ANES001 IRB Application

- Protocol Number
  - ANES 001
- Protocol Date (Version #1)
  - 4/3/2017
- Study Title
  - Effects of Various PO medication Combinations on Patient Satisfaction after Cataract Surgery
- Sponsor Name
  - Maggie Jeffries, MD
- Investigators (including sub-investigators)
  - Maggie Jeffries, MD – Primary Investigator
  - Secondary Investigators-
    - Volker Eisele, MD
    - Melinda Castrol, MD
    - Edward Wade, MD
    - Mark Mayo, MD
    - Ciprian Georghe, MD, PhD – data collection and analysis
- Address / Phone - Contact details
  - Maggie Jeffries
  - 2726 Bissonnet Ste 240-505, Houston, TX 77025
  - 832-390-4477
- Source of external funding (if applicable)
  - Self funded
- Hypothesis or Study Synopsis
  - We hypothesize that the combination of Valium, Tramadol and Zofran is superior to the substantially more expensive MKO melt in patient satisfaction after cataract surgery.
- Background
  - The MKO melt is being pushed as the latest and greatest anesthetic medication for cataract surgery and has the advantage that it eliminates the need for an IV in 85% of patients. This alternative, however, is very cost limiting.
- Study Goals and Objectives
  - We wanted to see if our current regimen (valium only) or a combination similar to the MKO melt (valium + tramadol + zofran) are as good if not better than the MKO melt for anesthesia and how many patients could have indeed gone with an IV (didn't need any extra medications).
- Subject Selection
  - We plan to enroll 600 patients total. 200 patients in each of the 3 arms:
    - Valium 10mg PO
    - Tramadol 100mg PO, Valium 10mg PO, Zofran 4mg PO

        - MKO melt x 2 SL (total of versed 6mg, ketamine 50mg, Zofran 4mg)
    - All patients scheduled for cataract surgery under Dr. Mayo and/or Dr. Wade will be enrolled on the day of surgery. They will be randomized to which arm they are in by random envelopes.
    - Exclusion criteria:
        - Age <18 years
        - Patient is not suitable for the medications for reasons such as unsteady gait, cane, wheelchair, severe dementia (unable to consent), terminal illness
        - Allergy to a medication in protocol
- Study procedures / research method
    - Our participants will need to answer 2 questions before discharge from the PACU and answer 7 questions the following day when our nurse calls them. Currently, we already call all patients the day after surgery to see how things went so we will just have more specific questions.
    - We will be collecting the following information:
        - Age
        - Gender
        - Ethnicity
        - 1^{st} or 2^{nd} eye
        - Axial length
        - ASA status
        - Obesity
        - OSA
        - Number of allergies
        - History of anxiety
        - Current use of benzos
        - Current use of narcotics
        - Bradycardia <= 50
        - ESRD/dialysis
        - Times: Meds received, laser time, surgical start and stop time
        - IV Medications given (fentanyl, versed, brevital, other)– must be asked for my surgeon or patient only and reason documented (pain, anxiety, other)
        - Difficulty of IV placement – number of tries, was it painful?
        - Recovery survey –questionnaire for at discharge and during phone call the next day

- Risk / Safety Information
    - There are no perceived risks to the participants
- Monitoring and reporting of Adverse Events/Serious Adverse Events
    - The study doesn't involve anything adding risk to the patient. Risks of anesthesia are already present as we currently practice and all hospital transfers due to anesthesia are reportable events per state rules and regulations.
- Study Oversight

- Kirby Glen Surgery Center Governing body has approved the study and will provide oversight.

- Data Management
  - Data will be managed by principal investigator Maggie Jeffries, MD into a database in her home office that is password protected.
- IRB Review / Ethics / Informed Consent
  - The informed consent form has been submitted. This study also presents no additional risk to the patient outside of the anesthetic risk they would already have without the study.
  - No persons under the age of 18 will be enrolled in the study. No persons who cannot consent for themselves will be enrolled in the study. No employees of our center will be enrolled in the study. No persons who cannot read English will be enrolled in the study. No persons with a terminal illness will be enrolled in the study.
- Confidentiality
  - A patient sticker will be on the data collection sheet while the patient is in the center until the final phone call has taken place the day after surgery. These sheets are kept at the surgery center in medical records at a fully HIPAA compliant surgery center.
  - Once data on a patient is complete on the data collection sheet, the patient sticker will be removed and placed in the shredder at the surgery center.
  - Data collection sheets will then be picked up weekly by Maggie Jeffries, MD and entered into the database at her home office. The home computer where data will be kept is password protected and only used by Maggie Jeffries, MD. These sheets which now contain no patient information, will be kept in a locked file cabinet until the completion of the study and publication is complete. When appropriate, all sheets will also be shredded.
  - Access to the data will only be Maggie Jeffries, MD until data collection is complete and at that time, all investigators will have access to participate in preparing the data for publication.
- Intended Use of Data
  - Our data can impact how anesthesia is performed for cataract surgery around the country. This is one of the most common surgeries performed.
  - We plan on publishing our data in Anesthesia and/or Ophthalmology journal (s) as well as submit as poster presentations at Anesthesia and/or Ophthalmology national meetings. No patient identifying information will be used as it is scrubbed from the data before data entry occurs (as above).

____Maggie Jeffries MD_____ ___4/3/17_____

Signature of Investigator/Researcher Date