recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB/IEC. The IRB/IECs written unconditional approval of the study protocol and the informed consent form will be in the possession of the Investigator before the study is initiated. The IRB/IECs unconditional approval statement will be transmitted by the Investigator to the Sponsor prior to the shipment of study supplies to the site. This approval must refer to the study by exact protocol title and number and should identify the documents reviewed and the date of review.

Protocol and/or informed consent modifications or changes may not be initiated without prior written IRB/IEC approval except when necessary to eliminate immediate hazards to the patients or when the change(s) involves only logistical or administrative aspects of the study. Such modifications will be submitted to the IRB/IEC and written verification that the modification was submitted and subsequently approved should be obtained.

The IRB/IEC must be informed of revisions to other documents originally submitted for review; serious and/or unexpected adverse experiences occurring during the study in accordance with the standard operating procedures and policies of the IRB; new information that may affect adversely the safety of the patients of the conduct of the study; an annual update and/or request for re-approval; and when the study has been completed.

16.3 Informed Consent Form

Informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Subjects (21 CFR 50.25[a,b], CFR 50.27, and CFR Part 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

The Investigator will prepare the informed consent form, assent and HIPAA authorization and provide the documents to the Sponsor or designee for approval prior to submission to the IRB/IEC. The consent form generated by the Investigator must be acceptable to the Sponsor and be approved by the IRB/IEC. The written consent document will embody the elements of informed consent as described in the International Conference on Harmonisation and will also comply with local regulations. The Investigator will send an IRB/IEC-approved copy of the Informed Consent Form to the Sponsor for the study file.

A properly executed, written, informed consent will be obtained from each subject prior to entering the subject into the trial. Information should be given in both oral and written form and subjects must be given ample opportunity to inquire about details of the study. If appropriate and required by the local IRB/IEC, assent from the subject will also be obtained. If a subject is unable to sign the informed consent form (ICF) and the HIPAA authorization, a legal representative may sign for the subject. A copy of the signed consent form (and assent) will be given to the subject and the original will be maintained with the subject's records.

16.4 Publications

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

16.5 Investigator Responsibilities

By signing the Agreement of Investigator form, the Investigator agrees to:

1. Conduct the study in accordance with the protocol and only make changes after notifying the Sponsor (or designee), except when to protect the safety, rights or welfare of subjects.
2. Personally conduct or supervise the study (or investigation).
3. Ensure that the requirements relating to obtaining informed consent and IRB review and approval meet federal guidelines, as stated in § 21 CFR, parts 50 and 56.

4. Report to the Sponsor or designee any AEs that occur in the course of the study, in accordance with §21 CFR 312.64.
5. Ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
6. Maintain adequate and accurate records in accordance with §21 CFR 312.62 and to make those records available for inspection with the Sponsor (or designee).
7. Ensure that an IRB that complies with the requirements of §21 CFR part 56 will be responsible for initial and continuing review and approval of the clinical study.
8. Promptly report to the IRB and the Sponsor (or designee) all changes in the research activity and all unanticipated problems involving risks to subjects or others (to include amendments and IND safety reports).
9. Seek IRB approval before any changes are made in the research study, except when necessary to eliminate hazards to the patients/subjects.
10. Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements listed in § 21 CFR part 312.

APPENDIX 1. EXAMPLE OF SCHEDULE OF STUDY VISITS

	BASELINE VISIT (2-4 WEEKS BEFORE SURGERY) (05/20/2024) ZOOM/PHONE	DAY OF SURGERY VISIT 2 (06/01/2024) Preoperative	DAY OF SURGERY VISIT 2 (06/01/2024) Intraoperative	DAY OF SURGERY VISIT 2 (06/01/2024) Postoperative	VISIT 3 – (06/02/2024) ZOOM/PHONE Postoperative Day 1	VISIT 4 – (06/07/2024) ZOOM/PHONE Postoperative Day 7
Informed Consent	X					
Review demographics and assign participant ID	X					
Medical History	X					X
Abbreviated Physical Exam		X		X		
Vital Signs		X	X	X		
Oximetry (non-invasive)		X	X	X		
Assign follow-up dates	X			X		
Procedure			X			
Administer surveys						
1. ISAS				X	X	X
2. QoR-15					X	X
3. FRI					X	X
4. MoCA-BLIND	X					
5. ECog	X					
6. PQRS	X			X	X	X
Gather feedback				X		X
Randomization	X					
Concomitant Medication Review	X	X	X			
Adverse Experiences		X	X	X	X	X

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APPENDIX 3. PROTOCOL UPDATE LOG

Protocol Version	Date	Updates	Notification to IRB Date	IRB Version
1.5	12/19/2023	Initial Submission	12/22/2023	1.0
1.8	01/16/2024	Removing comments and reformatting	12/22/2023	1.1
1.8	01/17/2024	1. Removing benefits to ophthalmologists and ophthalmologist-specific objectives 2. Addition of several surveys (ISAS, FRI, QoR-15) and timepoints 3. Addition of non-invasive oximetry collection 4. Removal of CRF and addition of electronic database 5. Addition of abbreviated P/E and specifying when PACU surveys will be completed i.e., 30 min after arrival 6. Reformatting Appendix 1	12/22/2023	1.2
1.10	03/09/2024	1. Reformatting ToC 2. Addition of ECog 3. Clarifying secondary outcomes i.e., intervention fidelity, post-operative anesthesia-related complications, quality of recovery after surgery 4. Making the trial placebo-controlled and first-eye only 5. Clarifying risks from placebo and oral alprazolam 6. Implementing Qualtrics-source documents	03/09/2024	1.3
1.10	03/21/2024	Standardized MAC for both groups; introduced tertiary response	03/21/2024	1.4
1.12	04/11/2024	1. Clarification of patient risks in both groups with respect	04/18/2024	1.5

		to medication; Introduction of procedures for all risks if they occur. 2. Clariying the study design for both groups i.e., what will be provided for both and therapies 3. Reformatting 4. Clarifying prohibited medications; fentanyl and midazolam are allowed, but will be a protocol violation if introduced 5. Blinding analysis 6. Clarifying procedures for study staff to document and observed, not perform normal clinical duties		
1.12	05/06/2024	Changing .docx to .pdf for IRB; no changes; first IRB approved study protocol	05/06/2024	1.6
1.13	05/22/2024	Addition of the PQRS and MoCA-BLIND, not MoCA	05/22/2024	1.7
1.14	06/06/2024	Reformatting	06/06/2024	1.8
1.14	06/06/2024	Changing .docx to .pdf for IRB	06/06/2024	1.9
1.14	06/07/2024	Reformatting	06/07/2024	1.10
1.14	06/12/2024	Changing .docx to .pdf for IRB	06/07/2024	1.11
1.15	06/12/2024	Removing FRI, PQRS, and QoR-15 from PACU and adding them to POD1	06/12/2024	1.12
1.15	11/08/2024	1. Increase enrollment size to 20 and lowering enrollment age to 60 2. Clarification of FRI	11/08/2024	1.13
1.16	01/27/2025	1. Adding Appendix 3 of protocol changes 2. Removing congenital defects as an SAE. Item was an artifact and was not related to the trial 3. Reformatting and clarifying version numbers; incorrectly	01/27/2025	1.14

		tracked previously		
1.17	07/03/2025	Addition of "surgeon satisfaction" secondary aim	07/03/2025	1.15
1.18	07/10/2025	Addition of surgeon participation risks, instruments, appendix item, methods	07/14/2025	1.16
1.19	07/23/2025	Removed surgeon name from surgeon satisfaction survey & added PI signature Formatting changes	07/23/2025	1.17
1.20	10/27/25	Clarified objectives, endpoints, and statistical analysis plans as part of a pilot, feasibility study Fixed typos	10/27/2025	1.18

APPENDIX 4. SURGEON SATISFACTION SURVEY

CaTNAPS-1 SURGEON SATISFACTION SURVEY

Date:

Questions	Response
1. Did any of your patients participate in the CaTNAPS-1 study?	☐ Yes → *If yes, survey continues to Q2.* ☐ No → *If no, survey is complete.*
2. I was satisfied with the amount of sedation my patients received.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much
3. My patients' pain was well controlled.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much
4. My patients' anxiety levels were well controlled.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much
5. There was no undesired movement during surgery among study participants.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much

6. Study participants were cooperative during surgery.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much
7. There was no operative deviation or complication during surgery among study participants.	☐ Disagree very much ☐ Disagree moderately ☐ Disagree slightly ☐ Agree slightly ☐ Agree moderately ☐ Agree very much
If question 7 is marked with any variation of "Disagree", respond to the Ocular Intraoperative Complications assessment.	
Comments:	
Signature of person completing above fields Signature: _____ Date: _____	

CaTNAPS-1 OCULAR INTROPERATIVE COMPLICATIONS

Date:

Complication	Yes	No	Comments
Descemet Detachment	☐	☐	
Hyphema	☐	☐	
Iris prolapse	☐	☐	
Vitreous prolapse	☐	☐	
Zonular dialysis	☐	☐	
Unplanned sulcus IOL	☐	☐	
Iridodialysis	☐	☐	
Retained nucleus	☐	☐	
Posterior capsule tear	☐	☐	
Other: *e.g., Aqueous misdirection* *Corneal burn* *Suprachoroidal hemorrhage*	☐	☐	
Comments:			

Signature of person completing above fields

Signature: _____

Date: _____