Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

Date: 03/03/2020
NCT03381599

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS
RESEARCH PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Revised 2.1.2014 **Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.**

Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Hand written forms will not be accepted.

1. PROPOSED START DATE of STUDY: May 1, 2017

PROPOSED REVIEW CATEGORY (Check one): ☑ **FULL BOARD** ☐ **EXPEDITED**

SUBMISSION STATUS (Check one): ☐ **NEW** ☐ **REVISIONS (to address IRB Review Comments)**

2. PROJECT TITLE: Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Application

3. Dr. Michael Goodlett	MD	Athletics	goodlmd@auburn.edu
PRINCIPAL INVESTIGATOR	**TITLE**	**DEPT**	**AU E-MAIL**
349 S Donahue Dr #200			
MAILING ADDRESS		**PHONE**	**ALTERNATE E-MAIL**

4. FUNDING SUPPORT: ☐ N/A ☐ Internal ☑ External Agency: VCOM ☐ Pending ☑ Received

For federal funding, list agency and grant number (if available).

5a. List any contractors, sub-contractors, other entities associated with this project:

Andrews Research and Education Foundation, Edward Via College of Osteopathic Medicine, Arthrex, Inc.

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):

NA

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

☑ **Research Protocol Review Form** (All signatures included and all sections completed)
(Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)

☑ **CITI Training Certificates** for all Key Personnel.

☑ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.

☑ **Appendix A**, "Reference List"

☑ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.

☑ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.

☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).

☐ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.

☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

FOR ORC OFFICE USE ONLY

DATE RECEIVED IN ORC: _____ by _____ **PROTOCC**
DATE OF IRB REVIEW: _____ by _____ **APPROVA**
DATE OF IRB APPROVAL: _____ by _____ **INTERVAL**
COMMENTS:

The Auburn University Institutional Review Board has approved this Document for use from
12/07/2016 to 12/06/2017
Protocol # 16-398 AR 1612

6. GENERAL RESEARCH PROJECT CHARACTERISTICS

6A. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): ☑ New Data ☐ Existing Data

Will recorded data directly or indirectly identify participants? ☐ Yes ☑ No

Data collection will involve the use of:

- Educational Tests (cognitive diagnostic, aptitude, etc.)
- Interview
- Observation
- Location or Tracking Measures
- ✓ Physical / Physiological Measures or Specimens (see Section 6E.)
- Surveys / Questionnaires
- Internet / Electronic
- Audio
- Video
- Photos
- Digital images
- Private records or files

Other: _____

6B. Participant Information

Please check all descriptors that apply to the target population.

☑ Males ☐ Females ☐ AU students

Vulnerable Populations

☐ Pregnant Women/Fetuses ☐ Prisoners ☐ Institutionalized

☐ Children and/or Adolescents (under age 19 in AL)

Persons with:

☐ Economic Disadvantages ☐ Physical Disabilities

☐ Educational Disadvantages ☐ Intellectual Disabilities

Do you plan to compensate your participants? ☑ Yes ☐ No

6C. Risks to Participants

Please identify all risks that participants might encounter in this research.

☑ Breach of Confidentiality* ☐ Coercion

☐ Deception ☑ Physical

☐ Psychological ☐ Social

☐ None

☐ Other:

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

6D. Corresponding Approval/Oversight

- Do you need IBC Approval for this study?
  ☑ Yes ☐ No
  If yes, BUA # 751 Expiration date 02/07/2020
- Do you need IACUC Approval for this study?
  ☐ Yes ☑ No
  If yes, PRN # _____ Expiration date _____
- Does this study involve the Auburn University MRI Center?
  ☐ Yes ☑ No
  Which MRI(s) will be used for this project? (Check all that apply)
  ☐ 3T ☐ 7T
  Does any portion of this project require review by the MRI Safety Advisory Council?
  ☐ Yes ☑ No
  Signature of MRI Center Representative: _____
  Required for all projects involving the AU MRI Center
  Appropriate MRI Center Representatives:
  Dr. Thomas S. Denney, Director AU MRI Center
  Dr. Ron Beyers, MR Safety Officer

7. PROJECT ASSURANCES Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Application

A. PRINCIPAL INVESTIGATOR'S ASSSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
    a. Conducting the project by qualified personnel according to the approved protocol
    b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Research Compliance
    c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
    d. Promptly reporting significant adverse events and/or effects to the Office of Research Compliance in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise ORC, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Research Compliance before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Dr. Michael Goodlett	M C Goodlett	031517
Printed name of Principal Investigator	**Principal Investigator's Signature**	**Date**

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and/or adverse events and/or effects to the ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.

Dr. Michael Goodlett	M Goodlett	031517
Printed name of Faculty Advisor / Sponsor	**Faculty Advisor's Signature**	**Date**

C. DEPARTMENT HEAD'S ASSSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Dr. Michael Goodlett	Michael S Goodlett	031517
Printed name of Department Head	**Department Head's Signature**	**Date**

8. **PROJECT OVERVIEW: Prepare an abstract that includes:**
(350 word maximum, in language understandable to someone who is not familiar with your area of study):

a) **A summary of relevant research findings leading to this research proposal:**
(Cite sources; include a "Reference List" as Appendix A.)
b) **A brief description of the methodology, including design, population, and variables of interest**

a.) Orthopaedic practitioners have begun to augment surgical procedures and treat degenerative conditions, such as osteoarthritis, with injections of bone marrow aspirate. Clinical application studies have suggested that success is dependent upon the number of stem cells harvested and utilized. The number of stem cells harvested by bone marrow aspiration is variable and dependent upon patient demographics, aspiration technique, and location of harvest. Pharmaceutical mobilization, with agents such as filgrastim (Neupogen), followed by peripheral harvest of stem cells has supplanted bone marrow aspirate for hematologic oncologic clinical practice of stem cell transplant, with established safety and efficacy. Greater quantities of cells can be harvested, and these cells are similar to cultured bone marrow derived cells, with established multi-potentiality and differentiation potential to the mesodermal lineage. Previous study has determined that the optimal dosage of filgrastrim for mobilization is 10 mcg/kg/day, with hematopoietic stem cell counts after four days of filgrastim mobilization averaging approximately 20,000 to 54,000 cells per milliliter. With these previous studies in mind, one unit of blood, the amount routinely withdrawn during blood donation, may contain 9 million to 24 million stem cells. The Arthex Angel system uses centrifugation and optics to divide bone marrow or blood into different components which contain cells, proteins, and plasma in varying amounts in each component. By selecting one of the components, clinicians can concentrate stem cells or other proteins available from bone marrow or blood. We believe that the Arthrex Angel system combined with peripheral mobilization can isolate a greater number of stem cells than bone marrow aspirate.

b.) We theorize with a pharmaceutical mobilization method and the Arthrex Angel system, clinicians can harvest more stem cells than with bone marrow aspiration. The proposed study is a controlled laboratory study involving 10 healthy volunteers where we will compare the stem cell content of bone marrow aspiration to the stem cell content of pharmaceutical mobilization and blood harvest. Once the potential participant has cleared the screening and consenting and completed the medical interview and laboratory blood testing, a bone marrow sample will be collected from the iliac crest (See attachment G) The sample will be tested to determine stem cell content and analyzed for the presence of proteins which are of interest in orthopaedic treatments. The sample will be processed with the Arthrex Angel system, and then undergo the same stem cell and protein analysis. Thirty days following the base line bone marrow collection point, the volunteers will receive a dose of Filgrastim given by a subcutaneous injection daily for four serial days. On the fifth day, a blood sample will be collected with an analysis of the stem cell population and protein analysis as previously described. The sample will be concentrated with, the Arthrex Angel system, and then undergo the same stem cell and protein analysis.

9. **PURPOSE.**
a. **Clearly state the purpose of this project and all research questions, or aims.**

The purpose of this study is to determine the safety and efficacy of pharmaceutical mobilization and blood harvest for orthopaedic point of care application, by comparing the stem cell and beneficial protein composition of mobilized blood to the stem cell and beneficial protein composition of bone marrow. While previous mobilization studies have evaluated CD 34 + cells for hematologic applications, no study has quantitatively nor qualitatively studied all cell markers expressed by stem cells after mobilization with orthopaedic indications in mind. We will also investigate the platelet and cytokine composition of the concentrated product as well as one of the blood separation by-products, the platelet poor plasma component.

b. **How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)**

The results of this project will be presented at Orthopaedic conferences and published in an Orthopaedic journal to disseminate the information to clinical medical practitioners.

10. **KEY PERSONNEL.** Describe responsibilities. Include information on research training or certifications related to this project. **CITI is required. Be as specific as possible.** (Include additional personnel in an attachment.) *All key personnel must* ***attach CITI certificates of completion.***

Principle Investigator Dr. Michael Goodlett **Title:** MD **E-mail address** goodlmd@auburn.edu

Dept / Affiliation: Athletics

Roles / Responsibilities:

Perform physical examinations and adminsiter filgastim, [PROJECT OVERSITE]

Individual: Adam Anz **Title:** MD **E-mail address** adamanz@andrewsortho.com

Dept / Affiliation: Andrews Institute

Roles / Responsibilities:

Perform bone marrow sample collection and blood collections

Individual: Kenny Brock **Title:** Professor **E-mail address** kbrock@auburn.vcom.edu

Dept / Affiliation: Edward Via College of Osteopathic Medicine

Roles / Responsibilities:

Perform clinical analysis of samples collected and data analysis

Individual: Joseph Edison **Title:** DO, Professor **E-mail address** jedison@auburn.vcom.edu

Dept / Affiliation: Edward Via College of Osteopathic Medicine

Roles / Responsibilities:

Perform physical examinations and administer filgrastim.

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: Dr. Siraj Abdullah **Title:** DO, Professor **E-mail address** sabdullah@auburn.vcom.edu

Dept / Affiliation: Edward Via College of Osteopathic Medicine

Roles / Responsibilities:

Perform physical examinations and administer filgrastim

11. **LOCATION OF RESEARCH. List all locations where data collection will take place.** (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible. Attach permission letters in Appendix E.**
(See sample letters at http://www.auburn.edu/research/vpr/ohs/sample.htm)

Auburn University Sports Medicine Clinic, 349 South Donahue Dr, Suite 200 Auburn,AL. 36849
Edward Via College of Osteopathic Medicine, Research lab 104, 910 S. Donahue Dr., Auburn, AL 36832

12. PARTICIPANTS.

a. **Describe the participant population you have chosen for this project including inclusion or exclusion criteria for participant selection.**

☐ **Check here if using existing data, describe the population from whom data was collected, & include the # of data files.**

The proposed study is a controlled laboratory study involving 10 healthy male volunteers. Inclusion criteria will involve volunteers: age 19-39. Previous mobilization studies have found no variation with age or with sex. Female volunteers will be excluded to avoid the potential of any fetal risks from administration of filgastrim during pregnancy. Other exclusion criteria will include: volunteers who are under 50.0 kg [110#]or over 100 kg[220#], volunteers who have a medical history involving any of the following medical conditions - a previous allergic reaction to filgrastim, lidocaine, or any other injectable numbing agent, diabetes, autoimmune disorders, blood disorders, disorders requiring immunosuppression, cancer, an ongoing infectious disease, or significant cardiovascular, renal, hepatic or pulmonary disease, sickle cell or other blood disorders. Volunteers who have a WBC over 20,000/mcL upon initial screening CBC. Volunteers with physical examination findings of abdominal tenderness to palpation, splenomegaly, or unclear lung fields will also be exclude. Volunteers that consent but fail the medical interview or laboratory blood testing will receive partial compensation.

b. **Describe, step-by-step, in layman's terms, all procedures you will use to recruit participants.** *Include in Appendix B a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at http://www.auburn.edu/research/vpr/ohs/sample.htm.)*

Volunteers will be recruited utilizing flyers placed at the Auburn University Sports Medicine Clinic, at the Edward Via College of Osteopathic Medicine, and by word of mouth (Appendix B).

c. **What is the minimum number of participants you need to validate the study?** 10

How many participants do you expect to recruit? 30

Is there a limit on the number of participants you will include in the study? ☐ **No** ☑ **Yes – the # is** 10

d. **Describe the type, amount and method of compensation and/or incentives for participants.**

(If no compensation will be given, check here: ☐)

Select the type of compensation: ☑ Monetary ☐ Incentives

- ☐ Raffle or Drawing incentive (Include the chances of winning.)
- ☐ Extra Credit (State the value)
- ☐ Other

Description:

Compensation will be in the amount of $500 for each participant.
Partial compensation of $100 will be available to individuals who consent but do not pass the medical interivew or laboratory blood screening.

13. **PROJECT DESIGN & METHODS.**

a. **Describe, step-by-step, all procedures and methods that will be used to consent participants. If a waiver is being requested, check each waiver you are requesting, describe how the project meets the criteria for the waiver.**

- ☐ **Waiver of Consent (including using existing data)**
- ☐ **Waiver of Documentation of Consent (use of Information Letter)**
- ☐ **Waiver of Parental Permission (for college students)**

Volunteers will be identified through recruitment flyers and word of mouth. Once volunteers are identifed, a screening visit will be scheduled. During the initial visit a screening form will be completed and reviewed. If an individual answers "yes" to any of the intial screening exclusion questions, they will be informed that they do not qualify, and they will be informed that they can keep their screeing form. If all answers are "no" then they will hand in their form. Once the screening requirements are met, the informed consent will be administered to ensure the volunteer understands what is involved in the study (see Attachment H). Dr. Goodlett or Dr. Anz will be available to answer and questions or provide clarifications. After the volunteer has consented to participate in the study, a medical interview and a blood test (complete blood count) will be conducted by Dr. Goodlett or Dr. Anz. The medical interview will include a complete physical examination and review of the blood test to ensure that no exclusion conditions exisit. Physical examination will include vital signs including height/weight, head/neck, cardiovascular, lung, and abdominal examinations. If the volunteer has no exclusion criteria they will be scheduled for the first visit during which a bone marrow sample and blood sample will be collected.

b. **Describe the research design and methods you will use to address your purpose. Include a clear description of when, where and how you will collect all data for this project.** Include specific information about the participants' time and effort commitment. (*NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol.* ***If additional space is needed for this section, save the information as a .PDF file and insert after page 7 of this form.***)

See Attached Appendix G

13. **PROJECT DESIGN & METHODS.** *Continued*

c. **List all data collection instruments used in this project, in the order they appear in Appendix C.**
(e.g., surveys and questionnaires **in the format that will be presented to participants**, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

Laboratory data will include CBC with differentials, characterization of cell content with histology smear, results from flow cytometry, and results from ELISA testing. All data will by organized by an anonymous identifier and will not be linked or identifiable to the study participants.

d. **Data analysis: Explain how the data will be analyzed.**

Numbers of cells will be determined per microliter of total volume collected. Cytokine levels will be determined according to volume collected.

14. **RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research.** ***If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use in Appendix D.*** *(Examples of possible risks are in section #6D on page 2)*

Bone marrow aspiration may present a risk of infection, bleeding or pain at harvest site.

Filgrastim (Neupogen, Amgen, Thousand Oaks, California) is human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. Filgrastim is approved in the US for several indications, including the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Mobilization allows for the collection of increased numbers of progenitor cells compared with collection by leukapheresis without mobilization or direct bone marrow harvest. Contraindications to the use of Filgrastim include patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as Filgrastim or Pegfilgrastim. Most common adverse reactions in patients undergoing peripheral blood progenitor cell mobilization and collection (≥ 5% incidence) are bone pain, pyrexia (fever) and headache. Although extremely rare, cases of splenic rupture, acute respiratory distress syndrome, serious allergic reactions, fatal sickle cell crisis, capillary leak syndrome, cutaneous vasculitis, and glomerulonephritis have been reported in patients undergoing treatment with Filgrastim. For this reason, patients will be monitored with a review of symptoms and a physical examination upon each visit, including ascertaining blood pressure and pulse, as well as a lung, heart, and abdomen examination. Clinical trials involving mobilization with Filgrastim and healthy PBSC donors have proven this to be a safe process. In one study involving cancer patients, 126 patients received Filgrastim for PBPC mobilization.14 Adverse events related to Filgrastim consisted primarily of mild-to-moderate musculoskeletal symptoms, reported in 44% of patients. These symptoms were predominantly events of medullary bone pain (33%). Headache was reported related to Filgrastim in 7% of patients. Information about the long-term follow-up and safety of granulocyte colony-stimulating factor administration to healthy donors is available from registry data. The Spanish National Donor Registry was developed to record the short- and long-term results of granulocyte colony-stimulating factor administration to mobilize peripheral blood progenitor cells in normal donors, with data published on 736 donors, with 320 donors followed for 2 years or more. Bone pain (90%) and headache (33%) were the most frequently reported granulocyte colony-stimulating factor-related side effects. Changes in blood counts were minimal and mainly affected white blood cell counts, which returned to normal values within 2 years after granulocyte-colony stimulating factor administration. No patient developed a hematologic malignancy. Additional published studies have agreed that the standard regimen of 10 mcg/kg/day is safe when administrated to normal subjects with the most common adverse reactions involving bone pain, pyrexia and headache.
The recommended dose of Filgrastim for the mobilization of PBPC is 10 µg/kg/day SC, either as a bolus or a continuous infusion. It is recommended that Filgrastim be given for at least 4 days.

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals. ***Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D. (Samples can be found online at http://www.auburn.edu/research/vpr/ohs/sample.htm#precautions)***

The initial screening form will be used to exclude individuals that may have increased risk by participating in the study. By utilizing the screening process and the medical examination we have minimized the potential risks of complications due to the administration of filgrastrim. On each day of presentation for the study, the volunteers will complete a review of systems and undergo a physical examination. After bone marrow aspiration, a self care instruction sheet will be used to guide care and address any potential complications.

In the event of any major adverse event, the principal investigator will be immediately notified and the IRB will be notified within 2 business days. In the event of any major adverse event, a decision by the principal investigator will be made to continue or immediately halt the study, and the IRB will be notified. Major adverse events will include any medical conditions of the heart, lungs, or abdomen which present an immediate or subsequent concern to the volunteer's health. Minor adverse events will include headache, bone pain, fever, nausea, diarrhea. Participants will be given self-care home instructions (Appendix D) and will be contacted 7 days after sample collections as a follow-up.

If using the Internet or other electronic means to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

NA

16. **BENEFITS.**

a. **List all realistic direct benefits participants can expect by participating in this specific study.**
(Do not include "compensation" listed in #12d.) Check here if there are no direct benefits to participants. ☑

The participants may receive no direct benefits from participation in the study.

b. **List all realistic benefits for the general population that may be generated from this study.**

The general population will indirectly benefit by the advancement of orthopaedic technologies involving stem cells.

17. PROTECTION OF DATA.

a. **Data are collected:**

☐ **Anonymously with no direct or indirect coding, link, or awareness of who participated in the study (Skip to e)**

☐ **Confidentially, but without a link of participant's data to any identifying information (collected as "confidential" but recorded and analyzed as "anonymous") (Skip to e)**

☑ **Confidentially with collection and protection of linkages to identifiable information**

b. **If data are collected with identifiers or as coded or linked to identifying information, describe the identifiers collected and how they are linked to the participant's data.**

Participants will be assigned a unique code (letter-number combination) to track samples collected for laboratory analysis.

c. **Justify your need to code participants' data or link the data with identifying information.**

Samples from multiple days will be collected from the same individual and will need to tracked by a unique code, accordingly.

d. **Describe how and where identifying data and/or code lists will be stored.** (Building, room number?) **Describe how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.**

Data will be stored on an external hard drive in a locked office, VCOM, Room 203. IRB-approved and participant-signed consent forms will be stored in a locked cabinet as well for 3 years after the study is completed.

e. **Describe how and where the data will be stored** (e.g., hard copy, audio cassette, electronic data, etc.), **and how the location where data is stored is separated from identifying data and will be secured in your absence. For electronic data, describe security**

Data will be stored on an external hard drive in a locked office, VCOM, Room 203.

f. **Who will have access to participants' data?**
(*The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit.*)

The data will be in the possession of Dr. Kenny Brock (Co-PI) and only the co-investigators will have any access to the data.

g. **When is the latest date that identifying information or links will be retained and how will that information or links be destroyed?**
(Check here if only anonymous data will be retained ☑)

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE OF PROJECT: **Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications**

INVESTIGATOR: Michael Goodlett, MD
Auburn University

CO-INVESTIGATORS: Adam Anz, MD
Andrews Orthopaedic and Sports Medicine Center
Andrews Research & Education Foundation

Kenny Brock, DVM, MS, PhD
Edward Via College of Osteopathic Medicine

SITE(S): AU Sports Medicine Clinic

SPONSOR: VCOM

INVESTIGATOR CONTACT INFORMATION:

INTRODUCTION:

In order to decide whether you wish to participate in this research study, you should understand why the study is being done, how the study will be run, the types of study procedures involved, your time commitments, and the possible risks and/or benefits to make an informed decision. This process is known as "informed consent."

This written consent form provides detailed information about the research study. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. Before you decide to take part in this study, you may want to think about it more, or discuss it with family or friends. You can take a copy of this form home with you before making your decision. Your participation in this study is voluntary. You should not join this research study until all of your questions are answered to your satisfaction.

If you wish to participate in this research study, you will be asked to sign this consent form. You will be asked to sign before any study procedures are done. You will be given a copy of this consent form to keep for your records.

PURPOSE OF THE RESEARCH STUDY:

You are being asked to participate in research being conducted by Auburn University, Edward Via College of Osteopathic Medicine, and the Andrews Research and Education Foundation (AREF). This study is investigating the optimal method for harvesting stem cells from adults for uses involving the treatments of bone, cartilage, and other musculoskeletal tissues. Orthopaedic doctors treat injuries and diseases involving bone, cartilage, muscle, and tendon. Some of these tissues have a difficult time healing after injury or surgery and also have changes that occur with age, such as joint degeneration. Orthopaedic doctors have begun to investigate stem cells and how they can help improve treatment options. Current studies have focused on adult, autologous stem cell sources, which means that the stem cells are harvested from the person who is requiring the treatment of the stem cells. Some studies have suggested that success of stem cell treatments is dependent upon the number of stem cells harvested and used. Cancer doctors have been using stem cell treatments for bone marrow transplant for many years. To harvest stem cells for bone marrow transplant, cancer doctors utilize a man-made form of a natural hormone, which causes the release of stem cells from the bone marrow cavity into the blood stream. This process is called stem cell mobilization and involves injection of a drug under the skin. This study involves a drug called Filgrastim, which is also called Neupogen as a brand name. It is a synthetic form of a natural hormone, human granulocyte colony-stimulating factor (G-CSF), which is in your blood in certain amounts at certain times. It is synthesized by a drug company called Amgen and is produced by recombinant DNA technology. Filgrastim is approved in the US for several purposes, including the mobilization of stem cells from the bone marrow into the blood stream for collection.

Neupogen, also known as filgrastim, is the drug which has been used the longest for this purpose. After stem cells are mobilized from the bone marrow to the blood stream, these cells can be harvested from the blood stream using a centrifugal device to separate the whole blood into a concentrated fraction rich in stems cells. The cancer doctor community has been safely using stem cell mobilization and apheresis harvest for decades. This volunteer study will compare the effectiveness of collecting stem cells from bone marrow aspiration verses whole blood following stem cell mobilization with Filgrastim.

SELECTION OF SUBJECTS:

The proposed study is a controlled laboratory study involving 10 healthy, male volunteers. Volunteers will undergo a bone marrow aspirate followed by stimulation for the release of stem cells from the bone marrow to the peripheral blood. Samples of bone marrow and blood will be collected. The collected samples will be analyzed in a clinical research laboratory. Tests will be performed to identify the various types of cells and the number of cells in the samples. Additional tests will be performed to evaluate molecules of the immune system.

Individuals interested in being involved will first meet with Dr. Goodlett, MD or Dr. Anz, MD to ensure that they can be involved considering their medical history as well as ensure that they understand what will be involved in the study. This meeting is called a screening visit. Dr. Goodlett and Dr. Anz will be available for any questions and clarifications.

The screening visit will consist of the following:

1. Completion of a screening form.
2. Explanation of the consent process and completion of consenting
3. A Medical interview consisting of a physical examination by Dr. Goodlett, MD or Dr. Anz, MD which also involves the collection of a blood sample for laboratory testing. Laboratory tests will include a complete blood count (CBC) and blood coagulation studies (PI, PTT, INR).

Ten healthy, male volunteers will be recruited. Volunteers must be age 18-39. Volunteers cannot participate if they have a history of the following medical conditions – prior adverse events with Filgastrim (Neupogen) administration, bleeding or clotting disorder, diabetes, autoimmune disorders, disorders requiring or causing immunosuppression, history of cancer, Hepatitis B, Hepatitis C, HIV, patients with an ongoing infectious disease or significant cardiovascular, renal or hepatic disease. Volunteers with a weight of 49.9 kg or less and 99.9 kg or more will be excluded.

RESEARCH PROCEDURES:

After the screening form is completed you will go through the informed consent process. Once you have agreed and consented you will have a medical interview. The medical interview will include a physical examination of vital signs including height/weight, head/neck, cardiovascular, lung, and abdominal examinations. Following the physical examination a 5.0 ml (1 tsp) blood sample will be collected for laboratory testing for CBC and WBC differential and blood coagulation parameters. Once you have completed the medical interview process and everything is acceptable, your first study visit will be scheduled. At the initial visit a 5.0 ml (1 tsp) blood sample will be collected. In addition, 60 ml (4 tbs) of blood will be collected for a base-line, non-mobilized sample to be analyzed in the clinical research laboratory. Following the collection of a blood sample, a 60 ml (4 tbs) sample of bone marrow aspirate will also be collected from your posterior iliac crest in the back of your hip area by Dr. Anz. Collection will involve numbing your skin and the bone with a numbing medicine called Lidocaine. Numbing the skin involves the sensation of a pin prick and a burning sensation like a bee sting. After the skin and bone is numb a small incision (4 mm, which is about 1/8th of an inch)will be made in the skin, a bone marrow aspiration needle will be pushed into the bone, and bone marrow will be aspirated. The numbing medicine eliminates sharp intense pains from the incision, and patients often report a mild pressure and ache with advancement of the bone marrow needle into the bone and aspiration of marrow. Once the bone marrow aspirate is collected, this sample will be analyzed in the clinical research laboratory to determine the yield of bone marrow stem cells. At the completion, you will be given a home self-care instruction sheet and you will be contacted by phone after 7 days to follow-up and make sure you have no concerns or complications. At the completion of this visit, you will be scheduled for an additional five visits in a row occurring 30 days following the initial visit. This first study visit will take approximately 30 to 45 minutes.

On the first day of the scheduled visits, you will receive a short physical examination and a 5.0 ml (1 tsp) blood sample will be collected for CBC and WBC differential counts. In addition, you will receive an injection under the skin of your thigh of the medication Filgastrim (Neupogen). You will return each subsequent day for 3 more days. A total of 4 serial Filgastrim injections are required. These visits will be identical to the first visit, involving a short physical examination, a blood sample, an injection under the skin of the medication Filgrastim (Neupogen). On the fifth day, you will

receive a short physical examination and a 60 ml (4 tbs) blood sample will be collected for further analysis in a clinical research laboratory. These 5 visits will take approximately 30 minutes each. You will be given a home self-care sheet and you will be contacted by phone to determine if you have any concerns or if any undesired side effects have occurred. It is estimated that the study will require approximately 4-5 hours of your time.

RISKS AND DISCOMFORTS:

Risks of bone marrow collection may include, pain at the time of harvest, infection, and bleeding. Contraindications to the use of Filgrastim include patients with a history of serious allergic reactions to this drug or similar drugs. Most common adverse reactions in patients receiving this drug are bone pain, fevers, and headache. Although extremely rare, there have been cases of rupture of the spleen (which is an organ in your abdomen), breathing problems, serious allergic reactions, fatal sickle cell crisis, serious blood circulation problems, skin problems, and kidney problems have been reported in patients undergoing treatment with this drug. For this reason, you will have a brief physical examination upon each visit.

Although there are rare cases of serious problems, studies involving healthy volunteers and this process have proven to be safe for the majority of patients. In one study involving cancer patients, 126 patients received this drug for stem cell collection. Problems were mild-to-moderate muscle and bone pain in 44% of patients. The most common pain was bone pain. Headaches were reported in 7% of patients. There is information about the long-term safety of this method of stem cell collection. The Spanish National Donor Registry was developed to record the short- and long-term results. In 736 donors, bone pain was reported in 90% and headaches in 33%. There were mild changes in blood counts mainly involving white blood cell counts, which returned to normal in 2 years. No patient developed a blood cancer. Additional studies have agreed that this process is safe with the most common adverse reactions involving bone pain, fever, and headache.

BENEFITS:
There is no immediate direct benefit of this study to your health. All of your blood cells and bone marrow stem cells will be used for testing in the VCOM clinical research laboratory. There may be an indirect benefit of progressing orthopaedic technologies involving stem cells.

CONFIDENTIALITY:
All personal information is strictly confidential and no names will be disclosed except as required by law. Your individual performance will not be reported, only the results of all participants as a group. During the course of this study, your information will be identified by a code (letter-number combination). Any new information that might develop during the course of the project will be provided to you if that information might affect your willingness to participate in the project.

All information and data collected during this research will be recorded on the appropriate forms and stored in a locked room in the VCOM facility. In addition all subject data forms, including summary information and spreadsheets, will be scanned and stored in a secure password protected folder on an external hard drive that only the study investigators will have access to, and will be permanently deleted following publication of any and all manuscripts written as a result of this research. Records related to this study will be retained in a secure location for a period of 3 years after the completion of the study. At this time, all records will be properly destroyed.

HIPAA STATEMENT

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information. This section describes your rights and explains how your health information will be used and disclosed for this study.

During this study, the researchers will need to use personal health information about you. Your personal health information is health information about you that could be used to identify you because it includes information, such as your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, or the types, dates, and results of various tests and procedures. This may include information in your medical record and information created or collected during the study. By signing this consent, you are agreeing to allow the research personnel to use your personal health information to carry out this study.

By signing this document, you also allow the research staff to disclose your personal health information to outside entities involved in completing the project. The study data that the researchers send to these entities will not include your name, address, or social security number, but instead, will be designated with a code number. However, your medical records can be reviewed or copied at the study site by regulatory authorities or other oversight bodies, including the Institutional Review Board. The purpose of these reviews is to make sure the study is being conducted properly and that the data is being collected correctly, or for other purposes allowed by law.

Your personal health information may no longer be protected by the privacy rule once it is disclosed. Your personal health information will be kept as confidential as possible under the law; however, absolute confidentiality cannot be guaranteed.

If you cancel this authorization, the researchers will no longer use or disclose your personal health information under the authorization for this study, unless it is needed to preserve the scientific integrity of the study. Information obtained before you cancel this authorization may still be used by the researchers.

COST AND COMPENSATION:

There will be no cost to you for participating and you will receive $500 for participating in this research. In the unlikely event of an emergency, the medical staff will provide basic first aid medical treatment. However, if you were to require additional medical care as a result of participating in this study, you would need to contact your personal physician at your own expense. There is no current plan to compensate you for your medical costs.

Auburn University, Edward Via College of Osteopathic Medicine and The Andrews Research and Education Foundation do not have programs for compensating subjects for injury or complications related to human subject research.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. Your decision will not change any present or future relationships with the investigators institutions.

QUESTIONS:

It is your right, as a research participant, to ask questions at any time regarding the procedures involved and any aspects of this study including the potential benefits or risks. For any questions you may have for the researcher, you may contact Dr. Anz at (334) 728-1998, or by e-mail at **anz.adam.w@gmail.com or Dr. Goodlett at (334-750-1293)**

If you have questions about your rights as a research subject, or if you have questions, concerns or complaints about the research, you may contact the Auburn University Institutional Review Board (IRB)* at (334-844-5966) or by email at irbadmin@auburn.edu. The IRB will not be able to answer some types of questions, such as questions about appointment times.
*The IRB is a group of individuals who independently review research

STATEMENT OF CONSENT TO PARTICIPATE IN THIS RESEARCH STUDY:
By signing this consent form I agree to and acknowledge the following statements:

I agree to participate as a subject with the understanding that my participation is completely voluntary, and that I may withdraw at any time without prejudice by sending a written request to the researcher at the VCOM c/o Dr. Brock, 910 S. Donahue Dr., Auburn, AL 36832.

I have read and understand the above information and have been given the opportunity to discuss it and ask questions.
I understand that this authorization does not have an expiration date.
I have received a copy of this authorization form for my records.
I have been informed that I may contact the investigators by phone at (334)319-1335, or by e-mail at kbrock@auburn.vcom.edu, in order to answer any questions that I may have at any time during my participation.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

The Auburn University Institutional Review Board has approved this Document for use from
12/07/2016 to 12/06/2017
Protocol # 16-398 AR 1612

English Text size: A A

michael goodlett ID: 924988 | Log Out | Help

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Auburn University Courses

Course	Status	Completion Record	CE Credits	Survey
Genetic Research	Passed 12/31/2016	View/Print Share	Not Available	Post-course evaluation
International Research	Passed 01/08/2017	View/Print Share	Not Available	Post-course evaluation
IRB Member	Passed 01/08/2017	View/Print Share	Apply Now	Post-course evaluation
Research at/with the Veteran's Administration	Passed 01/08/2017	View/Print Share	Not Available	Post-course evaluation
Research in Public Elementary and Secondary Schools	Passed 01/07/2017	View/Print Share	Not Available	Post-course evaluation
Research Involving Pregnant Women, Human Fetuses, and Neonates	Passed 01/07/2017	View/Print Share	Not Available	Post-course evaluation
Research Involving Prisoners	Passed 01/06/2017	View/Print Share	Not Available	Post-course evaluation

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research Involving Prisoners
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216636
- **Completion Date:** 06-Jan-2017
- **Expiration Date:** 06-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	06-Jan-2017	4/4 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

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- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research Involving Prisoners
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216636
- **Report Date:** 24-Feb-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	06-Jan-2017	4/4 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research Involving Pregnant Women, Human Fetuses, and Neonates
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21237717
- **Completion Date:** 07-Jan-2017
- **Expiration Date:** 07-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	07-Jan-2017	3/3 (100%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research Involving Pregnant Women, Human Fetuses, and Neonates
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21237717
- **Report Date:** 24-Feb-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	07-Jan-2017	3/3 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research at/with the Veteran's Administration
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216634
- **Completion Date:** 08-Jan-2017
- **Expiration Date:** 08-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 80

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	07-Feb-2016	4/5 (80%)
Auburn University (ID: 12239)	08-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research at/with the Veteran's Administration
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216634
- **Report Date:** 24-Feb-2017
- **Current Score**:** 91

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	07-Feb-2016	4/5 (80%)
Auburn University (ID: 12239)	08-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research in Public Elementary and Secondary Schools
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21237716
- **Completion Date:** 07-Jan-2017
- **Expiration Date:** 07-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	07-Jan-2017	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Research in Public Elementary and Secondary Schools
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21237716
- **Report Date:** 24-Feb-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	07-Jan-2017	5/5 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** IRB Member
- **Stage:** Stage 1 - Basic Course
- **Description:** This Basic Course is appropriate for IRB or Ethics Committee members.

- **Record ID:** 21237715
- **Completion Date:** 08-Jan-2017
- **Expiration Date:** 08-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	30-Dec-2016	3/3 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	07-Feb-2016	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	07-Mar-2016	3/3 (100%)
Students in Research (ID: 1321)	07-Mar-2016	5/5 (100%)
History and Ethical Principles - SBE (ID: 490)	30-Dec-2016	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 498)	07-Mar-2016	7/7 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	30-Dec-2016	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	31-Dec-2016	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	07-Mar-2016	5/5 (100%)
Assessing Risk - SBE (ID: 503)	31-Dec-2016	5/5 (100%)
Informed Consent - SBE (ID: 504)	31-Dec-2016	5/5 (100%)
Informed Consent (ID: 3)	07-Mar-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	31-Dec-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	07-Mar-2016	4/4 (100%)
Records-Based Research (ID: 5)	07-Mar-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	31-Dec-2016	5/5 (100%)
Research with Prisoners - SBE (ID: 506)	31-Dec-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	06-Jan-2017	4/4 (100%)
Research with Children - SBE (ID: 507)	07-Jan-2017	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	07-Mar-2016	3/3 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	07-Jan-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	07-Jan-2017	3/3 (100%)
International Research - SBE (ID: 509)	08-Jan-2017	5/5 (100%)
International Studies (ID: 971)	08-Jan-2017	3/3 (100%)
Internet-Based Research - SBE (ID: 510)	08-Jan-2017	4/5 (80%)
FDA-Regulated Research (ID: 12)	07-Mar-2016	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	07-Mar-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	08-Jan-2017	4/4 (100%)
Hot Topics (ID: 487)	07-Feb-2016	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	07-Mar-2016	5/5 (100%)
The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)	08-Jan-2017	6/7 (86%)
Auburn University (ID: 12239)	08-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** IRB Member
- **Stage:** Stage 1 - Basic Course
- **Description:** This Basic Course is appropriate for IRB or Ethics Committee members.

- **Record ID:** 21237715
- **Report Date:** 24-Feb-2017
- **Current Score**:** 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	07-Mar-2016	7/7 (100%)
Students in Research (ID: 1321)	07-Mar-2016	5/5 (100%)
Informed Consent (ID: 3)	07-Mar-2016	5/5 (100%)
History and Ethical Principles - SBE (ID: 490)	30-Dec-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	07-Mar-2016	4/4 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	30-Dec-2016	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	07-Mar-2016	3/3 (100%)
Records-Based Research (ID: 5)	07-Mar-2016	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	31-Dec-2016	5/5 (100%)
Genetic Research in Human Populations (ID: 6)	31-Dec-2016	5/5 (100%)
Assessing Risk - SBE (ID: 503)	31-Dec-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	06-Jan-2017	4/4 (100%)
Informed Consent - SBE (ID: 504)	31-Dec-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	07-Mar-2016	3/3 (100%)
Privacy and Confidentiality - SBE (ID: 505)	31-Dec-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	07-Jan-2017	3/3 (100%)
Research with Prisoners - SBE (ID: 506)	31-Dec-2016	5/5 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Research with Children - SBE (ID: 507)	07-Jan-2017	4/5 (80%)
FDA-Regulated Research (ID: 12)	07-Mar-2016	5/5 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	07-Jan-2017	5/5 (100%)
International Research - SBE (ID: 509)	08-Jan-2017	5/5 (100%)
International Studies (ID: 971)	08-Jan-2017	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)
Internet-Based Research - SBE (ID: 510)	08-Jan-2017	4/5 (80%)
The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)	08-Jan-2017	6/7 (86%)
Research and HIPAA Privacy Protections (ID: 14)	07-Mar-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	08-Jan-2017	4/4 (100%)
Hot Topics (ID: 487)	07-Feb-2016	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	07-Mar-2016	5/5 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	30-Dec-2016	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	07-Mar-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	07-Feb-2016	4/5 (80%)
Auburn University (ID: 12239)	08-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** International Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216635
- **Completion Date:** 08-Jan-2017
- **Expiration Date:** 08-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
International Studies (ID: 971)	08-Jan-2017	3/3 (100%)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** International Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216635
- **Report Date:** 24-Feb-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
International Studies (ID: 971)	08-Jan-2017	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Genetic Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216633
- **Completion Date:** 31-Dec-2016
- **Expiration Date:** 31-Dec-2019
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Genetic Research in Human Populations (ID: 6)	31-Dec-2016	5/5 (100%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Name:** michael goodlett (ID: 924988)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** athletics / sports medicine
- **Phone:** 334-844-9821

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** Genetic Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 21216633
- **Report Date:** 24-Feb-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Genetic Research in Human Populations (ID: 6)	31-Dec-2016	5/5 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)	31-Dec-2008	3/3 (100%)
Human Subjects Research at the VA (ID: 13)	31-Jan-2009	3/3 (100%)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Siraj Abdullah (ID: 5684570)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Email:** sfa0004@auburn.edu
- **Institution Unit:** Sports Medicine
- **Phone:** 334-844-9919

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** HIPAA and Human Subjects Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 20354562
- **Completion Date:** 19-Sep-2016
- **Expiration Date:** 19-Sep-2019
- **Minimum Passing:** 80
- **Reported Score*:** 80

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Research and HIPAA Privacy Protections (ID: 14)	19-Sep-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Name:** Siraj Abdullah (ID: 5684570)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Email:** sfa0004@auburn.edu
- **Institution Unit:** Sports Medicine
- **Phone:** 334-844-9919

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** HIPAA and Human Subjects Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 20354562
- **Report Date:** 07-Mar-2017
- **Current Score**:** 80

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Research and HIPAA Privacy Protections (ID: 14)	19-Sep-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Name:** Siraj Abdullah (ID: 5684570)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Email:** sfa0004@auburn.edu
- **Institution Unit:** Sports Medicine
- **Phone:** 334-844-9919

- **Curriculum Group:** IRB #1 Health Science Emphasis - AU Personnel - Basic/Refresher
- **Course Learner Group:** IRB #1 Health Science Emphasis - AU Personnel
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Key Personnel (including AU Faculty, Staff and Students) and Faculty Advisors involved primarily in biomedical research with human subjects.

- **Record ID:** 20354563
- **Completion Date:** 19-Sep-2016
- **Expiration Date:** 19-Sep-2019
- **Minimum Passing:** 80
- **Reported Score*:** 84

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	11-Aug-2016	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	11-Aug-2016	4/5 (80%)
Informed Consent (ID: 3)	11-Aug-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	19-Sep-2016	4/5 (80%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	19-Sep-2016	4/4 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	19-Sep-2016	4/5 (80%)
Students in Research (ID: 1321)	19-Sep-2016	3/5 (60%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Siraj Abdullah (ID: 5684570)
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Email:** sfa0004@auburn.edu
- **Institution Unit:** Sports Medicine
- **Phone:** 334-844-9919

- **Curriculum Group:** IRB #1 Health Science Emphasis - AU Personnel - Basic/Refresher
- **Course Learner Group:** IRB #1 Health Science Emphasis - AU Personnel
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Key Personnel (including AU Faculty, Staff and Students) and Faculty Advisors involved primarily in biomedical research with human subjects.

- **Record ID:** 20354563
- **Report Date:** 07-Mar-2017
- **Current Score**:** 91

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Sep-2016	5/5 (100%)
Informed Consent (ID: 3)	11-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	19-Sep-2016	4/4 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	11-Aug-2016	3/3 (100%)
Privacy and Confidentiality - SBE (ID: 505)	19-Sep-2016	4/5 (80%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	11-Aug-2016	4/5 (80%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	19-Sep-2016	4/5 (80%)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Adam Anz (ID: 3392104)
- **Email:** anz.adam.w@gmail.com
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** Orthopedics
- **Phone:** 3347281998

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** HIPAA and Human Subjects Research
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 19283512
- **Completion Date:** 29-Sep-2016
- **Expiration Date:** 29-Sep-2019
- **Minimum Passing:** 80
- **Reported Score*:** 80

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Research and HIPAA Privacy Protections (ID: 14)	29-Sep-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Adam Anz (ID: 3392104)
- **Email:** anz.adam.w@gmail.com
- **Institution Affiliation:** Auburn University (ID: 964)
- **Institution Unit:** Orthopedics
- **Phone:** 3347281998

- **Curriculum Group:** IRB Additional Modules
- **Course Learner Group:** HIPAA and Human Subjects Research
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 19283512
- **Report Date:** 29-Sep-2016
- **Current Score**:** 80

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Research and HIPAA Privacy Protections (ID: 14)	29-Sep-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Kenny Brock (ID: 4497760)
- **Email:** kbrock@auburn.vcom.edu
- **Institution Affiliation:** Edward Via College of Osteopathic Medicine (ID: 2278)
- **Institution Unit:** Biomedical
- **Phone:** 3343191335

- **Curriculum Group:** Human Research
- **Course Learner Group:** Protection of Human Research Subjects
- **Stage:** Stage 1 - Stage 1

- **Report ID:** 14483662
- **Completion Date:** 10/23/2015
- **Expiration Date:** 10/22/2018
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	10/01/15	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	10/01/15	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	10/01/15	5/5 (100%)
Informed Consent (ID: 3)	10/02/15	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	10/02/15	4/4 (100%)
Records-Based Research (ID: 5)	10/04/15	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	10/05/15	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	10/05/15	5/5 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	10/05/15	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	10/05/15	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	10/05/15	3/3 (100%)
FDA-Regulated Research (ID: 12)	10/22/15	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	10/23/15	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	10/23/15	5/5 (100%)
International Studies (ID: 971)	10/23/15	3/3 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	10/23/15	3/3 (100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	10/23/15	3/3 (100%)
Students in Research (ID: 1321)	10/01/15	10/10 (100%)
Edward Via College of Osteopathic Medicine (ID: 14732)	10/23/15	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Kenny Brock (ID: 4497760)
- **Email:** kbrock@auburn.vcom.edu
- **Institution Affiliation:** Edward Via College of Osteopathic Medicine (ID: 2278)
- **Institution Unit:** Biomedical
- **Phone:** 3343191335

- **Curriculum Group:** Human Research
- **Course Learner Group:** Protection of Human Research Subjects
- **Stage:** Stage 1 - Stage 1

- **Report ID:** 14483662
- **Report Date:** 10/24/2015
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	10/01/15	7/7 (100%)
Students in Research (ID: 1321)	10/01/15	10/10 (100%)
Edward Via College of Osteopathic Medicine (ID: 14732)	10/23/15	No Quiz
Informed Consent (ID: 3)	10/02/15	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	10/02/15	4/4 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	10/01/15	3/3 (100%)
Records-Based Research (ID: 5)	10/04/15	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	10/05/15	5/5 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	10/05/15	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	10/05/15	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	10/05/15	3/3 (100%)
FDA-Regulated Research (ID: 12)	10/22/15	5/5 (100%)
International Studies (ID: 971)	10/23/15	3/3 (100%)
The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)	10/24/15	7/7 (100%)
Research and HIPAA Privacy Protections (ID: 14)	10/23/15	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	10/24/15	4/4 (100%)
Hot Topics (ID: 487)	10/24/15	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	10/23/15	5/5 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	10/23/15	3/3 (100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	10/23/15	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	10/01/15	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	10/05/15	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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Phone: 305-243-7970
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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Joseph Edison (ID: 3594298)
- **Email:** jedison@vcom.edu
- **Institution Affiliation:** Edward Via College of Osteopathic Medicine (ID: 2278)
- **Institution Unit:** Sports Medicine
- **Phone:** 334-442-4000

- **Curriculum Group:** Biomedical Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in **Biomedical Research**. This course contains text, embedded case studies AND quizzes.

- **Report ID:** 19845473
- **Completion Date:** 06/22/2016
- **Expiration Date:** 06/21/2020
- **Minimum Passing:** 80
- **Reported Score*:** 93

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Research Misconduct (RCR-Basic) (ID: 16604)	06/08/16	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	06/08/16	4/5 (80%)
Authorship (RCR-Basic) (ID: 16597)	06/09/16	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	06/09/16	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	06/21/16	5/5 (100%)
Using Animal Subjects in Research (RCR-Basic) (ID: 13301)	06/22/16	5/5 (100%)
Conflicts of Interest (RCR-Basic) (ID: 16599)	06/22/16	5/5 (100%)
Collaborative Research (RCR-Basic) (ID: 16598)	06/22/16	4/5 (80%)
Research Involving Human Subjects (RCR-Basic) (ID: 13566)	06/22/16	4/5 (80%)

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COURSEWORK TRANSCRIPT REPORT**

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Auburn University

Auburn University, Alabama 36849-5382

Institutional Biosafety Committee
115 Ramsay Hall Basement

Telephone: (334) 844-5966
FAX: (334) 844-4391

February 08, 2017

TO: Dr. Michael Goodlett
Sports Medicine

FROM: Dr. Mark Liles
Institutional Biosafety Committee, Chair

SUBJECT: Approval of BUA #751 Research Project

Your research proposal, *"Quantification of Stem Cells after Peripheral Mobilization and Harvest for Orthopedic Point of Care Application"* has been approved for 3 years as listed below by the Auburn University Institutional Biosafety Committee (IBC).

BUA Number: **751**
Application requires: **BL2 containment**
Additional comments: **None**
Expiration Date: **February 07, 2020**

If you have further questions or intend to modify this research, please do not hesitate to contact the IBC at biosafe@auburn.edu

APPENDIX A
References

Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

Related Literature (list of current [*last 5-years*] relevant studies):

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11. Saw KY, Anz AW, Merican S, Tay YG, Ragavanaidu K, Jee CS, McGuire DA. Articular Cartilage Regeneration with Autologous Peripheral Blood Progenitor Cells and Hyaluronic Acid After Arthroscopic Subchondral Drilling: A Report of 5 Cases with Histology. *Arthroscopy.* 2011 Apr; 27(4):493-506.
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13. Saw KY, Anz AW, Jee CS, Ng RC, Mohtarrudin N, Ragavanaidu K. High tibial osteotomy in combination with chondrogenesis after stem cell therapy: a histologic report of 8 cases. *Arthroscopy.* 2015 May; epub ahead of print.

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APPENDIX B
Flyer

Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

Interested in participating in a clinical research study?

We are seeking 10 healthy male volunteers wanting to advance stem cell research. We are looking for volunteers 19 to 39 years of age and weighing between 110 and 220 lbs.

Estimated 5 hours total for participation.

Reimbursement will be provided for time.

The Auburn University Institutional Review Board has approved this Document for use from 12/07/2016 to 12/06/2017
Protocol # 16-398 AR 1612

To find out if you are eligible to participate in this research study, please call 334-442-4001.

VCOM
Edward Via College of Osteopathic Medicine
AUBURN

Patient Information
Neupogen® (nu-po-jen)
(filgrastim)
injection

What is Neupogen?
Neupogen is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.
Acute Radiation Syndrome: The effectiveness of Neupogen for this use was only studied in animals, because it could not be studied in people.

Do not take Neupogen if you have had a serious allergic reaction to human G-CSFs such as filgrastim or pegfilgrastim products.

Before you take Neupogen, tell your healthcare provider **about all of your medical conditions, including if you:**

- have a sickle cell disorder.
- have kidney problems.
- are receiving radiation therapy.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex). You should not give Neupogen using the prefilled syringe if you have latex allergies. Ask your healthcare provider about using the vial if you have latex allergies.
- are pregnant or plan to become pregnant. It is not known if Neupogen will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Neupogen passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive Neupogen?

- Neupogen injections can be given by a healthcare provider by intravenous (IV) infusion or under your skin (subcutaneous injection). Your healthcare provider may decide subcutaneous injections can be given at home by you or your caregiver. If Neupogen is given at home, see the detailed "Instructions for Use" that comes with your Neupogen for information on how to prepare and inject a dose of Neupogen.
- You and your caregiver should be shown how to prepare and inject Neupogen before you use it, by your healthcare provider.
- Your healthcare provider will tell you how much Neupogen to inject and when to inject it. Do

not change your dose or stop Neupogen unless your healthcare provider tells you to.

- If you are receiving Neupogen because you are also receiving chemotherapy, your dose of Neupogen should be injected at least 24 hours before or 24 hours after your dose of chemotherapy.
- If you miss a dose of Neupogen, talk to your healthcare provider about when you should give your next dose.

What are the possible side effects of Neupogen?
Neupogen may cause serious side effects, including:

- Spleen rupture. Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach (abdomen) area or your left shoulder.
- A serious lung problem called acute respiratory distress syndrome (ARDS). Call your healthcare provider or get emergency medical help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- Serious allergic reactions. Neupogen can cause serious allergic reactions. These reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you have any of these symptoms, stop using Neupogen and call your healthcare provider or get emergency medical help right away.
- Sickle cell crises. You may have a serious sickle cell crisis if you have a sickle cell disorder and receive Neupogen. Serious sickle cell crises have happened in people with sickle cell disorders receiving Neupogen that has sometimes led to death. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- Kidney injury (glomerulonephritis). Neupogen can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms:
  - swelling of your face or ankles
  - blood in your urine or dark colored urine
  - you urinate less than usual
- Capillary leak syndrome. Neupogen can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - swelling or puffiness and are urinating less than usual
  - trouble breathing
  - swelling of your stomach-area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness

- Decreased platelet count (thrombocytopenia). Your healthcare provider will check your blood during treatment with Neupogen. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with Neupogen. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- Increased white blood cell count (leukocytosis). Your healthcare provider will check your blood during treatment with Neupogen. **The elevated white blood count could last 2 years.**
- Inflammation of your blood vessels (cutaneous vasculitis). Tell your healthcare provider if you develop purple spots or redness of your skin.

The most common side effects of Neupogen include aching in the bones and muscles.
These are not all the possible side effects of Neupogen. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Neupogen?

- Store Neupogen in the refrigerator between 36˚F to 46˚F (2˚C to 8˚C).
- Do not freeze.
- Keep Neupogen in the original carton to protect from light or physical damage.
- Do not shake Neupogen.
- Take Neupogen out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any Neupogen that has been left at room temperature for longer than 24 hours.
- After you inject your dose, throw away (dispose of) any unused Neupogen left in the vials or prefilled syringes. Do not save unused Neupogen in the vials or prefilled syringes for later use.

Keep Neupogen out of the reach of children.

General information about the safe and effective use of Neupogen.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Neupogen for a condition for which it was not prescribed. Do not give Neupogen to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Neupogen that is written for healthcare professionals.

What are the ingredients in Neupogen?
Active ingredient: filgrastim
Inactive ingredients: acetate, polysorbate 80, sodium, sorbitol, and water for Injection
Neupogen® (filgrastim)
Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799 U.S.A.
US License No. 1080 1xxxxxx v15

APPENDIX I

Monitoring Form

Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

Volunteer Number: _____

24 Hour After Mobilized Blood Collection

1. Date of Phone Call: _____
2. Time of Phone Call: _____
3. Question asked- How is your general health been and did you find the study uncomfortable
4. Volunteer's Comments:

_____
_____
_____
_____
_____

7-day After Mobilized Blood Collection

1. Date of Phone Call: _____
2. Time of Phone Call: _____
3. Question asked- How is your general health been and did you find the study uncomfortable
4. Volunteer's Comments:

_____
_____
_____
_____
_____

APPENDIX D

Home self-care sheet

Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

Bone marrow biopsy care sheet

General information

1. Your bone marrow biopsy site contains a pilot incision about the width of your pinkie finger nail, and this usually takes 24-48 hours for proper wound closure.

   Side effects that are common include:

   a. Slight bruising

   b. Slight oozing (which should subside within the first day)

   c. Slight pain for up to 24 hours after the procedure

2. **If the bleeding does not subside after you've left the medical clinic** (i.e., *there are signs of non-stop bleeding through your bandage*), then please call the following personnel (in order):

   a. Dr. Goodlett 334- 750-1293

   b. Dr. Adam Anz 334-728-1998

   c. Dr. Kenny Brock 334-319-1335

   One of these three persons will coordinate for someone to examine you.
   (*you may also text your name and that you're facing issues with your wound closure*)

Instructions for care

1. Keep the bandage on and report back to the laboratory **the day after** your procedure to ensure you are healing properly.

   I _____ will report back to Dr. Goodlett's medical staff at _____ (AM/PM) to ensure I have not complications.

2. You may shower the night of the biopsy, but please keep the bandage on for 24 hours until the site is re-inspected.

APPENDIX D

Home self-care sheet

3. During the first 48 hours, please abstain from:
    a. **Drinking >3 servings of alcohol**; to facilitate wound closure
    b. **Using NSAIDs** (Aspirin, ibuprofen, Advil, Aleve, Bayer, Motrin); to facilitate blood clotting at the wound site.
4. For 5 days after, please abstain from:
    a. **Swimming or taking a bath** (pool, tub, hot tub, etc.); to facilitate wound closure

You will receive a follow-up call 7 days following your procedure to ensure you are doing well.

If you have any concerns, please do not hesitate to call the individuals listed above and discuss your concerns.

APPENDIX G
Methods and Procedures

Quantification and Qualification of Stem Cells after Peripheral Mobilization and Harvest for Orthopaedic Point of Care Applications

The proposed study is a controlled laboratory study involving 10 healthy male volunteers. Once volunteers have been enrolled after clearing the screening form, consenting, and passing the medical screening and laboratory blood screening, a first collection visit for blood collection and bone marrow aspiration will be scheduled at the Auburn University Sports Medicine Clinic. Appendix H, a Neupogen information handout will be given during the consent process. During the first collection visit, another physical examination will be performed, including vital signs, height/weight, head/neck, cardiovascular, lung, and abdominal examinations. A standard venipuncture will be performed on the left or right upper extremity. A 5.0 mL vaccutainer tube will be filled with blood and a 60.0 ml syringe pre-filled with 8 ml of citrate anticoagulant will be filled with blood. The blood in the 5 mL vacutainer will be analyzed with flow cytometry, a histologic smear, a CBC with WBC differential, and chemokine/cytokine analysis with ELISA testing. The blood in the 60.0 mL syringe will be processed with the Arthrex Angel system. Processing produces three components: a plasma component, a buffy coat component, and a red blood cell component. The stem cells reside in the buffy coat component, and there are proteins of orthopaedic interest in the plasma component. The buffy coat component will be analyzed by flow cytometry, a histologic smear, a CBC with WBC differential, and chemokine/cytokine analysis with ELISA testing. The plasma component will undergo chemokine/cytokine analysis with ELISA testing. Next a bone marrow aspiration will be performed. This will involve having the volunteer lay on their side, outlining the iliac crest with ultrasound, prepping the skin with a sanitizing agent, numbing the skin with 20 mL of 1% lidocaine, a 1 cm incision in the skin, advancing a trocar into the bone marrow cavity, aspirating 5 cc of bone marrow with a 5 mL syringe and placement of the sample into a 5 mL vaccutainer syringe, and filling a 60.0 ml syringe pre-filled with 8 ml of citrate anticoagulant with bone marrow aspirate. The bone marrow in the 5 mL vacutainer will be analyzed by flow cytometry, a histologic smear, a CBC with WBC differential, and chemokine/cytokine analysis with ELISA testing. The bone marrow in the 60.0 mL syringe will be processed with the Arthrex Angel system. The buffy coat layer will be analyzed by flow cytometry, a histologic smear, a CBC with WBC differential, and chemokine/cytokine analysis with ELISA testing. The plasma layer will undergo chemokine/cytokine analysis with ELISA testing. Patients will then be scheduled for four mobilization visits followed by a second collection visit. The first of the four mobilization visits will be approximately thirty days after the first collection visit.

Approximately thirty days following the first collection visit, volunteers will undergo 4 serial days of mobilization. On the first day of the mobilization process, patients will undergo a 5 mL blood draw to obtain a CBC with WBC differential. After the blood draw, the patients will have a 10 mcg/kg dose of filgrastim administered subcutaneously into the thigh. Dosages will be rounded to 300 mcg, 600 mcg, 780 mcg, 840 mcg. Appendix H, a Neupogen information handout will be given after Neupogen administration. On days 2, 3, and 4 volunteers will undergo additional blood draws, for CBC with WBC differential determinations, and additional 10 mcg/kg dosages of filgrastim. On day 5, volunteers will have a standard venipuncture on the left or right upper extremity. A 5.0 mL vaccutainer tube will be filled with blood and a 60.0 ml syringe pre-filled with 8 ml of citrate anticoagulant. The blood in the 5 mL vaccutainer will be analyzed by flow cytometry, a histologic smear, and a CBC with WBC differential. The blood in the 60.0 mL syringe will be processed with the Arthrex Angel system. The buffy coat

component will be analyzed by flow cytometry, a histologic smear, a CBC with WBC differential, and chemokine/cytokine analysis with ELISA testing. The plasma layer will undergo chemokine/cytokine analysis with ELISA testing.

Due to the use of filgrastim, a safety and data monitoring plan will be implemented. This plan will include a follow-up phone call between the volunteers and Dr. Anz at the 7 day and 28 day time points after the last visit of the study. Patient's will be asked an open ended question: "How has your general health been and did you find the study uncomfortable. " Responses will be summarized in Appendix I "Monitoring Form." Expected side effects include bone pains and muscle aches. Any unexpected severe adverse events will be discussed with Dr. Goodlett and the IRB notified. Drs. Goodlett and Lisenby will review Appendix I Forms at 6 month time intervals.

Response Memo to Reiewers Requests for IRB protocol # 16-398

Dear Dr. Goodlett,

Your revisions to your protocol entitled " Quantification and Qualification of Stem Cells After Mobilization and Harvest for Orthopaedic Point of Care Application" were reviewed by the IRB. Before your protocol can be approved, additional information and revisions are requested.

The IRB's comments are as follows:

1. *"Start date needs to be later than approval.*
   Start Date Changed to May 1st 2017

2. *Consent Document*
   Drop last sentence of Cost and Compensation paragraph. "The treatment will be at your own expense.".
   Sentence Erased

3. *Add IRB email to contact information for the IRB."*
   Email Added.