SECTION 1

PROPOSAL RESEARCH GRANT APPLICATION

Application Detailed Instructions Link

Total Amount Requested: $ 50,000

DATE: July 31, 2017

This request is made by the undersigned, who also agree(s) to comply with the following:

(1) Funds granted as a result of the request are to be expended for the purposes set forth herein.
(2) All reports or original investigations supported by any grant made as a result of this request shall acknowledge support provided by the Orthopaedic Trauma Association.
(3) Reports will be made as required and necessary records and accounts, including financial and property controls, will be maintained and made available to the Orthopaedic Trauma Association.

<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>DEPARTMENT</th>
<th>SIGNATURE</th>
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</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td>MD</td>
<td>Orthopaedics</td>
<td></td>
</tr>
<tr>
<td>Samuel Hailu</td>
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<td></td>
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</tbody>
</table>

| Principal Investigator:   | MD    | Orthopaedics |           |
| Biruk Lambisso            |       |              |           |
| Sandra Hobson             | MD    | Orthopaedics |           |
| Lewis G. Zirkle           | MD    | Orthopaedics |           |
| Amy M. Cizik              | PhD, MPH | Orthopaedics |           |

OTHER INVESTIGATORS ASSOCIATED WITH PROJECT:

Addis Ababa University
Phone: +251 911 23 25 07
Email: lbiruklw@yahoo.com

Emory University
Phone: 434 841 3236
E-mail: sandralhobson@emory.edu

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Richland, Washington
Phone: 509 371 1107
Email: lewis.zirkle@signfracure.org

University of Washington
Phone: 206 819 0651
Email: amorgan2@uw.edu

Institution Name and Address:
Black Lion Hospital, Addis Ababa University
11 Zambia St.
Phone: +251 115 52 29 95
Email: orthopedics.som@aa.edu.et
### ABSTRACT OF RESEARCH PLAN

**PROJECT TITLE:**

Effect of silver or bleach irrigation solution on prevention of infection following open tibia fractures: A randomized controlled trial

**Abstract of research plan:** Please provide an abstract of 250 words or less with 5 underlined phrases for a project summary. Please avoid summaries of past accomplishments and the use of the first person. The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

**Background:** Early initiation of antibiotics, operative irrigation and debridement, and sterile dressing of open fractures are accepted measures taken to minimize infection of open fractures. However, the choice of irrigation fluid and postoperative dressing in a resource-limited setting remains controversial. In low-income countries, sterile normal saline is often very costly. Therefore, providers are often forced to choose between unsterile distilled water or a bleach solution.

**Objective:** The aim of this study is to determine the effectiveness of ionic colloidal silver solution irrigation and dressing in the prevention of infection after open tibia fractures.

**Methodology:** This is a three-arm randomized controlled trial comparing the use of colloidal silver solution, 0.025% bleach solution, and normal saline irrigation and dressing of open tibia fractures in adults. 255 adult patients with open tibia fractures excluding Gustilo-Anderson (GA) type IIC will randomized into three grounds. The intervention will be identical for all treatment groups according to a standard protocol except for the irrigation and dressing solutions. The primary outcome of the study is the infection rate. Secondary outcomes include wound healing, fracture union, duration of hospitalization, number of unplanned reoperations in 6 months and quality of life measured using the EQ-5D. Each outcome will be assessed at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after the initial intervention. Ultimately, this research has the rare opportunity to impact a large portion of the world’s population with a relatively low cost.
The study will be conducted within the Department of Orthopaedic Surgery, Black Lion University Hospital (BLH), Addis Ababa University, Addis Ababa, Ethiopia. The hospital is also known by its local name Tikur Anbessa Hospital. It is 850-bed tertiary referral hospital serving the capital city of Ethiopia with a population of at least three million people.\(^1\) BLH has over twenty departments providing specialty care. It is also the primary educational hospital and research center for Ethiopia, a country with a population of over 100 million people\(^2\) – almost one-third of the population of the United States. The Department of Orthopaedic Surgery has a stand-alone building dedicated solely to orthopaedic surgeries, clinics, and research on the BLH campus. This building contains 75 beds and 4 operating rooms for dedicated orthopaedic use. Operating rooms are available for use 24/7. The hospital is equipped with 24/7 running central laboratory with well-equipped microbiology department with culture and sensitivity facility.

BLH currently owns two colloidal silver generators capable of producing sufficient quantity and concentration of silver solution for the purposes of this study. Both generators are in good working condition. BLH has adequate storage space within the orthopaedic building to store the generated solution material needed for this project. Finally, BLH has multiple working computers and computer laboratory space more than adequate to perform data collection and analysis relevant for this project.

BLH currently has the surgical capacity to appropriately surgically treat tibial shaft fractures for the purposes of this study, including a sufficient stock of relevant implants such as external fixators and SIGN intramedullary nails.
SECTION 4

RESEARCH PLAN

Click for Research Plan Instructions

A. SCIENTIFIC AIMS (not exceed 400 words)

The aim of this study is to assess the effect of colloidal silver irrigation and dressing and 0.025% bleach irrigation solution and dressing on infection rates of open tibia fractures compared to sterile normal saline. This study investigates this in the setting of a major tertiary academic referral hospital in a low-income country. The null hypothesis is that there is no significant difference in infection rate between the three groups.

In low-income countries, sterile normal saline is often very costly. Therefore, providers are often forced to choose between unsterile distilled water or a bleach solution. Additionally, many patients with open fractures have a delayed presentation or delayed time to initial irrigation and debridement. In this different setting, it is unclear whether the non-superiority of solutions containing additives over normal saline would remain valid.

The primary outcome of this study is infection, including both superficial and deep infections. Secondary outcomes include patient function and quality of life as measured by the EuroQol-5 Dimensions (EQ-5D); wound healing including time to complete healing, rate of change in wound area or volume, or both, or time to skin grafting; nonunion; length of hospital stay; number of repeat operative irrigation and debridements; and re-operation within six months. Planned surgical revision will not be considered an adverse secondary outcome. Additionally, patient age, sex, length of time from injury to presentation, comorbidities, and time to administration of antibiotics will be recorded and considered as potential confounding variables. OTA-Open Fracture Classification (OTA-OFC) will also be collected.

If these results demonstrate superiority of open fracture treatment with any single solution, this study could be repeated as a multi-center trial in collaboration with neighboring institutions. If bleach irrigation solution and dressing seems superior in this study, other institutions could adopt this method with relatively little increase in cost. Alternatively, if these results demonstrate that sterile saline is superior, then the effort of using bleach solution could be discontinued in good conscience. Finally, if silver with distilled water is superior, then a cost and feasibility analysis could be performed to see if this could be substituted for irrigation solution at intuitions with poor access to sterile normal saline.

Ultimately, this research has the rare opportunity to impact a large portion of the world’s population with a relatively low cost.
Prevention of infection following open fractures has always challenged physicians and surgeons. Different established measures such as early initiation of prophylactic systemic and local antibiotics, prompt irrigation and debridement, fracture stabilization, and early soft tissue coverage are taken to prevent infection from developing. Despite all these measures, up to 50% of all Gustilo-Anderson (GA) type III fractures become infected.\(^4,5\) Additionally, one study reported that post-operative infection rate following intramedullary nail fixation of open and closed fractures is higher with decreased country income level, meaning that patients in low-income countries are especially vulnerable.\(^6\)

Effect of bacterial wound burden on wound healing has long been demonstrated.\(^7\) Irrigation is used to supplement systematic and thorough debridement in removing foreign material and decreasing bacterial load.\(^8\) However, choice of additives to the irrigation fluid is still controversial.\(^9\) Use of antibiotic additives in irrigation solution has not been shown to be superior in human studies while it adds cost, promotes resistance, and carries risk of anaphylaxis. Antiseptics have concentration-dependent detrimental effects on the viability and function of host cells. Although some antiseptics can be diluted enough to be nontoxic to cells in culture while retaining some bactericidal activity, there is little information about their use in open fractures.\(^5,10\)

Antiseptic solutions such as povidone iodine, bleach solution, and chlorhexidine have been used as additive of irrigation. But their effectiveness in lowering infection rates is still unclear in a low-income setting with a different environment and more delayed fracture presentation. Clinical studies have confirmed that bleach solution is bactericidal to organisms commonly encountered in open wounds.\(^11\)–\(^13\) Unfortunately, there exists substantial in vitro evidence that these solutions adversely affect the viability of host cells grown in cell culture. However, the detrimental effect of povidone iodine and bleach solution is concentration dependent.\(^7\) Modified bleach solution in 0.025% concentration is proved to be safe.\(^11\)

Electrically generated colloidal silver is another additive has been shown to have broad antimicrobial spectrum of action.\(^14\)–\(^16\) Not only it is effective alone but silver has also been shown to enhance susceptibility of bacteria to antimicrobials.\(^17,18\) Silver dressings has been shown to significantly increase susceptibility of bacteria to systemic antibiotics.\(^17\)

This work directly relates to the OTA’s mission, vision, and value statements by investigating a potential substantial improvement in care for the injured patient, involving an international team of investigators, and potentially prompting a change in hospital or even country-wide policy regarding open fracture treatment.
C. PREVIOUS WORK DONE ON THE PROJECT *(Not to exceed 400 words)*

Faculty at BLH including investigators named on this study have performed previous work investigating fracture epidemiology and infection rates to better estimate the necessary sample size for this study. In an epidemiology study published in 2005, Ahmed et. al report that 1177 adult patients presented to BLH with a tibia fracture within a three-year period.\(^\text{19}\) If averaged over one-month periods, this is approximately 32 to 33 tibia fractures of unknown type per month. A more recent follow-up study investigating tibia shaft fractures specifically revealed an incidence of 93 tibia fractures of unknown type within a three-and-one-half month period.\(^\text{20}\) Of these, 35 were open tibial shaft fractures. Among these, 9/35 (25.7\%) were Gustilo-Anderson type I, 8/35 (22.9\%) were type II, 12/35 (34.3\%) were type IIIA, 5/35 (14.3\%) were type IIIB and 1/35 (2.9\%) was type IIIC.\(^\text{20}\) Additionally, some necessary equipment including the colloidal silver generators have already been obtained specifically for this project.
D. METHOD (not to exceed 1200 words and 4 pages)

Study Design: Three-arm single-blind randomized controlled trial

Null Hypothesis: There is no significant difference in infection rate among open fractures irrigated and dressed with either colloidal silver solution (CSS), 0.025% bleach solution (DBS), or normal saline solution (NSS).

Sample Size Estimation:
Sample size was estimated assuming the infection rate for the control intervention to be 30%. It was estimated that this intervention would reduce the rate by 20% with 90% confidence interval and 80% power. Therefore, 74 patients per group are needed based on power analysis alone. To account for potential loss to follow-up, each group will contain 85 patients.

Randomization:
This study aims for 255 patients total with 85 per arm. Patients will be randomly allocated to treatment groups using a computer-based random number generator. The treating surgeon can identify the solution type during use. Therefore, the patient will be blind to the intervention but the treating surgeon will not. Only one eligible fracture per patient will be included in the study. The study fracture will be the most severe fracture type based GA type if a patient has multiple eligible fractures.

Inclusion criteria:
Patients will be included if they meet all the following criteria: uninfected open fracture of the tibia; extra-articular fracture; less than seven days from injury to first operative debridement; open fracture without vascular injury requiring repair (GA type IIIC); aged 18 years or older.

Exclusion criteria:
Patients will be excluded if they meet any of the following criteria: GA type IIIC open fracture; active clinical infection on presentation; intra-articular fracture; open fracture with more than seven days to first operative debridement; history of previous wound infection or osteomyelitis in the affected bone or leg (knee to ankle); previous fracture with retained hardware; less than 18 years of age; immunocompromised states specifically diagnosis of HIV, diagnosis of diabetes mellitus, immunosuppressive medication within past six months, severe renal or hepatic impairment; current prisoners; and unable to provide informed consent.

Patient Recruitment and Screening:
Please see Figure 1: Study trial conduct procedure

Study tools and Method
The primary outcome of the study is the infection rate. Secondary outcomes include time to wound healing, time to fracture union, duration of hospitalization, number of unplanned reoperations in 6 months and quality of life measured using the EQ-5D. Each outcome will be assessed at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after the initial intervention. Additionally, each fracture will be classified according to the OTA-OFC on presentation.21

Standardized Intervention:
In all the groups standardized interventions listed below will be undertaken:
1. Wound will be dressed with sterile gauze and temporarily stabilized via splint in emergency department (ED).
2. Prophylactic IV antibiotics will be administered in ED: ceftriaxone for Gustilo-Anderson types I and II, ceftriaxone and gentamycin for Gustilo-Anderson type III, and ceftriaxone, gentamycin, and metronidazole for gross and farmyard contamination.
3. Operative irrigation and debridement will be performed by the on-call resident after the study team has randomly allocated the patient to specific study group.

4. The injured extremity will be prepared with iodine and draped using sterile technique. Irrigation protocol will be as explained on next page and adequate debridement will be made by removing all gross debris, contaminant and dead tissue (muscle, fat, fascia, skin and bone).

5. Irrigation volume will be according to GA classification (Type I - 3 L, Types II and III – 6 L)\(^3\) of randomized solution then steriley dressed with a dressing that has been gently soaked in the same solution.

6. External fixator or intramedullary nailing will be used for fracture management based on surgeon’s choice.

7. Wounds will be irrigated and debrided every 2-3 days as deemed appropriate by the treating surgeon with the same irrigation solution as initially randomized.

8. Wounds will be closed primarily in GA types I and II; for GA types IIIA and IIIB the closure will be determined by the treating surgeon and may include acute or delayed primary closure, negative wound pressure therapy, split thickness skin graft, and/or fasciocutaneous or muscle flaps.

**Standard intervention for patients who develop infection (see figure?)**

1. Operative irrigation debridement will be performed every 2-3 days with the same irrigation solution as initial randomization

2. Twice daily dressing change will be done in the wards.

3. Cultures and sensitivities will be determined from intraoperative deep sample

4. Antibiotics will be given based on culture and sensitivities.

5. Implants will be retained unless it is difficult to control infection.

6. Fracture will be stabilized with external fixator if implants are removed or if not already stabilized by implants

**Data collection and analysis**

Data will be collected by either a trained research coordinator, trained resident, or trained physician in the emergency department, during hospitalization, and during subsequent clinic visits. A trained biostatistician will assist with statistical analysis. In short, an analysis of variance will be performed to determine if there is a significant difference between the study arms. Multivariate analysis will be used to identify potential confounding variables.

**Timeline**

The study designers anticipate a data collection period of approximately two years to recruit 255 patients with open tibial shaft fractures excluding GA type IIIC based on previously collected data.\(^{19,20}\) The data collection period is scheduled for March 2018 through March 2020. Prior to data collection, a research coordinator will be recruited to oversee data collection and analysis. Once grant funding obtained in early 2018, this funding will be used to obtain additional necessary supplies as detailed in the budget. A preliminary mid-collection analysis will be conducted in March of 2019 to investigate whether there are significant differences between any groups. The final data analysis will be performed in April and May of 2020 with a plan to submit for publication by the summer of 2020.

**Ethics regarding human subjects**
The specific inclusion and exclusion criteria are described above. The anticipated characteristics of the subject population are primarily young adults with a higher male predominance. They will be almost exclusively of native Ethiopian background with the majority (approx. 80%) from within the greater Addis Ababa area and the remainder from surrounding regions. General health status will likely be fair to good as patients with immunodeficient states will be excluded as described above.

This study has previously been approved by the BLH IRB at an earlier date. Because the PI left Ethiopia for fellowship, the study needed to be deferred. The PI has now returned and is well-established in Ethiopia, and this IRB is in the process of being renewed. Consent forms both in English and Amharic languages have been prepared and will thoroughly be explained verbally to the patient and any individuals accompanying the patient. All questions will be answered. The issues of confidentiality (the participant name or address will be used privately only to contact them in case the need arises) and privacy (interviews will be undertaken in a private situation as much as possible) will be respected by all involved in the study. Additionally, participants will be informed that they have a full right to refuse or discontinue participating at any time and their action will not have any effect on the care they receive.
REFERENCES (not to exceed 2 pages)

## F. FIGURES (if figures added outside of the text pages – **not to exceed 1 page**)

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<thead>
<tr>
<th>Steps</th>
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<th>Data collected</th>
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<td>Screening Form</td>
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Figure 1. Study trial conduct procedure
NAME: Samuel Hailu
TITLE: MD
Asst. Prof Ortho Surg
BIRTHDATE: May 15, 1985
PLACE OF BIRTH: Gondar, Ethiopia
NATIONALITY: Ethiopian (has active US visa status)
SEX (right click on the check in box/properties/default value/checked Male Male Female)

EDUCATION

<table>
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<td>Addis Ababa University, Addis Ababa, Ethiopia</td>
<td>MD</td>
<td>06/2009</td>
<td>Medicine</td>
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<tr>
<td>Addis Ababa University, Addis Ababa Ethiopia</td>
<td>Specialty certificate</td>
<td>02/2014</td>
<td>Orthopaedic Surgery</td>
</tr>
<tr>
<td>University of Toronto, Toronto Canada</td>
<td>Fellowship</td>
<td>12/2015</td>
<td>Orthopaedic Trauma/Arthroplasty</td>
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RELATIONSHIP TO PROPOSED PROJECT: Principal investigator

MAJOR RESEARCH INTEREST:
Orthopaedic trauma, pelvic and acetabular injuries, hip/knee arthroplasty

HONORS:
2009: Outstanding graduate of class of 2009 Medical Graduates, University of Addis Ababa
2012: Young Enthusiastic Orthopaedic Surgeon of 2012, Ethiopian Society of Orthopaedics and Traumatology
March 2014: OTC Foundation 4-week orthopaedic trauma travel fellowship to Harborview Medical Center, University of Washington, Seattle, WA
Jan 2015: Prakash Foundation low income country surgical scholarship, University of Toronto, Canada
2017: Recognition award for Pelvic and acetabulum work contribution as the only fellowship trained pelvic surgeon in Ethiopia, Ethiopian Society of Orthopaedics and Traumatology

OTHER RESEARCH SUPPORT
RESEARCH AND/OR PROFESSIONAL EXPERIENCE:


   Presented it on 15th annual ESS conference, Hawassa, Ethiopia

   Presented on 10th SIGN annual conference, Richland, Washington, USA
   Presented on 2011 EMA annual conference Addis Ababa, Ethiopia

   Presented on 6th annual ESOT meeting, Addis Ababa, Ethiopia

5. Surgical Treatment of Chronic Elbow Dislocation Allowing Early Range of Motion: Operative Technique and Clinical Results: accepted by JOT for publication

6. **Ongoing projects:**
   1. **Principal Investigator**, Biomechanics of associated both column acetabulum fixation options
   2. Principal Investigator: Pelvic and Acetabulum fracture Epidemiology and surgical outcomes in Addis Ababa
   3. **Local Principal investigator**: INternational ORthopaedic MUlticenter Study in Fracture Care (INORMUS)
   4. **Local Principal investigator**: Hipattck

Professional experience:

1. Lecturer, Department of Surgery, Black Lion Specialized Hospital, Addis Ababa University. June, 2009-January 2010.
2. Chief Resident, Department of Orthopedics, Black Lion Specialized Hospital, Addis Ababa University. January- December, 2013
NAME: BIRUK L.WAMISHO

TITLE: Consultant Orthopaedic Surgeon, Associate Professor, Head of Department

BIRTHDATE (Mo., Day, Yr.)
Aug 23, 1974

PLACE OF BIRTH (City, State. Country)
Shashemene, Ethiopia

NATIONALITY (If non-US citizen indicate visa status): ETHIOPIAN

SEX (right click on the check in box/properties/default value/checked)
Male ☒
Female ☐

EDUCATION (Begin with baccalaureate training and include postdoctoral.)

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<td>Gondar College of Medical Sciences, Ethiopia (1992-1999)</td>
<td>Degree of Doctor of Medicine</td>
<td>1999</td>
<td>Medicine (Human)</td>
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RELATIONSHIP TO PROPOSED PROJECT: CO-Investigator

MAJOR RESEARCH INTEREST: Orthopaedic Trauma, General Orthopaedics, Cartilage

HONORS: Many

OTHER RESEARCH SUPPORT: MoST National grant for Disability Rating Project.

RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)

I have been a Medical Doctor in public service for the last 20 years. I treat orthopaedic patients, teach residents and conduct related researches. Interested & involved in Medical Ethics and leadership.

Current Research Projects in Progress:

- MSK tumors at Blacklion Hospital: three decades analysis of magnitude and trends
- Waiting List for Orthopaedic Surgery at Black-Lion Hospital. What is happening while waiting?
- Retrograde femur nailing in Adolescents: Experimental Animal Study on Sheep.
- Transfusion Practice at Black-Lion Hospital/ blood donation
- Impact of Saturday Free Surgery on a patient waiting list.
- Orthopaedic Case-Mix and 30 year trends in a single department
- Permanent Physical Disability Rating in Ethiopia: Development of a Software.
More than 25 publications, recent ones:


Title: Adult limb fractures in Tikur Anbessa Hospital caused by road traffic injuries: Half year plain radiographic pattern.

Daniel Admassie, Tekle Yirga, Biruk L. Wamisho

Main author: Daniel A. Co-authors List: Biruk L.W, Tekle Yirga

Hard copy available:

Website: [http://ejhd.uib.no/ejhd-v24-n1/ejhdv24-n01-cover.html](http://ejhd.uib.no/ejhd-v24-n1/ejhdv24-n01-cover.html)


Title: Chronic Osteomyelitis at Tikur Anbessa Hospital, Addis Ababa University, Ethiopia. Biruk, W.L. & Wubshet, K.

Main author: Biruk L.W. Co-author List: Wubshet, K. Type; Original article.

Website: [http://www.bioline.org.br/abstract?id=js07005&lang=en](http://www.bioline.org.br/abstract?id=js07005&lang=en)


Website: [http://www.bioline.org.br/abstract?id=js09017&lang=en](http://www.bioline.org.br/abstract?id=js09017&lang=en)


NAME
Sandra Hobson

TITLE
MD

BIRTHDATE (Mo., Day, Yr.)
August 17, 1987

PLACE OF BIRTH (City, State. Country)
Lynchburg, VA, USA

NATIONALITY (If non-US citizen indicate visa status)
US

SEX (right click on the check in box/properties/default value/checked
Male
Female

EDUCATION (Begin with baccalaureate training and include postdoctoral.)

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<tr>
<td>Virginia Tech; Blacksburg, VA, USA</td>
<td>B.S.</td>
<td>2009</td>
<td>Chemical Engineering, GPA 4.0</td>
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<tr>
<td>University of Virginia; Charlottesville, VA, USA</td>
<td>MD</td>
<td>2014</td>
<td></td>
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<tr>
<td>Emory University, Atlanta, GA, USA</td>
<td>Resident</td>
<td>2019</td>
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RELATIONSHIP TO PROPOSED PROJECT
Resident co-investigator

MAJOR RESEARCH INTEREST
Access to orthopaedic and spine care in US and abroad

HONORS
Alpha Omega Alpha, Gold Humanism Honors Society, Phi Beta Kappa, Tau Beta Pi
Virginia Tech 2009 First in Class with class rank 1st of 6562

OTHER RESEARCH SUPPORT
None at current time

RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)

Select Ongoing Research, Publications, and Presentations

Yablanski V, Hobson S, Mardjetko S, Clements D, Ananthakrishnan D. Impact of seed implant donation on availability of spine surgical services in Bulgaria.

Garrard EC, Braly B, Simpson A, Hobson S, Heller JG. “A retrospective radiographic review of fusion rates at 3 months for one and two level anterior cervical disectomy and fusion with and without recombinant Bone Morphogenetic Protein-2.”


Hobson SL, Valeev EF, Stanton JF, Császár AG. Is the adiabatic approximation sufficient to account for the post-Born-Oppenheimer effects on molecular electric dipole moments? Molecular Physics 2009;107:1153-1159
### International Experience

<table>
<thead>
<tr>
<th>Location</th>
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<tr>
<td>Addis Ababa, Ethiopia</td>
<td>02/2/17 – 02/26/17</td>
<td>Visiting Resident Orthopaedic Surgeon, Black Lion University Hospital</td>
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<td>Accra, Ghana</td>
<td>05/1/16 – 05/08/16</td>
<td>Visiting Resident Orthopaedic Surgeon, FOCOS Orthopaedic Hospital with Dr. Boachie-Adjei</td>
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<td>Geneva, Switzerland</td>
<td>04/2014 – 05/2014</td>
<td>Intern, World Health Organization, Programme for Emergency and Essential Surgical Care (EESC)</td>
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<td>Kigali, Rwanda</td>
<td>02/2014</td>
<td>Visiting Medical Student, Centre Hospitalier Universitaire de Kigali (CHUK)</td>
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<tr>
<td>Copenhagen, Denmark</td>
<td>07/2008 – 08/2008</td>
<td>Student, Technical University of Denmark</td>
</tr>
<tr>
<td>Paris, France</td>
<td>05/2007 – 06/2007</td>
<td>Student, Alliance Française</td>
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### Professional Society Leadership and Board Positions

#### Emory University Department of Orthopaedics
- Selection committee member for visiting rotating medical student selection 2016 – present
- Resident advisor to medical student orthopaedic interest group 2015 – present
- Interviewer for orthopaedic residency interviews 2014 – present

#### Ruth Jackson Orthopaedic Society
- Committee Member, Scientific Committee 06/2017 – present

#### American Academy of Orthopaedic Surgeons (AAOS)
- Committee Member, Resident Practice Management Committee 03/2015 – 03/2016

#### American Medical Association (AMA) and Medical Society of Virginia (MSV) Leadership Positions
- Director to the Board of Directors, MSV Foundation 08/2013 – 07/2014
- Associate Director to the Board of Directors, MSV Foundation 08/2012 – 07/2013
- Delegate to the AMA Medical Student Section (AMA-MSS) for UVASOM 06/2012, 06/2013
- Committee Member, AMA-MSS National Committee on Long-Range Planning (COLRP) 01/2012 - 07/2012
- Student Representative to the Board of Directors, MSV Political Action Committee 07/2011 – 07/2012
<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>BIRTHDATE (Mo., Day, Yr.)</th>
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<tbody>
<tr>
<td>Lewis G Zirkle</td>
<td>MD</td>
<td>7/23/40</td>
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<tr>
<th>PLACE OF BIRTH</th>
<th>NATIONALITY (If non-US citizen indicate visa status)</th>
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<tr>
<td>Pittsfield, Massachusetts, US</td>
<td>US</td>
<td>Male ☑, Female □</td>
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**EDUCATION** (Begin with baccalaureate training and include postdoctoral.)

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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
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<tr>
<td>Davidson College</td>
<td>BS</td>
<td>1962</td>
<td>Biology – chemistry</td>
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<tr>
<td>Duke University Medical Center</td>
<td>MD</td>
<td>1966</td>
<td>Medicine</td>
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**RELATIONSHIP TO PROPOSED PROJECT**
Participant and research

**MAJOR RESEARCH INTEREST**
Fracture treatment in developing countries

**HONORS**
- humanitarian award – Duke University Medical Center and AAOS
- John W. Kuykendal award, Davidson College

**OTHER RESEARCH SUPPORT**
None

**RESEARCH AND/OR PROFESSIONAL EXPERIENCE** (Start with present position: list ALL experience relevant to project. Include publications.)
- Pres. and founder – SIGN fracture care international


Stephens, Kyle R. DO; Shahab, Faseeh MBBS; Galat, Daniel MD; Anderson, Duane MD; Shahabuddin MBBS, FCPS (Ortho); Whiting, Paul S. MD; Lundy, Douglas W. MD; Zirkle, Lewis G. MD. Management of Distal Tibial Metaphyseal Fractures with the SIGN Intramedullary Nail in 3 Developing Countries. Journal of Orthopaedic Trauma. December 2015. Volume 29, Issue 12, P e469-e475.


Zirkle, L.G.: Understanding the Impact of Our Creativity; Orthopreneur, July/August 2010


Paul DeVasConCellos; Susmita Bose; Haluk Beyenal; Amit Bandyopadhyay; Lewis G. Zirkle.: Antimicrobial Particulate Silver Coatings on Stainless Steel Implants for Fracture Management. Elsevier


Patrick Sekimpi, Kanu Okike, Lewis Zirkle, Andrew Jawa; Fe,pra; Fracture Fixation in Developing Countries. Journal of Bone and Joint Surgery Inc. 2011


**NAME:** Cizik, Amy M.  
**TITLE:** Research Assistant Professor  
**BIRTHDATE (Mo., Day, Yr.):** [ ]  

**SEX** (right click on the check in box/properties/default value/checked  
Male [ ]  
Female [X]  

**PLACE OF BIRTH (City, State. Country):**  
**NATIONALITY (If non-US citizen indicate visa status):**  

**EDUCATION** (Begin with baccalaureate training and include postdoctoral.)

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<th>FIELD OF STUDY</th>
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<tr>
<td>University of Missouri-Kansas City, Kansas City, MO</td>
<td>BA</td>
<td>07/2001</td>
<td>Chemistry</td>
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<tr>
<td>University of Missouri-Kansas City, Kansas City, MO</td>
<td>BA</td>
<td>07/2001</td>
<td>Psychology</td>
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<tr>
<td>University of Kansas, Kansas City, KS</td>
<td>MPH</td>
<td>05/2004</td>
<td>Public Health and Epidemiology</td>
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<tr>
<td>University of Washington, Seattle, WA</td>
<td>PhD</td>
<td>12/2016</td>
<td>Health Economics and Outcomes Research</td>
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**RELATIONSHIP TO PROPOSED PROJECT:** Coinvestigator and biostatistician  
**MAJOR RESEARCH INTEREST:** health economics and outcomes researches with a clinical focus in orthopaedics

**HONORS**
- 2001 Certificate of Appreciation presented by the American Cancer Society
- 2002 Kansas Health Institute Summer Internship Program
- 2003 University of Kansas Graduate Student Travel Scholarship
- 2011 Eli Lilly Pre-doctoral Endowed Fellowship Stipend
- 2012 Thomas Francis, Jr. Global Health Travel Fellowship
- 2014 Graduate School Fund for Excellence and Innovation Travel Award
- 2016 University of Washington, School of Pharmacy, Reducing Barriers for the Ambitious Scholarship

**OTHER RESEARCH SUPPORT**
- **1R21 AR068632 Flum (PI) 09/15/2015-08/31/2018**
  Topical Antibiotic Treatment for Spine Surgical Site Infections.
  This grant supports several pilot and feasibility studies that are necessary to enable the execution of a cluster randomized controlled trial (cRCT) of in-wound antibiotics for spine fusion surgery.
  Role: Co-Investigator (0.10 FTE)

- **R21AR068009 Flum (PI) 07/01/2015-06/30/2018**
  This study aims to identify and address modifiable factors may improve spine fusion surgery outcomes.
  Role: Co-Investigator (0.10 FTE)

- **Surgical Dynamics Chair, University of Washington Chansky (Chair) 2014 – 2017**
  The goal of this chair is to provide research support to surgical faculty members in the field of spine research.
  Role: Staff Scientist, Clinical Research Administration

- **Synthes Endowed Fund, University of Washington Chansky (Chair) 2009 – 2017**
  The purpose of this endowment shall be to set patient-centered standards of care for the surgical solutions to spinal disorders. The fund will provide support to bring together spine surgeons, clinical researchers and basic scientists in this effort.
  Role: Staff Scientist
RESEARCH AND/OR PROFESSIONAL EXPERIENCE


Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1VYC62kNGV5m/bibliography/40000710/public/?sort=date&direction=descending

Professional Experience
2007-15 Abstract Reviewer and Session Moderator, Undergraduate Research Symposium, University of Washington
2010-14 Scholar Member, Institute of Translation Health Sciences
2011-13 Student Member, International Society for Pharmacoeconomics and Outcomes Research
2014-17 Associate Member, Orthopaedic Research Society
**SECTION 6**

**RESEARCH SUPPORT, SUBMISSIONS**

Please combine the information on this page for PI and Co-PI. Add additional lines and pages as needed, there is no word limit in this section.

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<tbody>
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<td><strong>SOURCE OF SUPPORT</strong></td>
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<td>Please see above descriptions.</td>
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