PROTOCOL TITLE:

Peripherally inserted internal jugular catheters: an observational study

PRINCIPAL INVESTIGATOR:

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Anesthesiology Department

VERSION NUMBER:

1

DATE:

February 20, 2018

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

Is this a clinical trial under ICH-GCP E6? ☐ Yes ☒ No

If yes, please confirm that the research team is familiar with and agrees to comply with the investigator requirements cited in ICH-GCP E6. ☐ Yes ☐ No

ICH-GCP E6 can be accessed by copying and pasting this URL into your browser:
http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

Table of Contents

1. Objectives 3
2. Background 3
3. Study Design 5
4. Inclusion and Exclusion Criteria 5
5. Number of Subjects 6
6. Study Timelines 6
7. Study Endpoints 6
8. Research Setting 6
9. Resources Available 6
10. Prior Approvals 7
11. Multi-Site Research 7
12. Study Procedures 7
13. Data Analysis 8
14. Provisions to Monitor the Data to Ensure the Safety of Subjects 8
15. Withdrawal of Subjects 9
16. Data Management/Confidentiality 9
17. Data and Specimen Banking 10
18. Risks to Subjects 10
19. Potential Benefits to Subjects 10
20. Recruitment Methods 11
21. Provisions to Protect the Privacy Interests of Subjects 11
22. Economic Burden to Subjects 11
23. Compensation 12
24. Compensation for Research-Related Injury 12
25. Consent Process 12
26. Documentation of Consent 13
27. Study Test Results/Incidental Findings 13
28. Sharing Study Progress or Results with Subjects 14
29. Inclusion of Vulnerable Populations 14
30. Community-Based Participatory Research 14
31. Research Involving American Indian/Native Populations 14
32. Transnational Research 14
33. Drugs or Devices 14

Checklist Section 14

1. Objectives

1.1. This is an observational study intended to characterize the time-to-placement of peripherally-inserted internal jugular (PIJ) catheters in appropriate patients. As secondary outcomes and to ensure participant safety, the investigators will record and evaluate adverse outcomes, but the study is not powered to detect rare adverse events.

1.2. As an observational study, there is not a specific hypothesis to test; rather this study is intended to estimate the time required to place PIJ catheters in appropriate patients.

2. Background

2.1. Gaining peripheral IV access is a routine part of anesthesia practice in patients undergoing surgical procedures. Adequate IV access allows for the infusion of induction agents, medications, fluids or blood products throughout the perioperative course. Often in practice, we encounter patients in which peripheral access may be difficult to obtain. The use of ultrasound guided insertion is a common method to assist in placement of a peripheral IV in these difficult to access patients. Reasons for difficult access include those who are obese, IV drug abusers, dark skinned, or dehydrated. In addition to the initial IV, placement of a second IV after induction is occasionally necessary for the infusion of additional fluids or mediations as well as providing an alternate line in the event of failure of the first IV. When placement of a catheter is difficult, alternative methods have been established for gaining IV access, including cannulation of the EJ (external jugular vein), or the deep brachial or basilic veins under ultrasound guidance. In addition to these methods, recent studies have proposed a technique of placing a peripheral catheter directly into the internal jugular vein under ultrasound guidance. What is unique about this method is the use of a regular angiocatheter, not a central venous line, and that it is for temporary usage for situations when peripheral access is difficult to obtain.

2.2. The investigators have not gathered preliminary data on this topic.

2.3. Several studies have demonstrated this technique, mainly in Emergency Department and ICU patients. One case series of 9 patients describes placing a peripheral IJ in those with unobtainable IV access [1]. 64 mm angiocatheters were used to cannulate the IJ under ultrasound guidance. All catheters were labeled for removal within 72 hours and all patients were followed up via chart review one year later. Two of 9 catheters failed due to kinking within the first 48 hrs. There were no apparent adverse outcomes in any patient including deep vein thrombosis, bacteremia, endocarditis or pneumothorax.

A second prospective case series studied 9 patients who had placement of a peripheral-IJ, when other access could not be obtained and the patient did not initially require a central line [2]. Follow-up with all patients was attempted within a week. On follow-up, the seven patients who were successfully contacted denied any fevers, chills, swelling or pain at the site of catheter entry.

In a multicenter, non-comparative trial at a resident affiliated hospital and 2 tertiary care urban academic centers, 83 attempts were made in 74 patients with high frequency ultrasound probe [3]. The patients performed Valsalva and an 18g 4.5 cm catheter was placed. Catheters remained in place at a maximum of 24 hours. Initial success rate was 88% and the mean procedure time was 4.4 min (range 1-10.5 mins). Line infection and complications were evaluated by home contact after discharge with no reports of pneumothorax, line infection, or arterial puncture.

Another prospective observational study was performed on consecutive patients admitted to ICU or medical ward with difficult IV access [4]. A 2.5in 18g catheter was placed. 20 catheters were placed in 19 patients (one patient had one catheter exchanged for another after 7 days). 16 were placed on the 1st attempt and the remaining 4 were placed successfully on the 2nd attempt. Average time to place was 5.3 mins (2-10 mins). There were no signs of fever, neck pain/stiffness, or hematoma on follow up. There were no immediate complications noticed.

A Prospective convenience study was conducted in 2 urban academic centers in 33 patients. High frequency linear ultrasound probe was used along with two types of catheters 18g 6.36 cm (2.5 in) catheter and a 20g 5.7 cm (2.2 in.) catheter]. Median time to placement was 4 minutes. There were no immediate complications observed nor was there any evidence or clinical suspicion for complication of line placement at 6 week follow up. One patient had a positive blood culture for Staph Aureus at 1 week follow up but this patient was admitted for sepsis.

To our knowledge, there are no studies in which cannulation of the internal jugular vein under ultrasound guidance has been performed by anesthesia providers in patients undergoing a surgical procedure. All the abovementioned studies reviewed showed that this was a relatively easy and quick procedure that resulted in no major complications. This is a safe and feasible option that can be performed quickly in patients that require large IV access but in whom IV access is difficult to obtain.

References:

1. Zwank, M. D. (2012). Ultrasound-guided catheter-over-needle internal jugular vein catheterization. The American journal of emergency medicine, 30(2), 372-373.

2. Teismann, N. A., Knight, R. S., Rehrer, M., Shah, S., Nagdev, A., & Stone, M. (2013). The ultrasound-guided “peripheral IJ”: internal jugular vein catheterization using a standard intravenous catheter. The Journal of emergency medicine, 44(1), 150-154.

3.Moayedi S et al. Safety and Efficacy of the “Easy Internal Jugular (IJ)”: An Approach to Difficult Intravenous Access. J Emerg Med 51(6): 636 – 642. PMID: 27658558

4.Butterfield M et al. Using Ultrasound-Guided Peripheral Catheterization of the Internal Jugular Vein in Patients with Difficult Peripheral Access. Am J Ther 2015. PMID 26469683

5. Kiefer D et al. Prospective evaluation of ultrasound-guided short catheter placement in internal jugular veins of difficult venous access patients. Am J Emerg Med 2016; 34(3): 571 – 81. PMID: 26776533.

3. Study Design

3.1. This is an observational study with one arm. All enrolled patients will receive a peripheral angiocatheter in the internal jugular vein. As this is a single-arm study, blinding is not applicable.

4. Inclusion and Exclusion Criteria

4.1. Recruitment will occur among adult (age >18 years) elective-surgery patients, who do not require central venous catheters, in the UNMH operating rooms.

4.2. There are two potential inclusion criteria among these elective surgery patients; Patients who:

- require a second intravenous access line (IV) as determined by the anesthesiologist, *or*
- require a primary IV and are determined by the anesthesiologist to have difficult IV access, defined as two or more failed attempts at peripheral IV placement, in the absence (as noted above) of an indication for a central venous catheter.

4.3. Exclusion criteria:

- Infection over the intended peripheral angiocatheter insertion site
- Cervical spine injury or instability
- Known abnormal neck anatomy
- Pregnancy
- Prisoners
- Clinical indication for central venous catheter
- Any pre-existing suspicion for bacteremia

4.4. Adults unable to consent (as determined by ability to provide consent for surgery), minors, pregnant women, and prisoners will not be approached for enrollment.

4.5. Minors are being excluded from participation because the study will occur at the UNMH Main operating rooms rather than at UNM Children's Hospital, and children are only brought to the main OR in unusual circumstances. This exclusion will also serve to eliminate variation in the primary outcome caused by pediatric patients' small physical size and distinct anesthetic management.

5. Number of Subjects

5.1. This is a single-site study, and the investigators plan to enroll approximately 60 subjects, but no more than 70.

5.2. A sample of approximately 60 subjects will allow the investigators to estimate the true population mean procedure duration to within approximately ±0.25 sample standard deviations from the sample mean, with 95% confidence.

6. Study Timelines

6.1. Describe:

- The PIJ catheter will remain in place as clinically indicated during and immediately after surgery. It is intended for temporary use. Data collection on a given participant (in the form of medical chart review) will continue for events occurring up to one week after surgery in order to capture any complications that were not immediately observable.
- Investigators anticipate that approximately one year will be sufficient to enroll the planned sample size.
- Study completion is expected to take approximately one year after enrollment is complete.

7. Study Endpoints

7.1. The primary outcome is the time required to prepare and place a PIJ catheter. Secondary outcomes include: location of insertion, depth of insertion, number of attempts, and complications (e.g. hematoma, pneumothorax, carotid punctures, thrombosis, insertion site infection) that are related to PIJ placement, in the opinion of the investigators.

7.2. Investigators will stop the placement procedure and remove the PIJ at any time that they believe doing so would be in the patient's interest, e.g. carotid puncture. Placement will be abandoned and alternative means of IV access will be attempted if the third attempt to place the PIJ is unsuccessful, or earlier if the clinician performing the procedure finds a clinical reason to do so.

8. Research Setting

8.1. The research will be conducted in the main surgical suites of UNM Hospital, and in appropriate areas for authorized access to the patient EMR (electronic medical record).

8.2. Potential subjects will be identified and recruited from among investigators' regular patients at the UNM surgical suites, in pre-operative holding areas.

8.3. All research procedures will occur in the UNM surgical suites.

9. Resources Available

9.1. PI Tony Yen MD is a board-certified anesthesiologist, and Associate Professor at UNM. Investigators Sean Morgan MD and Lia Hoffner MD are resident physicians in the Anesthesiology department at UNM. Investigator Tim Petersen PhD is a Research Information Specialist in the Anesthesiology department at UNM, with extensive

experience in study design, analysis, and reporting. All research procedures will be performed by personnel who have appropriate training, experience, and authorization.

9.2. All clinical decisions will be made by appropriate providers who are duly authorized and credentialed to do so.

9.3. Other resources:

- UNM's operating rooms handle a high caseload, and the investigators anticipate little difficulty in recruiting 60 relevant patients from among them in one calendar year.
- Engagement in research activities is an expected part of all investigators' job duties, so conducting this study is not anticipated to conflict with their clinical, scientific, or administrative duties.
- The UNM surgical suites are equipped with the personnel, supplies, and equipment necessary to respond to any eventuality that may arise as a result of participation in this study.
- A copy of the HRRC-approved protocol will be distributed among the investigators prior to commencement of any research activities. All investigators work in the same department, so communication among them is already routine.

10. Prior Approvals

10.1. The completed Departmental Review Form is included with the initial application for review of this protocol.

10.2. This study does not involve ionizing radiation, biological specimens, or administration of particular drugs.

11. Multi-Site Research

11.1. This is not a multicenter study.

12. Study Procedures

12.1. After recruitment and consent, a resident or attending physician in the Department of Anesthesiology who is an investigator in this study will place the PIJ catheters for this study, under ultrasound guidance. Clean technique similar to that used for traditional peripheral intravenous catheters will be used, including chlorhexidine prep, caps, and sterile ultrasound gel with sterile occlusive bandage over the ultrasound transducer. For patients included in this study because of a clinically-determined need for a second IV line, the catheter will be placed after anesthesia induction. Patients included because of difficult IV access will have the PIJ catheter placed prior to induction.

The size of the angiocatheter will be left to the clinical discretion of the placing anesthesiologist, from among these choices: 18 G x 2.5 inches, 16 G x 2 inches, or 14 G x 2 inches. All angiocatheters will be radiopaque in order to permit visualization in the event of any required imaging. Catheters will be placed with visualization under dynamic ultrasonography using a Sonosite S-nerve ultrasound machine with 13-6 MHz 25mm linear array. All catheters and ultrasound components are being used in accordance with their labeling.

The depth of catheter insertion into the internal jugular vein will be determined, and the catheter will be removed/replaced immediately if it is found to extend less than 1.0 cm into the vessel. If the catheter is removed or replaced, routine care will be followed: pressure will be held until bleeding subsides and the site dressed appropriately (e.g. gauze with tape or adhesive bandage). No more than three attempts will be made before abandoning the effort to place a PIJ catheter.

The PIJ catheter will be secured as per normal practice, with an adhesive IV securing device and an occlusive bandage placed over both the IV and its securing device.

The PIJ catheter will be used as usual during surgery; as a means to administer vasopressor medications, transfusions, and other medications necessary for intraoperative anesthesia management. It will not be used for total parenteral nutrition (TPN) or other continuous nutrient infusions.

In most cases, the PIJ catheter will be removed as usual before the patient is transferred to the floor, intensive care unit, or discharged home. In some cases, however, an appropriately authorized clinician may determine that the PIJ line should stay in place longer, such as when no other intravenous access is available, or when a patient's hemodynamic status requires active pressor administration. If extended use of the PIJ line is indicated, it will be removed when it is either replaced by a means of intravenous access (e.g. routine IV or sterilely-placed central catheter) appropriate to the patient's condition, or when IV access is no longer needed.

Procedural data will be collected on the day of surgery, and chart review will occur after surgery in order to capture any IV-related complications within the first week that were not immediately apparent. The data sheet is included with this application.

13. Data Analysis

13.1. As this is an observational study intended to provide initial characterization of the time to place PIJ lines and a rough estimate of complication rates, data analysis will focus on traditional summary statistics; e.g. mean or median, as well as standard deviation or interquartile range as appropriate depending on distribution normality, and percentages for categorical data.

13.2. As noted in section 5.2 above, a sample of approximately 60 patients will permit the investigators to estimate the true population mean for the primary outcome to within approximately ±0.25 standard deviations from the mean, with 95% confidence.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects. Describe:

14.1. The PI will perform data and safety monitoring.

14.2. The PI will review the collected data, which already includes relevant safety outcomes. The PI will refer to the EMR as appropriate to obtain relevant context on any adverse events.

14.3. The PI will conduct one interim review of the secondary outcomes after data collection is complete for approximately 30 patients.

14.4. Intravenous catheters are in widespread use, as are the related but more invasive central access catheter and peripherally-inserted central catheter, and their safety profiles are well established. It is not anticipated that the medical literature will report new findings that call the safety of this study into question.

14.5. The PI will review the incidence of adverse events related to PIJ use in this study to determine whether they exceed the incidence that would be expected with the use of more typical IV locations.

14.6. The PI will terminate the study in the event of any morbidity/mortality that is both significant and likely due to the procedure under investigation, in the PI's opinion.

14.7. The PI will notify HRRC in the event of study termination under 14.6 above.

15. Withdrawal of Subjects

15.1. The investigators have not identified any circumstances under which a participant may be withdrawn from the research without their consent.

15.2. Withdrawal may be completed safely by simply removing the PIJ line as in normal procedures and ceasing data collection.

15.3. Partial withdrawal may be relevant for patients enrolled due to difficult IV access, as their placement procedure will be completed prior to anesthesia induction. Despite providing informed consent, participants may change their minds about needle placement in the neck/shoulder area once the procedure begins. Partial withdrawal will be offered in these cases, where the needle may have been inserted, so as to permit continued data collection of any adverse events.

15.4. If a patient elects to fully withdraw, data collection will cease, but existing data will be maintained.

15.5. The consent document contains information about withdrawal procedures and limitations.

16. Data Management/Confidentiality

16.1. Most members of the research team are physicians who interact with these and similarly-situated patients on a daily basis.

16.2. The research does require the use of direct identifiers (e.g. MRN) in order to accurately obtain complication data and link it to procedural data.

16.3. The research requires the use of Private Health Information (PHI), but the investigators will not disclose any identifiable information except as required by law.

16.4. The data do not include information that is typically considered to be sensitive, such as HIV status, substance abuse, or criminal behavior.

16.5. The investigators do not plan to pursue a Certificate of Confidentiality.

16.6. All investigators have completed routine UNM Health Sciences Center (HSC) training on the secure management and use of patient data. Identifiable data on paper forms will be maintained in a locked cabinet in a restricted area, and in electronic format will be stored on HSC secure servers, which are password-protected.

16.7. The investigators do not plan to code data. Data will be deidentified upon completion of data collection and entry into a spreadsheet stored on UNM HSC secure servers, but will be identifiable until that point in order to permit accurate linkage of procedural and outcome data.

16.8. Any questionable entries in the paper data sheets will be verified by reference to the EMR, as appropriate.

16.9. Identifiable data will not be transmitted to outside entities, except as required by law.

16.10. Identifiable data will not be collected or transported by the internet; only on UNM HSC secure servers.

16.11. Study records will be maintained for 3 years after closure as required by federal regulations.

16.12. Photographs and recordings of audio/video will not be used.

17. Data and Specimen Banking

17.1. Identifiable data will not be banked, but the investigators may maintain deidentified data indefinitely for related purposes, such as for power analyses in future projects.

18. Risks to Subjects

18.1. All research involves risks of loss of confidentiality, inconvenience, stress, and emotional upset. All participants are drawn from a population that requires alternate or enhanced IV access for clinical reasons. This research does not modify the risks of IV access in general. These risks include bleeding, infection, and blood clots. Because of its use of the internal jugular vein, this research poses rare risks of carotid artery puncture and pneumothorax.

18.2. IV placement is a routine part of medical care, and the relevant anatomy is very well-known, so it is extremely unlikely that this research would present unforeseen risks.

18.3. Pregnancy is an exclusion criterion, so risks to fetuses are not relevant in this study.

18.4. Some participants would already receive PIJ catheters due to difficult IV placement in other locations. The investigators are taking steps to minimize the likelihood and severity of risks. PIJ placement will be conducted under ultrasound guidance to permit real-time visualization of the needle as well as relevant anatomical structures. In addition, the placement will be performed with clean technique involving chlorhexidine (or equivalent) prep, caps, sterile ultrasound gel, and sterile occlusive bandage over the ultrasound transducer. The investigators have chosen an angiocatheter length that allows secure placement without undue risk of inadvertently "reaching" inappropriate anatomical structures. Any catheter placed less than 1.0 cm into the vessel will be removed. The protocol stipulates that total parenteral nutrition (TPN) or other continuous nutrient infusions will not be administered through the PIJ catheter. Routine catheter securing and occlusive bandage will be used, and the catheter will be removed prior to transfer to floor/ICU/discharge unless there is a clinical reason why it should temporarily remain, in the judgment of an investigator. Finally, application of the inclusion/exclusion criteria will help to reduce risks, as they were chosen primarily for reasons of patient safety.

19. Potential Benefits to Subjects

19.1. Subjects may benefit in several ways, although any benefits are mitigated as noted in section 19.2 below. For patients included because of difficult IV access, the internal jugular vein offers a larger (and thus likely easier to place) and more reliable location for this access. For patients in whom a second IV line is indicated, the use of the PIJ may permit increased catheter gauge, and thus increased rate of administration of relevant fluids in unexpected emergency situations. Application of the inclusion/exclusion criteria is likely to result in a patient sample in whom discomfort related to multiple unsuccessful IV attempts may be reduced, as well as overall placement time, which would reduce the time spent under anesthesia.

19.2. These benefits are mitigated to some extent because all participants are drawn from a population that already requires enhanced IV access, either in the form of a second IV line or an alternative placement site in the case of difficult access at more traditional sites. Patients who meet the inclusion/exclusion criteria but who do not participate in this study will still receive enhanced IV access, and some of them may receive IV placement in the internal jugular vein regardless of participation.

20. Recruitment Methods

20.1. Potential subjects will be recruited from among UNM Hospital surgical patients, who are regular patients of the investigators, in the pre-operative holding areas during the routine pre-surgical consultation between the anesthesia provider and patient. An investigator will first ask whether the patient is interested in participating in research about IV placement. If the patient expresses interest, the study will be explained in more detail and the consent process will commence.

20.2. Clinician investigators already review patients' charts prior to surgery. Patient characteristics in the inclusion/exclusion criteria are already considered as part of this routine review.

20.3. Recruitment will be verbal only; no advertisements will be used.

21. Provisions to Protect the Privacy Interests of Subjects

21.1. Recruitment will occur in the pre-operative holding areas, which are already sufficiently private for confidential doctor/patient conversations. Recruitment will be handled by clinicians already authorized and expected to make contact with relevant patients. Recruitment and consent will not require the disclosure of information beyond routine medical information. The patient experience will not be greatly modified by participation in this study; the only change is the specified location of the IV, in a sample of patients who may already receive an IV in this location. Similarly, participants will not be observed by atypical personnel.

22. Economic Burden to Subjects

22.1. Patients (or their 3rd-party payers) will be responsible for the cost of PIJ placement. However, this cost is negligible, because all participants are drawn from a population who already requires IV placement, and all supplies used in this study are the same as

in routine IV placement. The investigators do not anticipate any change to patient cost as a result of participation in this study.

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
PIJ placement	All	☐	☒
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Surgery	All	☐	☒
Anesthesia	All	☐	☒
Hospitalization (as appropriate)	All	☐	☒
Medications and supplies	All	☐	☒
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

22.2. Patients (or third-party payers) will be responsible for any costs related to adverse outcomes; this is discussed in the consent form.

23. Compensation

23.1. Participants will not be compensated.

24. Compensation for Research-Related Injury

24.1. Subjects will be responsible for any costs of research-related injury. This is communicated in the consent documentation.

25. Consent Process

25.1. Consent will be obtained prior to research-related intravenous access.

25.1.1. An investigator will obtain consent. All investigators have completed appropriate HIPAA, CITI, and related training as required by UNM HSC and by HRRC.

25.1.2. The consent process will take place in the pre-operative holding areas immediately after recruitment. These areas are sufficiently private for confidential doctor-patient conversations.

25.1.3. The possibility of coercion or undue influence is reduced in several ways. All participants are drawn from a population that already requires alternative or enhanced IV access (either a second line, or an alternative placement when routine placement is difficult), and this study simply specifies the location of this enhanced/alternate access, so the benefits of participation are mitigated. There is

no compensation for participation. All prospective participants will be assured that there is no consequence for declining participation; participation is strictly voluntary.

25.1.4. Participation in this study only entails specification of an IV placement site, in the context of patients for whom more routine locations may not be suitable, and who may receive PIJ placement regardless of participation. The consent decision is thus comparably complex to the decisions surrounding anesthesia management that are already routinely handled entirely within the preoperative anesthesia consultation. The appropriateness of day-of-surgery consent for anesthesia studies has also been the topic of scientific investigation, and the results clearly indicated that longer intervals in which to consider participation do not automatically benefit participants. This recent study (Murphy et al., "Consent for Anesthesia Clinical Trials on the Day of Surgery," Anesthesiology 2016; 124:1246-55) showed that patients approached for consent to participate in anesthesia-related research on the day of surgery tend to be satisfied with the consent process, feel that the protocol was well explained and comprehended, and that the setting was appropriate. Conversely, these patients **strongly disagreed** that they were anxious at the time of consent, felt obligated to participate, or regretted participating. Importantly, the use of a preadmission telephone call to describe the research protocol and provide extended time for patients to consider their participation did not change these results.

25.1.5. Investigators do not anticipate that ongoing consent will be at issue during this study, because patients' active participation (i.e. having the IV line in place) is relatively brief.

25.1.6. Consenting investigators will ask prospective participants to describe the study briefly in their own words in order to ensure understanding.

25.1.7. Subjects will be given a copy of the signed consent.

Subjects not fluent in English

25.1.8. The investigators do not anticipate enrollment of patients who do not speak English. A majority of UNM Hospital surgical patients do speak English, so relatively few patients with insufficient English fluency to understand the consent materials would be encountered during the enrollment period.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

25.1.9. Patients in this category will not be enrolled.

Subjects who are not yet adults (infants, children, teenagers)

25.1.10. Minors will not be enrolled.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

- The investigators are not seeking waiver or alteration of the consent process.

26. Documentation of Consent

26.1. A proposed consent form is included with this application.

27. Study Test Results/Incidental Findings

27.1. **Individual Results:** This study does not involve laboratory tests or other findings outside routine medical care. Relevant routine information is already shared with patients as appropriate, and this study does not change the delivery of information to patients.

27.2. **Incidental Findings:** The investigators do not anticipate any incidental findings to be generated by this study.

28. Sharing Study Progress or Results with Subjects

28.1. Investigators do not plan to share in-progress study results with patients.

28.2. Investigators do not plan to share final study results with patients, because the data will be deidentified before the final analysis.

29. Inclusion of Vulnerable Populations

29.1. This research does not target any of the populations typically identified as vulnerable.

29.1.1. The research does not target UNM students or employees, but such persons may be incidentally involved. As with other prospective participants, these patients will be assured that the participation decision has no bearing outside the immediate treatment context.

29.1.2. The research does not target economically disadvantaged persons, but the lack of compensation should mitigate any questions about coercion of this group, and the recruitment and consent processes should ensure understanding.

29.1.3. The research does not focus on seriously or terminally ill patients.

29.1.4. Pregnancy is an exclusion criterion, and the study does not involve any neonates.

29.1.5. The research does not involve prisoners.

29.1.6. The research does not involve minors or cognitively impaired adults.

30. Community-Based Participatory Research

NA.

31. Research Involving American Indian/Native Populations

31.1. NA.

32. Transnational Research

32.1. NA.

33. Drugs or Devices

33.1. The research does not involve drugs. It does not specify device selection, but the Device Checklist is completed below.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

Partial Waiver of HIPAA Authorization for Screening/Recruitment
Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

1. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☐ Yes. Describe:

   ☒ No

2. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

3. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☒ True

   ☐ False

II. Vulnerable Populations

A. Adults with Cognitive Impairments
NA.

B. Children
NA.

C. Pregnant Women and Fetuses
NA.

D. Neonates of Uncertain Viability or Nonviable Neonates
NA.

E. Nonviable Neonates
NA.

F. Biomedical and Behavioral Research Involving Prisoners
NA.

III. Medical Devices

Complete this checklist if the research evaluates the safety or effectiveness of a medical device. If more than one medical device is being evaluated, provide the requested information for each.

A. Device Name: *This study does not specify any particular angiocatheter, except as to length/gauge and that it be radiopaque in case of any required imaging. The investigators believe that this is not a device study per se, since all relevant patients would already receive one or more IV placements with any of a variety of related IV catheters, and the catheter is not specified. This is simply a study of one particular anatomical location for IV placement. All catheters are being used in accordance with their labeling.*

B. Manufacturer: *Not specified.*

C. Does the research involve a Significant Risk Device under an IDE?

☐ Yes. Include documentation of the FDA approval of the IDE with your submission. *Acceptable methods of documentation include: (1) FDA letter noting IDE number and approval status; (2) Industry sponsor letter noting IDE number and FDA approval status; or (3) FDA-approved industry sponsor protocol with IDE number noted*

☒ No

D. Is the research IDE-exempt?

☒ Yes. Include a FDA letter with your submission noting the determination that the research is IDE-exempt or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is IDE-exempt*.

☐ No

E. Does the research involve a Non-Significant Risk (NSR) Device?

☒ Yes. Include a FDA letter with your submission noting the determination that the research is NSR or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is NSR**.

☐ No

* This FDA guidance includes a description for when a device study is exempt from the IDE requirements:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

**This FDA guidance includes information on how to differentiate between Significant Risk and Non-Significant Risk device studies:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf