

**Utility of Ultrasound in
Identification of Midline and
Placement of Epidural in
Severely Obese Parturients**

NCT03100968

Document Date: 06/19/2015



Human Subjects Protocol (HSP)



Form Version: October 5, 2012

- **You are applying** for IRB review of the research described in this form.
- **To avoid delay**, respond to all items in order and include all required approvals and documents.
- **To complete the form**, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck. For more tips, see www.uab.edu/irb/forms.
- **Mail or deliver all materials to AB 470**, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

- Convened (Full) IRB *or*
 Expedited—See the Expedited Category Review Sheet, and indicate the category(ies) here: 1 2 3 4 5 6 7

1. IRB Protocol Title: Utility of Ultrasound in Identification of Midline and Placement of Epidural in Severely Obese Parturients: A Randomized, Prospective Study

2. Investigator, Contacts, Supervisors

- a.** Name of Principal Investigator: Mark F. Powell
Degree(s)/Title: MD/Assistant Professor BlazerID: powelma
Dept/Div: Anesthesiology and Perioperative Medicine Mailing Address: JT845
UAB ZIP: 6810
Phone: (205) 907-8557 Fax: (205) 975-5963 E-mail: powelma@uab.edu
- b.** Name of Contact Person: Cindy Louderback Title: Administrative Associate
Phone: 934-6007 E-mail: clouderback@uab.edu Fax: 975-9732
Mailing Address (if different from that of PI, above): JT 804
Name of Contact Person: Alicia Kindred Title: Research Associate Phone: 205.934.4711
E-mail: akindred@uab.edu Fax: 205.975.0761
Mailing Address (if different from that of PI, above): JT 867

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and any Co-Investigators or Other Investigators comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed in the protocol and persons obtaining informed consent have completed initial IRB training and will complete continuing IRB training each year;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;

- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: _____

Date: 6/19/15

c. List all staff who will be involved with the design, conduct, and reporting of the research, their degree(s) and job title, and any additional qualifications. Include individuals who will be involved in the consent process. Repeat the table below for each individual.

Note. For studies involving investigational drugs, include all investigators who will be listed on FDA Form 1572 and attach a copy, if applicable. Send the IRB a copy of Form 1572 anytime you update the form with the FDA.

Role: Co- -OR- Other -AND/OR- Consent Process
 Full Name: Caylen Nevins Schlitz
 Primary UAB Dept.: Anesthesiology
 (Employer if not UAB)
 Degree(s) / Job Title: MD/ Resident
 Additional Qualifications
 pertinent to the study: _____

Role: Co- -OR- Other -AND/OR- Consent Process
 Full Name: Stacy Wade
 Primary UAB Dept.: Anesthesiology
 (Employer if not UAB)
 Degree(s) / Job Title: MD /Instructor/Fellow
 Additional Qualifications
 pertinent to the study: _____

Role: Co- -OR- Other -AND/OR- Consent Process
 Full Name: Yasser Sakawi
 Primary UAB Dept.: Anesthesiology
 (Employer if not UAB)
 Degree(s) / Job Title: MD /Professor
 Additional Qualifications Medical Director/OB Anesthesiology
 pertinent to the study: _____

Role: Co- -OR- Other -AND/OR- Consent Process
 Full Name: Marsha Wakefield
 Primary UAB Dept.: Anesthesiology
 (Employer if not UAB)
 Degree(s) / Job Title: MD /Associate Professor
 Additional Qualifications
 pertinent to the study: _____

d. Is the principal investigator a student, fellow, or resident? Yes No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name: _____
 Degree(s) / Job Title: _____
 Additional Qualifications
 pertinent to the study: _____

Telephone: _____

E-Mail: _____

Signature: _____

- e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol: **Dr. Mark Powell is an attending anesthesiologist who is a member of the core faculty who provide care for the patients in this study population at the Women and Infant's Center. If not physically present, he will be immediately available by phone or pager to answer questions.**
- f. Is medical supervision required for this research? Yes No
If Yes, who will provide the supervision?
 PI will provide -OR- Name: _____ Telephone: _____
If other than PI, obtain signature of person providing medical supervision:
Signature _____
- g. Describe the process that ensures that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions: **All personnel involved in the design or conduct of this research study will have successfully completed and maintained UAB IRB required human subjects research training, which includes the importance of measures to protect patient confidentiality. The research protocol will be presented in the OB/Anesthesia recurring monthly meeting. All suggestions to improve the study are considered. Prior to initiation of the study, Dr. Powell will meet with all co-investigators to discuss the objectives and consent process of the study.**

3. Funding

Is this study funded? Yes No

If No, specify that costs of the study will be covered by funds from the UAB department or other source named: **Department of Anesthesiology**

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant or Contract: _____

b. PI of Grant or Contract: _____

c. Office of Sponsored Programs Proposal Number: _____

(or enter "Pending" and provide upon receipt from OSP)

d. Sponsor, Funding Route (check and describe all that apply):

Gov't Agency or Agencies—Agency name(s): _____

Department of Defense (DoD): Identify DoD component: _____

Department of Energy (DOE)

Department of Justice (DOJ)

Department of Education

NIH Coop. Group Trial—Group name: _____

Private Nonprofit (e.g., Foundation)—Name: _____

Industry, investigator-initiated—Name: _____ Describe the funding arrangement: _____

Note. Western IRB reviews industry-sponsored protocols unless the investigator initiated the research, or the study qualifies for expedited review or involves gene therapy.

UAB Departmental/Division Funds—Specify: _____

4. Conflict of Interest—Human subjects research involving a disclosed financial interest is subject to IRB review following review by the Conflict of Interest Review Board.

The following definitions are used for Item #4:

Immediate family means spouse or a dependent of the employee. *Dependent* is any person, regardless of his or her legal residence or domicile, who receives 50% or more of his or her support from the public official or public employee or his or her spouse or who resided with the public official or public employee for more than 180 days during the reporting period.

Financial Interest Related to the Research means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

For each investigator and staff member involved in the design, conduct and reporting of the research (see Items 2.a. and 2.c.) answer the questions below: **(Repeat the section below for each individual)**

Name: Mark F. Powell, MD

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the investigator's responsibilities of any value.
- Compensation related to the research unless it meets two tests:
 - Less than \$5,000 in the past year when aggregated for the immediate family.
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

Name: Caylen N. Schlitz, MD

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the investigator's responsibilities of any value.
- Compensation related to the research unless it meets two tests:
 - Less than \$5,000 in the past year when aggregated for the immediate family.
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

Name: Stacy Wade, MD

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the investigator's responsibilities of any value.
- Compensation related to the research unless it meets two tests:
 - Less than \$5,000 in the past year when aggregated for the immediate family.
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

Name: Yasser Sakawi, MD

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the investigator's responsibilities of any value.
- Compensation related to the research unless it meets two tests:
 - Less than \$5,000 in the past year when aggregated for the immediate family.
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

Name: Marsha Wakefield, MD

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the investigator's responsibilities of any value.

- Compensation related to the research unless it meets two tests:
 - Less than \$5,000 in the past year when aggregated for the immediate family.
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

5. Locations Involved

a. Describe the facilities available for the conduct of the research. For research on UAB campus, include building names and room numbers: **UAB Women & Infants Center, Labor & Delivery Unit**

b. Indicate all "performance sites" that will provide space, services, facilities, potential or actual participants, or other support for this protocol.

- The Kirklin Clinic (TKC)
- University of Alabama Hospital (UAHosp)
- The Children's Hospital of Alabama (TCHA)
- Callahan Eye Foundation Hospital (CEFH)
- UAB Highlands
- Jefferson County Dept. of Health (JCDH)
- Birmingham Veterans Affairs Medical Center (BVAMC)
- General Clinical Research Center (GCRC)—inpatient
- General Clinical Research Center (GCRC)—outpatient
- General Clinical Research Center (GCRC) at The Kirklin Clinic (TKC)
- Other (i.e., Any performance site not listed above, including those covered by subcontracts related to this protocol)—Describe: _____

c. Is this study a clinical trial requiring clinical services at one of the performance sites listed in Item b above? Yes No

If Yes, Fiscal Approval Process (FAP)-designated units complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP, see www.uab.edu/osp/clinical-billing-review.

d. Is this a field study? Yes No

If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors: _____

e. Is the study to be undertaken within a school, business, or other institution that does not have an institutional review board? Yes No

If Yes, attach a statement of any contacts with and approvals from the appropriate institution officials.

Note. Documentation of all such approvals must be received by the UAB OIRB before IRB approval will be issued.

f. Has this protocol or project been reviewed by another IRB, similar review board, or departmental review committee(s) that authorizes the use of its patient populations? Yes No

If Yes, provide name of the review board(s): _____ and for each board listed, enter either the date of latest approval(s) or "PENDING": _____ or reasons not approved: _____. *If this protocol is subsequently rejected or disapproved by another review board, the UAB IRB must be notified promptly. Attach copies of approvals/disapprovals.*

g. Will any of the participants be from the Birmingham Veterans Affairs Medical Center? Yes No

If Yes, attach VA IRB approval or notification from the VA Research and Development Department that the study has been submitted to the VA IRB for review.

h. Will the study be conducted at or recruit participants from the Jefferson County Department of Public Health (JCDH)? Yes No

If Yes, attach notification that the protocol has been approved by JCDH or the Alabama Department of Public Health IRB.

6. Multi-Site Studies

a. Is the investigator the lead investigator of a multi-site study? Yes No

b. Is UAB a coordinating site in a multi-site study? Yes No

c. If you answered **Yes** to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants.

Include, at a minimum, the following items:

- o IRB approvals from other sites
- o Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- o Interim results.
- o Protocol modifications.

7. **Drugs:** Will any drugs or supplements be used/studied in this protocol? Yes No
If Yes, attach the Drug Review Sheet.

8. **Devices:** Will any devices be studied in this protocol or used for a purpose other than for which they were approved by the FDA? Yes No
If Yes, attach the Device Review Sheet.

9. Special Approvals

a. Does this project involve the use of radioisotopes? Yes No
If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this project include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? Yes No
If Yes, attach documentation of approval from Chairman of the Infection Control Committee of the appropriate facilities.

c. Does this project involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? Yes No

If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

- d. Does this project require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? Yes No

If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

- e. Does this project use stored (existing) specimens from a repository? Yes No

If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: _____

10. Use of Specimens

Does this project involve collecting specimens from participants and storing them for future research? Yes No

If Yes, complete a-h. If no, skip to Item 11

- a. How will specimens be obtained, processed, distributed, and stored?

- b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)?

- c. How will clinical data associated with the specimens be collected and stored?

- d. What participant-identifying information will be collected and linked to the specimens?

- e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens).

- f. Will specimens be shared with other investigators in the future? Yes No

If Yes, what identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? Also **if yes**, outline your procedure for assuring IRB approval for release and use prior to release of specimens.

Note. Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

- g. Will biological samples be stored for future use? Yes No

If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases.

- h. Is genetic testing planned?

Yes No

If Yes, describe the planned testing here and see "DNA/Genetic Testing" in the Guidebook for consent requirements.

11. Gene Therapy

Does this project involve gene therapy or administering recombinant materials to humans? Yes No

If Yes, submit the Gene Therapy Project Review Panel Report -OR- If this is a vaccine trial that is exempt from the NIH Guidelines For Research Involving Recombinant DNA Molecules, submit the Protocol Oversight Review Form For Clinical Vaccine Trials.

12. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "personal health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of health care)? Yes No

If Yes, complete a-e as described.

a. Will the data/information be stored or managed electronically (on a computer)? Yes No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution). Yes No

If Yes, attach copy of privacy notices from institution/entity, and provide the name of institution/entity: _____

c. Indicate which, if any, of the listed entities below would provide information or maintain health information collected for this protocol and/or where health information that been collected will be stored/maintained.

- The Kirklin Clinic
- University of Alabama Hospital
- The Children's Hospital of Alabama
- Callahan Eye Foundation Hospital
- UAB Highlands
- Jefferson County Department of Health
- School of Dentistry
- School of Health Professions
- School of Medicine
- School of Nursing
- School of Optometry
- University of Alabama Health Services Foundation
- UAB Health Centers
- Viva Health
- Ophthalmology Services Foundation
- Valley Foundation
- Medical West - UAB Health System Affiliate

Health System Information Systems:

- HealthQuest
- Cerner Millennium (Lab, Radiology, UED, Surgery)
- EMMI - Master Member Index
- Horizon - IPV (IVR/CDA/CRIS)
- CareFlow Net
- Eclipsys (PIN)
- IMPACT
- None—**If None, skip to Item 13.**

d. Indicate which of the listed identifiers would be associated/linked with the protected health information (PHI) used for this protocol.

- Names
- Geographic subdivisions smaller than a State
- Elements of dates (except year) related to an individual
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
- Biometric identifiers
- Web universal resource locators (URLs)
- Internet protocol address numbers
- Full-face photographic images
- Any other unique identifying number—Describe: _____

Note. Codes are not identifying as long as the researcher cannot link the data to an individual

- None—**If None, skip to Item 13.**

e. Choose one plan to describe your use of the personal health information:

- The data collected meet the specifications for a "limited data set"
—Attach Data Use Agreement or Business Associate Agreement
- Research staff will obtain authorization from each patient to use the information
—Attach Patient Authorization form, complete except for patient name and IRB protocol number
- PI requests Waiver of Patient Authorization to use the information
—Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.
- Number each page of the Human Subjects Protocol (i.e., Page X of Y).

13. Purpose—in nontechnical, lay language

Summarize the purpose and objectives of this protocol, including any related projects, in one short paragraph.

This study will address the utility of ultrasound in the placement of an epidural catheter in severely obese parturients. Identification of midline can often be difficult using the standard method of palpation in obese patients. We will determine if the use of ultrasound decreases the amount of time and number of attempts required to place the epidural.

The study will be conducted on the labor and delivery unit at the Women and Infants' Center. Participants will include laboring parturients who request an epidural. Inclusion criteria: patient request for an epidural and a diagnosis of severe obesity (BMI \geq 35). Exclusion criteria: BMI $<$ 35, patient refusal of a labor epidural, coagulopathy, platelets $<$ 80,000, prior spine procedure or instrumentation, a diagnosis of scoliosis, and an intracranial or spinal mass. The primary outcomes for the study will be time required to locate midline of the back using ultrasound or palpation and time required for epidural placement. The secondary outcomes for the study will be (1) number of attempts or passes required for placement, (2) epidural failure rate, and (3) time difference between provider groups (junior resident, senior resident, attending).

14. Background—in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the formulation of this study. Include any relevant past or current research by the Principal Investigator. For drug and device studies summarize the previous results (i.e., Phase I/II or III studies).

The use of ultrasound has expanded into many areas of medicine including the identification of bony landmarks to facilitate epidural placement in obstetric anesthesia. Using ultrasound for epidural placement has become popular over the last decade with several studies being published on the topic. The likely increase in popularity for ultrasound use in the obstetric population is the need to more reliably locate bony landmarks as the traditional palpation technique has been shown to be an inaccurate way to accomplish this. One study reports that only 55% of the documented interspinous spaces during neuraxial anesthesia were correctly identified by palpation.

There have been several articles reporting the use of ultrasound in neuraxial anesthesia but none identifying its utility in the obese population. In patients with BMI $<$ 35 or those who have easily palpable spines, there is no statistical difference in number of attempts or patient satisfaction. In other studies where there were no limitations on BMI, there was a significant difference in number of attempts, patient satisfaction, successfulness of the block, and occurrence of dural puncture with the use of ultrasound. One study reports that these results are even more significant in resident trainees. In this study, investigators evaluated the use of ultrasound scanning by first year residents and found that identification of midline and measurement of the depth of the epidural space significantly decreased the number of attempts required and decreased the epidural failure rate.

Given the fact that the long-taught palpation technique can be inaccurate and studies have validated the use of ultrasound for epidural placement, ultrasound technique is routinely taught by the obstetric anesthesiologists to the anesthesiology residents at UAB. Also, since both techniques are considered standard practice at UAB, anesthesia providers (residents, fellows, and faculty) are free to choose either technique to locate bony structures of the back prior to epidural placement. Since no current study has specifically addressed its use in the obese pregnant patient, we would like to validate its use in this population.

15. Participants (Screening and Selection)

- a. How many participants are to be enrolled at UAB? Patient Participants: 150
Provider Participants: 80

If multi-center study, total number at all centers: N/A

- b. Describe the characteristics of anticipated or planned participants.

Sex: Female

Race/Ethnicity: All parturients in active labor

Age: 19-45

Health status: Healthy

Since we will be tracking anesthesia provider training level and times, they will also be considered as participants in this study. Each provider eligible for participation will have been properly trained in both epidural placement and use of ultrasound to place the epidural. All providers are over the age of 19 in our department, and it will be all inclusive in terms of sex and race.

Note. If data from prior studies indicate differences between the genders or among racial/ethnic groups in the proposed research or if there are no data to support or to negate such differences, Phase 3 clinical trials will be required to include sufficient and appropriate entry of gender and racial/ethnic subgroups so that trends detected in the affected subgroups can be analyzed. If ethnic, racial, and gender estimates are not included in the protocol, a clear rationale must be provided for exclusion of this information. If prior evidence indicates that the results will not show gender or racial differences, researchers are not required to use gender or race/ethnicity as selection criteria for study participants. They are, however, encouraged to include these groups. See Section II. Policy of the NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH – Amended, October, 2001) for further details.

- c. From what population(s) will the participants be derived?

Women who are in active labor who have BMI ≥ 35 and desire a labor epidural. For anesthesia providers, participants will be from the Department of Anesthesiology at UAB and will include residents, obstetric anesthesiology fellows, and faculty.

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants:

Recruitment will be drawn from women who arrive to the UAB Labor & Delivery floor for a planned vaginal delivery. They will be the same patients who are already consented for labor epidurals.

Describe the inclusion/exclusion criteria:

Eligibility Criteria: patient request for a labor epidural, BMI ≥ 35 . Eligibility criteria for anesthesia providers include those providers trained in both epidural placement and use of ultrasound for epidural placement.

Exclusion Criteria: BMI < 35 , patient refusal of a labor epidural, coagulopathy, platelets $< 80,000$, prior spine procedure or instrumentation, a diagnosis of scoliosis, and an intracranial or spinal mass. Exclusion criteria for anesthesia providers: those not trained in epidural placement or use of ultrasound for epidural placement.

- d. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.

Patient Participants: There will be a total of 150 participants randomized into two groups: palpation group (P) and ultrasound group (U). The randomization will be a 1:1 randomization. The technique will be chosen by randomly drawing a sealed envelope from a box that will contain a card with either palpation or ultrasound written on it. The palpation group will have an epidural placed after manual palpation of the spine. The ultrasound group will have an epidural placed after identifying midline with the ultrasound. There are no placebo or sham treatment groups. There will be no randomization of anesthesia provider. Any available anesthesia provider (if eligible to participate in the study) will place the epidural.

Provider Participants: Since we will continue with our standard practice of epidural placement, all providers trained in both ultrasound use and epidural placement will be able to place the epidural. This process will not be randomized. Providers will be chosen based on availability (i.e. if a patient requests an epidural at the time only one qualified provider is available, then that provider will place the epidural) or patient request (i.e. if a patient requests a certain qualified provider by name or level of training such as a fellow or faculty request). The provider training level will be documented on the data sheet.

e. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

Prisoners: Attach SPRF—Prisoners

Minors (<19 years old): Attach SPRF—Minors

Employees or students at institution where research conducted

Persons who are temporarily decisionally impaired

Persons who are permanently decisionally impaired (e.g., mentally retarded)

Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: Our goal is to demonstrate the usefulness of ultrasound in the placement of labor epidurals in severely obese parturients. This will be the patient population from which we will recruit. Informed, written consent will be obtained prior to persistent labor pains are experienced by the patient or medications are given to alter mental status. No treatment will be withheld from the patient. If she declines to participate in the study but requests an epidural, then an epidural will still be placed and anatomy will be identified by either palpation or ultrasound by the anesthesia provider, as both are considered standard practice.

If employees and students meet the inclusion criteria, they are eligible to participate. This special group, although included, will not be targeted by the protocol.

f. List any persons other than those directly involved in the study who will be at risk. If none, enter "None": None

g. Describe the process (e.g., recruitment, chart review) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening. (See <http://main.uab.edu/show.asp?durki=61981>.)

We will first identify the patients who are admitted to the labor & delivery unit for planned vaginal delivery. Those patients who have BMI ≥ 35 and desire a labor epidural will then be approached by either the PI or one of the co-investigators and consented for the study if they choose to participate. The recruitment process will begin prior to any obstetric intervention that may induce pain or altered mental status to the patient.

- h. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., databases) from which you will recruit participants.

The IMPACT Labor & Delivery Room list will be used to identify potential participants.

- i. Describe the procedures for screening potential participants.

Once a patient is admitted to the labor and delivery suite, we will review their medical record to see if she is eligible to participate by meeting the above inclusion/exclusion criteria. Once this is determined, we will then discuss the study with the patient and obtain informed, written consent if they choose to participate.

16. Protocol Procedures, Methods, and Duration of the Study—in nontechnical language

- a. Describe the study methodology that will affect the participants—particularly in regard to any inconvenience, danger, or discomfort.

Providers: All investigators involved in this study have received training in use of the ultrasound for epidural placement and use the ultrasound in routine practice. Prior to being allowed to participate in the study, the anesthesia provider must demonstrate proficiency in the use of ultrasound. This will be accomplished on our obstetric anesthesia simulation model. Patients: Once informed consent is obtained, participants in the study will be randomized to either have the midline of their back located by ultrasound (U) or by palpation (P). After midline is located, the epidural catheter will be placed in routine fashion. Providers: Each provider will be timed on two events during epidural placement: (1) from start to completion of ultrasound exam/palpation exam and (2) from local injection of lidocaine at the skin to injection of the test dose. The primary outcomes for the study will be time required to perform the ultrasound/palpation exam of midline and time required for epidural placement. The secondary outcomes for the study will be (1) number of attempts or passes (defined as the need to remove the needle to the skin and redirect towards the epidural space) required for placement, (2) epidural failure rate (defined as inability to achieve a T10 level after 1 hour of epidural infusion and at least 10 mL of a local anesthetic bolus), and (3) time difference in provider level (junior resident, senior resident, attending).

- b. What is the probable length of time required for the entire study (i.e., recruitment through data analysis to study closure)?

1 year

- c. What is the total amount of time each participant will be involved?

Patients and Providers: Approximately 90 minutes. Depending on the difficulty of epidural placement, actual time of epidural placement could range from 5 to 30 minutes. However, we will continue to monitor each patient in standard fashion after epidural placement. Since we are documenting the incidence of failed epidurals and are defining a failed epidural as above (with minimal time needed of 1 hour), then the study will take approximately 90 minutes to complete, with the majority of the study being standard monitoring of the patient post-epidural placement.

- d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "not applicable."

Patients and Providers: Phase 1: placement of the labor epidural: 5 to 30 minutes

Patients and Providers: Phase 2: identification of failed epidurals: 60 minutes from placement of epidural

- e. List the procedures, the length of time each will take, and the frequency of repetition, and indicate whether each is done solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population. *Insert additional table rows as needed.*

Patients and Providers:

Procedure	Length of Time Required of Participants	Frequency of Repetition	Research (Res) -OR- Routine Care
<u>Ultrasound identification of midline</u>	<u><5 minutes</u>	<u>1</u>	<input checked="" type="checkbox"/> Res <input type="checkbox"/> Routine
<u>Palpation to identify midline</u>	<u><5 minutes</u>	<u>1</u>	<input type="checkbox"/> Res <input checked="" type="checkbox"/> Routine
<u>Placement of labor epidural</u>	<u><30 minutes</u>	<u>1</u>	<input type="checkbox"/> Res <input checked="" type="checkbox"/> Routine
<u>Monitor epidural</u>	<u>1 hour</u>	<u>1</u>	<input type="checkbox"/> Res <input checked="" type="checkbox"/> Routine

- f. Will an interview script or questionnaire be used? Yes No
If Yes, attach a copy.

- g. Will participants incur any costs as a result of their participation? Yes No
If Yes, describe the reason for and amount of each foreseeable cost.

- h. Will participants be compensated? Yes No
If Yes, complete i-v:

- i. Type: (e.g., cash, check, gift card, merchandise): _____
 ii. Amount or Value: _____
 iii. Method (e.g., mail, at visit): _____
 iv. Timing of Payments: (e.g., every visit, each month): _____
 v. Maximum Amount of Payments per Participant: _____

17. Describe the potential benefits of the research.

Patient/Provider: If identification of midline with an ultrasound decreases the time and number of attempts in placing a labor epidural, future use of the ultrasound will decrease patient discomfort and increase patient satisfaction. Use of the ultrasound would also decrease the amount of time that patient is positioned for epidural placement therefore decreasing the time that fetal monitoring is difficult.

18. Risks

- a. List the known risks—physical, psychological, social, economic, and/or legal—that participants may encounter as a result of procedures required in this protocol. Do not list risks resulting from standard-of-care procedures. *Note. Risks included in this protocol document should be included in the written consent document.*
Patients: Risks of the study include the potential to have more attempts to locate the epidural space with the epidural needle and a higher risk for failure of the epidural requiring replacement of the epidural catheter if requested. Although not proven, we believe these risks might be higher in the palpation group.

Patients and Providers: There is also the risk of breach of confidentiality.

- b. Estimate the frequency, severity, and reversibility of each risk listed.

N/A

- c. Is this a therapeutic study or intervention? Yes No
If Yes, complete the following items:
i. Describe the standard of care in the setting where the research will be conducted: _____
ii. Describe any other alternative treatments or interventions: _____
iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: _____
- d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? Yes No
If Yes, describe the provisions that have been made to make these resources available.

- e. Do the benefits or knowledge to be gained outweigh the risks to participants? Yes No
If No, provide justification for performing the research: _____

19. Precautions/Minimization of Risks

- a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

Patients: Standard of care practice will occur with all epidural placements. We will keep within our traditional practice of difficult epidural placement in both study groups: if one provider is having difficulty with epidural placement (loosely defined as placement lasting greater than 20 minutes), then a different provider will attempt epidural placement. The second provider will be free to use either technique to locate midline. This will be documented in both the electronic record and on the data sheet.

Patients and Providers: Data will initially be collected on paper records which will be kept in a locked filing cabinet in the PI's secure, locked office. The paper data records will be transferred to a secure research server maintained by the Department of Anesthesiology. The research server is HIPAA compliant and has researcher specific restricted access, and is password protected. This research server is backed up to another secure research server at a different location. All investigators in the study are IRB trained in confidentiality and this will be maintained.

If study involves drugs or devices skip Items 19.b. and 19.c., go to Item 20, and complete the Drug or Device Review Sheet, as applicable.

- b. If hazards to an individual participant occur, describe (i) the criteria that will be used to decide whether that participant should be removed from the study; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

Patients: If at any time the use of palpation or ultrasound or if placing the epidural with either technique the patient is randomized to causes undue harm or distress to the patient, then the epidural procedure will be stopped and the patient will be removed from the study. During this time, options to control labor pains will be discussed with the patient, including the use of intravenous pain medications or re-attempting to place the epidural. If the patient desires a second attempt at epidural placement, she will not be re-recruited for the study. The new anesthesia provider placing the epidural will freely choose either technique to locate the patient's midline – ultrasound or palpation. Continuous vital sign monitoring, which includes documentation of a pain score, will continue in normal fashion by the labor and delivery nurse.

The anesthesia provider will be readily available to assess the patient during her labor and delivery per our standard practice. As per our standard practice, the anesthesia provider will evaluate the patient within 24 hours after delivery to assess for any complications.

Providers: If at any time the anesthesia provider feels uncomfortable or incapable of using the randomized technique to identify midline, he or she will be removed from the study. They will be allowed to freely choose their technique of choice in identifying midline. If this occurs, the participating patient in the study will be informed that she is no longer randomized and will be removed from the study. The patient will still receive standard of care treatment as described above.

At the mid-point of the study, our results will be reviewed by our statistician and if there is a highly significant result in either group, the study will be discontinued due to the overwhelming benefit of either palpation or ultrasound. Since patients are only recruited for the study the day of their epidural, no patients will need to be contacted if the study is discontinued.

- c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire study and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants.

After a significant number of patients have been enrolled, we will perform a preliminary analysis of the data. If the data suggests there is a strongly significant benefit (or harm) to a certain group, such as much prolonged time in placement or a significantly improved success rate, we will end the study. Since patients are only enrolled in the study during their labor and delivery (as opposed to prolonged follow-up), there should be no special precautions that would need to be taken. Recruitment would just end due to the study ending.

20. Informed Consent

The answers below pertain to the patient participants. We are asking for a waiver of informed consent for the provider participants.

- a. Do you plan to obtain informed consent for this protocol? Yes No
If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

- b. Do you plan to document informed consent for this protocol? Yes No
If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

- c. How will consent be obtained? Once a potential candidate is determined, PI or a co-investigator will discuss the study with the patient in a private setting and allow for any questions. Once the study is explained and all questions are answered, informed written consent will be obtained by the PI or co-investigator before any obstetric intervention occurs that might cause pain or altered mental status to the patient.

- d. Who will conduct the consent interview? PI or a co-investigator.

- e. Who are the persons who will provide consent or permission? The participant.

- f. What steps will be taken to minimize the possibility of coercion or undue influence?
All patients will be approached the day of admission in accordance with our current practice. If patients are experiencing extreme pain because of contractions, they will not be approached for the study.

- g. What language will the prospective participant or the legally authorized representative understand? English
- h. What language will be used to obtain consent? English
- i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "no such effect."
No such effect
- j. If any project-specific instruments will be used in the consenting process, such as flip charts or videos, describe the instrument(s) here, and provide a copy of each. If not, enter "not used."
Not used
- k. How long will participants have between the time they are told about the study and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. The 24-hour minimum will not be feasible or practical for this study, since the time between admission for induction of labor and placement of a labor epidural will be less than 24 hours. Therefore, we will begin the consent process when the patient has arrived on the Labor and Delivery floor.

21. Procedures to Protect Privacy

Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear your conversation with potential participants, individuals will not be publicly identified or embarrassed).

Patients: All patients will be recruited through direct and private interview with them by either the PI or co-investigator. They will read the informed consent document explaining the research project. All questions and concerns will be answered.

Providers: Anesthesia provider data will have no personal identifying markers except for training level.

22. Procedures to Maintain Confidentiality

- a. Describe the manner and method for storing research data and maintaining confidentiality. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the departmental and all computer systems used to store protocol-related data, and describe how access to that data will be limited to those with a need to know.

Patient data will be gathered through direct interview with the patient and through secure password-protected online medical records. Anesthesia provider data will have no personal identifying markers except for training level. Also the times as discussed above will be documented. Data will initially be collected on paper and will be kept in a locked filing cabinet in the locked office of the PI. The paper data records will be transferred to a secure password-protected research drive maintained by the Department of Anesthesiology. The research drive is HIPAA compliant and has researcher specific restricted access. This research server is backed up to another secure research server at a different location.

- b. Will any information derived from this study be given to any person, including the subject, or any group, including coordinating centers and sponsors? Yes No
If Yes, complete i-iii.

- i. To whom will the information be given? Information will be shared with the UAB Anesthesiology faculty and residents and other entities within the UAB Health System for quality improvement. Information may be presented at scientific meetings, conferences, or may be published.
- ii. What is the nature of the information? Findings from study. Information regarding participant demographics will only be presented in aggregate form – age, sex, race, differences in pre-existing medical conditions, and variables in procedure management.
- iii. How will the information be identified, coded, etc.? Information will be de-identified and will be presented in aggregate form. None of the 18 HIPAA identifiers will be disclosed.

23. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None."

None