NCT02526186

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Battlefield Auricular Acupuncture for Control of Post-partum Pain

PROTOCOL FOR CLINICAL INVESTIGATION – NON-EXEMPT HUMAN

PROTOCOL SUMMARY

1. Title:

Battlefield Auricular acupuncture for control of post-partum pain.
FWH20150072H

2.0. Principal Investigator (PI): **PI:**

Name	Paul Crawford, MD
Rank/Corps or Civilian Rating	Col
Date of IRB Approved CITI Training & Date of Good Clinical Practice Training	12/28/17
Branch of Service	USAF
AD Mil/DoD Civilian/Ctr/Non-DoD Civ	AD Mil
Department & Base	Family Medicine Residency, Nellis AFB
Phone & Pager #	(702) 653-3298
E-Mail Address & AKO/DKO E-Mail Address	paul.f.crawford.mil@mail.mil

3.0. Research Plan:

3.1. Purpose:

The purpose of this study is to compare battlefield auricular acupuncture plus standard of care versus standard of care in the reduction of pain, use of pharmacological analgesics, and satisfaction with experience in mothers in the immediate post-partum period.

3.2. Hypotheses, Research Questions or Objectives:

Does battlefield auricular acupuncture provide significant pain control for mothers in the immediate post-partum period?

4. Brief Summary of the study:

We will conduct a randomized controlled trial to determine whether the addition of battlefield auricular acupuncture to standard of care is effective for control of postpartum pain for mothers in the immediate post-partum period. Post-partum patients (DoD beneficiaries) 18 years or older, regardless of gravida/parity, who plan to have a childbirth in a hospital setting will be offered the opportunity to participate in the study through PCM referrals and posted advertisements. After a minimum of 6 hours post-vaginal delivery or 24 hours post caesarean section subjects will be given treatment according to their randomization group. Subjects will be assessed on pain control, overall satisfaction with pain management, and the amount of pharmacological pain medications used. Safety of measures will also be assessed to include infection rates, syncope, vertigo, and hypotension.

5. Subjects:

Post-partum females (DoD beneficiaries). Age 18 years or older, will be recruited at the Mike O'Callaghan Military Medical Center. No other special populations (e.g., children, military basic trainees, prisoners, detainees) will be recruited.

6. Inclusion/exclusion criteria:

Inclusion:

- Post-partum female (DoD beneficiaries).
- Age 18 years or older
- Pain score rating post-delivery of greater or equal to 4/10.

Exclusion:

- Absence of one or more ears
- Active cellulitis of ear
- Ear anatomy precluding identification of acupuncture landmarks
- Non-English speaking
- Use of Hearing Aids that preclude the use of ear acupuncture
- Known allergy to gold

7. Number of Subjects: TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide): Nellis 90

8. Use of an Investigational New Drug: N/A

9. Use of an Investigational Device: Sedatelec ASP Original Gold Acupuncture needles, 510(k) exempt as Class II device under 21 CFR 880.5580

10. Use of a Placebo: N/A

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Name	Paul Crawford, MD
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Branch of Service	USAF
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Department & Base	Family Medicine Residency, Nellis AFB
Phone & Pager #	(702) 653-3298
E-Mail Address & AKO/DKO E-Mail Address	paul.f.crawford.mil@mail.mil

2.1. Associate Investigators (AI): See form A2 Study Personnel

2.2. Research Assistants (RA) & Coordinators (RC): See form A2 Study Personnel

2.3. The research relevance of this protocol focuses on:
[ ] Diagnosis [X] Treatment [ ] Medical Utilization/Managed Care [ ] Prevention [ ] Medical Readiness [ ] Other

2.4. Location(s):

a. Collaborating Facilities: N/A
b. Air Force Sites seeking Regional IRB: Jill Clark, (702) 653-3298
c. List study sponsors: N/A

3. Research Plan:

3.1. Purpose:
The purpose of this study is to compare battlefield auricular acupuncture plus standard of care versus standard of care in the reduction of pain, use of pharmacological analgesics, and satisfaction with experience in mothers in the immediate post-partum period.

3.2. Hypotheses, Research Questions or Objectives:
Does battlefield auricular acupuncture provide significant pain control for mothers in the immediate post-partum period?

3.3. Significance:
If effective, battlefield auricular acupuncture techniques can be used as a safe method of pain control in the immediate post-partum period and result in greater satisfaction with the labor and delivery experience as well as reduce complications associated with increased pharmacological interventions.

3.4. Military Relevance:
This research will directly benefit the healthcare of active duty members and beneficiaries who undergo delivery in the DoD healthcare system. Given the cost savings in avoiding pharmacological medications or other invasive interventions, this study may also provide long-term health care cost savings and improve mission efficiency.

3.5. Background and Review of Literature:
Acupuncture is one of the oldest medical procedures still practiced regularly today. There is a diverse array of styles and techniques that speak to the specific culture and era in which it was developed. While the exact proposed mechanism of action of acupuncture on pain is not completely elucidated, it is clear that there are profound physiological effects. Specifically, stimulation with acupuncture excites nerve fibers that cause the release of endogenous opioids and oxytocin that result in functional changes in multiple organ systems. Beta-endorphin levels have been known to regulate pain control, blood pressure, and body temperatures have been observed to increase in the brain tissues after acupuncture (1). Functional MRI studies have also demonstrated increased activation in specific regions of the brain that correlates with established acupuncture and electro acupuncture points compared against sham points (2, 3). Auricular acupuncture follows this same premise and refers to piquering various points on the ear that are believed to have functional effects to targeted areas of the body to achieve the desired result.

Ear acupuncture (referred to as Battlefield Acupuncture or "BFA" in this study) is a technique developed by Niemtzow (4) and refers to piquering 5 specific points on the ear with semi-permanent acupuncture needles for acute pain relief. As opposed to traditional auricular acupuncture, this technique uses a simple, systematic approach to placing the needles that can be learned by providers in a short amount of time. Because the needles are semi-permanent, the needles stay in place after the patient leaves the encounter and are allowed to fall out on their own over time. BFA is widely used today and has been taught at the Helms Medical Institute acupuncture course, Uniformed Services Academy of Family Physicians Annual Conference, and at the Malcom Grow Medical Center Acupuncture Clinic. While the use of ear acupuncture specifically has limited data to support its effectiveness, there is a growing body of evidence to support the use of auricular acupuncture as an effective modality in relieving acute pain. This includes pain in the intra and post-operative period (5, 6, 7), low back pain and pelvic pain associated with pregnancy (8), and migraines (9).

The management of labor pain is a subject of great interest as the diversity of options available reflects this fact. A Cochrane Review on pain management in labor details the array of pain management strategies ranging from pharmacological to non-pharmacological. The current best evidence suggests epidurals, combined spinal epidurals, and inhale analgesia are the most effective (10). However, there is a paucity of quality evidence regarding pain control methods in the immediate post-partum period. A literature review regarding evidence based post-partum pain control strategies reveals no large clinical trials and a small retrospective study that examined interindividual variability in codeine requirements based on select genetic polymorphisms (11). The only studies examining the use of acupuncture in the peripartum period were for labor pain, labor induction, and cephalic version (12, 13, 14). There is no published literature regarding the use of acupuncture or BFA for the use of postpartum pain management.

3.5.1. Bibliography:

1. Andersson S, Lundeberg T. Acupuncture--from empiricism to science: functional background to acupuncture effects in pain and disease. Med Hypotheses. 1995;45(3):271.
2. Fang JL, Krings T, Weidemann J, Meister IG, Thron A. Functional MRI in healthy subjects during acupuncture: different effects of needle rotation in real and false acupoints. Neuroradiology. 2004;46(5):359.
3. Wu MT, Sheen JM, Chuang KH, Yang P, Chin SL, Tsai CY, Chen CJ, Liao JR, Lai PH, Chu KA, Pan HB, Yang CF. Neuronal specificity of acupuncture response: a fMRI study with electroacupuncture. Neuroimage. 2002;16(4):1028.
4. Niemtzow, R., Battlefield Acupuncture. Medical Acupuncture; vol 19, number 4, 2007.
5. Usichenko, T., et al. Auricular Acupuncture Reduces Intraoperative fentanyl requirement during hip arthroplasty- A randomized double blinded study. Acupuncture & Elecotro-therapuetics Res, Int. J; Vol 31, pp 213-221, 2006
6. Taras, I., et al. Auricular acupuncture for pain relief after ambulatory knee surgery: a randomized trial. CMAJ January 16, 2007, 176(2): 179-183.
7. Usichenko, et al. Auricular acupuncture for post-operative pain control: a systematic review of randomised clinical trials. Anaesthesia. <http://www.ncbi.nlm.nih.gov/pubmed?term=usichenko%20auricular%20acupunture%20sytematic%20review> 2008 Dec;63(12):1343-8.
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9. Allais, G.,et al. Ear acupuncture in unilateral migraine pain. Neurol Sci 2010 Jun; 31 Suppl 1:S185-7.
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11. Baber M, et al. The pharmacogenetics of codeine pain relief in the post-partum period. Pharmacogenomics J. 2015 Mar 10. doi: 10.1038/tpj.2015.3.
12. Levett K, Smith C, et al. Acupuncture and acupressure for pain management in labour and birth: A critical narrative review of current systematic review evidence. Complementary Therapies in Medicine (2014) 22, 523—540.
13. Smith C, Collins C, et al. Acupuncture or acupressure for pain management in labour (Review). *Cochrane Database of Systematic Reviews* 2011, Issue 7. Art. No.: CD009232. DOI: 10.1002/14651858.CD009232.
14. Van den Berg I, et al. Cost-effectiveness of breech version by acupuncture-type interventions on BL 67, including moxibustion, for women with a breech foetus at 33 weeks gestation: a modelling approach. Complement Ther Med. 2010 Apr;18(2):67-77.

3.6. Research Design and Methods:

Female subjects (DoD beneficiaries), ages 18 years or older, meeting the inclusion criteria will be offered an opportunity to participate. To randomize subjects, we will employ a random number generator, which will minimize difference between study groups. PCM referrals and posted advertisements will be utilized for recruiting subjects to the study.

Screening Visit:

- Obtain signed Informed Consent document and HIPAA Authorization.
- Review past medical history in Armed Forces Health Longitudinal Technology Application (AHLTA) to verify the

inclusion/exclusion criteria and including previous encounter, vital signs review, medication list, co-morbidities, demographics, problems list, prior obstetric history, and note any prior acupuncture received.

- Record: Date of birth, age, gender, race, ethnicity, last 4 of social security number, current email address.

Randomization:

Subjects will then be randomized into one of two groups by one of the Research Coordinators using a random number generator:

- **Group 1**: Standard of care only.
- **Group 2**: Standard of care plus Battlefield acupuncture at treatment sites Cingulate gyrus, thalamus, omega 2, shen-men, point zero in both ears (see figures 1-5). The 5 needles will remain in each ear for up to 7 days or allowed to fall out on their own (the patient will be instructed not to remove the needles).
    - Subject's ears will be cleansed with an alcohol swab
    - Subjects will be given a handout of standard BFA Discharge Instructions including what an infection looks like and what to do in the event of an infection (see attached).

Visit 1: Will occur after a minimum of 6 hours post vaginal birth (up until hospital discharge) to avoid disturbing maternal infant bonding or a minimum of 24 hours post caesarean section to avoid confounding with the anesthesia:

- Subject will be given treatment according to their randomization group.
- All subjects, regardless of randomization group, will be instructed to have no heavy meals, no excessive hot or cold foods, no heavy exercise or intercourse, and no alcohol for 6 hours.
- Satisfaction with post-partum pain management will be assessed with the following questions:
    - On a scale of 0 to 10, how satisfied were you with your pain management after delivery? (dissatisfied 0 – 10 very satisfied)
    - Would you use auricular acupuncture for future pain management? (Yes or no) (for those in the acupuncture group only)
    - On a scale of 0-10, with 10 being the worst pain, what is your level of pain?

In hospital data collection:

Data will be collected each day until the patient has been discharged from the hospital. Subjects will be contacted either in person or via phone and the hospital stay will vary from patient to patient:

- We will review the subject's medical record and record RN Recorded Pain assessments, Delivery method (either Caesarean section or spontaneous vaginal delivery), Delivery complications (vaginal lacerations, use of episiotomy, operative vaginal delivery, shoulder dystocia, post-partum hemorrhage), Birth weight, Maternal Parity, and record what pain medications they are taking.
- We will ask subjects if they prefer to be contacted in-person or via telephone while in the hospital.
- Satisfaction with post-partum pain management will be assessed with the following questions:
    - On a scale of 0 to 10, how satisfied were you with your pain management after delivery? (dissatisfied 0 – 10 very satisfied)
    - Would you use auricular acupuncture for future pain management? (Yes or no) (for those in the acupuncture group only)
    - On a scale of 0-10, with 10 being the worst pain, what is your level of pain?
    - Are the needles still in place? If yes, how many in each ear?

Post hospital discharge:

Each day up until 10 days post Visit 1. Subjects will be contacted phone and the following information will be collected:

- Satisfaction with post-partum pain management will be assessed with the following questions:
    - On a scale of 0 to 10, how satisfied were you with your pain management after delivery? (dissatisfied 0 – 10 very satisfied)
    - Would you use auricular acupuncture for future pain management? (Yes or no) (for those in the acupuncture group only)
    - On a scale of 0-10, with 10 being the worst pain, what is your level of pain?
- We will record what pain medications they are taking including drug name, strength, and total doses since discharge from the hospital.

Placement of Battlefield Acupuncture:

Battlefield auricular acupuncture utilizes up to 10 needles (see figure 6). The ear Acupuncture points include Cingulate gyrus, thalamus, omega 2, shen-men, point zero (see figures 1-5). The subject will receive five needles on each ear. Intermittent placement checks by the medical acupuncturist will be performed.

The acupuncture being performed in this study is a standard acupuncture technique for the treatment of pain. The physicians performing the treatment are trained in this acupuncture technique. As such, all physicians trained in this procedure will be able to perform the acupuncture for treatment of research subjects.
The Food and Drug Administration (FDA) regulates acupuncture needles as a class II medical device, because they are intended for use in the cure, mitigation, treatment, or prevention of disease in man or are intended to affect the structure or function of the body of man. The FDA regulates the acupuncture needles (see 21 CFR 880.5580), but not the practice of acupuncture itself. The needles being used are Sedatelec ASP Original Gold needles, which are exempt from premarket notification by the FDA for use in acupuncture and will be used in accordance with their FDA approved labeling.

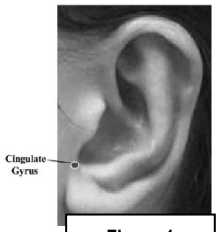

Figure 1

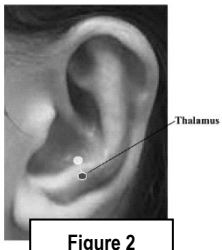

Figure 2

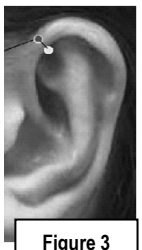
Figure 3

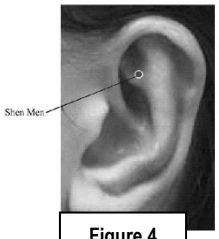

Figure 4

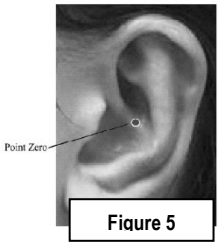

Figure 5


Figure 6

3.6.1. Interventions, Observations, or Data Sought:
We will review the subject's medical record and record the following standard of care items: RN Recorded Pain assessments, delivery method (either Caesarean section or spontaneous vaginal delivery), delivery complications (vaginal lacerations, use of episiotomy, operative vaginal delivery, shoulder dystocia, post-partum hemorrhage), birth weight, and maternal parity. Before discharge, we will also assess the patient's satisfaction with her post-partum pain control via a short questionnaire as detailed above. After delivery of the battlefield acupuncture and the first post-hospital discharge day, the patient will be contacted by the research coordinators and assessed on their overall pain scale (scale of 0 to 10) and the amount of pain medicines utilized over the past 24 hours. Post-hospital discharge follow-up will continue for up to 10 days post Visit 1 for each study group.

3.6.2. Data Collection and Processing:
Data will be collected and recorded in a spreadsheet. At the conclusion of the study, all personally identifying information will be removed prior to analysis based on AFI 33-332, "The Air Force Privacy and Civil Liberties Program" and the "National Institute of Standards and Technology Special Publication (NIST SP 800-88) for the approved methods to destroy PII". Each subject will be asked to place their de-identified study-related data into the "Nellis Acupuncture Research Data Repository (FWH20140048H)" for future research. If the subject does not give their authorization, then all de-identified study-related data will be destroyed no later than at the closure of the study.

3.6.3. Setting:
Post-partum females (DoD beneficiaries), age 18 years or older, at the Mike O'Callaghan Military Medical Center. No other special populations (e.g., children, military basic trainees, prisoners, detainees) will be recruited.

3.6.4. Date(s): June 2015 through June 2017

3.6.5. Source of Research Material:

Source of Research Material per Participant (Procedures)	# Routine Care	# Research Driven	# Total Procedures
Medical Record review	0	2	2
Acupuncture	0	1	1
Questionnaire	0	Up to 11	Up to 11

3.6.6. Subjects:
Post-partum females (DoD beneficiaries), age 18 years or older, will be recruited at the Mike O'Callaghan Military Medical Center. No other special populations (e.g., children, military basic trainees, prisoners, detainees) will be recruited.

3.6.7. Inclusion/Exclusion Criteria:
Inclusion:
- Post-partum female (DoD beneficiaries).
- Age 18 years or older
- Pain score rating post-delivery of greater or equal to 4/10.

Exclusion:
- Absence of one or more ears

- Active cellulitis of ear
- Ear anatomy precluding identification of acupuncture landmarks
- Non-English speaking
- Use of Hearing Aids that preclude the use of ear acupuncture
- Known allergy to gold

3.6.8. Instrumentation: N/A

4.0. Human Subject Protection:

4.1. Recruitment:
All potentially eligible patients will be offered an opportunity to participate. Primary Care Managers (PCMs) who are not part of the research team will be informed about the study and provided information on the inclusion/exclusion criteria. PCM referrals and posted advertisements will be utilized for recruiting subjects to the study. Some patients may be patients of the PI or AI, however, they will have the study staff recruit their patients to prevent any misconception of coercion or undue influence. If a potential subject is identified by the treating PCM and is interested in obtaining more information about the study, the patient will either be provided a contact number to the Research Staff, the Research Staff will be given the potential subject's contact information by the PCM with the patient's oral or written authorization, or the PCM will come and get the Research Staff to speak with the patient directly.

4.2. Consent Processes:
Informed Consent and HIPAA authorization will be sought in advance from each prospective subject and appropriately documented in accordance with 32 CFR 219.117. Potential candidates will be notified about the study either through posted advertisements or by their care provider and will be given the opportunity to consent by one of the referred study coordinators. The study coordinator will provide a written copy of the Informed Consent Document (ICD). The subject may decline to consent without prejudice. At the subjects' discretion, they may take the ICD home to discuss further prior to making a decision. If the subject consents, a copy of the ICD will be given to the subject. No vulnerable populations are included in this research study. Subjects who cannot provide Informed Consent will not be allowed to participate. No Legally Authorized Representatives (LAR) will be utilized. Some subjects may be patients of the Investigators; however, the Investigators will have the study coordinators recruit their subjects to prevent any misconception of coercion or undue influence.

4.3 Participation Compensation: Subjects will not be paid for participation in this study.

4.4. Assent Process: N/A

4.5. Benefits:
There may be no direct benefits to the subjects for participating in this study. However, patients may benefit from a reduction in pain.

4.6. Risks:
The potential risks to participate in this study are minimal. There is a risk of inadvertent breach of confidentiality. The risks of battlefield auricular acupuncture associated with participating in this research study include:

LIKELY: *Likely and not serious:*
- Pain at insertion site
- Bleeding
- Flare of signs or symptoms (i.e. post-partum pain)

LESS LIKELY: *Less Likely and not serious:*
- Infection

4.7. Costs: N/A

4.8. Safeguards for Protecting Information:
The research consents will be stored in a locked cabinet in a locked room. Medical records will be annotated with ICD-10 code Z00.6 to reflect the subject's participation in a research study. All research data including patient demographics will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The research

data will be de-identified and any links to identifiable data will be destroyed as soon as possible. The research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval.

4.9. Safeguards for Protecting Subjects:
The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents (*e.g.*, consent forms, data pulls) and pertinent hospital or clinical records readily available for inspection by the local IRB and over sight staff for confirmation of the study data.

4.9.1. Minimizing Risks:
These risks will be minimized by cleaning the acupuncture site with an alcohol swab prior to placement. If at any time the patient reports a side effect, they will be referred to one of the Investigators for care.

4.9.2. Vulnerable Populations:
This research will not involve any treatment decisions related to the pregnancy or viability of the nonate, and if such questions come up, the Principle Investigator (PI) will refer the subject to their Primary Care Manager (PCM) and will not participate in any pregnancy or neonate-related decision making or guidance.

4.9.3. Clinical Care:
All subjects will receive standard of care regardless of inclusion into this study. If at any time a subject experiences any injury or adverse effects, appropriate clinical care will be given or subject will be referred to appropriate provider.

4.9.4. Injury Compensation: N/A

4.9.5. Data Safety Monitoring:
The trial will be conducted in compliance with this protocol, International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), and any applicable national and international regulatory requirements. The principal and associate investigators will be monitoring all aspects of the study in accordance with the appropriate regulations and will have regular meetings with periodic quality control of data documentation and collection. The objectives of the monitoring meetings will be:
1) To verify the prompt reporting of all data points, including reporting Serious Adverse Events (SAEs) and checking availability of signed informed consent,
2) To compare individual subject records, data pulls and/or the study source documents/case report forms (supporting data, laboratory specimen records and medical records to include physician progress notes, nurses' notes, subjects' hospital charts),
3) To ensure protection of study subjects, compliance with the protocol, and accuracy and completeness of records.

The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents (*e.g.*, consent forms, data pulls) and pertinent hospital or clinical records readily available for inspection by the local IRB and over sight staff for confirmation of the study data.

5.0. Alternatives: The only alternative is not to participate in this study.

6.0. Data Analysis:

6.1. Outcome Measures:
Does battlefield auricular acupuncture provide significant pain control for mothers in the immediate post-partum period?
- Pain reduction by at least 50%
- Pharmacological pain control reduction
- Satisfaction with pain management in the immediate post-partum period

6.2. Sample size estimation/power analysis:
We are planning a study of a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 4. If the true difference in the mean response of matched pairs is 2, we will need to study 33 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

6.3. Statistical Analysis: We will use a ROC analysis using pain scores collected and repeated measures of ANOVA will be used.

6.4 Number of Subjects:

Number of subjects planned for Nellis	Enrolled in Study	90	to result in	66	completing the study.

TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide): 90

7. Duration of Study: Approximate duration of the study: *2 years*

8. Local and External Support Services: None

9. Intramural (GME) and Extramural Funding Support: None

10. Conflict of Interest: No financial, personal, or off duty employment conflicts of interest exist.

11. Use of an Investigational New Drug, use of a Drug for a non-FDA approved purpose, use of an investigative device or use of a placebo:

This research uses an Investigational New Drug **[] YES** [X] **NO**
This research uses a FDA approved drug for a non-FDA approved purpose **[] YES** [X] **NO**
This research uses an Investigational Device [X] **YES** **[] NO**
This research uses a placebo. **[] YES** [X] **NO**

12. Medical Research Area for the Study: (Pick as many as appropriate)

[] Analytical Chemistry	[] Anatomy	[] Anesthesiology	[] Biochemistry
[] Cardiovascular Surgery	[] Cardiology	[] Cell Biology	[] Dentistry
[] Dermatology	[] Dietetics	[] Electrophysiology	[X] Endocrinology
[] Emergency medicine	[] Gastroenterology	[] General Surgery	[] Hematology
[] Histology	[] Immunology/Allergy	[] Infectious Disease	[] Microbiology
[] Molecular Biology	[] Neonatology	[] Neurology	[] Neurosurgery
[] Nursing	[] OB/GYN	[] Occupational Medicine	[] Occupational Therapy
[] Oncology	[] Ophthalmology	[] Oral/Maxillofacial Surgery	[] Orthopedics
[] Pathology	[] Pediatrics	[] Pharmacology	[] Physical Therapy
[] Mental Health	[] Radiology/Imaging	[] Urology	[X] Wellness
[] Other (state):			

13. Attachments:

1. Form A: Certificate of Compliance
2. Form A1: Study Personnel
3. Informed Consent Document
4. HIPAA Authorization Document
5. Use of an Investigational Device in Research
6. BFA Discharge Instructions
7. Recruitment: Advertisement