1) Protocol Title

a) Title: Continuous Noninvasive Blood Pressure Monitoring During Sedation for High-Risk Patients Undergoing Gastrointestinal Endoscopy

b) Protocol Version 1.1, 7/9/26

2) Objectives

This is a single-site observational, before/after cohort study comparing intermittent blood pressure measurement using an oscillometric arm cuff to continuous noninvasive blood pressure (cNIBP) measurement using the Acumen IQ finger cuff. The study is designed to determine the impact of the use of continuous noninvasive blood pressure monitoring on the incidence of hypotension in high-risk patients undergoing sedation for upper or lower endoscopic procedures.

Specific aims:

a) The primary aim is to determine the impact of the use of continuous noninvasive blood pressure monitoring on the incidence of hypotension for high-risk patients undergoing sedation for upper and lower endoscopic procedures.

b) Secondary aims are to evaluate the impact of continuous blood pressure monitoring on total IV fluid administered, total vasopressor administered, intra-operative depth of sedation, post-operative nausea and vomiting (PONV), and the time to discharge readiness.

Primary Hypothesis (stated as the null):

Continuous noninvasive blood pressure monitoring will not decrease the percentage of participants who experience hypotension, defined as MAP < 65 mmHg for a total duration ≥ 5 minutes during procedure and post-procedure recovery period

Secondary Hypotheses:

In addition, we will evaluate the impact of continuous noninvasive blood pressure monitoring on:

- the area under the curve of MAP < 65mmHg
- the intraoperative time-weighted average of MAP < 65mmHg
- the total duration of systolic blood pressure (SBP) < 90mmHg or 30% change from baseline as measured from average measurement from right and left upper extremities
- the number of hypotensive events (defined as MAP < 65mmHg) for at least one minute
- the number of patients with hypotensive events (defined as MAP < 65mmHg) for at least one minute
- the total amount of propofol administered
- the total volume of IV fluid administered
- the total vasopressor administered
- the intra-operative depth of sedation
- the incidence of post-operative nausea and vomiting (PONV)
- the time to discharge readiness.

How this research will add to existing knowledge and how the outcomes of this project will be used:

Approximately 50 million patients undergo GI endoscopic procedures annually in the U.S. Approximately 1/3 of these patients have existing comorbidities characterized as an ASA status of 3 or higher. Hypotension is a common side effect during procedural sedation. The incidence of hypotension will vary with the definition, but thresholds of MAP < 65mmHg or absolute thresholds of SBP < 90mmHg, or >20% change relative to baseline, have consistently been associated with worse outcomes and end-organ injury. Patients with preexisting comorbidities may be more susceptible to hypotension and associated adverse events.

Procedural sedation outside the operating room has benefits for patients and healthcare systems due to shorter treatment duration. However, differing levels of monitoring equipment or intensity of monitoring in procedural and PACU areas may result in delayed or missed diagnoses of hypotension. Current routine monitoring of blood pressure is intermittent, using the oscillometric arm cuff. The intermittent measures lead to both missed episodes and delayed treatment of hypotension. Continuous noninvasive blood pressure monitoring has been shown to reduce overall incidence of hypotension compared to intermittent oscillometric measurements.

As evidence continues to illuminate the risks associated with intraoperative hypotension, logic supports the role of continuous blood pressure monitoring for more patients. The primary aim of this study is to evaluate the impact of continuous noninvasive blood pressure monitoring on the incidence of hypotension for higher-risk adult patients undergoing sedation for gastroendoscopic procedures. Secondary outcome measures evaluate potential impacts on other peri-operative outcomes. The information collected is designed to guide potential improvements in patient care and outcomes.

3) Enrollment Numbers

a) Total number of subjects to be enrolled in this study: 200

b) Rationale:
Initial estimates, based only on clinical observations, are for 100 patients in Cohort 1 and 100 patients in Cohort 2. Because there are no good literature estimates of the variability of the primary outcome, 30 patients will be enrolled into Cohort 1 (Routine Care) and analyzed to establish appropriate sample sizes using a power analysis. Enrollment numbers will be modified, if necessary, based upon this analysis.

4) Inclusion and Exclusion Criteria

a) Inclusion Criteria:

Age ≥ 50 years
ASA Physical Status ≥ 3
Scheduled for upper or lower endoscopic procedure with planned propofol administration
Planned oscillometric blood pressure monitoring using arm cuff without an arterial pressure catheter.

b) Exclusion Criteria:
Age <50 years
ASA Physical Status 1 or 2
Patients known to be pregnant
Patients with an existing arterial pressure catheter
Patients on mechanical circulatory support
Patients with planned intubation for procedure
Patients with a difference in systolic blood pressure measurement between right and left upper extremities > 10 mmHg
Patients with extreme contraction of the smooth muscle in the arteries and arterioles of the arm and hand, such as may be present with Raynaud's disease
Patients with an inability to place the noninvasive finger cuffs due to anatomy, skin condition, or obstructive paraphernalia (such as false nails)

c) Age Range:
≥50 years

d) Screening procedures to determine eligibility:
Following review of the surgical schedule, patients will be screened for possible inclusion. Recruitment will be by direct discussion between the prospective candidates and the study investigators prior to their scheduled surgical procedure. The investigators will provide the consent form in person and give the prospective subject sufficient time to review the consent form and discuss the study with friends and family.

The screening of patients will require the investigators to access personal health information to identify prospective subjects without HIPAA authorization. The research could not be practically carried out without this waiver of consent. The risk of harm from contacting the participants is greater than the risk of the study procedures. The participants' rights and welfare will not be adversely affected by waiving consent. This protected health information will not be inappropriately reused or disclosed to any other person or entity. To further safeguard all protected health information, the data will not be labeled with any personal identifying information, or with a code that this research team can link to personal identifying information. The data will not be stored with any identifiers.

5) Procedures Involved

This is a single site, observational, before and after cohort study comparing peri-operative outcomes in patients undergoing upper or lower endoscopy with sedation with the current standard of intermittent oscillometric blood pressure measurement using arm cuff to the same peri-operative outcomes in patients who also have continuous noninvasive blood pressure measurement.

Two hundred eligible patients with planned propofol administration will be enrolled into one of two cohorts. A pilot sample of the first 30 patients will be used for power analysis to determine if the total sample size will need to be modified. Participants enrolled in the pilot will be included in the total sample size of the study. In the first (before) cohort, participants will have blood pressure measured via standard of care oscillometric arm cuff with simultaneous blinded continuous blood pressure measurement using the noninvasive finger cuff connected to a HemoSphere monitor. The screen of the HemoSphere monitor will not be visible to the members of the anesthesia care team. All other peri-operative management will be as per current routine. In the second (after) cohort, Patient management and procedures will be identical to cohort 1 only for these patients, the screen of the HemoSphere monitor will be visible to the members of the anesthesia care team and provide continuous blood pressure information. In this second cohort (after), additional information discovered via the continuous monitor might prompt the care team to confirm the observations, however, any evidence of hypotension will be corroborated by the current standard of intermittent blood pressure measurement.

All data required for analysis is routinely recorded in the electronic medical record, with the exception of the blood pressure measurements from the HemoSphere monitor which are stored at 20 second intervals. This data will be downloaded directly from that monitor into an Excel spreadsheet following completion of the surgical procedure. The HemoSphere monitor is FDA approved and used routinely throughout the UC Davis operating rooms for continuous blood pressure monitoring. Statistical analysis will employ standard unpaired group comparisons using GraphPad Prism version 11.0.0 for Windows, GraphPad Software, Boston, Massachusetts USA, www.graphpad.com.

6) Study Timelines

Following their provision of informed consent, each patient will participate from the beginning of their surgical procedure until hospital discharge on that same day.

This study is anticipated to require 24 months for completion of patient enrollment.

Primary analysis of the data is expected to require 4 months.

7) Study Endpoints

a) The primary study endpoint is the percentage of participants who experience hypotension, defined as MAP < 65 mmHg for a total duration ≥ 5 minutes during procedure and post-procedure recovery period

We will also evaluate multiple intra-operative and post-operative secondary endpoints including:
- the total area under the curve of MAP < 65mmHg calculated as mmHg·minutes
- the intraoperative time-weighted average of MAP < 65mmHg calculated as (mmHg·minutes)/surgical time
- the total duration of systolic blood pressure (SBP) < 90mmHg or 30% change from baseline as measured from average measurement from right and left upper extremities calculated in minutes
- the number of hypotensive events (defined as MAP < 65mmHg) for at least one minute
- the number of patients with hypotensive events (defined as MAP < 65mmHg) for at least one minute
- the total amount propofol administered calculated as mg/kg
- the total volume of IV fluid administered calculated as ml/kg
- the total vasopressor administered calculated as mg
- the intra-operative depth of sedation calculated as minimum and average PSI/min
- the incidence of post-operative nausea and vomiting (PONV)
- the time to discharge readiness, in minutes after arrival in PACU

b) Primary or secondary safety endpoints:
As a non-interventional, observational study of current routine peri-operative practice, there are no pre-defined safety endpoints.

8) Recordings

This research involves:

☐ Audio recordings

☐ Photographs

☐ Video recordings with audio

☐ Video recordings without audio

☒ None of the above

9) Data and/or Specimen Management and Confidentiality

a) Identifiers that will be collected during the course of this study:
Following their provision of informed consent, each patient will be assigned a study number. This study number will be linked to the patient's medical record number or a separate enrollment log. All data will be collected, stored and

analyzed in association with the patient study number. All data from the medical record and monitoring devices will stored on a secure, password protected computer.

b) If any identifiers will be stored, how long will they be kept?
   All data will be destroyed 1 year following publication of the results of this study.
c) For data that is coded with a linking key, at what point will the linking key be destroyed?
   All data will be destroyed 1 year following publication of the results of this study.
d) For any recordings, at what point will the recordings be destroyed?
   Not applicable
e) If this research is both federally funded *and* you are using identifiable data/specimens, please explain why this research cannot be completed using de-identified data/specimens:
   Not applicable

10) Provisions to Monitor the Data to Ensure the Safety of Subjects

Not applicable.
This study is an observational study only. The data collected will not be used to guide clinical decisions or change the course of the patient's intended clinical care. The patient will continue to be monitored with clinical standards throughout the duration of their hospital stay.

11) Withdrawal of Subjects

Informed consent discussions will explicitly include emphasis that neither patient enrollment nor patient withdrawal from the study will result in any alterations to the standard clinical care. Subjects may elect to withdraw at any time. If this occurs, all data collected will be deleted and clinical care will continue as per routine.

12) Risks to Subjects

☒ This research may pose the risk of loss of confidentiality. The risk will be minimized through the data protection plan.

No financial, social or psychological risks are anticipated to be associated with participation in this study as it is only observational with the recording of standard post-operative assessments.

Any adverse events will be reported to all co-investigators and the IRB within 48 hours of occurrence.

13) Potential Benefits to Subjects

☒ Research subjects are not likely to receive any benefit from the proposed research, but others may benefit from the knowledge obtained.

There is no specific benefit to the individual subjects for participation in this research protocol. The clinical benefits of continuous non-invasive blood

pressure measurements have been explored in other clinical settings. It is possible that this additional information may function similarly and provide earlier warning of critical hemodynamic changes, resulting in improved care and better outcomes.

14) Provisions to Protect the Privacy Interests of Subjects

Potential study candidates will be identified following review of the surgical schedule. The attending surgeon will be contacted to confirm the appropriateness of the patient and identify any steps that are indicated to protect the subjects' privacy interests. Patient recruitment and informed consent will be obtained in the UCDMC perioperative suite only when there is sufficient time for a complete discussion between the investigator and the patient. Recruitment will be by direct discussion between the prospective candidates and the study investigators prior to their scheduled surgical procedure. The investigators will provide the consent form in person and give the prospective subject sufficient time to review the consent form and discuss the study with friends and family.

15) Sharing of Results with Subjects

☒ Results will not be shared with subjects

☐ Results will be shared with subjects - Describe:

There are no plans to share the specific results of this study with the study subjects because it is observational and the information that is collected will have no impact on their treatment or care.

16) Data/Specimen Banking

a) Will the data or specimens ever be used by you or other researchers to answer a different research aim that is not included in this study?

☐ Yes - Complete the remainder of Section 16.

☒ No

17) Multi-Site Research

Not applicable

18) Community-Based Participatory Research

The anticipated experience acquired from this proposed study will further characterize the clinical benefits of continuous blood pressure monitoring. The potential benefits of this change may help a clinician anticipate and pre-empt critical hemodynamic events. Observational studies such as this proposed study are required to guide further, more comprehensive follow-up studies. At this stage there is limited opportunity for community involvement in the design or conduct of this research.

19) Compensation for Research-Related Injury

This is an observational study of current clinical practice and as such, involves no more than minimal risk to the study subjects. No additional compensation is available.

20) Economic Burden to Subjects

There is no charge or additional cost for participation in this study. Neither the patient nor their insurance carrier will be charged for taking part in the research.

21) Review Requirements

Some research projects require specific IRB determinations.

a) Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA?

☐ Yes

☒ No

Title of research study: **Continuous Noninvasive Blood Pressure Monitoring During Sedation for High-Risk Patients Undergoing Gastrointestinal Endoscopy**

Investigators: David Asseff, MD (Principle Investigator), Nathaen Weitzel, MD, Neal Fleming, MD, PhD (Co-Investigators)

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

Key Information about This Research Study

You are invited to take part in a research study. The purpose of this research is to collect continuous blood pressure monitoring data using a noninvasive finger cuff in adults undergoing upper or lower endoscopy. You are invited to be in this study because you are at least 50 years of age, you have moderate or severe systemic disease and are scheduled to undergo a procedure that requires sedation using propofol. Your participation in this research will last only for the duration of this hospital visit. We expect about 200 people at UC Davis to join and take part in this research.

Being in this study will involve the placement of one additional cuff around your finger that will continuously measure your blood pressure. In one group of patients your anesthesia care team will not be able to see the information from this finger cuff. In the other group of patients your anesthesia care team see the measurements from the finger cuff in addition to all of the other, standard monitors.

All research studies have some risk. Risks of this study include discomfort where the cuff is applied, and discoloration of the finger tip where the cuff is placed. These risks are described in detail later in this document. Any additional information provided by the finger cuff will be confirmed using standard monitors prior to any treatment. There is the possibility that you may benefit from participation in this study, but we cannot promise any benefits to you or others for taking part in this research. The information that is collected from this study may help us advance our technologies and better treat future patients.

Here are some reasons you may not want to be in this research: The most important risks or discomforts that you may expect during this study are from the finger cuff wich may include mild discomfort from the inflation where the cuff is applied and transient discoloration of the fingertip.

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Your participation in this study is voluntary. You do not have to be in this study if you do not want to. Your alternative is to not take part in the research. You will not lose any services, benefits, or rights you would normally have if you choose not to take part.

The rest of this form gives a more complete description of this study. Please read this form carefully. You can ask any questions you need to help you choose whether or not to join this study. Information to help you understand research is online at https://irb.ucdavis.edu/for-research-participants/

What if I have Questions?

If you have any questions about this research, or you believe that you've been injured or harmed as a participant of this research, please contact the investigator at (916) 734-2011 or dasseff@health.ucdavis.edu.

For non-emergency issues you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are in a research study and you wish to talk to the anesthesiology resident on call. Someone is available to answer the operator line 24 hours a day. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) by phone: (916) 703-9158, by email: hs-irbeducation@ucdavis.edu, or by mail: 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

How is this research funded?

This research is being funded by the UC Davis Department of Anesthesiology & Pain Medicine.

Why is this research being done?

The purpose of this research is to evaluate the potential for improved patient care associated with continuous blood pressure monitoring data using a noninvasive finger cuff.

What happens if I say yes, I want to be in this research?

If you decide to join this research study, the researchers will collect background information about you, such as your sex, age, height, weight, race/ethnicity, and medical history. Your blood pressure will be taken from each arm using an arm cuff before your procedure. Both the standard blood pressure arm cuff and the finger cuff will be placed on you during your surgery. You will be enrolled in one of two groups.

In group A, your anesthesia care team will monitor your blood pressure using a standard arm cuff, but they will not be able to see the data from the finger cuff.

In group B, your anesthesia care team will monitor your blood pressure using a standard arm cuff and they will also see the blood pressure measurements from the finger cuff. The information from your regular blood pressure and all other monitors used during your procedure will be collected. Information about your medications and any fluids given to you during and after your procedure will also be collected.

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If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form will be filed in your electronic medical record (EMR) and your study participation will be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

How is being in this study different from my regular health care?

If you take part in this study, the only difference between your regular care and the study is the continuous measurement of your blood pressure throughout your participation in this study.

This study is not part of your health care.

What are my responsibilities if I take part in this research?

If you take part in this research, you will need to follow any instructions provided to you by the research team and tell the research team if you have any questions or concerns.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if your health changes and staying in the study is no longer in your best interest.

Is there any way being in this study could be bad for me?

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm or discomfort related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

Some patients (less than 1 in 10) find the pressure from the continuous blood pressure mpnitoring finger cuff uncomfortable and others are concerned by the discoloration of the finger tip because venous blood return is slowed by the measurement

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As with all research, there is a chance of a breach of confidentiality (your personal information could be seen by people outside of the research study without your permission). To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the information we collect, and on the data resulting from the research. Instead, we will use a code on the collected information, and we will keep a link between the code and your medical record number identity in a different location.

In addition to these risks, this research may hurt you in ways that are unknown at this time.

Will being in this study help me in any way?

Being in this study will not help you directly. But your taking part in the study may benefit other people in the future by helping us learn more about how to best monior patients like you during their endoscopies.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. Neither you nor your insurance carrier will be charged for your taking part in the research. All additional costs associated with the study will be paid by the department.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out-of-pocket expenses related to your participation, such as travel costs.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are required to keep these records confidential. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this web site at any time.

We will access protected health information (e.g., your medical record) for this study and you will be asked to sign a separate form, commonly referred to as a HIPAA authorization, to give your permission.

Federal law provides additional protections for your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Will I receive any results from this research?

You will not receive any of the results from this research.

Will information collected be used for other research?

We will use your information to conduct this study. The data collected for this research may also be used for future research studies. We will not share any personally identifiable information. Our goal is to make more research possible. These studies may be done by researchers at this institution or other institutions, including commercial entities. Data may be placed in one or more external scientific databases for access and use. We will not ask you for additional permission to share de-identified information.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date

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