

The University of Vermont Committees on Human Research

Request for Modification/Amendment to Approved Protocol



Study modifications may not be instituted until you have received written approval from the Committee. Form completion instructions are on the web site.

1. **CHRMS** ☒ **CHRBS** ☐ #: **16-642** **Principal Investigator (PI):** **Dr. Michael Blankstein**

Protocol/Project Title: **Perioperative Surgeon-Family Communication**

Contact Name: **Dr. Michael Blankstein** **Contact Email:** **Michael.blankstein@uvmhealth.org**

2. **Sponsor Study #:** **N/A** **Sponsor's Amendment Number:** **N/A** **Date of Protocol Amendment:** **7/20/16**

Date of Consent Version (if applicable)

3. Request for Revisions

A. Did IRB staff specifically request that you submit this amendment? ☐ Yes ☒ No

B. Is this protocol a Cancer Center protocol (involve the study of cancer)? ☐ Yes ☒ No

i. If yes, provide the date the amendment was approved by the Protocol Review Committee of the Cancer Center.

C. Is this protocol a General Clinical Research Center protocol? ☐ Yes ☒ No

If yes, make sure that you have submitted this amendment to that Committee as well.

D. Check all that are applicable, explain in E. below, and attach supporting documentation.

<input type="checkbox"/> Scientific Changes to Protocol	<input type="checkbox"/> Change in Study Title
<input type="checkbox"/> Eligibility/Ineligibility Criteria Changes	<input type="checkbox"/> Changes to Consent Form (may affect currently approved HIPAA authorization)
<input checked="" type="checkbox"/> Change in Protocol Procedures	<input type="checkbox"/> Changes to Information Sheet or other previously approved materials given to subjects for information purposes
<input type="checkbox"/> Change Requiring Re-consent (HIPAA authorization may be necessary)	<input type="checkbox"/> Editorial Changes in HIPAA authorization (may occur when consent is revised)
<input type="checkbox"/> Study Suspension	<input type="checkbox"/> Closure to Accrual (e.g. interventions and/ or follow-up still occurring locally)
<input checked="" type="checkbox"/> Addition or change to surveys, questionnaires, etc.	<input type="checkbox"/> Change in Sponsor (contact the office if you have a new or additional sponsor)
<input type="checkbox"/> Change in Compensation	<input type="checkbox"/> Change in Collaborating Sites (may need agreement, see manual guidance.)
<input type="checkbox"/> Increase in Accrual Target to:	<input type="checkbox"/> Request for Review of Recruitment Materials
<input type="checkbox"/> Other – Describe below in E.	<input type="checkbox"/> Request for Review of Retention Materials
	<input type="checkbox"/> Request to share data/specimens with another institution (agreements may be required)

E. Provide a description and justification for the requested change(s) listed in Section C. above.

Research Protections Office, 213 Waterman Bldg, 85 South Prospect St, Burlington, VT 05405, (802) 656-5040

Changes in Protocol Procedures: Although the survey questions have been drafted using previously validated surveys, due to necessary modifications, we believe we should test the reproducibility of this study. To do so, we will administer the survey via telephone to twenty participants one day after the initial administration of the survey (which they will complete in the waiting room, as all other participants will do). We will use this information to confirm that the results of the study are reproducible.

Survey Changes: We have added age, socioeconomic status, and sex to the survey. We believe that the demographic information may affect the levels of satisfaction and anxiety of the family members, and this would be valuable information to obtain. In addition, University of Vermont Medical Center has launched a new website that allows family members to track their family members during the perioperative period. Access to this website may affect the levels of anxiety. We have added a question to the survey asking if they were aware of this website, and if so, if they made use of it.

F. Grant Funding Changes

The IRB has the following regulatory mandate:

"Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board."

To meet this mandate, the IRB has to be made aware of when originally pending (including JIT) grants have subsequently been awarded or when supplements have been awarded. This gives us the opportunity to review the subsequent version of the grant in respect to the currently approved protocol. It is at this point that you need to revise your consent, if applicable, to include the new sponsor.

Check the Appropriate Funding Change Below

- ☐ Resubmission of Grant that was not previously funded (Note: If this is a new competing grant or a renewal, an amendment is not appropriate, a new protocol is required.)
- ☐ Original Grant has now been funded
- ☐ Supplemental Grant funding has been received

If any of the options above are checked, provide the specific grant information below.

InfoEd Proposal #

Grant # (full number including the version # related to the submission)

Is this new grant identical to the originally approved grant/protocol. ☐ Yes ☐ No

If yes, skip to #10 below. If no, explain the changes below and formally request an amendment to the protocol by completing this form. (Note: Now is when you would need to revise your consent, if applicable, to include the new sponsor.)

Confirm that the new corresponding grant is attached to this submission. ☐ Confirmed

☐ Grant Funding has ended

Do you wish to close the protocol? ☐ Yes ☐ No

If yes, you must submit a continuing review form.

If no, and you are still using a consent, you must remove the reference to the old sponsor and put in the new one. List below the new sponsor.

G. Supporting sponsor documentation for this amendment is attached. ☐ Confirm by checking here.

4. Is this change being submitted as a result of safety information already submitted to the IRB?

☐ Yes ☐ No

If yes, provide the date of the safety information and a brief description of the safety information: (example: IDB submitted on 1/1/2001 with increased risk of seizures)

5. Does the proposed change affect the risk to subjects, either increase or decrease?

☐ Yes ☐ No

If yes, please explain:

NOTE: Any change in research procedures that has active federal sponsorship that could result in an increased risk to human subjects will require prior NIH approval before implementation. Find guidance here <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html>

6. After review of the proposed change, in the opinion of the Investigator, does the currently approved consent form require revision in order to adequately convey the potential risks of study participation? *If yes, remember to attach a highlighted and a clean copy of a fully revised consent form for new subjects. If subjects are already enrolled into the study you need to develop and attach a consent addendum for review.*

☐ Yes ☒ No

If yes, please explain:

7. Are there subjects currently enrolled? ☒ Yes ☐ No

If yes, describe the process for re-consent.

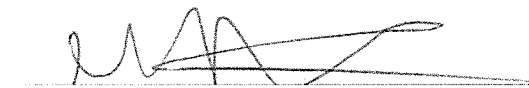
Re-consent will not be required. We will not be administering the revised survey to the family members who have already completed the survey.

What is your approximate timeframe for informing current subjects? *Failure to inform subjects in a timely manner may be considered noncompliance depending upon the new information.*

We will not be informing subject who have completed the original survey.

8. Additional Comments:

9. Principal Investigator Signature

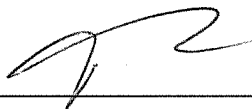


Date 7/21/16

This amendment has been reviewed and approved. _____ Full ☒ Expedited _____ Administrative

Committee Official Signature: _____

Name and Title of Committee Official: _____



7/27/16

Date

David Kaminsky, M.D.
Chair, Committee on Human Research in the
Medical Sciences

Administrative Staff: _____

Name and Title of Staff: _____

Date

Thank you for taking the time to take part in our survey! The data from this study will allow us to identify family preferences regarding updates from the surgical team. This information can then be used to improve patient and family satisfaction in the perioperative period.

Family Member Demographic Information

Age: _____

Sex (circle one): F / M / Other

Highest educational degree you have attained (check one):
 _____ High School diploma or equivalent (GED)
 _____ Associate degree
 _____ Vocational degree
 _____ Bachelor's degree
 _____ Master's degree
 _____ Professional degree
 _____ None of the above

1. How are you related to the patient (i.e parent, spouse, partner, son, daughter, etc)?

2. Please rate your level of satisfaction with your overall experience today in the perioperative area by circling the answer that best describes your satisfaction (with 1 being extremely unsatisfied and 5 being extremely satisfied).

None at all	Extremely low	Somewhat low	Not high or low	Somewhat high	Extremely high
0	1	2	3	4	5

3. Please rate your level of anxiety during the surgery by circling the answer that best describes your anxiety (with 0 being none at all and 5 being extremely high).

None at all	Extremely low	Somewhat low	Not high or low	Somewhat high	Extremely high
0	1	2	3	4	5

4. Please rate your level of satisfaction with the number of updates provided during the perioperative period (with 1 being extremely unsatisfied and 5 being extremely satisfied).

None at all	Extremely low	Somewhat low	Not high or low	Somewhat high	Extremely high
0	1	2	3	4	5

5. Please check all that apply regarding the frequency of updates you received during the perioperative period.

- ☐ Updates were too frequent
- ☐ Updates were too infrequent
- ☐ I was satisfied with the number of updates I received

6. In an ideal scenario, at which time points during surgery would you like to be updated? (Check all that apply)

- ☐ Patient is entering the OR
- ☐ Initial skin incision has been made
- ☐ Critical part of the case is complete, and closure is about to begin
- ☐ Closure is complete, and patient will be transferred to the recovery room when ready
- ☐ Patient is leaving the OR

7. Please check all that apply regarding the amount of detail in the updates you received during the perioperative period.
<input type="checkbox"/> Updates were too detailed <input type="checkbox"/> Updates were lacking enough detail <input type="checkbox"/> I was satisfied with the amount of detail in the updates
8. In your opinion, what would be the ideal method to deliver updates to family members during surgery?
<input type="checkbox"/> Human communication <input type="checkbox"/> Text message <input type="checkbox"/> Pager <input type="checkbox"/> Application for electronic device (cell phone, tablet, etc.) <input type="checkbox"/> Television Screen in the Waiting Room
9. At what point during the perioperative period would you prefer to have a consult with the surgeon? Please select one answer.
<input type="checkbox"/> Critical part of the case is complete, and closure is about to begin <input type="checkbox"/> Closure is complete <input type="checkbox"/> Upon transfer to the recovery room
10. Were you aware the University of Vermont Medical Center has a new website that allows family members to track the status of their loved one in the OR?
<input type="checkbox"/> Yes <i>If yes, did you utilize this website (circle one): Yes / No</i> <input type="checkbox"/> No
11. Please feel free to provide any feedback and/or suggestions regarding the communication with family members during the perioperative period.

For Research Team to complete:

Date of Procedure:

Time into OR:

Time out of OR:

Length of the procedure:

Type of Procedure:

Surgeon:

Spinal vs. GA:

Group:

Thank you for taking the time to take part in our survey! The data from this study will allow us to identify family preferences regarding updates from the surgical team. This information can then be used to improve patient and family satisfaction in the perioperative period.

<i>Family Member Demographic Information</i> Age: _____ Sex (circle one): F / M / Other Highest educational degree you have attained (check one): <table border="0" style="display: inline-table; vertical-align: top;"> <tr><td>___</td><td>High School diploma or equivalent (GED)</td></tr> <tr><td>___</td><td>Associate degree</td></tr> <tr><td>___</td><td>Vocational degree</td></tr> <tr><td>___</td><td>Bachelor's degree</td></tr> <tr><td>___</td><td>Master's degree</td></tr> <tr><td>___</td><td>Professional degree</td></tr> <tr><td>___</td><td>None of the above</td></tr> </table>						___	High School diploma or equivalent (GED)	___	Associate degree	___	Vocational degree	___	Bachelor's degree	___	Master's degree	___	Professional degree	___	None of the above
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For Research Team to complete:

Date of Procedure:

Time into OR:

Time out of OR:

Length of the procedure:

Type of Procedure:

Surgeon:

Spinal vs. GA:

Group:

Human Subjects Research Protocol

The Common Human Subjects Protocol Cover Form **must** be completed and **attached** to the front of this form. This Protocol form should be completed for any human subjects research proposal that does not have a specific "protocol," such as a grant application. This form must be submitted along with a copy of the complete grant proposal and all the information in this form **must** be consistent with that proposal. This protocol form, once IRB approved, will be the working protocol for that research. **When completing this document, do not refer to page numbers within your grant.** If revisions are necessary during the course of the research, amendments should refer to this protocol form, not the grant proposal. Enter responses for all sections. Check N/A if the section does not apply.

PROTOCOL SUMMARY

Project Title:

Protocol Version Date:

Perioperative Surgeon-Family Communication	4/14/16
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Principal Investigator: Dr. Michael Blankstein

Grant Sponsor: N/A

Grant Number:

N/A

(For grants routed through UVM, indicate the OSP Proposal ID # located at the top of the OSP Routing Form)

Lay Language Summary: (Please use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) a brief statement of the problem and related theory supporting the intent of the study, and (2) a brief but specific description of the procedure(s) involving the human subjects. Please do not exceed one single-spaced 8 ½ X 11" page.)

It has been shown that perioperative communication plays an important role in reducing family member anxiety and improving overall satisfaction while they are waiting for surgical patients. As the notion of patient and family centered care has evolved over the years, it has become clear that patients' family members require attention and care during the perioperative period. Studies have suggested that family members who received periodic updates during their loved ones' surgeries report less anxiety and a better overall experience than families who do not receive the periodic updates. However, there have been no studies conducted that investigate the optimal timing and level of detail of the surgeon-family communication. The proposed study aims to determine the effect of strategic communication with patients' relatives during the perioperative period on their satisfaction, anxiety and overall experience. We hypothesize that the greatest patient and family satisfaction would come from receiving critical strategic updates during vital time points of the surgical procedure.

This will be a survey-based study. On the day of the surgery, a research team member will inform the patient and family that a study is being conducted to investigate the effect of perioperative communications on family satisfaction and anxiety. It will be explained that each family will randomly be assigned to two communication pathways, and there will be a short survey for them to complete post-surgery. In the control pathway, the surgeon will communicate with the family per his/her usual practice near the completion of the surgical procedure. In the intervention group, the families will receive additional standardized electronic updates via pagers at three pivotal moments: 1) Initial skin incision has been made, 2) Critical part of the case is completed and closure has begun, 3) Closure is complete, and patient is about to be transferred to the recovery room. Then, the surgeon will communicate the final update near the end of the surgical procedure per his/her usual practice.

After the surgery is complete, and both control and intervention groups have received the final update, a research team member will locate the waiting family and administer the post-operative survey rating their satisfaction and anxiety levels using Likert scale questions (1-5 scale). In addition to the survey, basic demographic information of the patient and family member completing the survey, as well

as the number of people in the waiting party, will be reported.

PURPOSE AND OBJECTIVES

Purpose: *The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.*

Multiple studies have shown that perioperative communication is important in reducing family member anxiety and improving the overall experience of family members waiting for surgical patients. In fact, perioperative communication and attentiveness have been identified as the two most important determinants of perceived surgeon performance. Moreover, surgeons agree that perioperative communication is important and report feeling as though the patients' family members are pseudo-patients, requiring attention and treatment, and perceive reduced family anxiety as a necessary component toward understanding post-operative status updates and findings.

Communication and empathy is even more important in the case of adverse outcomes. Family members of ICU patients rated attitude, clarity of message, and ability to ask questions as most important when receiving bad news. The CARE/SHARE models of establishing rapport with patients and families suggests it is best to wait until all information is available before speaking with the family, particularly in the event of adverse surgical outcomes. However, presently there is no agreed upon standardized time to deliver post-operative news to patients' families, with some surgeons delivering news before a procedure is entirely complete.

We have identified several times at which different surgeons deliver news in the perioperative period: 1) As soon as the major part of the procedure is completed, 2) While the patient is sutured at the close of the surgery, 3) Once the patient is extubated, and 4) Once all auxiliary information is obtained (x-rays, neurovascular examination, etc.) and the patient is awake. While there is anecdotal evidence that it may be concerning to patients' families to not receive an update at the scheduled ending time of a procedure, actual family preference remains undetermined. In a study by Blum et al, families were surveyed regarding perioperative stress and experience satisfaction. Those receiving periodic updates from a circulating nurse (calling every two hours) reported less anxiety and a better overall experience than the group of families who did not receive periodic updates. However, no study currently exists that examines the optimal timing and level of detail of surgeon-family communication.

References. *Include references to prior human or animal research and references that are relevant to the design and conduct of the study.*

1. Davis Y, Perham M, Hurd AM, Jagersky R, Gorman WJ, Lynch-Carlson D, Senseney D. Patient and family member needs during the perioperative period. *J Perianesth Nurs*. 2014 Apr;29(2):119-28. doi: 10.1016/j.jopan.2013.05.013. PubMed PMID: 24661481.
2. Gordon CR, Rezzadeh KS, Li A, Vardanian A, Zelken J, Shores JT, Sacks JM, Segovia AL, Jarrahy R. Digital mobile technology facilitates HIPAA-sensitive perioperative messaging, improves physician-patient communication, and streamlines patient care. *Patient Saf Surg*. 2015 May 23;9:21. doi: 10.1186/s13037-015-0070-9. eCollection 2015. PubMed PMID: 26136830; PubMed Central PMCID: PMC4487585.
3. Herd HA, Rieben MA. Establishing the surgical nurse liaison role to improve patient and family member communication. *AORN J*. 2014 May;99(5):594-9. doi: 10.1016/j.aorn.2013.10.024. PubMed PMID: 24766921.
4. Leske JS. Effects of intraoperative progress reports on anxiety levels of surgical patients' family members. *Appl Nurs Res*. 1995 Nov;8(4):169-73. PubMed PMID: 8579349.
5. Puopolo R, Cordasco J. Intraoperative progress reports to families of surgical clients: a missed opportunity. *Can Oper Room Nurs J*. 1999 Mar-Apr;17(1):21-6. Review. PubMed PMID: 10578743.

6. Schmocker RK, Cherney Stafford LM, Siy AB, Leverson GE, Winslow ER. Understanding the determinants of patient satisfaction with surgical care using the Consumer Assessment of Healthcare Providers and Systems surgical care survey (S-CAHPS). *Surgery*. 2015 Jul 17. pii: S0039-6060(15)00503-6. doi: 10.1016/j.surg.2015.06.018. [Epub ahead of print] PubMed PMID: 26195107.
7. Jordan AL, Rojnica M, Siegler M, Angelos P, Langerman A. Surgeon-family perioperative communication: surgeons' self-reported approaches to the "surgeon-family relationship". *J Am Coll Surg*. 2014 Nov;219(5):958-67. doi: 10.1016/j.jamcollsurg.2014.05.019. Epub 2014 Jul 16. PubMed PMID: 25256372.
8. Jurkovich GJ, Pierce B, Pananen L, Rivara FP. Giving bad news: the family perspective. *J Trauma*. 2000 May;48(5):865-70; discussion 870-3. PubMed PMID: 10823529.
9. Gilbey P. Qualitative analysis of parents' experience with receiving the news of the detection of their child's hearing loss. *Int J Pediatr Otorhinolaryngol*. 2010 Mar;74(3):265-70. doi: 10.1016/j.ijporl.2009.11.017. Epub 2009 Dec 29. PubMed PMID: 20042242.
10. Taylor D, Hassan MA, Luterman A, Rodning CB. Unexpected intraoperative patient death: the imperatives of family- and surgeon-centered care. *Arch Surg*. 2008 Jan;143(1):87-92. doi: 10.1001/archsurg.2007.27. Review. PubMed PMID: 18209158.
11. Stone AM, Lammers JC. The uncertainty room: strategies for managing uncertainty in a surgical waiting room. *Perm J*. 2012 Fall;16(4):27-30. PubMed PMID: 23251113; PubMed Central PMCID: PMC3523930.
12. Blum EP, Burns SM. Perioperative communication and family members' perceived level of anxiety and satisfaction. *ORNAC J*. 2013 Sep;31(3):14, 16-9, 34-6, passim. English, French. PubMed PMID: 24261110

Objectives: *Clearly state the primary and secondary objective(s) of the study.*

With a focus on patient and family centered care, we aim to determine the effect of strategic communication with patients' relatives during the perioperative period on their satisfaction, anxiety and overall experience. We hypothesize that the greatest patient and family satisfaction would come from receiving critical strategic updates during vital time points of the surgical procedure.

METHODS AND PROCEDURES

Study Design: Describe the research design, including a description of any new methodology and its advantage over existing methodologies.

This is a survey-based study. The survey has been adopted from a previously validated survey, and modified accordingly.

Procedures: Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc. Include required screening procedures performed before enrollment and while on study. Please provide in table, list or outline format for ease of review. (describe and attach all instruments)

Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.

Prior to the surgery, a member of the research team will review each case to determine if the surgery meets study criteria. The exclusion criteria include: surgeries lasting less than two hours, patients under the age of 18, non-speaking patients and/or families, or patients that do not have family members present in the pre-operation area. On the day of the surgery, a research team member will inform the patient and family that a study is being conducted to investigate the effect of perioperative communications on family satisfaction and anxiety. It will be explained that each family will randomly be assigned to two communication pathways, and there will be a short survey for them to complete post-surgery. In the control pathway, the surgeon will communicate with the family per his/her usual practice near the completion of the surgical procedure. In the intervention group, the families will receive additional standardized electronic updates via pagers at three pivotal moments: 1) Initial skin incision has been made, 2) Critical part of the case is completed and closure has begun, 3) Closure is complete, and patient is about to be transferred to the recovery room. A member of the surgical team will be responsible for sending these updates. Then, the surgeon will communicate the final update near the end of the surgical procedure per his/her usual practice.

After the surgery is complete, and both control and intervention groups have received the final update, a research team member will locate the waiting family and administer the post-operative survey rating their satisfaction and anxiety levels using Likert scale questions (1-5 scale). We adopted a previously used survey and modified it accordingly. In addition to the survey, basic demographic information of the patient and family member completing the survey, as well as the number of people in the waiting party, will be reported. When the family member has completed the survey, they will leave the survey in a secure drop box in the waiting area.

To ensure that the results of the survey are reproducible, we will take twenty subjects who completed the survey and ask permission to call them one day after the initial survey. We will then compare the results of the two surveys.

For research involving survey, questionnaires, etc.: Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation. (describe and attach all instruments)

☐ Not applicable

The paper survey will be administered after the final update has been received by the family in the waiting area. A member of the research team will deliver the survey to the family member, and there will be a collection box in the waiting area for the completed surveys. There will be no identifying information on the survey. The survey will be administered only once per family, and it has a total of six questions.

Statistical Considerations: Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.

We will be examining the relationship between patient families' levels of anxiety and satisfaction with the number of updates received during the perioperative period. We will include a minimum of 96 participants, with 48 cases in each study group. This study sample was chosen using previous data collected in a similar study¹⁰. Although this study did not administer surgical updates at specific time points, as we propose, they used a similar method of analyzing anxiety and satisfaction levels. Using their mean anxiety ratings, along with the standard deviations, a power analysis revealed that for a power of 0.8 with a significance of 0.05, the proposed study will require a total of 96 participants.

Risks/Benefits: Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.

There are no potential risks of this study. The survey does not require the subjects to report any identifying information. The data from this study will allow us to evaluate whether satisfaction and anxiety may be reduced with timely updates. This information can then be used to improve patient and family satisfaction in the perioperative period.

Therapeutic Alternatives: List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.

☒ **Not Applicable**

Data Safety and Monitoring: The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.

The Principal Investigator will perform safety reviews annually.

Adverse Event and Unanticipated Problem (UAP) Reporting: Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.

All guidelines established in the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting policy" will be followed.

Withdrawal Procedures: Define the precise criteria for withdrawing subjects from the study. Include a description of study

¹⁰ Blum EP, Burns SM. Perioperative communication and family members' perceived level of anxiety and satisfaction. ORNAC J. 2013 Sep;31(3):14, 16-9, 34-6, passim. English, French. PubMed PMID: 24261110.

requirements for when a subject withdraws him or herself from the study (if applicable).

If the family decided not to complete the survey after the surgery is complete, they will be removed from the study population.

Sources of Materials: Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.

Research material will be obtained from the administered survey

DRUG AND DEVICE INFORMATION

Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.

Drug (s)

☒ Not applicable

Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source. (attach investigational drug brochure)

Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.

Storage and stability – for both intact and mixed products.

Administration – Describe acceptable routes and methods of administration and any associated risks of administration.

Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.

Is it FDA approved: (include FDA IND Number)

1. in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.
2. for the route of administration specified? If no, provide justification for route and describe the method to accomplish.
3. for the intended action?

Device (s)

☒ Not applicable

Device name and indications (attach investigational device brochure)

Is it FDA approved: (include FDA IDE Number)

1. for indication specified? If no, provide justification for proposed use and source of the device.

Risk assessment (non-significant/significant risk) - PI or sponsor needs to assess risk of a device based upon the use of the device with human subjects in a research environment.

SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

Subject Selection: Provide rationale for subject selection in terms of the scientific objectives and proposed study design.

Subjects will include family members of orthopaedic surgical patients. We believe that the role of surgeon-family communication and periodic updates play an increased role on family members' anxiety and satisfaction during surgeries of longer duration, so surgeries lasting less than two hours will not be included in the study. We will also exclude patients under the age of 18 years old and non-English speaking patients and/or families to ensure that consent is valid.

Vulnerable Populations: Explain the rationale for involvement of special classes of subjects, if any. Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).

☒ **Not applicable**

Number of Subjects: What is the anticipated number of subjects to be enrolled at UVM/UVM Medical Center and in the case of a multi-center study, with UVM/UVM Medical Center as the lead, the total number of subjects for the entire study.

There will be a minimum of 96 subjects. We anticipate approximately 200, and all subjects will be enrolled at UVM/UVM Medical Center.

Inclusion/Exclusion Criteria: Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.

Inclusion criteria includes all families of orthopaedic surgical patients of the surgeons involved in this research study. Exclusion criteria include surgeries lasting less than two hours, patients under the age of 18 years old, and non-English speaking patients and/or families. Each orthopaedic surgical case will be reviewed for eligibility prior to the surgery date by a member of the research team.

Inclusion of Minorities and Women: Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.

Women and minorities will be included, given that they meet inclusion criteria listed above.

Inclusion of Children: Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. If children are excluded then provide appropriate justification. Provide target accrual for this population.

Patients under the age of 18 are excluded from this study. Communication with families during the time of surgery is different for pediatric patients than for adult patients. For example, parents are often able to escort children into the operating room.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

N/A

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

☒ **Not applicable**

Recruitment: Describe plans for identifying and recruitment of subjects. All recruitment materials (flyers, ads, letters, etc) need to be IRB approved prior to use.

PI/Collaborators will recruit their own patient's and their families

FINANCIAL CONSIDERATIONS

Expense to Subject: If the investigation involves the possibility of added expense to the subject (longer hospitalization, extra studies, etc.) indicate in detail how this will be handled. In cases where the FDA has authorized the drug or device company to charge the patient for the experimental drug or device, a copy of the authorization letter from the FDA or sponsor must accompany the application. Final approval will not be granted until the IRB receives this documentation.

There are very limited circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, provide a justification as to why this is appropriate and acceptable. For example, if the study involves treatment that is documented standard of care and not investigational, state so. In these cases, the protocol and the consent should clearly define what is standard of care and what is research.

N/A

Payment for participation: Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.

☒ **Not applicable**

Collaborating Sites. When research involving human subjects will take place at collaborating sites or other performance sites when UVM/UVM Medical Center is the lead site, the principal investigator must provide in this section a list of the collaborating sites and their Federalwide Assurance numbers when applicable. (agreements may be necessary)

☒ **Not applicable**

INFORMED CONSENT

Consent Procedures: Describe the consent procedures to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent. Specify the form(s) that will be used e.g. consent (if multiple forms explain and place identifier on each form), assent form and/or HIPAA authorization (if PHI is included). These form(s) must accompany the protocol as an appendix or attachment.

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions asked were answered.

On the day of the surgery, a research team member will inform the patient and family that a study is being conducted to investigate the effect of perioperative communications on family satisfaction and anxiety. Consent will be implied upon the completion of the survey. No PHI is included in this study.

Information Withheld From Subjects: Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe plans for post-study debriefing.

☒ **Not applicable**

Attach full grant application, including budget information and/or any contract or draft contract associated with this application.