Anesthesia Counseling, Consent, & Professionalism
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JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
- **When submitting JHM IRB eForm A (new or revised), enter the date submitted to the field at the top of JHM IRB eForm A.**

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1. Abstract

There is a substantial body of work regarding the written anesthesia consent form. As a result, the written anesthesia consent form has become a standard requirement throughout the United States of America. However, there has been little examination of verbal aspects of anesthesia consent and of the value of the preoperative anesthesia discussion that should take place prior to surgery. Non-anesthesia medical studies have indicated that inadequate patient-physician communication and an inadequate patient-physician relationship will result in misunderstanding and an increased malpractice risk. Lack of understanding of the duties and responsibilities of anesthesiologists is also damaging to the professional status of the field of anesthesiology. This study will utilize patient interviews and questionnaires to examine the degree of awareness that the patients and their families possess regarding what general anesthesia is, the duties and responsibilities of the anesthesiologist, the role of the anesthesiologist within the operating room and the specifics of what they are agreeing to by signing the consent form. If it is determined that a more structured and thorough pre-anesthesia discussion will help patients and their families understand what general anesthesia is, understand the specific responsibilities of anesthesiology providers, understand the professional status of anesthesiologists, give them a better feeling of autonomy and better understand what they are agreeing to by signing the consent form, then there will be substantial ramifications to the priority and importance given to pre-anesthesia discussions nationwide. Secondary benefits include influences on anesthesia residency training and malpractice actions against anesthesiologists. Improved patient satisfaction with the anesthesia experience is another potential secondary benefit.

2. Objectives (include all primary and secondary objectives)

Primary objectives: - Determine the percentage of people with an accurate knowledge of what general anesthesia is. - Define the public's perception of the role of the anesthesiologist in the operating room. - Help patients and the public to better understand the risks and safety aspects of anesthesiology Secondary objectives - Improve anesthesiologist–patient relations. - Decrease the likelihood of malpractice suits. - Improve the professional standing of anesthesiology. - Patients will know that the anesthesiologist is not a person who just puts them to sleep and then abandons them. - Decrease fear of the anesthesia experience. - Decrease fear of the anesthesia face-mask. - Improve medical student recruitment into anesthesiology as a career choice.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The perioperative period can be fraught with a whole range of emotions from fear, depression and anxiety to calmness. The first patient encounter with his or her anesthesiologist most commonly occurs on the day of his or her procedure, and usually just a few hours before the procedure. This places an extraordinary responsibility in a

relatively short amount of time upon the anesthesiologist to engender confidence in his or her ability to provide the safest care for that patient. The more successful the anesthesiologist is in establishing a sense of professionalism and confidence, the more likely the patient will achieve satisfaction with the provider; the less successful the anesthesiologist, the less the patient's satisfaction. This has implications, if not for the direct outcome of the patient's procedure, certainly for the patient's perception of the success of the procedure's outcome.

Of note is that the journal *Current Opinion in Anaesthesiology* recently published an article titled "Communication between anaesthesiologists and patients: how are we doing it now and how can we improve?" [Curr Opin Anaesthesiol 22(3):431–435, 2009]. The article is a review on the subject of anesthesiologist–patient communication. In the results section of their article, the authors state, "Anaesthesiologists and patients may have different 'agendas' during their consultations, with anaesthesiologists focusing more on information and patients more on the emotional aspects of care. As effective communication implies a two-way process, anaesthesiologists should be aware of this." Within this article, the authors perceptively point out the lack of residency education regarding anesthesiologist–patient communication. "Many of the techniques used by experienced anaesthesiologists have not been formally taught to them, but have been learned instead as part of the informal or 'tacit' knowledge of anaesthetic practice." It is possible that issues related to the public's understanding of the anesthesia specialty and the professional standing of anesthesiology in the eyes of the public, other physicians, and other health care providers is partly a result of the specialty's failure to communicate effectively to the public. In the same way, the fact that a patient can have nine previous general anesthesia experiences but not really know what general anesthesia is or what the anesthesiologist was doing while he was asleep represents a communication failure on behalf of all of his previous anesthesia providers as well as the process with which we train anesthesia residents to communicate with patients. The authors of the above quoted *Opinions in Anaesthesiology* article state it well in their introduction, "Despite its importance in everyday practice, and its prescription as an essential part of postgraduate training in aneaesthesiology in many countries, communication between anaesthesiologists and patients has been little studied."

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Research Procedures will be integrated into the routine part of the preoperative pre-anesthesia session. .

A member of the study team will approach the anesthesiologists who will be in the control arm of the study. None of the study team members will be in a supervisory or evaluative role to the potential anesthesiologists to be approached. Patient participants will be approached and asked if they are interested in participating. Those who are interested and eligible will undergo the research informed consent process. Patients will be divided into a **control group** and an **intervention group**. Both groups will receive the above described post-operative questionnaires with the addition of selected questions regarding their prior experience with anesthesia, and their understanding of what the anesthesiologist is responsible for. During the post-operative questionnaire they will also be asked what percentage of the signed anesthesia consent they read and if they recall anything about it. The questionnaire will be completed postoperatively, over the phone or in person, no more than 3 days after the day of the procedure.

The **control group** will have their pre-op discussion performed by an anesthesiologist in a manner commensurate with their routine for preoperative discussion. These anesthesiologists are not part of the study team.. These anesthesiologists will be approached by a member of the study team and asked for permission to participate and be observed; then their patients will also be approached for participation. These anesthesiologists will be audio-recorded. Remotely, a study team member will review the audio-recording and will use a check list to assess the content communicated during the preoperative discussion. The amount of time that the discussion takes will also be recorded.

The **intervention group** will have their pre-op discussion performed by one of the two study anesthesiologists who will perform their discussion with knowledge of specific material that must be addressed prior to completion of the discussion including:

1. Description of the type of anesthesia administered
2. Description of what that type of anesthesia is (eg. what is general anesthesia?)
3. The expected anesthesia related procedures to be performed and the possibility of additional procedures performed if necessary.
4. anesthesia risk
5. Intraoperative communication with the rest of the operating room team
6. Communication to the patient that everything done will be in the interest of safety
7. Plans for pain and nausea control
8. An offer to address any additional questions that the patient may have

These anesthesiologists will also be -audio-recorded. Remotely, a study team member will review the audio-recording and will use a check list to assess the content communicated during the preoperative discussion. The amount of time that the discussion takes will also be recorded.

A comparison of the questionnaire results between the control and intervention groups will be made, and data will be statistically analyzed at the end of the study and data entry period.

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 4 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required. N/A

c. Study duration and number of study visits required of research participants. Study duration is anticipated to be 6 months and does not require any follow up visits from the research participants.

d. Blinding, including justification for blinding or not blinding the trial, if applicable. Patients will be blinded to the group that they are assigned to. (control vs. intervention).

e. Justification of why participants will not receive routine care or will have current therapy stopped. This study does not interrupt routine care for patients.

f. Justification for inclusion of a placebo or non-treatment group.

A control group is used to show the standard without the intervention and will be used to compare any similarities or differences to outcomes in the intervention group. Having a **control group** eliminates the potential impact of all other variables.

g. Definition of treatment failure or participant removal criteria.
Failure of treatment could be failure to complete pre-anesthesia session; participants can be removed if it is later determined that the patient is not eligible; for example, if the patient ended up getting consented for spinal anesthesia instead of general anesthesia.

h. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely. When the study ends, it will not affect a participant's routine care that is received outside the study. If a participant's participation

ends prematurely, but after informed consent was obtained, then only the information obtained prior to the end of participation would be used as part of the study. If informed consent is not obtained, participant will not participate in the study. If research consent is obtained but surgery case is cancelled on the day of surgery, participant will be removed from study.

5. Inclusion/Exclusion Criteria

Inclusion Criteria: Adult patients undergoing general anesthesia for elective cases
Exclusion Criteria: Patients under age 18; Patients not undergoing general anesthesia

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used. N/A
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. N/A

Justification and safety information if non-FDA approved drugs without an IND will be administered. N/

7. Study Statistics

a. Primary outcome variable: Recall of risks, understanding of anesthetic plan
b. Secondary outcome variables. Anxiety relief
c. Statistical plan: Pearson's Chi-squared statistic for categorical variables and Mann-Whitney U Tests for scaled variables.

d. Early stopping rules.
Study may be stopped at any time if there is a medical or public health emergency.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
There are no anticipated medical risks associated with participation in this study.

b. Steps taken to minimize the risks.
Maintain confidentiality and privacy. Give patients option to withdraw from study at any time. Wearing of masks throughout the perioperative period. Patient data will be de-identified with the Safe Harbor Method that removes 18 Protected Health Information (PHI) Identifiers. This de-identification process will be pursued at the time of data entry.

c. Plan for reporting unanticipated problems or study deviations.
Any unanticipated problems or deviations may be reported to the IRB.

d. Legal risks such as the risks that would be associated with breach of confidentiality.
There are no anticipated legal risks, including those associated with a breach of confidentiality. Participants will be de-identified during and after the data collection process.
e. Financial risks to the participants.
There are no anticipated financial risks to participants.

9. Benefits

a. Description of the probable benefits for the participant and for society.

Participants will contribute to general knowledge in this area, and results may be shared in publications.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Patients will not be compensated in this study.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no anticipated costs to patients.