CARILION CLINIC INSTITUTIONAL REVIEW BOARD

IRB RESEARCH APPLICATION INSTRUCTIONS

NOTE: This is a protected document!
All responses will now appear as originally formatted and can be adjusted.

This application is for use by researchers proposing to conduct human subjects research at Carilion Clinic, including the Jefferson College of Health Sciences, or who will use Carilion services as part of the research process. The application is for use by the Carilion Institutional Review Board, a committee charged with protecting the rights and welfare of human subjects in research. The entire application must be completed if the proposed research involves Carilion faculty, employees, students, facilities or patients.

Research protocols may be reviewed at convened meetings of the IRB or through a single reviewer process involving the IRB chair and staff. The type of review is determined by the nature of the project, the level of potential risk to research subjects and the characteristics of the subject population. The final determination of the type of review applicable to a study is made by the IRB.

- **Full Board Reviews:** Research that would require review at a convened meeting of the IRB would include but is not limited to research that involves: 1)more than minimal risk, 2)vulnerable populations, 3)experimental drugs or devices 4)invasive procedures, or 5)deception (e.g., in behavioral research). A schedule of IRB meetings can be found on the Carilion IRB website.

- **Expedited or Exempt Reviews:** Some studies may not require review by the convened IRB, but may be eligible for "Expedited review" or "Exempt status" after review by one or more IRB members. Expedited studies involve no more than minimal risk to subjects. Federal regulations define minimal risk as the probability that the magnitude of harm or discomfort anticipated in the research are not greater in of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Some research may be Exempt from further review once this initial determination is made. The Carilion IRB must determine whether proposed studies meet the criteria for Expedited or Exempt review.

Submission Instructions
All Full Board, Expedited, and Exempt study submissions to the IRB should be submitted using this application. Investigators should send the completed application to the IRB electronically. If the researcher believes his or her project meets the criteria for Expedited or Exempt submissions, please send the application to Janet McDowell at jdmcdowell@carilionclinic.org
For Full Board submissions, please send the application to Meredith Talmadge at mttalmadge@carilionclinic.org. Signature pages may be sent electronically or faxed to (540) 985-5323. For further information call 853-0728.

Note: Consent Form and Information Sheets should be submitted in Word, not in pdf, because IRB staff may need to make revisions and edits to these documents. Each CV should be sent in a separate electronic document so that IRB staff can file them individually in our electronic filing system.

Please do not copy this page when submitting paper copies to the IRB office.

Carilion Clinic Institutional Review Board

INSTITUTIONAL REVIEW BOARD APPLICATION

REGISTRATION WITH DEPARTMENT OF RESEARCH & DEVELOPMENT

PER INSTITUTIONAL POLICY ALL PROJECTS MUST BE SUBMITTED WITH AN R&D PRE-APPROVAL OR APPROVAL LETTER STATING YOU ARE READY TO SUBMIT TO THE IRB. DO YOU HAVE YOUR R&D LETTER?

☒ Yes (If yes, you MUST attach your R&D letter to this submission.)
☐ No (If no, do not submit your IRB project until you have your R&D letter.)

You may contact the R&D Department at 540-985-8510.

SECTION I: APPLICATION DATA

Date Completing Form: 11/24/2017
(Please change with each revision)

Complete Title of Study: A Standardized Patient Education Video Program for Improvement of Post-Operative Recovery after Outpatient Upper Extremity Surgery

Research Team (All individuals, whether Carilion associates or not, participating in the conduct of research under the direction of the principal investigator, including investigators, coordinators, those obtaining consent, etc.):

Carilion Principal Investigator: Cassandra Mierisch Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Mailing Address (if external):
Phone: 540-588-8076 E-mail: crmierisch@carilionclinic.org Fax: 540-857-5306

Other Investigator: Peter Apel Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: pjapel@carilionclinic.org Fax: 540-857-5306

Other Investigator: Cay Mierisch Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: CMMierisch@carilionclinic.org Fax: 540-857-5306

Study Coordinator: Allison Bell Credentials: MPH
Inter-office address:
Role & Responsibilities:
Mailing Address (if external):
Phone: 540-224-4661 E-mail: aephillips2@carilionclinic.org Fax:

Other Research Team Member: Soleille Everest Credentials: VTCSOM Medical Student
Role & Responsibilities: Creation of study materials, data collection, analysis
Inter-office address:
Mailing Address (if external): 610 S Jefferson Street Apartment 712, Roanoke VA 24011

Phone: 919-516-3713 E-mail: severest@carilionclinic.org Fax:

Other Research Team Member: Min Wang Credentials: PhD
Role & Responsibilities: RedCAP, Technology and Analytics
Inter-office address: Manager, Health Analytics Research Team, Carilion Administrative Services Bldg
Mailing Address (if external):
Phone: 540-510-4514 E-mail: mmwang@carilionclinic.org Fax:

NOTE: See last page of application to add additional investigators and research team members.

All research team members must complete Carilion IRB education requirements before research can be approved. Further information regarding education requirements can be found on the Carilion IRB web site: http://www.carilionclinic.org/Carilion/IRB.

1. Has the Principal Investigator ever had any research suspended or terminated by an IRB?

   ☐ Yes ☒ No

   - If yes, please explain:

2. Has any version of this research protocol ever been submitted to any other IRB?

   ☐ Yes ☒ No

   - If yes, please attach a copy of all IRB correspondence

3. Has the Principal Investigator ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority or is the Principal Investigator currently the subject of such a proceeding?

   ☐ Yes ☒ No

   - If yes, please explain:

4. Have any of the other investigators or study team members ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority, or are any currently the subject of such a proceeding?

   ☐ Yes ☒ No

   - If yes, please explain:

5. **Location of Research**:

   - Check the facility where research activities will take place (please check all that apply):

   ☐ CRMH ☐ CNRVMC ☐ JCHS ☐ CC Physician's Office
   ☐ CRCH ☐ CFMH ☐ CRMH Rehab ☒ Other: Carilion Institute of Orthopedics and Neurosciences (ION)

   - List all departments within the facility where research activities will take place: Carilion Orthopedics

6. **Collaboration:**

   - Will this research involve collaboration with another institution? ☐ Yes ☒ No
   - If yes, name the institution:

7. **Sponsor:**

   - Will this research be sponsored by an institution outside of Carilion? ☐ Yes ☒ No
   - If yes, name the institution:

8. **Funding Source** (check only one):

   ☒ Carilion RAP grant
   ☐ Federal/state agency (specify):
   ☐ Other grant (specify):
   ☐ Industry/commercial (specify):
   ☐ Private, non-profit (specify):
   ☐ No funding; equipment, supplies, and/or services will be provided (specify company):
   ☐ No funding; no equipment, supplies, and/or services will be provided
   ☐ Other (specify):

9. Anticipated Start Date: October 1st, 2017

10. Estimated Time Needed to Complete Study: September 30, 2018

SECTION II: DRUG, DEVICE AND BIOLOGIC STUDIES ONLY ☒ N/A

11. What is the name(s) of the drug, device or biologic that will be used in this study:

12. Please attach documentation to confirm FDA approval of this drug, device or biologic. Check one below:
    ☐ Package Insert
    ☐ Printed Information from the FDA website confirming FDA approval
    ☐ Letter from FDA granting approval
    ☐ Not available; FDA has not approved

13. Does the research study involve an Investigational New Drug (IND) or Biologic? An IND number is required if a drug or biologic is used in a manner outside the labeling approved by the FDA.

☐ Yes ☒ No

- If yes, please provide the IND number assigned by the FDA. If an IND number is not available please explain why an IND was not obtained. If you believe the drug is exempt from IND approval, please submit an IND Determination form that can be found on the IRB web site. Note: Investigators may be asked to have an IND determination application submitted to the FDA.

14. Does the research involve a device that is being used outside the labeling approved by the FDA?

☐ Yes ☒ No

If yes:

- Please provide the Investigation Device Exemption (IDE) number provided by the FDA:

- Attach one of the following:
  - ☐ FDA letter granting an IDE
  - ☐ A letter from the sponsor or investigator/sponsor stating the study device is non-significant risk
  - ☐ A letter explaining why the investigation is exempt from IDE requirements

SECTION III: STUDY PROTOCOL

15. **Study Abstract:** Provide a brief, non-technical summary of the study, including study purpose and methods.

The purpose of this study is to quantify the impact of a formalized pain management education program on the outcome and experience of patients undergoing outpatient, upper extremity, orthopedic surgery. Outcome measures include the validated Quality of Recovery-15 patient survey and PROMIS survey (selected short forms evaluating pain and medication side effects), as well as measures of patient behavior (amount of pain medication used, number of calls/visits to a medical provider for pain-related concerns), pain levels (1-10 scale), reported side effects, and patient knowledge as measured on a follow-up questionnaire. It is the premise of this study that patient education regarding perioperative pain management could benefit patients in several ways:

1) empowering patients to make informed decisions regarding the pain medications and modalities they choose,
2) reducing the incidence and severity of pain medication related side effects or complications,
3) improving post-operative pain control,
4) improving patient satisfaction, and
5) reducing the use of narcotic.

Four hundred (400) adult patients undergoing elective outpatient, upper extremity, orthopedic surgeries will be recruited by the surgeon-investigators. Patients will be randomized to view one of two educational programs: 1) a 2-video series regarding post-operative pain management or 2) a video regarding wound care and activity. Randomization will be stratified based on initial narcotic prescription size, which has been shown to influence narcotic use, and baseline pain medication use.[1]

These patients will be encouraged to review the video online in the week before surgery. An intake enrollment form will be completed by an investigator using demographic information available in the chart.

Participants in both arms will complete their Patient Education Study Diary daily, for 7 days following their surgery. There are two versions of this diary: the Wound Education Version asks patients to report daily pain mediation use. The Pain Education Version does not include this section as patients in the pain management arm of the study record this information in their Recovery Diary.

[1] The guidelines have been developed in conjunction with the upper extremity surgeons to reflect their current practice. The purpose of the guidelines is to reduce inadvertent variability, particularly when residents and other providers provide the post-operative prescription. Despite the guideline, the surgeon is still encouraged to provide the pain medication prescription he/she feels is most appropriate for the patient.

The Patient Education Study Diary includes a daily pain scale, the QoR-15[1] on day 2, the selected PROMIS short forms on day 3 and knowledge quiz on day 7. It also contains opportunity to report dressing changes, co-analgesic modalities (ice, elevation, etc), and possible medication side effects. There are daily questions regarding confidence, feeling in control, and satisfaction. The final day also has questions regarding how many times the videos were viewed, the number of contacts with a healthcare provider for pain and wound related issues, and concurrent use of other sedating substances (sleeping pills, alchohol, street drugs, other sedating medications). . Patients in the control group (wound care) will also record all pain medications used each day along with any side effects of said medications. Participants in the intervention (pain management) group will record their pain medication use in the additional Recovery Medication Diary provided. The patient will return the diary at the first post-operative visit or by mail.

Patients may be contacted by phone within 7-10 days after the appointment if study materials are not complete. Information regarding the initial narcotic prescription, CPT procedure codes, concurrent NSAID prescription, and type of anaesthetic will be obtained from EPIC by chart review.

The patient will be contacted again by phone and/or mail 1 year after surgery (12-14 months) using the contact information available in EPIC to determine the self-reported prevalence of chronic pain and pain medication use (yes or no answers):

1. Do you have pain on a daily or weekly basis?
2. In the past year, have you taken prescription opioid (or narcotic) pain medication most days or most weeks?
3. In the past year, have any other pain medications (prescription or over the counter) most days or most weeks?

Measured outcomes will include: QoR-15 and PROMIS scores, number of narcotic pills used in the first week after surgery, daily pain level (by 0-10 rating scale), patient-reported satisfaction and feeling of control, related calls/visits to a health care providers, use of non-narcotic adjunct pain relief modalities, incidence of side effects and adverse events, demonstrated patient knowledge as measured by score on the follow-up quiz, and prevalence of chronic pain, long term narcotic and non-narcotic pain medication use. Positive improvements in some or all of these measurements are expected with this patient education intervention.

16. **Background:** Summarize background information about the research question(s.) Tell why the research is needed and include the relevance of this research to the contribution of this field of study. Also, provide references to relevant articles in the literature. (If you have more than 10 references, please submit the list of references as a separate attachment. Otherwise, please insert them here.)

Pain after surgery is a common experience and is not always well controlled. Results from a recent five-year survey of adult surgical patients (N = 300) showed ~86% experienced pain after surgery; of these, 75% had moderate/extreme pain during the immediate post-surgical period, with 74% still experiencing these levels of pain after discharge. Post-surgical pain was the most prominent pre-surgical patient concern, and nearly half reported they had high/very high anxiety levels about pain before surgery. [2]

In the case of outpatient orthopedic surgery at Carilion, there are no guidelines or standardized practice for pre-operative education of the patient regarding post-operative pain control. The majority of teaching regarding pain management is usually undertaken by the discharge nurse shortly after the patient has emerged from anesthetic at a time when the patient's ability to retain new knowledge may be compromised. Patients often leave hospital with local anesthetic or a block controlling their pain, only to experience a higher level of pain some hours later. Patients then generally have the option of several medication choices (acetaminophen, narcotic or narcotic-combination medications, and non-steroidal anti-inflammatories) with which to essentially self-medicate at home, in combination with non-pharmaceutical modalities. Some patients are also regular users of central nervous system depressors, such as muscle relaxants, sleeping pills, anti-depressants, and alcohol, which may contribute to risk of serious complications.

The importance of patient education regarding peri-operative pain control is agreed upon, although support in the literature, especially in the outpatient setting, is not strong. In 2016, a clinical guideline for the

management of post-operative pain was published jointly by American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council. Their recommendations included the following:
"Patients should be counseled on how to take pain medications safely and to manage side effects to optimize pain control and recovery with return to usual activities. This might be particularly important for the growing number of outpatient surgical patients. Patients and families should be informed that the use of other central nervous depressants (including alcohol) or illicit drugs in combination with opioids can result in accidental overdose and death. Discharge teaching should include a discussion of the plan for reduction and discontinuation of opioids as the acute pain resolves, as well as appropriate disposal of unused supplies of opioids and other medications."[3]

Pre-operative education for post-discharge pain control has been promoted by AORN: "Effective communication between the patient, designated support person(s), and perioperative team members enhances the patient's capacity for medication self-management after discharge." [4]

Specific communication about pain has been shown to correlate strongly with patient satisfaction. Five dimensions have been identified as impacting on patient satisfaction: information provision; physical comfort/discomfort; emotional support; involvement in care; and privacy. In an inpatient setting, higher self-report of pain was associated with lower levels of satisfaction. Patients reporting adequate teaching rated a higher satisfaction score (4.46) than patients reporting inadequate teaching. [2,5–8]

Patient education in the outpatient setting is essential in allowing the active participation of the patient in their own health care, and could reasonably increase patient safety in a way similar to in-hospital programs that have been shown to reduce medication errors. The effect of pre-operative patient education on decreasing narcotic use and improving pain control has been demonstrated on one study of 135 patients who were randomized to receive educational intervention vs no education.[9]

Recent interest in the over-prescription of narcotic pain medication after outpatient surgery has led to several studies which suggest standardized protocols for prescription sizes. The Hand Section of the Department of Orthopedics at Carilion clinic has recently submitted for publication a manuscript showing the effect of initial prescription size on narcotic use in this setting. We are also participating in a multi-center international trial of narcotic vs. non-narcotic analgesics for pain control after carpal tunnel surgery. Investigating the role of patient education in post-operative pain management is an extension of this line of research.

This study will be a prospective, randomized, placebo-controlled experimental study investigating the effect of a formalized patient education program (videos and recovery diary handout) on patient experience and outcome after outpatient orthopedic upper extremity surgery, using both validated and non-validated outcome measures.

17. **Objectives:** State the research hypothesis or the question that the research will answer. List the research objectives and expected outcomes. **A primary outcome or objective must be identified**. After the statement of the primary objective, secondary objectives may be listed. Objectives should be simple and specific.

    Hypothesis: Patient experience and outcome after outpatient upper extremity orthopedic surgery can be improved by a formalized education program (video and handout) regarding post-operative pain management.

    Primary outcome:

    1. QoR-15 scores (post-operative day "POD" 2),
        a. 15-question validated outcome measurement tool used in the setting of outpatient surgery which takes about 2.5 minutes to complete and includes pain as one of its outcome domains

    Secondary Outcomes:

2. PROMIS short forms administered on POD 3 – (GI belly pain 5a, GI nausea and vomiting 4a, Pain Intensity 3a, Pain Interference 4a, Sleep Disturbance 4a, Cognitive Function 4a)
3. number of narcotic pills used – 7 days,
4. daily pain level (by 0-10 rating scale) – 7 days,
5. patient-reported satisfaction and feeling of control (4 point rating scale)
6. number of pain-related calls/visits to a healthcare provider
7. use of non-narcotic adjunct pain relief medication and modalities
8. incidence of high risk activities (combining narcotics with muscle relaxants/sedatives/alcohol, etc.; combining prn NSAIDs with regularly dosed prescription NSAIDs, exceeding daily recommended doses)
9. incidence of side effects and adverse events,
10. demonstrated patient knowledge as measured by score on the follow-up quiz, and
11. prevalence of chronic opioid use.

Positive improvements in some or all of these measurements are expected with this patient education intervention. The Quality of Recovery-15 survey is a 15-question validated outcome measurement tool used in the setting of outpatient surgery which takes about 2.5 minutes to complete and includes pain as one of its outcome domains

18. **Study Design:** Give a description of the research design including use of placebo, randomization and an explanation of what is experimental. Include type of study: descriptive, retrospective, cross-sectional, longitudinal, prospective observational, pilot, experimental (controlled or non-controlled) or pilot.

    A prospective, randomized, controlled study. The experimental intervention is exposure of the subject to a standardized educational program on post-operative pain management, while the control is exposure to a standardized educational program on wound care.

19. **Study Population:** Describe the subject population, including age, gender, ethnic characteristics and health status. State the inclusion/exclusion criteria along with how this was determined, and by whom. Please state whether pregnant women, children, or other vulnerable groups will be included or excluded. Provide rationale for using or excluding special populations. State the number of subjects or subject records necessary to complete the research.

    400 patients undergoing outpatient, upper extremity, orthopedic surgery meeting the following inclusion and exclusion criteria will be recruited.

    Inclusion Criteria

    1. Adult (age 18 or older) patients planning elective outpatient orthopedic surgery procedures by a Carilion Clinic hand surgeon will be eligible for the study.

    Exclusion criteria will include:

    1. Patients unable or unwilling to provide informed consent
    2. Patients unable to unwilling to participate in the trial (poor English language skills, blindness, cognitively disadvantaged, poor literacy skills, other barriers to participation)
    3. Patients who are or suspect they may be pregnant.
    4. Patients for whom the medical provider, in his professional judgment, does not feel that the study protocol would be appropriate. (to be tracked)

    Inclusion and exclusion criteria were selected by the PI with the intention to make the study population as inclusive as possible to represent since the goal of the videos is the have them available

for general patient viewing. Pediatric patients and pregnant patients are excluded as these represent populations with special ethical and medical considerations (such as drug dosing, medication effect on the fetus) which are not addressed in this study. Also, the educational program is designed for adult learners.

20. **Methodology:** List all activities or procedures that will be performed (pre-treatment tests and medications, tests and medications used during therapy, diagnostic tests, x-rays, lab tests, questionnaires and other forms, interviews, chart reviews etc.) Describe how, when and where research activities will be administered and analyzed. **Distinguish any standard processes from those that are research.** Please describe activities/procedures in a step-by-step chronological order. State the length of time subjects will be in the study and the expected amount of time required for each study visit or activity.

1. Recruitment – 10 minutes

A desk-top sign advertising the study will be displayed in patient rooms used by the Hand Section providers for patient visits.

All patients who are consented or scheduled for surgery during a clinic visit with a Hand Section provider at the ION building (when a designated enrollment investigator is present/available) will be considered for the study. These patients will be referred to the designated enrollment investigator, who will present the participation opportunity to the patient after the conclusion of the visit with the provider. The designated enrollment investigator may be a study coordinator, medical student, or other investigator, but will not be the treating physician. Study coordinators will be utilized in this role whenever possible, although scheduling and budget restraints will make mixed coverage necessary.

The surgeon will inform the designated enrollment investigator (verbally) of the anticipated prescription class for use in randomization. The designated enrollment investigator will send the surgeon a staff message in EPIC to document that number for reference on the day of surgery.

Patients who agree to participate in the study will sign the consent form. The designated enrollment investigator will keep track of all patients who are consented for surgery but do not enroll in the study, collecting only the number of such patients and their reason for not entering the study (patient declines or which eligibility criterion is not met). No identifying data or other demographic data will be collected from patients who do not consent to enter the study. This information will be recorded in REDCap.

2. Randomization - < 1 minute

They will then be randomized to a study group using a REdCap stratified randomization protocol.

Randomization will by stratified by anticipated post-operative prescription (none, tramadol, 10 narcotic pills, 20 narcotic pills, 30 narcotic pills, >30 narcotic pills). Other factors that will be controlled for through randomization include:

1)

The surgeon and other treating providers will be blinded as to the randomization of the patient. In some cases, the patient may initiate a discussion with the surgeon which necessarily reveals the randomization – this is necessary to avoid interference with physician-patient communication (avoiding negatively impacting patient care) and will be considered acceptable for this study.

3. Data collection – enrollment phase – 10 minutes

An enrollment form is completed by the designated enrollment investigator based on patient interview and/or chart review at the time of enrollment.

At the pre-operative visit prior to video viewing, patients will complete, using REDCap online with the assistance of an investigator, the following:

I. Quality of Recovery 15 (2.5 minutes)

II. PROMIS short forms in the following domains: (approximately 6 minutes)
    a. Physical Health – Gastrointestinal - Belly Pain 5a
    b. Physical Health – Gastrointestinal – Nausea and Vomiting 4a
    c. Mental Health – Cognitive Function 4a
    d. Sleep Disturbance 4a
    e. Pain Intensity 3a
    f. Pain Interference 4a

4. Educational Intervention (experimental): (6-12 minute video, depending on randomization)
    1) Pain Management Education (Intervention)
        a. A series of two 6-minute videos. The first video, Managing Pain after Outpatient Surgery, Part 1, discusses a tiered approach to pain management, including rest, ice, elevation, distraction, and medication. Three classes of pain medication commonly used after surgery, including nonsteroidal anti-inflammatories, acetaminophen, and opioids, are discussed, including the role of each medication and the risks and side effects. Naloxone, an antidote to opioid medication for emergency use, is introduced. The second video, Managing Pain after Outpatient Orthopedic Surgery, Part 2, instructs the patient on how to make a Pain Plan with regard to post-operative pain medication, including the use of over the counter pain medications and a medication diary. (12 minutes)
        b. Recovery Medication Diary (1-7 minutes, daily, for 7 days)

    2) Wound Care Education (Control)
        a. A single video, Caring for Your Closed Wound, discusses the types of sutures that are used to close surgical wounds, the specifics of wound care and dressing changes, swelling management, restriction of physical activity, scarring of the surgical site and

methods to reduce scarring, and guidance on when to call their physician if they suspect something to be wrong following their procedure. (6 minutes)

Patients are encouraged to view the video(s) in the examining room of the clinic before departure on a tablet device. Patients who elect to watch the video will be offered a small bottle of water, due to the extended visit and as a "fidget" to aid in attention. The videos will also be "assigned" to the patient in MyChart through the GetWellNetwork, and also available for viewing online on the Carilion channel on YouTube.

5. Patient packet dissemination (< 1 minute)

All patients in the study will receive an enrollment package with includes a copy of the consent form, video web address, and Patient Education Diary (experimental or placebo version). Patients in the Pain Control Video group will also receive a Recovery Diary corresponding to the video.

6. Data Collection (1-7 minutes daily for 7 days)

Patients are invited to view the video on the GetWellNetwork through MyChart and on YouTube. Viewing will be tracked by patient report, and by tracking views on the GetWellNetwork. (Viewing by patient report will be used in statistical analysis, comparison to GetWellNetwork data will be exploratory.)

Participants in both arms will complete a Patient Education Study Diary daily for 7 days following their surgery. Patients in the control group (wound care) will also record all pain medications used each day along with any side effects of the medications. Participants in the intervention (pain management) group will record their pain medication use in the additional Recovery Medication Diary provided.

Patients will receive a phone call from either an investigator or the study coordinator on Day 1-3 and Day 5-7 to remind them to complete their diaries and to answer any questions the patient may have (see attached script).

Patients will return their diaries at their first post-operative visit. If they do not bring the diaries to the post-operative visit, they will be given a self-addressed, stamped envelope to facilitate return. Patients will be contacted by phone (with permission) <10 days and 14-21 days following surgery and again 21-28 days after surgery if they have not returned their study materials as a reminder.

The Follow-up Questionnaire will be completed at the 1st post-operative visit, or by phone within 7-10 days of that appointment. The patient will be contacted again by phone and/or mail 1 year after surgery

(12-14 months) using the contact information available in EPIC to determine the self-reported prevalence of chronic pain and pain medication use:

1. Do you have pain on a daily or weekly basis?
2. In the past year, have you taken prescription opioid (or narcotic) pain medication most days or most weeks?
3. In the past year, have you used pain medications (prescription or over the counter) most days or most weeks? (list medications used on a daily or weekly basis for pain)

7. Data Storage, Data Entry and Statistical Analysis

Paper copies of study materials containing confidential patient information will be stored in locked boxes in the nursing station and in locked drawers in locked areas of the clinic/physician offices. Electronic copies of study materials/collection tools containing patient identifiers/confidential information will be stored on the Carilion S drive or on REDCAP as appropriate. All paper and electronic copies will be retained for 7 years and destroyed according to Carilion accepted research procedure.

A working binder will be maintained for logistical purposes to track and coordinate enrollment, follow-up phone calls and visits, and collection of study materials. The binder will list subject number, name, phone number, dates of surgery and visits, and have columns to track progress through the study protocol. It will be maintained in a locked drawer in a locked office.

Data Entry will be carried out by the investigators.

Statistical analysis will be carried out with assistance of a Carilion Clinic biostatistician. Statistical analysis will include description of the study population and comparison of study groups based on demographic variables. This will include age, surgical site (hand, wrist, forearm/elbow, humerus/shoulder), and type of anesthesia (general vs. local) as these have been shown to affect post-operative narcotic use. Analysis regarding the effect of age, gender, and surgery and medication related variables on the outcome measures will also be carried out. Primary and secondary outcome measures will be

a. QoR-15 scores (primary outcome),
b. PROMIS scores,
c. number of narcotic pills used,
d. daily pain level (by 0-10 rating scale),

e. patient-reported satisfaction and feeling of control (4 point rating scale),
f. number of pain-related calls/visits to a healthcare provider
g. use of non-narcotic adjunct pain relief medications and modalities,
h. incidence of high risk activities (combining narcotics with muscle relaxants/sedatives/alcohol, etc.; combining prn NSAIDs with regularly dosed prescription NSAIDs, exceeding daily recommended doses)
i. incidence of side effects and adverse events,
j. demonstrated patient knowledge as measured by score on the follow-up quiz, and
k. prevalence of chronic pain, long term narcotic and non-narcotic pain medication use. .

Analysis regarding the effect of age, gender, and surgery and medication related variables on the outcome measures will also be carried out.

How this study differs from the usual care a patient will receive:

Patient education regarding post-operative pain management is usually conducted in an ad-hoc case-by-case basis by the physician or representative that enrolls a patient for surgery. Review of medication for discharge by the nurse at the surgery facility and written post-operative instructions which includes some discussion of post-operative pain control are formalized and a routine part of patient care. This study differs from standard care through the addition of a standardized pre-operative education program in the form of the Pain Management Video series and Recovery Diary to care of the intervention group, and the addition of the Wound Healing Video to the control group. No part of the normal patient care will be removed as part of this study.

21. **Data Collection:** Attach a copy of your data collection tool or spreadsheet listing exactly what data is to be gathered during this research study. Describe below the data collection methods and how data be compiled for assessment.

Data to be collected:

Patient Demographic Data:
Name
EMPI
CSN
MRN
Contact phone number
Age
Gender
Pre-existing pain medication use (opioids, acetaminophen, NSAIDS, lyrica, Neurontin)
Patient race, ethnicity, education level

Data Related to Surgery:

Date of Surgery
Surgical Procedure(s) and anatomic location
Patient weight
Anesthetic Type
Pain Medication Prescribed

Outcome Measure Data:

1. QoR-15 scores (primary outcome),
2. Selected short form PROMIS questionnaires,
3. number of narcotic pills used,
4. daily pain level (by 0-10 rating scale) for days 0-7,
5. patient-reported satisfaction and feeling of control (10 point rating scale),
6. calls/visits to a health care provider for pain or related concerns
7. use of non-narcotic adjunct pain relief medications and modalities,
8. incidence of side effects and adverse events
9. reported frequency of noting pain medication dose times,
10. demonstrated patient knowledge as measured by score on the follow-up quiz, and prevalence of chronic pain, long term narcotic and non-narcotic pain medication use.

Data will be collected by chart review (for demographic data and data pertaining to the surgery, anaesthetic, and initial narcotic prescription), physician and patient reporting, and by patient diary/surveys (which will be completed by the patient at home and returned at the follow-up visit or by mail). Follow-up phone calls will act as a reminder to help encourage completion of the study. Information regarding how many times a video was viewed will be collected by patient questionnaire (measured outcome to be used in analysis), reviewing Mychart data, and counting Youtube hits.

22. **Statistical Analysis:** State how qualitative and/or quantitative data will be analyzed. This must include a statement from a statistician that there is sufficient power to determine the primary study outcome or objective. Other outcomes may be listed as secondary and descriptive. If this is a proof of concept or feasibility study that includes limited efficacy testing, there must be a statistician statement that the appropriate design is in place to determine whether an intervention should be recommended for broader efficacy testing. If a study is meant to be solely descriptive, then results apply only to the sample being studied and conclusions cannot be drawn about the larger population; therefore, the primary outcome or objective must be limited in scope.

Standard descriptive statistics will be undertaken. All data will be integrated into a mixed model ANOVA with appropriate post-hoc comparisons by group as appropriate. Analysis will be carried out with the assistance of a qualified biostatistician.

Power Calculation and Sample Size:

The QoR-15 score is a validated outcome metric for quality of recovery (Stark 2013)[1] and is the primary outcome measure for this study. Thus, the QoR was chosen for the power analysis and sample size calculation. Using data from Stark et al 2013, the expected values for the QoR score are average (μ) of 120 and standard deviation (σ) of 25[1]. We would consider a difference of 8 points to be

clinically significant. Thus, using these values and with an α of 0.05 and β of 0.8, the calculated sample size is n = 154. Our study design will allow for a maximum attrition of up to 20% (39 patients), thus we will enroll 200 patients per group (rounding up from 193).

Our group performs approximately 2000 procedures annually (1,973 in FY2016), of which we anticipate 80% will be eligible for this study. Assuming a 50% enrollment rate, it is reasonable to project completion of enrollment in 6 months. Notably, the enrollment rate amongst eligible patients for our completed study on narcotic use after minor hand surgery was greater than 95%. However, this study does require more patient engagement, and so a more conservative estimate has been used. The video length as well as the length and complexity of the diary and surveys are being minimized. Patients will be contacted by phone (with permission) as well as have contact at their follow-up appointment(s) to assist with completion and return of materials. Self-addressed stamped return envelopes will be provided when the patient fails to bring study materials to the first post-operative visit.

Statistical review was conducted by: Ellen S. Lockhart (name of statistician)
Carilion (Department/Institution of statistician)

If no statistical review was done, explain why:

SECTION IV: RISKS AND BENEFITS

23. Summarize the possible risks to subjects and how they have been minimized in the study design. Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Define the level of risk (minimal risk, risk but with potential benefit to patient, risk but no benefit to patient). Describe any procedures that will be used to prevent or minimize risks or discomforts. Note: Most studies create at least a small risk of breach of confidentiality or privacy.

    This is a minimal risk study. Risks include breach of confidentiality due to the collection of patient protected health information. All collected data will be disclosed in the consent form.

24. Describe all costs, if any, subjects may incur as a result of being in this study.

    Subjects will not incur any costs additional to those they would incur as part of their routine care.

25. Describe how subjects will be compensated for injury incurred as a result of being in the study.

    This is a minimal risk study. Subjects will not be compensated for injury incurred as a result of being in this study.

26. Is any deception used in the study or any aspect of the study kept secret from the subjects, such as the full purpose of the study?

    ☐ Yes ☒ No

    - If yes, describe the deception involved and the debriefing procedures:

27. Describe any direct benefit to individual subjects, to the group of individuals with the disease process you are researching, and/or to society based on scientific knowledge gained. Explain how the potential benefits offered by this research outweigh the risks. (Please note: payments, gifts, or other free services given as a token for participation are not benefits, but instead are classified as compensation.)

    The investigators believe that both the Pain Management and Wound Care educational programs help patients be more prepared for their surgical recovery, although this has not been demonstrated experimentally. Data gathered during this study may help researchers understand what educational materials are helpful to patients making pain management decisions, and how these materials influence their pain management choices after surgery.

SECTION V: RECRUITMENT

28. Number of Subjects/Enrollment Goal. The enrollment goal must match the number of subjects needed to meet the primary outcome. If this is a retrospective record review, this figure is the number of records that will be used for analysis. Note: Once research begins and it is anticipated the enrollment goal will be exceeded, the IRB must be notified. In some cases, prior IRB approval must be given to exceed the enrollment goal.

    Locally: 400 At all Sites:

    *****If this study is a retrospective record review only, you may skip to Section VII*****

29. Will subjects receive any compensation or gifts to participate?

    ☒ Yes ☐ No ☐ N/A

    - If yes, specify payment amount, how it will be prorated and how payment will be made: The patient will be provided a "thank you" gift in the form of a Carilion branded "I made a DIFFERENCE!" cup (see recruitment flyer for image). The cups have been approved by Carilion Marketing. They are valued at $3.87. The cup will be given to the patient at their first post-operative visit, regardless of whether the patient has completed the study, withdrawn from the study, or is yet to return study materials.

30. Will you, the sponsor, or Contract Research Organization offer any fee to physicians for the referral of potential subjects?

    ☐ Yes ☒ No

31. Will recruitment materials be used?

    ☒ Yes ☐ No

    If yes, check all that apply and include with this submission:

    ☐ Brochure
    ☐ E-mail
    ☐ Recruitment letter
    ☒ Flyer/Poster
    ☐ Clinical trial website posting
    ☐ Radio/Television script
    ☐ Newspaper Ad
    ☐ Website advertisement (including Facebook, Craigslist, etc.)
    ☐ Telephone or in-person script
    ☐ Other (please specify):

STEP 1: IDENTIFICATION OF POTENTIAL SUBJECTS

To "identify" a potential subject refers to steps you plan to take to determine which individuals may qualify to participate in your study so that you can decide which individuals to contact about taking part.

32. How do you plan to identify potential subjects? (check all that apply)

    ☐ Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (own patient population)
    **Study team requests Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPPA Authorization for recruitment purposes*

    ☐ Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (other physicians/practices patient population)
    **Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*

    ☐ Potential subjects will not be directly identified by the researchers. The potential subject will obtain IRB-approved written information about the study from his or her health care provider/faculty or from an advertisement, flyer, brochure, website, etc. The potential subject would then contact the researcher if he or she is interested.

    ☐ Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study. Treating clinicians identify potentially eligible patients and provide researchers with patient contact information with patient permission documented (e.g. email/letter to researcher from treating clinician states patient permission given. Researcher documents permission in research record.)
    **Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*

    ☐ Contact information will be provided by a patient's Carilion health care provider without the patient's knowledge to the researchers AND this is a minimal risk study that does not involve investigative drugs, devices, biologics or medical or surgical procedures.
    **Study team requests Waiver of Informed Consent /HIPAA Authorization for recruitment purposes*

☐ Review of Registry/Database in which individuals have previously signed a consent giving their permission to be contacted for future studies
☐ Student Records
**Study team requests Waiver of Informed Consent for recruitment purposes*
☒ Other – please explain: see 33

33. Please describe the identification process. List all information you plan to collect during the identification process prior to contacting potential subjects. This includes the inclusion/exclusion criteria and demographics to determine if a person qualifies for a study before contacting that person to be a potential subject.

Treating providers, who are also investigators, will identify potential subjects that are 18 years of age or older and are planning/scheduling outpatient orthopedic surgery and will ask the patient (personally or through a treatment team delegate) if they would mind meeting with the designated enrollment investigator present in the clinic that day.

Script:

"Mr/Ms _____. I think you would qualify to participate in a study about educating patients before surgery. The study involves watching a video designed to help you prepare for surgery. Would you be interested in meeting with a study representative to see if you qualify and learn more? Don't feel any pressure - it won't affect your care either way."

If a patient does not wish to meet with the designated enrollment investigator, the designated enrollment investigator will be informed that one patient declined to meet with them, and that information will be retained for tracking purposes. If the treating provider knows that a patient who is meets inclusion criteria would not qualify for the study due to exclusion criteria, he or she will also pass on the information that one patient who is planning surgery was not referred for consideration for failing to meet exclusion criteria, and this information will be recorded.

34. Who will conduct the identification process?

☒ Principal investigator
☒ Other investigator (specify): Dr. Peter Apel, Dr. Cesar Bravo, Dr. Cay Mierisch, Dr. Horatiu Dancea, Dr. Hugh Hagan, Dr. Anthony Capito
☐ Research coordinator (specify):
☐ Other research team member (specify):

STEP 2: CONTACTING OF POTENTIAL SUBJECTS

To "contact" a potential subject refers to the initial contact method you plan to use to reach a potential subject to determine if he or she would be interested in taking part in your study.

35. How will potential subjects be contacted? (please check all that apply)

☒ Direct in-person contact
☐ Telephone call
☐ Letter
☐ E-mail
☐ Potential subject will not be contacted. Potential subject will contact the researchers by responding to a flyer, brochure, e-mail, etc.) **(Please skip to #39.)**

36. Who will contact the potential subject? (please check all that apply)

☒ Principal investigator
☒ Other investigator (specify names): Dr. Peter Apel, Dr. Cesar Bravo, Dr. Cay Mierisch, Dr. Horatiu Dancea, Dr. Hugh Hagan, Soleille Everest, Dr. Anthony Capitlr
☒ Research coordinator (specify names): Allison Bell
☐ Other research team member (specify names):

37. If potential subjects are patients of Carilion Clinic, please check the appropriate scenario:

☒ **Patients will be contacted by the researcher who is also the treating clinician** or by a member of his/her treatment personnel or by his/her Carilion research personnel. Potential subjects will be assured that their decision will not affect their treatment or care or relationship with the treating clinician.
**Submit letter, email, or phone script (if applicable) using appropriate IRB template.*
☐ **Patients will be contacted by their treating clinician who is not the researcher** by letter with information about the research study. ** Submit letter using appropriate IRB template.*

Check all that apply:

- ☐ The letter will be co-signed by the principal investigator and sent by the research team. **Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*
- ☐ The letter will indicate that the patient will be called by researchers to discuss study. The letter will include a telephone number to call or post card to return to indicate patient does not want to be contacted. **Submit phone recruitment script.*
- ☐ The research involves the collection of sensitive information (e.g. illegal behavior, drug, or alcohol use; mental illness; sexual behavior.) The letter will include a telephone number to call or post card to return if patient is interested in learning more. Patient will not be contacted until he/she calls or returns post card.

☒ **Researchers who ARE NOT treating clinicians of patients will contact patients**:

- ☐ after patients have given permission to a treating clinician to share contact information with the research team and permission is documented
- ☐ without the patients' prior permission AND this is a minimal risk study that does not involve investigative drugs, biologics or surgical procedures. *Check one:*
- ☐ Contact will be via letter, phone, direct-email. **Submit letter, email, phone script using the appropriate IRB template.*
- ☒ Potential subjects will be approached in person while at a Carilion Clinic hospital or clinic. **Submit recruitment script using the appropriate IRB template.*

38. If potential subjects are not Carilion Clinic patients, describe what will be said to potential subjects to introduce them to the research. If an investigator has direct authority over potential subjects who are students, medical residents or employees, then explain how recruitment will avoid undue influence. For example, someone from the research team who does not have direct authority will make the initial contact OR potential subjects will be assured a decision not to participate in the research will not affect grades or job evaluations. Submit any letter, email, phone or other recruitment script that will be used.

    N/A

STEP 3: SCREENING OF POTENTIAL SUBJECTS

To "screen" a potential subject refers to additional information that will be collected or activities that will take place after he or she has been identified and contacted and prior to obtaining informed consent for the study. This could include asking questions to a potential subject to determine whether he or she meets eligibility criteria. Note: To comply with HIPAA regulations, only the minimum necessary protected health information may be collected at this time. This means only questions relating to the inclusion and exclusion criteria may be asked.

39. Please describe the screening process for your study. Please include whether you plan to ask potential subjects to do anything or answer questions prior to signing an informed consent document. For example: patients will come to the first visit fasting, stop taking medications, change diet, etc.

    Patients will meet with the designated enrollment investigator and be evaluated for eligibility for participation in the study using the inclusion and exclusion criteria stipulated in the protocol.

☐ N/A **(If N/A, please skip to Section VI)**

40. Who will conduct the screening?

☒ Principal investigator
☒ Other investigator (specify): Dr. Peter Apel, Dr. Cesar Bravo, Dr. Cay Mierisch, Dr. Horatiu Dancea, Dr. Hugh Hagan, Emily Fischer,Dr. Anthony Capito Soleille Everest
☒ Research coordinator (specify): Allison Bell
☐ Other research team member (specify):

41. List all information you plan to record during the screening process. (Attach screening data collection tool or an inclusion/exclusion checklist.) **Study team requests Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPPA Authorization for recruitment purposes.*

Inclusion Criteria

1. Adult (age 18 or older) patients planning elective outpatient orthopedic surgery procedures by a Carilion Clinic hand surgeon will be eligible for the study.

Exclusion Criteria

1. Patients unable or unwilling to provide informed consent

2. Patients unable to unwilling to participate in the trial (poor English language skills, blindness, cognitively disadvantaged, poor literacy skills, other barriers to participation)
3. Patients who are or suspect they may be pregnant.
4. Patients for whom the medical provider, in his professional judgment, does not feel that the study protocol would be appropriate.

SECTION VI: STUDY POPULATIONS

42. Does the research involve intervention or interaction with individuals? (Examples include physical procedures, written or verbal communication with individuals, or surveys.)

☒ Yes ☐ No

*****If no, you may skip the remainder of this section and go directly to Section VII*****

43. Which vulnerable populations may be included in this study? Check all that apply:

☐ Children/Minors (less than 18 years old)
☐ Wards of State
☐ Pregnant women
☐ Fetuses
☐ Neonates of uncertain viability OR non-viable neonates
☐ Prisoners (Please contact IRB prior to submission of application.)
☐ Mentally disabled persons*
☐ Cognitively impaired persons*
☐ Limited or non-readers
☐ Non-English speakers (You must use either a translated consent form or short form. Contact IRB office.)
☒ Economically disadvantaged persons
☒ Educationally disadvantaged persons
☒ Employees under the investigator's supervision or authority
☐ Students under the investigator's supervision or authority
☐ Patients in emergency situations
☐ Terminally ill patients
☐ Others that may be vulnerable to coercion:

**If persons are without decision making capacity, please submit a Legally Authorized Representative Investigator Assurance Form. This form is located on the IRB website.*

44. If persons in any of the vulnerable groups checked above will be enrolled into this study, please explain the additional safeguards that will be used to protect the rights and welfare of those subjects. Check all that apply:

☒ For economically disadvantaged subjects, there will be no financial screening of potential subjects and any eligible patient will be allowed to enroll regardless of financial standing or insurance status.
☒ For educationally disadvantaged subjects, additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. The consent will be read to them if necessary.
☐ For limited or non-readers, the consent will be read to them and additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. This process and the subject's signature will be witnessed by someone who is not part of the research team.

☒ For students, medical residents, or employees under investigator's authority, an investigator, research coordinator, or other member of the research team that does not have direct authority over the students or employees will obtain information consent.
☐ Other (specify):

45. If this research does not exclude children please assess the level of risk involved (check only one):

☒ N/A
☐ Minimal risk (no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations)
☐ Greater than minimal risk but has potential benefit
☐ Greater than minimal risk but no foreseen benefit

46. For research involving children, will an assent form be used? Assent is not required if the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research. Please note: if the child is <7 years of age, a discussion is not required.

☐ Yes ☐ No ☒ N/A

47. Do you request a waiver of assent?

☐ Yes ☐ No ☒ N/A

If yes, please explain justification:

48. Does the research exclude pregnant women? ☒ Yes ☐ No

If you marked No above, then please affirm the following by marking each box:

☐ Preclinical studies and clinical studies have been conducted and provide data for assessing potential risks to pregnant women and fetuses, **or** it is not scientifically appropriate to do this.
☐ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman and/or fetus; **or,** if there is no such prospect of benefit, the risk to the fetus is minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
☐ Any risk is the least possible for achieving the objectives of the research.
☐ The research holds out the prospect of direct benefit to the pregnant woman and/or fetus, **or** no benefit for the woman nor fetus **and** risk to the fetus is minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
☐ Each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
☐ Individuals engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy.
☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

Please affirm the following by marking each box <u>if they apply to your research</u>:

☐ If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father will be obtained (father's consent need not be obtained if he is unavailable, incompetent, or temporarily incapacitated; or the pregnancy resulted from rape or incest).
☐ For children who are pregnant, assent and permission will be obtained.

49. If you plan to enroll subjects that may be cognitively impaired, describe how you plan to assess decision making capacity prior to consent:

Will consent be obtained from a surrogate decision-maker for incompetent subjects?

☐ Yes ☐ No

SECTION VII: INFORMED CONSENT

For guidance on required elements for a Carilion informed consent document, go to the Carilion IRB website; see New Submissions, Section 2, Informed Consent Guidelines.

50. Are you planning to obtain written (signed) informed consent from subjects for this research?

☒ Yes, I am planning to obtain consent and signature using a consent form **(If yes, please skip to #52)**
☐ No, I am planning to obtain consent without a signature using an information sheet **(Please go to #52)**
☐ No, I am planning to obtain only verbal consent **(Please go to #52)**
☐ No, I am requesting a Waiver of Informed Consent **(Please skip to #59)**

51. Please answer the following questions to request a Waiver of the Requirement to Obtain Signed Consent:

- Is the informed consent document the only record linking the subject and the research, and is the principal risk the potential harm resulting from a breach of confidentiality?

  ☐ Yes ☐ No

- Does the research involve any procedure for which written consent is normally required outside of the research context?

  ☐ Yes ☐ No

52. Describe the process of how informed consent will be obtained from study subject.

Patients who are interested in the study will meet with the designated enrollment investigator present in the clinic after their visit with their provider. The designated enrollment investigator with explain the study and review the consent form with the patient. If the patient wishes to participate, consent will be obtained. The patient will be offered some time to consider their decision or discuss participation with a family member or friend. As this is a minimal-risk study, same-day consent will be used. Requiring the study participant to attend an additional visit in order to give more time to consider participation would impose an undue burden on the study participant.

53. Who will conduct the consent discussion with the subject? (Check all that apply):

☒ Principal investigator
☒ Other investigator (specify): Dr. Peter Apel, Dr. Cesar Bravo, Dr. Cay Mierisch, Dr. Horatiu Dancea, Dr. Hugh Hagan, Emily Fischer Soleille Everest
☒ Research coordinator (specify): Allison Bell
☐ Other research team member (specify):
☐ For Survey Studies only: Information sheet will be mailed and no discussion will take place

54. Will a student (VTCSOM, Jefferson College, other college or university) be obtaining consent from subjects? (This does not include questionnaire or survey studies.)

☒ Yes ☐ No

If yes, then the Principal Investigator must sign an attestation of training at the end of this form.

55. Where will informed consent process take place:

☒ In a private room
☐ In a waiting room
☐ In an open ward
☐ In a group setting (Group consent is allowed only in special situations. Explain process):
☐ At potential subject's residence
☐ In emergency situations (Explain process):
☐ Online (Explain process):
☐ Over the phone (Phone consent is allowed only in special situations. Explain process):
☐ Other (specify):

56. How will you assure there is sufficient opportunity for the subject to consider whether to take part? Check all that apply:

☐ Subjects will be allowed to take home unsigned consent form for consideration prior to signing it
☐ Subjects will be allowed a waiting period of hours to consider their decision
☒ Other (specify): The patient will be offered some time during the interview, including a break, to consider their decision or discuss participation with a family member or friend. The patient will be allowed time to ask questions and for all questions to be answered to their satisfaction. As this is a minimal-risk study, same-day consent will be used. Requiring the study participant to attend an additional visit in order to give more time to consider participation would impose an undue burden on the study participant.

57. What questions will be asked to assess the subjects' understanding of informed consent? Check all that apply:

☒ What is the purpose of this research?
☒ What are the risks and benefits of being in this study?
☒ How is being in this study different from ordinary treatment?
☒ How long will you be in this study?
☐ Other (specify):

58. Please use Carilion IRB Informed Consent Templates located on our website. How will you assure the consent form or information sheet is written at a level that can be understood by the research subjects?

☒ Determine grade level and reading ease by using spelling and grammar function in Microsoft Word
Provide Scores Here: 9.4
☐ Use another readability formula or index (specify type used and results here):
Note: Consent Forms with difficult reading scores may be returned for editing and may delay IRB review

*****You may skip the remainder of this section and go directly to Section VIII*****

Waiver of Informed Consent

59. Does the research involve more than minimal risk (no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations) to subjects or to their privacy?

☐ Yes ☐ No

60. Will the waiver adversely affect the rights and welfare of the subjects?

☐ Yes ☐ No

61. Is the waiver needed because obtaining consent is impracticable? Please check the appropriate option below. Note, by choosing any option in this category you confirm that data will not include psychotherapy notes and that the study is not subject to FDA research regulations.

- This study is a retrospective medical record review and/or retrospective review of specimens. Obtaining informed consent is impracticable because of the large number of records and/or specimens involved. Note: If data/specimens are sought from a small group of patients, obtaining consent may be considered practicable even it is inconvenient.

  ☐ Yes ☐ No

- Obtaining informed consent is impracticable because the sample size is so large (e.g. population-base studies or epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

  ☐ Yes ☐ No

- Obtaining informed consent is impracticable because the research is looking at issues such as outcomes/morbidity data where not having access to data from all subjects would affect the statistical outcome of the study.

  ☐ Yes ☐ No

- Other reason obtaining informed consent is impracticable:

62. Will the research yield information of direct clinical relevance for the subjects?

☐ Yes ☐ No

63. Will subjects be provided with additional pertinent information after participation?

☐ Yes ☐ No

SECTION VIII: HIPAA

64. Do you plan to <u>access</u> a Carilion healthcare record during your research study?

☒ Yes ☐ No **(If no, please skip to #69)**

65. Please check whether these items will be <u>collected or recorded</u> from a Carilion healthcare record:

- name ☒ Yes ☐ No
- a geographic subdivision smaller than state except for the first three digits of the zip code ☐ Yes ☒ No
- an element of a date, except year, for dates related to an individual, including birth date, admission date, discharge date and date of death; and all ages over 89 and all elements of such ages may be aggregated into a category of age 90 or older ☒ Yes ☐ No
- telephone numbers ☒ Yes ☐ No

- fax numbers ☐ Yes ☒ No
- electronic mail address ☐ Yes ☒ No
- social security number ☐ Yes ☒ No
- medical record number ☒ Yes ☐ No
- health plan beneficiary numbers ☐ Yes ☒ No
- account numbers ☐ Yes ☒ No
- certificate/license numbers ☐ Yes ☒ No
- vehicle identifiers, including license plate number ☐ Yes ☒ No
- device identifiers and serial numbers ☐ Yes ☒ No
- Web Universal Resource Locators (URLs) ☐ Yes ☒ No
- Internet Protocol (IP) address numbers ☐ Yes ☒ No
- biometric identifiers, including finger and voice prints ☐ Yes ☒ No
- full face photographic images and any comparable image ☐ Yes ☒ No
- any other unique identifying number, characteristic, code ☒ Yes ☐ No

66. Do you plan to collect or record individually identifiable health information about subjects from a healthcare record at any other (non-Carilion) healthcare provider, health plan (e.g. insurer), employer, or healthcare clearinghouse (e.g. billing service) at any point in the project? (See list of identifiers above.)

    ☐ Yes ☒ No

    - If yes, please list <u>all</u> identifiers you plan to collect:

67. Will the individually identifiable data be related to or linked to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual?

    ☒ Yes ☐ No ☐ N/A, we are not collecting or recording any identifiers listed above

68. Will the individually identifiable data be created or received by any person or entity that is a health care provider or an employee of any part of Carilion?

    ☒ Yes ☐ No ☐ N/A, we are not collecting or recording any identifiers listed above

If you answered "yes" to #65 OR if you answered "yes" to #66, #67, AND #68 then you must either 1) obtain written HIPAA authorization from each research subject (in the informed consent form) or 2) request a HIPAA waiver.

69. Do you request a HIPAA waiver to conduct your research? ☐ Yes ☒ No

******If no, please skip to Section IX*****

A HIPAA waiver can only be granted if the research cannot practicably be conducted without the waiver and the use of the PHI poses no more than minimal risk to the privacy of the individuals.

<u>Waiver of Authorization (HIPAA Waiver)</u>

70. Describe how the use of PHI in this study poses no greater than minimal risk to participants' privacy.

71. When will identifiers be destroyed? (Identifiers must be destroyed at earliest opportunity)

    ☐ End of study
    ☐ Years after the end of the study (enter # of years)
    ☐ Other (please specify):

72. Could the research be carried out practicably without the use of PHI?

    ☐ Yes ☐ No

73. Is the waiver needed because obtaining HIPAA authorization is impracticable? Please check the appropriate option below.

    - ○ All information needed has been collected retrospectively (e.g. medical record review research). Not having access to data from all patients requested would create selection bias and therefore affect the statistical outcome of the research.

      ☐ Yes ☐ No

- The sample size required is so large (e.g. population-based studies, epidemiology research) that including only those samples/records/data for which authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

  ☐ Yes ☐ No

- Other reason obtaining authorization is impracticable:

74. Do you assure that any data identifying subjects used in this study will not be disclosed to anyone other than the research team, sponsor, and oversight groups?

    ☐ Yes ☐ No

75. Do you assure that you will not use this data for any other research unless you receive IRB approval?

    ☐ Yes ☐ No

SECTION IX: DATA PROTECTION PLAN

76. Is the private information being requested the minimum necessary to meet the research goals?

    ☒ Yes ☐ No ☐ N/A

77. What records or data will you be using or collecting? Check all that apply:

    ☒ New data for this study
    ☐ Data already collected for another research study
    ☒ Data already collected for administrative purposes
    ☒ Medical records; approximately how many records: 400
    ☐ Electronic information from clinical database
    ☐ Other:

78. Will any sensitive information be collected, such as information regarding sexual behavior, HIV status, recreational drug use, illegal behaviors, physical abuse, mental health disorders, etc.?

    ☒ Yes ☐ No

    - If yes, what sensitive information will be collected? sensitive information on possible drug misuse. The PI will seek a certificate of confidentiality from the NIH.

79. The standard at Carilion to protect identifiable data used in research is to use a code and link system. Two files should be kept in two separate secure locations. One file should use a unique code for each subject in connection with any sensitive or health information. The other file (the link) associates the unique code with subject identifiers (e.g. name, medical record number). Please describe how you will store data using the options below.

    ☐ **Retrospective Record Review Only:** The master list will contain direct subject identifiers such as name and MRN along with a unique subject code. It will be stored separately from the coded research data set at all times. The research data set will not include any HIPAA identifiers with the exception of a date.

    ☒ **Prospective Collection of Data**, including surveys or collection of new data: While initial collection of research data may contain identifying information, it must be stored using a code linked to the subject's identity using a master list. All HIPPA identifiers will be stripped from the initial research data collection data tools and replaced with a unique subject code.

    ☐ **Prospective Collection of Sensitive Data**, including surveys or collection of new data: Research data will be linked to identifiers by a unique subject code at all times. The code will be linked to a master list that contains identifying information. The master list and coded research data will be stored in separate locations.

80. Where will data be stored? Please check all that apply:

    ☒ Hardcopy data in a locked office in a locked cabinet
    ☐ Electronic data on a password protected, encrypted Carilion laptop
    ☐ Electronic data on a password protected, Carilion-encrypted flash drive
    ☒ Electronic data on a password protected, secure drive on a Carilion server

    Select the software to be used:

    ☒ Excel
    ☐ SoftMed ☒ Other: Describe REDCAP

No other storage options are permitted, including the use of personal laptops, flash drives or other portable devices. Data must not be placed in a cloud or other hosted environment. Any exceptions must be approved by the Carilion Privacy and Information Security Officer and documentation provided to the IRB.

81. Please describe how you plan to protect identifying information from improper use and disclosure by answering the questions below.

a) Who will have access to identifiers? Investigators and study coordinator
b) How will you limit access to the identifiers? Securing data collected on paper in locked cabinets with limited access and storing electronic data using encrypted, password protected files on the Carilion S Drive and/or in REDcap
c) When and how will the identifiers be destroyed? Destruction of data 7 years after completion of study, per Carilion guidelines.

SECTION X: MEDIA USE

82. Will any media be used to record subjects' voice or image?

☐ Yes ☒ No

- If yes, describe what media will be used, how the media will be used, and justify why it is necessary to use the media to collect data:

83. Will the subjects' voice or image be recorded without their knowledge?

☐ Yes ☒ No

- If yes, describe the deception and the debrief procedures:

SECTION XI: SAFETY & MONITORING

84. Describe the process for dealing with adverse events and unanticipated problems.

All adverse events or unanticipated problems will be immediately reported to the PI, who will be primarily responsible for assessing risk to study participants and suspending the study if significant risk is suspected until remediation can be planned and measures implemented. Adverse events will be reported to the IRB using the appropriate form in a timely fashion.

85. Is there a Data Safety Monitoring Board or other safety oversight committee?

☐ Yes ☒ No

- **If yes:**

What is the name of the board or committee?
If the DSMB is local, please name the members.
How frequently will the data be reviewed for safety?

☐ Every 3 months ☐ Every 6 months ☐ Annually ☐ Unknown
☐ Other:

- **If no:**

How will the data be monitored to ensure the safety of subjects? This is a minimal risk study. No formal interim data analysis is planned.

86. Are there plans for visits by sponsor monitors or auditors to review study documents for regulatory requirements?

☐ Yes ☒ No ☐ N/A

- If yes, Identify the group that will be conducting the monitoring/auditing visit(s) and the number of times you anticipate this occurring over the next year:

87. Does this project involve research using any of the following?

☐ Yes	☒ No	Mammalian cell/tissue culture (includes established cell lines or primary isolation of cell lines from tissue, blood, etc.)
☐ Yes	☒ No	Cultivated microorganisms (isolated, grown *in vitro* and used for non-diagnostic research, i.e. isolation of biohazardous organisms from patient samples)
☐ Yes	☒ No	Research animals
☐ Yes	☒ No	Molecular cloning, recombinant DNA or gene therapy techniques

If you checked yes on any of the above boxes, you are required to contact the Carilion Clinic Research Safety Committee at 985-8510 for important guidance.

SECTION XII: STORED DATA AND HUMAN BIOLOGICAL MATERIALS REPOSITORIES

Databases and specimen repositories, also known as registries or banks, are used to store data and/or specimens for future use. When the use is for clinical purposes or quality improvement, IRB approval is not required. However, when the use is for research purposes, the databases/repositories must be approved by the IRB (45 CFR 46 and 45 CFR 160 & 164).

88. Will this research collect and store data/specimens (blood, urine, biopsy tissue, saliva, etc.) for future research beyond the parameters of this study?

☐ Yes ☒ No

*****If no, you may skip the remainder of this section and go directly to Section XIII*****

89. Will the data/specimens collected for this research be stored in an existing repository at Carilion that is used for future research?

☐ Yes ☐ No

- If yes, provide repository name:

90. Will the data/specimens collected for this research be stored in a non-Carilion repository that is used for future research?

☐ Yes ☐ No

- If yes, attach a protocol or other information describing the repository operations.

91. Will the data/specimens collected be stored in a repository for future research that will be developed and operated by the researcher(s)?

☐ Yes ☐ No

- If yes, you must also submit a Specimen/Data Repository Application to the IRB

SECTION XIII: SUBMISSION INCLUSIONS

Please check which of the following required materials you are including with this submission. If information is submitted electronically, signature pages must be faxed or hand delivered (mailed).

☐ Protocol (Not required for investigator-initiated research; this application serves as protocol.)
☒ Main consent form(s)
☐ Tissue banking consent form
☐ Assent form, if required for research involving children
☐ Information sheet
☒ Grant application
☐ Investigator brochure for drug studies
☐ Completed Form 1572 for drug studies
☐ Manufacturer reference material for device studies
☐ Legally Authorized Representative Investigator Assurance Form
☒ Recruitment script or other recruitment materials
☒ Any subject questionnaire or survey
☒ Any data collection tool that will be used to record subject information
☒ Inclusion/Exclusion Checklist
☒ Curriculum Vitae if first-time applicant
☐ IRB fee, if applicable:
☐ $1,500 application fee for full-board industry-sponsored research
☐ $750 application fee for expedited industry-sponsored research

SECTION XIV: CERTIFICATION OF PRINCIPAL INVESTIGATOR

By signing this document the investigator confirms:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. If this study involves any funding or resources from an outside source, or if I will be sharing data outside of Carilion Clinic prior to publication, I will contact the Research & Development Department regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol approved by the IRB.
5. No subjects will be recruited or enrolled on this study until the investigator has received written notification of IRB approval.
6. No personnel will be allowed to work on this protocol until they have completed the required IRB training and the IRB has given its approval.
7. All personnel working on this study will follow all IRB Policies and Procedures and Guidelines as stated on the Carilion-IRB web site and all applicable HHS/FDA regulations.
8. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training or experience to undertake those tasks.
9. Implications of the study have been discussed with all Departments that might be affected by it and I have obtained their agreement for the study to take place.
10. Any materials used to recruit subjects will be approved by the IRB prior to use.
11. Any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB except when necessary to eliminate immediate hazards to the subjects.
12. Any serious deviation from or violation of the protocol will be reported to the IRB in writing within ten days of discovering the deviation/violation. Serious is defined as any deviation/violation that significantly affects the safety of the subjects or the scientific quality of the study.
13. Local adverse events that are serious, unexpected and related or possibly related will be reported to the IRB within seven calendar days of the site learning of the event.
14. Unanticipated problems that are unexpected, related or possibly related to the research, and place subjects or others at a greater risk of harm will be reported to the IRB within seven calendar days of the site learning of the problem.
15. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part will be promptly reported to the IRB.
16. The continuation status report for this study will be completed and returned to the IRB at least 30 days prior to the expiration date.
17. All subjects will sign a copy of the most current (non–expired) consent form prior to any study procedures being performed. Assent will be obtained from children prior to participating in study if required. Legal representatives may be substituted for subject if applicable.
18. The Carilion IRB office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
19. Research records will be maintained and the IRB is authorized to inspect these records.
20. Information gained during any research at Carilion is confidential. Specifically, information about Carilion, its patients, employees, physicians, and customers shall be kept confidential and not discussed in or out of Carilion except where it directly relates to legitimate clinical or research purposes. Any unauthorized access to Carilion patient, employee, physician or customer information through medical records, documents, computerized databases or otherwise is strictly prohibited and will be considered a serious breach of confidentiality which may result in immediate termination of research and/or other action.
21. If for any reason the principal investigator can no longer perform the duties as outlined above for an extended period of time, the investigator will close the study or transfer the duties of PI to the sub-investigator or to another qualified individual. Failure to do this will result in suspension of the study.

Carilion Principal Investigator (signature) Date

Dr. Cassandra Mierisch
Principal Investigator Name (printed)

Department Chair Signature: You must obtain the signature of the appropriate department chair or designee. This signature indicates that the research has scientific merit and that the research has appropriate support and resources to be conducted.

Department Chair or designee (signature) Date

Department Chair or designee name (printed)

Principal Investigator Attestation of Informed Consent Training for Students: I certify that the following student(s) who will be obtaining informed consent for this study will have observed a mock informed consent discussion or actual informed consent discussion conducted by an experienced research team member and have been observed conducting a mock informed consent discussion or actual informed consent discussion by an experienced research team member before being allowed to interact with study subjects. In addition, I certify these students have 1) Completed the Cornerstone research modules on "The informed Consent Process for Clinical Research" and "Recruitment of Study Subjects." 2) Viewed the video General Informed Consent Requirements" posted on the Education tab of the Office for Human Protections website https://www.hhs.gov/ohrp/education/training/ded_video.html 3) Viewed the 3 informed consent videos posted on the IRB website.

Soleille Everest VTCSOM
Student name (printed) Name of School

Student name (printed) Name of School

Student name (printed) Name of School

Principal Investigator (signature) Date

Principal Investigator name (printed)

Other Investigator: Cesar Bravo Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: CJBravo@carilionclinic.org Fax:

Other Investigator: Horatiu Dancea Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: hcdancea@carilionclinic.org Fax:

Other Investigator: Hugh Hagan Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: hjhagan@carilionclinic.org Fax:

Other Investigator: Dr. Anthony Capitl Credentials: MD
Inter-office address: Orthopedics, ION, 2331 Franklin Rd SW, Roanoke, VA 24014
Role & Responsibilities: Recruit patients and assist in completing study requirements
Mailing Address (if external):
Phone: 540-725-1226 E-mail: aecapito@carilionclinic.org Fax:

Other Investigator: Credentials:
Inter-office address:
Role & Responsibilities:
Mailing Address (if external):
Phone: E-mail: Fax:

Other Research Team Member: Credentials:
Role & Responsibilities:
Inter-office address:
Mailing Address (if external):
Phone: E-mail: Fax:

Other Research Team Member: Credentials:
Role & Responsibilities:
Inter-office address:
Mailing Address (if external):
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