

# STAR PROGRAM OVERVIEW AND SUBMISSION GUIDELINES

# **Student Training in Approaches to Research (STAR) Guidelines**

**Program Purpose**: Hands-on summer research experience for Loyola medical students, building skills in basic science and clinical research.

**Eligibility**: Loyola medical students in good standing, committed to a full-time, 8-week research schedule.

### Key Requirements:

- **Full-time Research**: 40 hours/week for 8 weeks.
- Educational Engagement: Attend STAR seminars and journal clubs
- **Presentation**: Required poster presentation at St. Albert's Day.

Mentorship: Loyola-affiliated mentor; each mentor may oversee up to 2 students.

### Important Dates:

- Letter of Intent Due: December 2, 2024
- Final Proposal Due: January 21,2025



# **Key Dates and Timelines**

- December 2, 2024: Letter of Intent (LOI) Due
  - Brief project summary required for initial review.
- January 21, 2025: Final Proposal Submission Due
  - Full research proposal, including background, methods, and anticipated results.
- March 17, 2025: STAR Participants Announced
  - Ensure mentor has reviewed and approved the proposal; obtain required IRB/IACUC if necessary.
- Summer 2025: Research Conducted
  - 8-week, full-time research (40 hours/week) with seminar and journal club participation.
- Fall 2025: Poster Presentation at St. Albert's Day
  - Share findings with the Loyola community.





# **Letter of Intent**

These proposals represent real, ongoing projects from your peers. Please do not publish these or reproduce them in any way. These must remain in-house for Loyola Students only.

# Letter of Intent (LOI) for STAR Program

**Purpose of LOI**: Formally declare intent to apply for STAR funding & establish the student's commitment and mentor's support.

### LOI Components:

- **Project Title & Summary**: Brief overview of the research topic.
- **Mentor Details**: Name, department, and role in the research project.
- Student-Mentor Acknowledgments:
  - Student awareness of STAR requirements and commitment to attend all seminars.
  - Mentor assurance of providing necessary resources .
  - Affirmation that funding is solely for student expenses.

### Submission Requirements:

- LOI submission deadline: December 2, 2024.
- Acknowledgment of responsibilities by both student and mentor.

### Tips for a Strong LOI:

- Keep concise but cover all project goals and requirements.
- Ensure mentor and student have discussed project feasibility in detail.

#### **Application Details**

#### Proposal Title

Investigating the Anti-LSC Efficacy of TAK1/TBK1 Parallel Blockade in MLL-AF9+ AML

#### Comments to the Administrator(s)

MLL-AF9+ acute myeloid leukemia (AML) cells can be separated into 3 subsets using the c-KTI (CD117) and FLT3 (CD135) surface markers. Leukemia stem cells (LSCs) are c-KIT+ and can further be separated based on FLT3 status: the least differentiated/most stem-like LSCs ("LMPP-like") are FLT3+ whereas the more differentiated/less stem-like LSCs ("GMP-like") are FLT3-. Non-stem AML cells ("blast cells") are negative for both c-KIT and FLT3.

Previous data from Cannova and Runde of our group have shown, respectively, that TAK1 and TBK1 (Ser/Thr protein kinases involved in TLR & NF-KB signaling) are differentially required for the survival of MLL-AF9+ LSCs: <u>GMP-like LSCs rely on TAK1</u> whereas <u>LMPP-like LSCs rely on TBK1</u>. As eradication of both pools of LSCs is necessary to maintain remission in AML, we propose parallel blockade of TAK1/TBK1 + standard daunorubicin/cytarabine chemotherapy as a potential means of AML therapy.

We will treat human MLL-AF9+ AML cell lines (in vitro) with TAK1 and TBK1 inhibitors, both separately and in combination, as well as with daunorubicin and cytarabine to determine potential anti-LSC/anti-AML efficacy. Flow cytometry will be the primary means of assessing change in/elimination of AML cell populations; use of a 3D matrix-based approach is being considered to augment our study, as a means of better mimicking the bone marrow microenvironment which is heavily regulated by stromal and endothelial cells.

#### Acknowledgment

#### Student Acknowledgment

[Acknowledged] The following student/research mentor team intends to submit an application for funding to the Stritch School of Medicine STAR Scholarship Program.

By submission of this Letter of Intent, we acknowledge and affirm:

The student is aware of all STAR requirements, including **<u>mandatory</u>** attendance at <u>all</u> STAR seminars, and that all requirements must be met in order to apply for funding.

The student will take the primary responsibility for completing the application.

The student and research mentor have had sufficient discussion so that the student will be able to submit a high quality STAR application.

The research mentor has all the necessary resources needed for the STAR research project and is responsible for providing same to the student. The STAR scholarship award is for the student's personal expenses associated with a summer research experience (i.e. housing, transportation, etc.) and is not to be used for research supplies.

# **LOI Examples**



#### **Application Details**

#### **Proposal Title**

Title: Using Machine Learning to Assess Accuracy of Clinical Practices Across Racial Subgroups

#### Proposal Abstract

#### Comments to the Administrator(s)

Clinical biases can be perpetuated by using risk thresholds that may not capture all patient populations, potentially leading to systematic risk of underprediction or overprediction. In this retrospective study, we intend to use machine learning using a natural language processing model to garner information from the Loyola University Medical Center's EHR. We will reference specific scores for cut-off values and determine if certain patient subgroups have different predicted probabilities for an outcome. Then, we will work on reestimation to examine if any methods can improve predictive accuracy. The specifics of this project's aims will be further refined with Dr. Joyce.

#### Acknowledgment

#### **Student Attestation**

[Acknowledged] I understand that all regulatory approvals (e.g IRB, IACUC) will need to be completed prior to the start of the project.

#### **Application Details**

#### **Proposal Title**

In Vitro Analysis of Antibiotic and Irrigation Effects on Staphylococcus aureus Biofilms and Staphylococcus aureus- Pseudomonas aeruginosa Co-Biofilms on Orthopedic Implant Materials

#### **Proposal Abstract**

Comments to the Administrator(s)

#### Acknowledgment

#### **Student Attestation**

[Acknowledged] I understand that all regulatory approvals (e.g IRB, IACUC) will need to be completed prior to the start of the project.

#### Application Details

#### Proposal Title

Factors Associated with Blood Pressure Control and Therapeutic Inertia

#### **Proposal Abstract**

Background: Hypertension (HTN), or high blood pressure (BP), affects nearly half of all United States (US) adults. Despite the cardiovascular risks associated with HTN, less than half of adults with HTN receive blood pressure (BP)-lowering medications in accordance with the 2020 international HTN practice guidelines. One major obstacle for achieving BP control is the failure of clinicians to intensify treatment when BP remains above therapeutic goals (<140/90 mmHg), a phenomenon termed "therapeutic inertia." Other factors include lack of automated office BP (AOBP) measurement to confirm elevated clinic BP readings, lack of timely follow-up visits for patients with uncontrolled BP, and low prescribing rates of diuretics and combination agents. In October of 2018, Loyola outpatient clinics enrolled in the Measure Accurately, <u>A</u>Ct Rapidly, <u>Partner with Patients (MAP) BP</u> control program, a nationwide HTN quality improvement program funded by the U.S. Congress and implemented by the American Medical Association (AMA). We previously utilized data from participating Loyola clinics that showed an approximate 10% increase in BP control rates after implementation of the MAP BP Program. However, we also showed that improvements in HTN control were not uniform across sex and age groups.

In this study, we will use an existing retrospective patient cohort that includes 21,861 patients who received care at one of 14 Loyola outpatient primary care clinics to determine factors associated with higher rates of BP control at the prescribing clinician level, following implementation of the AMA MAP BP program.

<u>Hypothesis</u>: Clinicians with higher rates of BP control will have higher rates of documented AOBP use when clinic BP reading exceeds 140/90 mmHg, have higher rates of prescriptions for thiazide diuretics and combination pills, and have more patient follow-up visits within 4 weeks of a clinic visit when BP exceeds 140/90 mmHg compared to clinicians with lower rates of BP control. Specific Aims:

- Stratify providers into tertiles of BP control rates (proportion of a provider's patient panel with HTN and BP reading <140/90 mmHg recorded at last clinic visit during 2019-2020).</li>
- Compare frequency of 1) documented AOBP use, 2) prescription rates for thiazide diuretics and fixeddose combination pills, and 3) frequency of 4-week follow up after clinic visits when BP exceeds 140/90 mmHe across tertiles of orovider BP control rates.
- Repeat analysis after controlling for baseline risk of cardiovascular disease (CVD) (defined as age 65+ vears and/or ICD10 codes for diabetes. CVD, and chronic kidney disease).

Brief Methods: Patient and provider level data from our retrospective patient cohort of 21,861 patients with HTN seen in one of 14 outpatient primary care clinics at Loyola during calendar years 2019-2020 will be analyzed using mixed effects modeling in STATA statistical software (StataCorp. College Station, TX). Mixed effects models will determine whether provider level factors (use of AOBP, prescribing thiazides and combination medications, and use of follow-up visits) differ by tertiles of provider level BP control rates for their patient panel.

Comments to the Administrator(s)

#### Acknowledgment

#### Student Attestation

[Acknowledged] I understand that all regulatory approvals (e.g IRB, IACUC) will need to be completed prior to the start of the project.



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# **MENTOR SECTION**

### **Research Activities for Student**

- Clearly outline specific tasks the student will undertake, linking them to the project's aims.
- Describe how these activities build relevant skills and align with the project goals.

### **Research Environment**

- Detail the lab or clinical setting, including access to facilities and tools essential for your research.
- Highlight the qualifications of the immediate research supervisor to demonstrate strong mentorship support.

### **Research Education Plan**

- Include structured educational components like lab meetings, journal clubs, and relevant seminars.
- Explain how each element supports learning and development in your research area.

### **Research Education Oversight**

- Describe the frequency and structure of mentor-student meetings to ensure progress.
- Mention any checkpoints for feedback on the project.

### **Research Activities for Student**

- Clearly outline specific tasks the student will undertake, linking them to the project's aims.
- Describe how these activities build relevant skills and align with the project goals.

#### MENTOR: Please describe: Research Activities for Student:

Mr. Dimond will work with an existing STATA database of patient data from 21,861 patients with a HTN diagnosis who received care at one of Loyola's 14 outpatient primary care clinics. He will analyze the data as described in the aims of this application. He will link patients and patient visits with a given prescribing clinician. For patients seen by more than one prescribing clinician, we will assign the patient to the prescribing clinician with whom the patient had the most visits. Patient panels for a given prescribing clinician will then be categorized by rates of BP control based on the last clinic visit during 2019-2020. Based on the BP control rates for a given patient panel, he will compare the frequency of documented AOBP for clinic visits with BP  $\geq$  140/90 mmHg, prescribing rates of thazide diuretics and combination medications, and frequency of 4-week follow-up visits following clinic visits when BP exceeded 140/90 mmHg. Analyses will be repeated after stratifying by high CVD risk defined as patient age  $\geq$  65 years, and/or ICD10 diagnosis of diabetes, cardiovascular disease or chronic kidney disease.

Once the analysis is complete, Mr. Dimond will create tables and figures for a manuscript and draft an abstract for St. Albert's Day. We also anticipate Mr. Dimond will submit an abstract to the American Heart Association or the American Society of Nephrology. Mr. Dimond will then work with Dr. Kramer to draft a manuscript which will be circulated to co-authors. We anticipate that HTN experts from the American Medical Association will be co-authors on the abstract and the manuscript. This will provide Mr. Dimond exposure to national experts and researchers within the field of HTN.

### MENTOR: Please describe:

 Research Activities for Student:

 Madison will be working on a project investigating the differences in biofilm eradication from stainless steel for a *S. aureus* biofilm compared to a polymicrobial biofilm using various irrigation solutions in vitro. The goal is to identify the how the polymicrobial nature of the biofilm affects efficacy of treatment in the presence of orthopaedic implants. During the STAR research time she will work in concert Dr. Preei Muire, PhD, who has extensive experience with microbiological research specifically as it pertains to the field of orthopedics. She will also work with Matthew Baldridge, a research assistant in my laboratory, who can assist her with day to day experimental tasks. During the experiment, Madison will have access to myself, Dr. Muire and Dr. Callaci for questions and troubleshooting. In addition to her

laboratory experiment, she will also participate in data analysis and poster/abstract preparation.



### **Research Environment**

- Detail the lab or clinical setting, including access to facilities and tools essential for your research.
- Highlight the qualifications of the immediate research supervisor to demonstrate strong mentorship support.

Describe the Research Environment: Dr. Cara Joyce is a biostatistician and an Assistant Professor in the Department of Medicine. She works with new and experienced investigators in a team science approach to design and plan studies, perform statistical analysis, and disseminate results. Much of her research has focused on clinical prediction modeling, from development and validation to prospective evaluation of models implemented in real-world settings, such as this project.

Dr. Joyce is also Director of the Biostatistics Core, leading a team of 8 statisticians conducting collaborative clinical research. The Biostatistics Core is a lively hub of members engaged in daily discussions of research methods and applications and has supported many student interns and trainees throughout her tenure as director.

### **Describe the Research Environment:**

Dr. Ashley Levack, Assistant Professor of Orthopaedic Surgery, Attending Orthopaedic Trauma Surgeon, and BSTRI faculty member will be the primary mentor. She has translational research experience in the realm of orthopaedic infection and local antibiotic delivery and has received a research development grant from the AO North America and funding from the Loyola Research Funding Committee to pursue her research. She has personally developed the protocols involved in her project and has previously mentored research assistants as well as a prior STAR students in the laboratory. She has dedicated benchtop space in the CTRE to perform translational research experiments. In addition, Madison will have the mentorship of Dr. Preeti Muire, a PhD researcher in Dr. Levack's laboratory with extensive experience with in vitro and in vivo microbiologic experiments pertaining to fracture-related infection research. Furthermore, Madison will have access to Dr. Levack's research collaborator Dr. John Callaci who has over 10 years of experience mentoring scientists at all levels of training. In addition, Madison will collaborate daily with Dr. Levack's research assistant Matthew Baldridge.



### **Research Education Plan**

- Include structured educational components like lab meetings, journal clubs, and relevant seminars.
- Explain how each element supports learning and development in your research area.

<u>Research Education Plan</u> (include required research meetings, seminars, journal clubs, etc. Note: clinical shadowing is not considered research education, with the exception of observation of specifically described clinical research activities.)

We have lab meeting every Friday afternoon; Austin will present his research data and relevant publications in our weekly lab meeting. We also have an annual lab retreat in July, where all lab members are asked to summarize their research project and give a detailed presentation on the current progress and future plans. In addition, Austin will attend the seminars and journal clubs in the LUC's Dept. of Cancer Biology, IPBS's BMBC program, and CBCC's Dept. of Hematology/Oncology with Dr. Kevin Barton and Dr. Patrick Hagen. Austin is also encouraged to attend the Grand Rounds every Friday morning for exposure to clinical research.

<u>Research Education Plan</u>: Gillian will learn about the statistical methods and models for detecting algorithmic bias, through a curated set of articles and book chapters accumulated on this evolving topic. I also teach courses in R programming, and have a lecture notes and lab activities to prepare Gillian for the data analysis. I will provide guidance and practical experience in data management, statistical programming, and model interpretation throughout the project. Gillian will attend the Biostatistics Core weekly meetings where we present on research methods and select journal club topics. Gillian may also attend study design consultations with Biostatistics Core team members ad hoc to gain more exposure to the process of developing and refining research projects.



### **Research EducationOversight**

- Describe the frequency and structure of mentor-student meetings to ensure progress.
- Mention any checkpoints for feedback on the project.

<u>Research Education Oversight</u> (including how often you commit to meeting with the student to ensure that the student receives an excellent research training experience.)

I will meet Austin 2-3 times a week to make sure he best understands the concept and experimental techniques of his research project. I will be available most of the time in my office for Austin if he has any research questions.

#### **Research Education Oversight**

I will meet with Madison one-on-one at least once per week to discuss her project and informally as often as required to make sure she stays on track. We will meet as a group once a week for lab meeting and he will have access to daily informal mentorship from Dr. Muire and members of the Callaci lab as well for help throughout her research time.



#### MENTOR:

<u>Research Activities for Student</u>: Gillian will lead in the design, data collection, and analysis of the proposed research project. She will prepare the IRB protocol and identify the variables needed from the clinical research database. Gillian will use the R programming language to prepare the data, perform the statistical analysis and modeling with my guidance, as well as drafting the tables/figures and developing a manuscript for peer review.

Describe the Research Environment: Dr. Cara Joyce is a biostatistician and an Assistant Professor in the Department of Medicine. She works with new and experienced investigators in a team science approach to design and plan studies, perform statistical analysis, and disseminate results. Much of her research has focused on clinical prediction modeling, from development and validation to prospective evaluation of models implemented in real-world settings, such as this project.

Dr. Joyce is also Director of the Biostatistics Core, leading a team of 8 statisticians conducting collaborative clinical research. The Biostatistics Core is a lively hub of members engaged in daily discussions of research methods and applications and has supported many student interns and trainees throughout her tenure as director.

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Research Education Oversight: Gillian and I will have a formal check-in at least weekly, and she has full access to me throughout the work week during the 8-week STAR program and beyond.



#### MENTOR: Please describe:

#### Research Activities for Student:

Mr. Dimond will work with an existing STATA database of patient data from 21.861 patients with a HTN diagnosis who received care at one of Loyola's 14 outpatient primary care clinics. He will analyze the data as described in the aims of this application. He will link patients and patient visits with a given prescribing clinician. For patients seem by more than one prescribing clinician, we will assign the patient to the prescribing clinician, for patients when the prescribing clinician with whom the patient had the most visits. Patient panels for a given prescribing clinician will then be categorized by rates of BP control based on the last clinic visit during 2019-2020. Based on the BP control rates of BP control rates of the compare the frequency of documented AOBP for clinic visits with BP ≥ 140090 mmHg, prescribing rates of thiazide diuretics and combination medications, and frequency of 4-week follow-up visits following clinic visits when BP exceeded 140090 mmHg. Analyses will be repeated after stratifying by high CVD risk defined as patient age ≥ 65 years, and/or ICD10 diagnosis of diabetes, cardiovascular divisiase or chronic kinkey disease.

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#### Describe the Research Environment:

Dr. Kramer is a HTN specialist who has mentored several STAR students in the past and every STAR student has published a manuscript. Dr. Kramer was a co-leader for the implementation of the AMA MAP BP program within Loyola clinics and helped develop the treatment protocol for the program. Mr. Dimond will be supported by the Loyola MAP BP team which includes Dr. Bea Probst who is the Director of Ambulatory Care Quality at Loyola and who heads the analytic team. The team also includes Dr. Talar Markosian who is a health services researcher with a strong background in statistics and use of STATA software. Loyola Medical Center also has two full-time analysts who will help pull data from the electronic medical record and merge with existing dataset and help with data cleasing and analysis. This project has been approved by Dr. Bea Probst and we have the full support of the Loyola AM AM PB PP torgram analysis team.

Mr. Dimond will meet with our research team on a weekly basis but will work at a computer outside of Dr. Kramer's office in the CTRE building. The computer has STATA software and he will have access to a printer and far machine.

#### Research Education Plan:

Mr. Dimond will utilize YouTube videos from STATA software company to learn the basics of STATA and he has already started this process. Please keep in mind that Mr. Dimond already knows how to use R statistical software because be learned on his own. Unfortunately, our team does not use R software so he now has to learn STATA software. I do not think this will be an issue as STATA software is more user friendly with pulldown menus. We have worked with multiple students in past and all students have been able to learn STATA without major issues or difficulties.

During weekly video conferences, we will work as a team to work through analytical issues and walk Mr. Dimond through the analytic plans. Dr. Kramer will also work with Mr. Dimond on a one-on-one basis to develop tables and figures with the data he has analyzed. We also have the support of a full-time data analyst if problems arise that Drs. Kramer or Markossian cannot solve.

Mr. Dimond will have a very rapid rate of learning during the STAR summer period. However, we have a dataset ready for him to use and we have gained experience with this dataset and have analytic support. We believe Mr. Dimond will gain skills in use of a new statistical software program (STATA) and will learn mixed effects modeling and use of electronic health data. He will also gain skills in creating tables, figures and drafting abstracts and manuscripts. We also anticipate he will present at a national meeting based on this work.

#### **Research Education Oversight:**

Mr. Dimond will be given the opportunity to work at a computer outside my office so we could meet face to face at least three times per week. Our research team will meet via video conference (Dr. Probst is in Montana) once a week to go over data and discuss any problems that arise.

#### MENTOR: Please describe:

#### **Research Activities for Student:**

Madison will be working on a project investigating the differences in biofilm eradication from stainless steel for a *S. aureus* biofilm compared to a polymicrobial biofilm using various irrigation solutions in vitro. The goal is to identify the how the polymicrobial nature of the biofilm affects efficacy of treatment in the presence of orthopædic implants. During the STAR research time she will work in concert Dr. Preei Muire, PhD, who has extensive experience with microbiological research specifically as it pertains to the field of orthopædics. She will also work with Matthew Baldridge, a research assistant in my laboratory, who can assist her with day to day experimental tasks. During the experiment, Madison will have access to myself, Dr. Muire and Dr. Callaci for questions and troubleshooting. In addition to her laboratory experiment, she will also participate in data analysis and poster/abstract preparation.

#### Describe the Research Environment:

Dr. Ashley Levack, Assistant Professor of Orthopaedic Surgery, Attending Orthopaedic Trauma Surgeon, and BSTRI faculty member will be the primary mentor. She has translational research experience in the realm of orthopaedic infection and local antibiotic delivery and has received a research development grant from the AO North America and funding from the Loyola Research Funding Committee to pursue her research. She has personally developed the protocols involved in her project and has previously mentored research assistants as well as a prior STAR students in the laboratory. She has dedicated benchtop space in the CTRE to perform translational research experiments. In addition, Madison will have the mentorship of Dr. Preeti Muire, a PhD researcher in Dr. Levack's laboratory with extensive experience with in vitro and in vivo microbiologic experiments pertaining to fracture-related infection research. Furthermore, Madison will have access to Dr. Levack's research collaborator Dr. John Callaci who has over 10 years of experience mentoring scientists at all levels of training. In addition, Madison will collaborate daily with Dr. Levack's research assistant Matthew Baldridge.

#### **Research Education Plan**

In addition to her laboratory work, Madison will participate in weekly collaborative lab meetings in which my and Dr. Callaci's laboratory personnel will be present and during which the STAR mentees will be expected to present their progress. She will also be expected to attend Alcohol Research Program and BSTI Institute seminars as well as monthly research meetings held in the Orthopaedic Surgery Department during her STAR training time. At the end of the STAR program, she will also participate in the AO PEER Principles of Clinical Research Course, which is led by Dr. Levack. As she has an interest in Orthopaedic Surgery, the Orthopaedic research meetings and AO PEER course should be especially relevant to her education.

#### **Research Education Oversight**

I will meet with Madison one-on-one at least once per week to discuss her project and informally as often as required to make sure she stays on track. We will meet as a group once a week for lab meeting and he will have access to daily informal mentorship from Dr. Muire and members of the Callaci lab as well for help throughout her research time. <u>MENTOR</u>: Dr. Jiwang Zhang, MD/PhD (<u>izhang@luc.edu</u>; Depts. of Radiation Oncology, Pathology, and Cancer Biology – Cardinal Bernardin Cancer Center) Please describe:

<u>Research Activities for Student</u> (specifically what research activities the STAR student will engage in):

Austin will use in vitro drug treatment followed by flow cytometric analysis to assess the role of TAK1 and TBK1 in the survival, differentiation, and self-renewal of GMP- and LMPP-like LSCs, and blasts, in MLL-AF9<sup>-</sup> mouse cells, human AML cell lines, and AML patient samples. We recently developed a novel technique to culture primary AML cells and have collected over 200 AML samples for this study; Austin will use this new assay to culture patient AML cells and then evaluate the response of AML cells to TAK1 and TBK1 inhibitor treatment. Both TAK1 and TBK1 inhibitors are available commercially.

<u>Describe the Research Environment</u> (include the name and qualifications of the STAR student's immediate research supervisor):

Austin will work together with Ryan Mack, an MD/PhD student, and Carmen Finley, an MS student in the same program Austin has graduated from this summer, to help him to optimize the drug treatment/flow cytometric analyses and culture conditions for primary AML cells. To better understand his research project, Austin is working together with Carmen and me on a review paper to summarize the literature on LSCs and TAKI/TBK1 signaling.

<u>Research Education Plan</u> (include required research meetings, seminars, journal clubs, etc. Note: clinical shadowing is not considered research education, with the exception of observation of specifically described clinical research activities.)

We have lab meeting every Friday afternoon; Austin will present his research data and relevant publications in our weekly lab meeting. We also have an annual lab retreat in July, where all lab members are asked to summarize their research project and give a detailed presentation on the current progress and future plans. In addition, Austin will attend the seminars and journal clubs in the LUC's Dept. of Cancer Biology, IPBS's BMBC program, and CBCC's Dept. of Hematology/Oncology with Dr. Kevin Barton and Dr. Patrick Hagen. Austin is also encouraged to attend the Grand Rounds every Friday morning for exposure to clinical research.

<u>Research Education Oversight</u> (including how often you commit to meeting with the student to ensure that the student receives an excellent research training experience.)

I will meet Austin 2-3 times a week to make sure he best understands the concept and experimental techniques of his research project. I will be available most of the time in my office for Austin if he has any research questions.

# **STUDENT SECTION**

# **Personal Statement - Goals for STAR Scholarship**

- Articulate personal and professional goals linked to the STAR research experience.
- Emphasize how this project aligns with career aspirations and contributes to growth.

**STUDENT**: In this brief personal statement, please indicate what you hope to attain from the STAR scholarship personally and professionally.

Throughout this project, I hope to learn about the intricacies of Biostatistics and Machine Learning in relation to relevant health outcomes with Dr. Joyce. In addition to the postpartum care attendance that these algorithms address, this work will provide me with the framework to better understand and implement Machine Learning. The methods to use the algorithm in this project are standard and can be applied to many other sectors. I intend to integrate algorithms into clinical practice and use them as a decision aid in conjunction with clinical judgment. Having accurate insight into the predicted risk of a future health outcome can be widely used to implement effective and tailored interventions.

Additionally, the mechanisms of uncovering bias in this study can likely be used elsewhere, and I hope to use algorithms to identify and help reduce healthcare disparities. Having a comprehensive understanding of how certain clinical decisions are determined can help ensure that I am not basing my decisions on skewed assumptions. This project will help provide deeper insight into the effectiveness of clinical decision support tools and help ensure that I use them in an informed way. I hope to eventually incorporate innovative tools that promote health equity into my practice.

Furthermore, I would be appreciate improving my ability to work with software programs like R that can help standardize statistical processes. This skill set will be helpful in the future for designing statistical projects and critically analyzing the medical literature that incorporates different statistical practices. I would also appreciate having the opportunity to have more experience sharing findings with the scientific community through presentations and publications.

**STUDENT**: After graduating from Clemson University in 2021, I worked full time for two years on the heart failure (HF) clinical trials unit of the Inova Heart and Vascular Institute in Fairfax, VA. It was there that my passion for research was born. I was extremely fortunate to be a part of many key aspects of human subjects research—from obtaining regulatory approval, to patient enrollment and follow up, data queries from the electronic medical record, statistical analysis, and even the presentation of eight abstracts at national conferences and the publication of 4 manuscripts as first or co-first author. This experience taught me how special research is in that it requires the multidisciplinary, collaborative, coordinated effort of many stakeholders to complete any project or accomplish a research goal.

Not only do you get to contribute to the scientific advancement of your field, but you also get the privilege of meeting and working closely with people from different disciplines, including patients, nurses, research coordinators, regulatory specialists, statisticians, and data scientists. I have a great appreciation for the ability of the electronic medical record to quickly and efficiently answer scientific questions utilizing large quantities of data from sizeable patient cohorts, and I recognize how important it is for aspiring physicians scientists to have a fundamental understanding of statistics, data science, and of the many nuances of research.

As I begin my career in medicine, my goal is to be not only an excellent clinician, but also a strong and effective researcher. I believe the STAR program will provide me with the unique opportunity to tackle a novel research project of my own under the mentorship of Dr. Holly Kramer and her team. I believe that this program and Dr. Kramer's mentorship will allow me to gain a better understanding and comfort with data science, data management, data analysis, and statistical principles, and grant me the opportunity to work with and learn from colleagues from many different departments within Loyola.

# **STUDENT SECTION**

# **Personal Statement - Goals for STAR Scholarship**

- Articulate personal and professional goals linked to the STAR research experience.
- Emphasize how this project aligns with career aspirations and contributes to growth.

**STUDENT**: In this brief personal statement, please indicate what you hope to attain from the STAR scholarship from a personal and professional standpoint.

With the STAR scholarship, I hope to make a meaningful contribution to leukemia research/treatment and develop my research and communication skills further. I earned my MS in Dr. Zhang's lab, graduating in the summer of 2023, after studying TBK1 using mouse models of MLL-AF9<sup>+</sup> AML and normal hematopoiesis. Near the end of my MS program, we hit a breakthrough on my project after observing that the LMPP-like subset of mouse LSCs was lost following genetic deletion of TBK1. Moreover, this finding strikingly complemented earlier work done in our lab by Joseph Cannova, an MD/PhD student who found that the GMP-like counterparts were similarly lost following genetic deletion of TAK1. My goal is to continue the TAK1/TBK1 research with the STAR scholarship, specifically by conducting in vitro analyses to determine how pharmacologic blockade of TAK1/TBK1 affects mouse/human AML cells and if this combination: A) eradicates GMP- and LMPP-like LSCs and, if so, how; B) also kills blasts; and ultimately, C) can augment standard AML frontline chemotherapy. My professional goal with the STAR scholarship is to push our TAKI/TBKI project forward so that we can eventually contribute to making AML more treatable. Personally, while I want to improve my technical and communication skills, my main interest in the STAR scholarship comes from my fascination with cancer biology and because I see this scholarship as a way I can try to help patients and their families. I understand our research is basic/foundational and thus is far away from directly helping patients; still, I genuinely hope that the work I would do with the STAR scholarship could someday be used to help alleviate the terrible burden of AML on patients and their families. I want to continue research as a physician, and the STAR scholarship will help me improve my skills to become an even more effective researcher, helping me care for today's and tomorrow's patients.

**STUDENT**: In my pursuit of the STAR scholarship, my primary goal is to further integrate research into my career as a physician. While I have a strong foundation in basic wet lab research and biotechnology, I am eager to delve into how research aligns with a surgical career and the unique questions it can address. Despite my relatively recent introduction to orthopedics during medical school, I have discovered a deep affinity for the specialty through active engagement in shadowing, conferences, and meetings. I realized how much my personality and interests align with the specialty and those who work within it. I hope that being involved in research helps me better understand the current issues the field faces, why certain protocols or materials are used, and further generates my interest in orthopedic surgery. As a female medical student, I understand the importance of mentorship, and I am keen on establishing a strong connection with Dr. Levack I see research as a powerful medium for fostering this connection, providing an avenue for Dr. Levack to gauge my dedication and interest, all while accommodating the demands of a busy physician's schedule. As Dr. Levack's STAR student. I would also have the opportunity to attend the AO PEER Principles of Clinical Research Course which would enhance my research skills specifically in the field of orthopedics.

# **Research Plan**

These proposals represent real, ongoing projects from your peers. Please do not publish these or reproduce them in any way. These must remain in-house for Loyola Students only.

# **Types of Research Projects**

# **Basic Science Research**

- **Goal**: Understand biological mechanisms and molecular pathways.
- **Methods**: Often involves laboratory techniques such as cell culture, molecular assays, and microscopy.
- Ideal For: Students interested in lab-based research and preclinical studies.

# **Clinical Prospective Studies**

- **Goal**: Observe outcomes as they occur in real-time, often evaluating the effect of an intervention.
- **Methods**: Collecting new data from participants over a specified period, often using surveys, clinical exams, or diagnostictests.
- Ideal For: Students interested in patient-focused, forward-looking research.

# **Clinical Retrospective Studies**

- **Goal**: Analyze existing data to explore outcomes, trends, or potential risk factors.
- **Methods**: Uses medical records, databases, or archived samples; statistical analysis is often crucial.
- Ideal For: Students looking to leverage existing data to address clinical questions.

# o <u>https://www.statsdirect.com/help/basics/prospective.htm</u>

# Abstract (1page) & Research Plan (2pages)

- Background and rationale
- Hypothesis and specificaims
- Research design and methods
- Anticipated results and interpretation
- References
  - (listed in short form, i.e. Block, et al. NEJM 112:132009)

# What should you include in your abstract?

- Introduction: background, <u>hypothesis</u>, why your research matters (significance)
- Methods: very simple means you used to answer the research question (specific aims)
- **Results:** summarize each finding into about one sentence
- Conclusions: summary of the findings you presented and overall impact (scientific achievements)

# **Basic Science Proposals: Key Components**

### **Background and Rationale**

- Describe the scientific problem and why it's important.
- Summarize current knowledge and gaps your study will address.

### Hypothesis and Specific Aims

• State a clear, testable hypothesis based on the background.

### **Research Design and Methods**

- Detail experimental techniques (e.g., cell culture, molecular assays).
- Include sample size, controls, and variables for reliability.

### Anticipated Results and Interpretation

- Describe expected outcomes based on the hypothesis.
- Explain how results will be analyzed and interpreted.

#### ABSTRACT: (Written by the student-not to exceed this space).

TITLE: In Vitro Analysis of Antibiotic and Irrigation Effects on Staphylococcus aureus Biofilms and Staphylococcus aureus- Pseudomonas aeruginosa Co-Biofilms on Orthopedic Implant Materials

#### Background and Significance:

Implant-related bacterial biofilm infections remain a current challenge in orthopedic surgery<sup>7</sup>. Biofilms, especially those formed by *Staphylococcus aureus* and *Pseudomonas aeruginosa*, lead to chronic infections, and the protective matrix capsule surrounding sessile cells hinders the effectiveness of antibiotics<sup>6</sup>. The inability to maintain sufficient antibiotic concentration often necessitates implant removal and revision surgeries<sup>7</sup>. Studies have shown CDC biofilm reactors to simulate conditions favoring biofilm growth, focusing on the comparison between single-species (*S. aureus*) and multi-species biofilms pose a greater challenge for elimination due to their heterogeneous composition<sup>7</sup>. The use of bioreactors and the investigation of different biofilm compositions aim to combating implant-related biofilm infections in orthopedic surgery.

#### Hypothesis:

The application of irrigation solutions will lead to a more pronounced reduction in colony-forming units (CFU5) within Staphylococcus aureus biofilms, as compared to the co-existing Staphylococcus aureus-Pseudomonas aeruginosa cobiofilms.

#### Specific Aims:

SPECIFIC AIM #1: Evaluate the efficacy of irrigation solutions on Staphylococcus aureus biofilms SPECIFIC AIM #2: Evaluate the efficacy of irrigation solutions on Staphylococcus aureus-Pseudomonas aeruginosa Co-biofilm

#### Brief Methods:

Plate S. aureus and P. aeruginosa overnight from glycerol stocks, culture overnight, and dilute 1/50 for an OD600 of 0.5A. Use 1mL of either S. aureus or both S. aureus and P. aeruginosa to inoculate the CDC biofilm reactor at 10° concentration. Place stainless steel coupons into the coupon holder. The reactor will incubate for 24hrs without flow (batch phase). Using a peristaltic pump, drip 10% TSB at 6.94ml/min will into the reactor for 72hrs with 0w (flow phase). Remove and rinse coupons with PBS then treat with antiseptic solution for 3min with either, 10% povidone-iodine (PI), a 1:1 mixture of 10% povidone-iodine plus 3% hydrogen peroxide (PI+HP), or PBS (control). Sonicate coupons for 5min at 22.5 kHz in 10mL PBS and plate to count CFUs. Antiseptic solutions will be considered efficacious if they produce a 3-log reduction in CFU counts compared to controls.

If the proposed study is successful, describe the expected scientific achievements: We expect to see the antiseptic solutions produce lower CFU counts than PBS, though we do not expect to completely eradicate infection. We also expect antiseptic solutions to be more effective within *S. aureus* biofilms, as compared to the co-existing *S. aureus-P. aeruginosa* co-biofilms.

# **Clinical Research Proposals: Key Components**

#### Background and Rationale

- Define the clinical problem, its impact, and why this research is needed.
- Reference gaps in existing clinical practices.

#### Hypothesis and Specific Aims

- State a clear, clinical hypothesis based on patient outcomes or interventions.
- Outline specific aims, tailored to your study type (prospective or retrospective).

### **Study Design and Methods**

- **Prospective**: Define participant recruitment, intervention details, and outcome tracking over time.
- **Retrospective**: Detail data sources (e.g., medical records), inclusion criteria, and variables analyzed from past cases.

### **Data Analysis Plan & Expected Outcomes**

- Specify tools and methods for data collection (surveys, EHR, imaging).
- Describe analytical methods (e.g., regression analysis, mixed-effects models) suited to clinical data.
- Outline the anticipated results and impact on clinical practice.
- Highlight how findings could influence guidelines or future treatments.

#### ABSTRACT

TITLE: The Evaluation and Bias Assessment of Clinical Decision Support Tools for Postpartum Care Non-Attendance Risk

#### **Background and Significance:**

Postpartum care is paramount in reducing the high rate of matemal mortality, as 50% of pregnancy-related deaths occur after birth. Machine learning and clinical prediction models may identify patients most vulnerable to non-attendance who may benefit from tailored interventions aimed at increasing attendance rates. Prior to implementation, evaluating performance and algorithmic fairness of machine learning models is essential for accurate and unbiased decisions, helping improve equity in outcome predictions.

#### Hypothesis:

Postpartum care prediction models developed for traditionally underserved populations may be effective in assessing risk for postpartum care non-attendance for patients seen at the Loyola Women's Health Associates (WHCA) clinic.

#### Specific Aims:

#### In this project, we aim to:

 Perform an external validation to determine the accuracy of two clinical decision support tools that identify patients at increased risk for postpartum care non-attendance based on data captured in the Electronic Health Record (EHR).
 Assess postpartum care tools for bias and fairness metrics to ensure models perform equivalently across important sub-groups (e.g. race/ethnicity, insurance status).

#### Brief Methods:

We will identify a retrospective cohort of patients seen at WHCA (n~700) for pre- and post-natal care, and will extract EHR variables from two published risk assessment tools. These variables will allow for computation of predicted probabilities for non-attendence (risk scores) to compare to actual post-partum care attendance. Risk tools will be evaluated for discrimination, calibration, and fairness, employing Aequitas, an opensource bias and fairness audit toolkit to help determine if the AI prediction models reveal unintended biases in vulnerable sub-groups.

#### If the proposed study is successful, describe the expected scientific achievements:

If this proposal is successful, this external validation of models previously developed could increase utility and uptake of important tools. Furthermore, the results could help provide insight to Loyola physicians about relevant factors that could predict (and reduce) non-attendance. We will disseminate our results at St. Albert's day and in a relevant clinical journal.

# **Additional Abstract Examples**

#### ABSTRACT:

Acute myeloid leukemia (AML) encompasses a group of blood cancers arising from the immature myeloid cells in the bone marrow. The most common type of blood cancer, AML is a highly aggressive disease. Aside from patients with acute promyelocytic leukemia (APL), an AML subtype that is uniquely treatable, <30% of all AML patients survive at least five years from their diagnosis. AML carries a characteristically poor prognosis mainly due to the persistence of drug-resistant leukemia stem cells (LSCs). LSCs cause disease relapse, with at least 50% of remission-achieving patients relapsing within three years of being diagnosed; LSCs are also believed to be responsible for treatment-resistant (refractory) AML, where 30-40% of patients cannot respond to therapy altogether. In 2011, Goardon et al. determined two distinct types of LSCs, GMP- and LMPP-like LSCs, co-exist in the blood of nearly all AML patients-thus, eradicating both types of LSCs is likely necessary to cure AML. Using an MLL-AF9-transduced (MLL-AF9") mouse model of AML, we demonstrated that GMP- and LMPP-like LSCs, respectively, are enriched in the FLT3" and FLT3" subsets of c-KIT+ AML cells, whereas the most differentiated AML cells (blasts) are all c-KIT-. Using genetic knockout techniques. Cannova and Runde of our group, respectively, have shown that the GMP-like LSCs rely on TAK1, whereas the LMPPlike LSCs rely on TBK1 for their survival; TAK1 and TBK1 are Ser/Thr protein kinases known best for their roles in activating the innate immune system. We hypothesize parallel blockade of TAK1 and TBK1 to selectively target both subsets of LSCs. We will test our hypothesis using TAK1- and TBK1-selective small molecule inhibitors alone and in combination in MLL-AF9<sup>+</sup> mouse bone marrow cells, human AML cell lines, and AML patient samples. Furthermore, we seek to determine the mechanistic basis by which inhibition of TAK1 and/or TBK1 ablates LSCs.

TITLE: Investigating the Anti-LSC Efficacy of TAK1/TBK1 Parallel Blockade in Mouse/Human AML Cells

Background and Significance: AML is a devastating cancer, afflicting -4 out of every 100,000 adults and ~7 out of every 1 million children in the United States annually. Aside from some targeted therapies available for select patient populations—such as patients with APL, CD33<sup>+</sup> AML, or those harboring *FLT3* mutations—the treatment landscape for AML has remained largely unchanged for the last forty years. AML continues to carry a bleak survival rate and inflict considerable short- and long-term morbidity and financial toxicity upon patients and their loved ones. The main reason AML remains such a deadly disease is due to the inability of current agents (including targeted therapies, like glasdegib [NCT03416179]) to kill LSCs reliably; without effective LSC-specific treatments, AML will continue to bear an almost invariably grim prognosis. LSC-specific agents are urgently needed to eradicate LSCs and reliably prevent relapse.

Hypothesis: If TAK1 and TBK1 are inhibited in parallel, then both the GMP- and LMPP-like LSC subsets of mouse/human AML cells will be ablated after being forced to differentiate (i.e., cells will become c-KIT).

Specific Aims: 1) To determine if pharmacologic TAK1/TBK1 parallel blockade can ablate the GMP- and LMPP-like LSC subsets in *MLL-AF9<sup>-</sup>* mouse bone marrow cells, human AML cell lines, and AML patient samples; 2) To determine if/how pharmacologic TAK1/TBK1 parallel blockade can effectively kill and/or induce the differentiation of the GMPand LMPP-like LSC populations (using the models listed in Aim 1).

**Brief Methods**: 1.0 x 10<sup>5</sup> mouse or 1.0 x 10<sup>6</sup> human AML cells will be seeded in each well of a 12-well plate using 100uL RPMI-1640 (liquid media); 2mL additional liquid media will be added, bringing each well's volume to 2.1mL. Cells will be incubated for 24h, then drugs (TAK1i +/- TBK1i +/- DMSO) will be added; cells will be incubated for an additional 24h before being collected, washed, stained (1.0 x 10<sup>6</sup> cells/tube, maximum), and analyzed via flow cytometry. Flow cytometric analyzes will include c-KIT, FLT3, CD11b, and CD115 for mouse cells and Annexin V, propidum iodide (PI), CD34, CD38, CD11b, CD62E, c-KIT, FLT3, CD244, CD4, CD69, CD115, and CD33 for human cells.

If the proposed study is successful, describe the expected scientific achievements: These data will support the Zhang lab's proceeding with an *in vivo* mouse model of *MLL-AFO*<sup>\*</sup> AML, where TAK1/TBK1 blockade will be added as augmentation to frontline AML chemotherapy (daunorubicin & cytarabine +/- TAK1i & TBK1i).

#### ABSTRACT:

TITLE: Factors Associated with Blood Pressure Control and Therapeutic Inertia

**Background and Significance:** Hypertension (HTN), or high blood pressure (BP), affects nearly half of all United States (US) adults.<sup>1</sup> Despite the cardiovascular risks associated with HTN, less than half of adults with HTN receive blood pressure (BP)-lowering medications in accordance with the 2020 international HTN practice guidelines.<sup>2</sup> One major obstacle for achieving BP control is the failure of clinicians to intensify treatment when BP remains above therapeutic goals (<140/90 mmHg), a phenomenon termed "therapeutic inertia.<sup>33</sup> Other factors include lack of automated office BP (AOBP) measurement to confirm elevated clinic BP readings, lack of timely follow-up visits for patients with uncontrolled BP, and low prescribing rates of diuretics and combination agents. In October of 2018, Loyola outpatient clinics enrolled in the Measure Accurately, Act Rapidly, Partner with Patients (MAP) BP control program, a nationwide HTN quality improvement program funded by the U.S. Congress and implemented by the American Medical Association (AMA).<sup>4</sup> We previously utilized data from participating Loyola clinics that showed an approximate 10% increase in BP control rates after implementation of the MAP BP Program.<sup>5</sup> However, we also showed that improvements in HTN control were not uniform across sex and age groups.<sup>5</sup>

In this study, we will use an existing retrospective patient cohort that includes 21,861 patients who received care at one of 14 Loyola outpatient primary care clinics to determine factors associated with higher rates of BP control at the prescribing clinician level, following implementation of the AMA MAP BP program.

<u>Hypothesis</u>: Clinicians with higher rates of BP control will have higher rates of documented AOBP use when clinic BP reading exceeds 140/90 mmHg, have higher rates of prescriptions for thiazide diuretics and combination pills, and have more patient follow-up visits within 4 weeks of a clinic visit when BP exceeds 140/90 mmHg compared to clinicians with lower rates of BP control.

#### Specific Aims:

- Stratify providers into tertiles of BP control rates (proportion of a provider's patient panel with HTN and BP reading <140/90 mmHg recorded at last clinic visit during 2019-2020).</li>
- Compare frequency of 1) documented AOBP use, 2) prescription rates for thiazide diuretics and fixed-dose combination pills, and 3) frequency of 4-week follow up after clinic visits when BP exceeds 140/90 mmHg across tertiles of provider BP control rates.
- Repeat analysis after controlling for baseline risk of cardiovascular disease (CVD) (defined as age 65+ years and/or ICD10 codes for diabetes, CVD, and chronic kidney disease).

Brief Methods: Patient and provider level data from our retrospective patient cohort of 21,861 patients with HTN seen in one of 14 outpatient primary care clinics at Loyola during calendar years 2019-2020 will be analyzed using mixed effects modeling in STATA statistical software (StataCorp. College Station, TX). Mixed effects models will determine whether provider level factors (use of AOBP, prescribing thiazides and combination medications, and use of follow-up visits) differ by tertiles of provider level BP control rates for their patient panel.

If the proposed study is successful, describe the expected scientific achievements: We hope to present our findings at the AHA Annual Scientific Sessions or the American Socjety of Nephrology meeting in 2024 and publish a manuscript.

# Writing a Strong Background

### Establish the Problem

- Clearly define the clinical or scientific issue your research addresses.
- Use data or statistics to highlight the problem's significance.

### **Review Relevant Literature**

- Summarize key findings from recent studies related to your topic.
- Identify any gaps in knowledge or areas needing further investigation.

### Highlight Importance of Your Study

- Explain why addressing this gap is crucial for advancing knowledge or improving patient care.
- Connect your study to broader impacts (e.g., reducing healthcare costs, improving patient outcomes).

### **Develop a Clear Narrative**

- Organize information logically, moving from general background to specific research needs.
- Use concise, straightforward language to enhance readability.

### **Conclude with Research Objective**

• Clearly state the objective of your study as it relates to the identified gap.

# **Background & Rationale: Clinical Examples**

#### **Background and rationale**

Despite medical innovation, the maternal mortality ratio has actually increased from 7.2 to 23.8 per 100,000 live births in the past few decades.<sup>1,2</sup> More birthing people are dying in the US from pregnancyrelated mortality compared to people in other high-income countries. Notably, non-Hispanic Black women have a 3-4 fold risk of pregnancy related death compared to non-Hispanic White women.<sup>2</sup> Over half of pregnancy-related deaths occur between seven days to one year postpartum.<sup>3</sup> Therefore, early postpartum care is critical in addressing pregnancy-related deaths, the majority of which are preventable. Previous work has evaluated modifiable and non-modifiable risk factors for non-attendance, and postpartum attendance rates have been shown to have associations with age, race, and insurance status, with a 73% six-week postpartum attendance rate for patients with commercial HMOs and a 61% rate for patients with Medicaid.<sup>4</sup> Thus, predictive algorithms may be the most accurate if they are tailored to the patient population seen at a clinic.

Two previous studies developed and internally validated postpartum care attendance algorithms using predictors from the prenatal care (PNC) period. Qafiti et al. developed a clinical risk assessment tool at a single hospital (n=587) and identified risk factors for non-attendance of the six-week postnatal visit, which included younger age, multiparity, Medicaid insurance, and later initiation of PNC.<sup>5</sup> Race was not reported, and all patients were enrolled in an insurance plan in the study. As such, the results of this single-center study may not apply to other populations, for example with uninsured patients or a different payor mix. Subsequently, a study by Tenfelde et al. identified patients who were less likely to return for postpartum care at a network of Federally Qualified Health Centers (n=50,022).<sup>1</sup> This assessment tool was designed for a population that was predominantly low-income, received Medicaid insurance, and persons of color. The predictors that were shown to contribute to postpartum care non-attendance included maternal age, lower parity, greater gestational age at first PNC visit, and fewer PNC visits. Maternal age and gestation age at first visit exhibited non-linear associations with non-attendance.

Prediction models must be externally validated for their performance and clinical usefulness prior to implementation.<sup>6</sup> To date, these models have not been evaluated in other external settings to assess their accuracy, fairness, or clinical utility. Validating the clinical decision support tools in the Loyola clinic provides an opportunity to identify patients who are most vulnerable for non-attendance. Further, implementing an auditing tool can help ensure that an algorithm is not systematically making biased predictions about subgroups within the clinic population.<sup>7</sup> Once validated, these tools can help inform interventions of modifiable risk factors, like the number of prenatal visits, for the high-risk patients identified at Loyola and other centers. This would allow clinics to allocate resources towards patients most likely not to attend their postpartum care visit and lead to improved perinatal outcomes.

#### **Background and rationale**

Hypertension (HTN), or high blood pressure (BP), is defined as systolic BP  $\geq$  140 mmHg and/or diastolic BP  $\geq$  90 mmHg and affects nearly half of all United States (US) adults and 1.4 billion people worldwide.<sup>1</sup> Uncontrolled BP remains a leading cause of heart disease, stroke, coronary and peripheral artery disease, and chronic kidney disease. Despite these risks, less than half of adults with HTN receive BP-lowering medications, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers, and diuretics in accordance with the 2020 international HTN practice guidelines.<sup>2</sup>

One major obstacle for achieving optimal HTN management is the failure of clinicians to intensify treatment when BP remains above therapeutic goals (<140/90 mmHg), a phenomenon termed therapeutic inertia.<sup>3</sup> Other factors include lack of automated office BP (AOBP) measurement to confirm elevated BP readings, lack of timely follow-up visits for patients with uncontrolled BP, and low prescribing rates of diuretics and combination agents. In October of 2018, Loyola outpatient clinics enrolled in the American Medical Association (AMA) Measure Accurately, Act Rapidly, Partner with Patients (MAP) Blood Pressure (BP) control program, a nationwide HTN quality improvement program to help combat therapeutic inertia and improve rates of BP control.<sup>4</sup> We previously utilized data from participating Loyola outpatient primary care clinics that showed an approximate 10% increase in rates of controlled BP after implementation of the AMA MAP BP Program.<sup>5</sup> However, we also showed that the improvements in BP control were not uniform across sex and age groups, and BP control rates remain modest.<sup>5</sup> In this study, we will use our retrospective cohort including 21,861 patients to examine physician behaviors that may contribute to higher rates of BP control.

# Background & Rationale: Basic Science Examples

#### **Background and rationale**

Acute myeloid leukemia (AML) is a group of blood cancers originating in the myeloid progenitor cells within the bone marrow (*e.g.*, common myeloid progenitor, myeloblast, ETC.) (*I-4*). AML is the most common cancer of the hematopoietic system and typically occurs around 68 years of age. AML is ~34% more common in biological males compared to females and, aside from the acute promyelocytic leukemia (APL) subtype, carries a 5-year survival rate of 29% for patients 20+ years of age. AML is commonly caused by chromosomal translocations, such as *MLL* rearrangements (*MLL-r<sup>\*</sup>*) (*J*). With the exception of APL—which can be treated effectively with tretinoin (*Vesanoid*<sup>®</sup>) + arsenic trioxide (*Trisenox*<sup>®</sup>) as it is caused by the *PML-RARA* translocation—frontline treatment for AML employs an intensive, two-phase chemotherapy (CTx) regimen of daunorubicin + cytarabine followed by single-agent, dose-escalated cytarabine (6). Despite generally being responsive to CTx, with 60-70% of patients achieving complete remission (CR), at least <u>half</u> of CR-achieving patients experience relapse within three years of their diagnosis (*J*). AML relapses due to the survival and expansion of a small pool of CTx-resistant leukemia stem cells (LSCs) (*8-14*).

Goardon *et al.* discovered that two types of LSCs (c-KIT<sup>+</sup> AML cells) exist in the peripheral blood of AML patients: the more-differentiated, FLT3<sup>-</sup> granulocyte-macrophage progenitor (<u>GMP)-like</u> LSCs and the less-differentiated, FLT3<sup>+</sup> lymphoid-primed multipotential progenitor (<u>LMPP)-like</u> LSCs; non-stem, non-leukemogenic AML cells (blasts) are c-KIT<sup>-</sup> (*15, 16*). Eradication of both types of LSCs is likely required to maintain CR of AML.

With *in vitro* and *in vivo* techniques, utilizing the *MLL-AF9* oncogene as our model of *MLL*-r<sup>+</sup> AML, our group has determined that GMP- and LMPP-like LSCs differentially rely on Ser/Thr protein kinases involved in Toll-like receptor (TLR)/NF-kB signaling for their survival (17-19). Cannova and Runde, respectively, found that <u>GMP-like LSCs require TAK1</u> and <u>LMPP-like LSCs require TBK1</u>. As well, Runde found that while mice given *Tbk1*<sup>NULL</sup> AML cells still develop AML, they develop a subcutaneous collection of AML cells (chloroma; a form of extramedullary AML) near the pelvis and also seem to survive longer than mice given control ( $Tbk1^{NUT}$ ) AML cells, though this observation regarding overall survival requires validation

#### **Background and rationale**

**Biofilms**: Implant-related bacterial biofilm infections remain a current challenge in orthopedic surgery<sup>7</sup>. Biofilm infections cause chronic infections, and these surface adherent communities of matrix-enclosed organisms are protected from many antibacterial factors. In orthopedic surgery, biofilms can develop on implants over months or years with little signs of inflammation. Antibiotics have been shown to treat free-floating "planktonic" cells, but showed no effects on the matrix-enclosed "sessile" cells adhered to the implant<sup>6</sup>. The matrix capsule protects sessile cells from sentinel immune cells and limits the diffusion of antibiotics<sup>7</sup>. These deeper residing cells have a lower metabolic state allowing them to persist in wound sites<sup>4</sup>. Inability to maintain an appropriate antibiotic concentration at the infection site often leads to implant removal and debridement. This can then lead to revision surgeries and prolonged hospitalization, which increases the chance of re-infection<sup>2</sup>.

**Bioreactors:** CDC biofilm reactors allow for the simulation of conditions that favor the growth of biofilms in a controlled setting. Previous studies have shown the reactor produces consistent growth, which is essential for comparing replicate experiments. Additionally, biofilms can be directly grown onto coupons made of common implant material<sup>4</sup>.

Staphylococcus aureus and Pseudomonas aeruginosa: S. aureus is the most common organism that results in biofilm formation<sup>5</sup>. In this experiment, we will be looking at S. aureus compared to a multi-species biofilm of S. aureus and P. aeruginosa. Multi-species biofilms are harder to eliminate than single-species due to their heterogeneous composition that confers a higher resilience to antimicrobial agents. Unfortunately, multispecies biofilm infections count for most cases<sup>3</sup>.

# How to form a hypothesis

- Your main research question!! Driving motivation and suspected finding of yourwork
- o Phrase as a sentence
  - Statement of fact
  - $\circ$  If/then format
  - Your hypothesis does not need to be right but it must be testable – should represent an exciting research question and your expected results

# **NOT HYPOTHESES**

- o We want to test treating liver cancer cells with sorafenib.
  - BUT We hypothesize that sorafenib may be an effective agent for inhibiting liver cancer cell growth is a hypothesis.
- Calling patients after they return home from their procedures seems to decrease the likelihood that patients return to the hospital.
  - BUT If patients received a post-operative follow-up phone calls from their surgeons, then their hospital admission rates may be reduced - is a hypothesis.

# **Hypothesis Example - Basic Science**

- o If TAK1 and TBK1 are inhibited in parallel, then both the GMP- and LMPP-like LSC subsets of mouse/human AML cells will be ablated after being forced to differentiate.
- We hypothesize that the simultaneous inhibition of TAK1 and TBK1 will lead to the arrest of GMP- and LMPP-like LSC subsets of mouse/human AML cells following differentiation.

\*blue text - funded hypothesis from your peer

# **Hypothesis Example - Basic Science**

- Postpartum care prediction models developed for traditionally underserved populations may be effective in assessing risk for postpartum care non-attendance for patients seen at the LWHA Clinic.
- If postpartum care prevention models are implemented at the LWHA Clinic, then we will be able to better assess risk for postpartum care non-attendance in traditionally underserved populations.

\*blue text - funded hypothesis from your peer

# **Crafting Specific Aims**

# **Developing SpecificAims**

- Divide your hypothesis into achievable aims that guide your study steps.
- Each aim should address a component of the hypothesis.

# Structuring SpecificAims

- Aim for 2-3 focused aims that logically build on each other.
- Keep each aim distinct to avoid overlap and clarify objectives.

# Tips for Strong Hypotheses and Aims

- Be concise: Avoid overly broad or complex statements.
- Stay realistic: Ensure aims are feasible within the study timeline.
- Make aims measurable: Define outcomes that can be quantified or clearly assessed.

# **Crafting Hypotheses and Specific Aims**

### **Basic Science Examples**

#### Hypothesis and specific aims

The application of irrigation solutions will lead to a more pronounced reduction in colony-forming units (CFUs) within *Staphylococcus aureus* biofilms, as compared to the co-existing *Staphylococcus aureus*-*Pseudomonas aeruginosa* co-biofilms.

#### SPECIFIC AIM #1: Evaluate the efficacy of irrigation solutions on S. aureus biofilms

An ORS conference proceeding from 2023 has previously shown that 10% povidone-iodine (PI) + hydrogen peroxide (HP) produced the lowest CFU counts for *S. aureus* biofilms<sup>1</sup>. This same antiseptic solution ratio shall be used in this experiment. 10% PI alone and PBS will also be used to irrigate. Additionally, commercially available products such as Irrisept or Bactisure may be considered.

SPECIFIC AIM #2: Evaluate the efficacy of irrigation solutions on *S. aureus – P. aeruginosa* Cobiofilms

The experiment will assess the ability of 10% PI+HP or 10%PI to effectively decrease CFU count within the complex co-biofilm setting, providing valuable insights into the broader applicability of this antiseptic solution for orthopedic implant materials contaminated with mixed-species biofilms.

### **Clinical Examples**

#### Hypothesis and specific aims

SA1: Perform an external validation to determine the accuracy of two clinical decision support tools that identify patients at increased risk for postpartum care non-attendance based on data routinely captured in the Electronic Health Record (EHR). <u>Rationale</u>: Internally validated published tools developed using patients seen at federally qualified health centers, and in general OB populations, are available but have not been externally validated for performance in new settings. <u>Hypothesis</u>: Previously developed risk prediction algorithms have sufficient accuracy and calibration to warrant their utilization in providing targeted interventions for patients seen in the Women's Health Associates Clinic at Loyola University Medical Center. <u>Approach</u>: Postpartum care attendance will be evaluated for patients seen for prenatal care over five years, where accuracy (sensitivity and specificity) and calibration (predicted versus actual risk) will be evaluated for the range of risk prediction scores.

SA2: To assess postpartum care tools for bias and fairness metrics to ensure models perform equivalently across important sub-groups (e.g. race/ethnicity, insurance status). <u>Rationale</u>: There is ongoing controversy about race and ethnicity as candidate variables in risk prediction algorithms. Patients otherwise similar on other risk factors should not be more or less likely to receive an intervention based on an algorithm because of race or ethnicity in application of a "fair" algorithm. <u>Hypothesis</u>: Models developed on multicenter FQHC data will have better accuracy, calibration, and fairness metrics within sub-groups compared to general population models. <u>Approach</u>: We will apply Aequitas, a toolkit to audit of the bias and fairness of algorithms, to consider false discovery, false omission, and false positive/negative rates of the two algorithms.

#### Hypothesis and specific aims

We hypothesize that if the TAK1 and TBK1 kinases are inhibited simultaneously, both the GMPand LMPP-like LSC subsets of AML cells will be ablated. Specifically, we hypothesize that <u>TBK1 blockade</u> will force LMPP-like LSCs into the GMP-like compartment and TAK1 blockade will force GMP-like LSCs into the blast cell compartment, the net result being an *ablation of both LSC compartments and resultant increase in the blast cell population*.

Specific Aim 1 - To determine if pharmacologic TAK1/TBK1 parallel blockade ablates the GMP- and LMPP-like LSC subsets of mouse/human AML cells in vitro.

Specific Aim 2 – To determine if pharmacologic TAK1/TBK1 parallel blockade can effectively kill and/or induce the differentiation of GMP- and LMPP-like mouse/human LSCs in vitro.

Hypothesis and specific aims: Clinicians with higher rates of BP control will have higher rates of documented AOBP use during their clinic visit when clinic BP reading exceeds 140/90 mmHg, have higher rates of prescriptions for thiazide diuretics and combination pills, and have more patient follow-up visits within 4 weeks of a clinic visit when BP exceeds 140/90 mmHg compared to clinicians with lower rates of BP control.

#### Specific Aims:

- Stratify providers into tertiles of BP control rates (proportion of a provider's patient panel with HTN and BP reading <140/90 mmHg recorded at last clinic visit during 2019-2020).</li>
- Compare frequency of 1) documented AOBP use, 2) prescription rates for thiazide diuretics and fixeddose combination pills, and 3) frequency of 4-week follow up after clinic visits when BP exceeds 140/90 mmHg across tertiles of provider BP control rates.
- Repeat analysis after controlling for baseline risk of cardiovascular disease (CVD) (defined as age 65+ years and/or ICD10 codes for diabetes, CVD, and chronic kidney disease).

# **Research Design and Methods: Best Practices**

### Align Research Methods with Specific Aims

- Ensure each method corresponds directly to a specific aim.
- Break down methods by aim to maintain clarity and focus.

### **Detailed MethodologySteps**

- Provide a step-by-step outline for reproducibility.
- Include protocols, data collection techniques, and timelines.

### **Define Variables and Controls**

- Specify independent, dependent, and control variables.
- Clarify how you'll manage confounding factors.

### **Ensure Ethical and IRB Compliance**

- Obtain necessary approvals for clinical research involving human subjects.
- Clearly describe data handling and confidentiality measures.

# **Research Design and Methods: Examples**

### **Basic Science Examples**

#### Research design and methods

Cell Culture: Plate S. aureus or P. aeruginosa from glycerol stocks overnight in a 37°C incubator on agar plates. Take an isolated colony from the agar plate and inoculated SnL of Tryptic Soy Broth (TSB) media in a 15mL conical tube. Place overnight cultures on a shaking incubator at 250rpm at 37°C overnight (24hrs). Dilute the liquid culture 1/50 using 8.82mL TSB: 180ul bacteria. Incubate for 90min on the shaking incubator (same settings). Centritinge and wash 3 times (2000rpm x 10min) at 25°C and resuspent in 8.82mL TSB. OD600 readings will be taken using a wavelength of 600m and using 1mL of TSB to blank. 1mL of culture should be used and the ideal range is (0.490A-0.510A). If the OD600 is below. 490A, place culture back on shaking incubator for 3-5 more minutes. The liquid subculture can be stored in 4°C up to 1 week. Do this for each bacterium.

Biofilm Growth: Autoclave all tubing, glass CDC Biofilm reactor beaker, coupon holder, metal coupons and tweezers for 60 minutes. All plastic tube connectors, screwdriver and plastic components of the CDC Biofilm

Reactor must be bleached and sprayed with 70% ethanol to prevent contamination. Insert metal coupon into coupon holding rod and place back into reactor. In this experiment, 4 coupons per irrigation solution will be tested for each of the biofilm groups. Connect all the tubing and ensure tight connections at tubing junctions. After setting up reactor, pour 500mL of TSB directly into the reactor with the outflow tube clamp shut. Piptett ImL of liquid subcluture of either *S*, anews or *P*, aeroginosa into the inoculation port, turn on site bar to 657pm and incubate for 24hrs. Use the peristalic pump to drip diluted 10% TSB at 27-30mL/72hrs. Turn on inflow pump to 7.2pm. Once both inflow pump and coutflow pump are running simultaneously, record

time. Check on reactor after 15 minutes to ensure even flow. Run CDC biofilm reactor for 72hrs, refreshing inflow media every 24hrs with 10%/TSB solution. Antiseptic Solution Treatment: After 72hrs, turn off reactor and place coupons in sterile test tube. Rinse

Perrospine Solitizion Treatment, Piner Janis, Ulti on reactor due pate Coopos with Solitic test thore, Kilse coupons with PBS to wash off pathoticine cells. Place coupons in test tubes filled with either 10% povidoneiodine (PJ), a 1:1 mixture of 10% povidone-iodine plus 3% hydrogen peroxide (PI+HP), or PBS. Let coupons sit for 3min.

Sonication: Remove coupons from the irrigation solution and place in new test tube with 10ml of phosphate buffered saline (PBS). Sonicate coupons in PBS for 5min at 22.5 kHz by pulsing for 5 seconds on and 5 seconds off for 5 minutes. Vortex tubes containing PBS and coupon for 10s.

CFU counts: Perform a 10-fold serial dilution of the sonicated PBS solution. Plate and incubate for 25hrs using 50ul of the diluted solution. Count number of CFUs.

Statistics: Evaluate for differences in CFU counts between irrigation solutions and control (PBS) for S. aureus using ANOVA comparison of means. Evaluate for differences in CFU counts between irrigation solutions and control (PBS) for P. aeruginosa using ANOVA comparison of means. Evaluate for differences in reductions of CFU counts among the same irrigation solutions between S. aureus/P. aeruginosa biofilms using a student test comparison of means for each irrigation solution tested.

#### **Research design and methods**

Following cell collection, 40uM-pore filtration, and washing, up to  $1.0 \times 10^6$  cells will be stained for flow cytometric analysis [protocol by (17)].

[1] To determine the effect of <u>TAKI/TBK1 parallel blockade</u> on mouse AML cells, 1.0 x 10<sup>6</sup> MIL-AF9<sup>+</sup> mouse bone marrow cells will be seeded in triplicate on a 12-well plate. Cells will be incubated at 37°C/5% CO<sub>2</sub>/100% humidity for 24h, then HS276 (TAK1-selective inhibitor [TAK1i]) and/or GSK8612 (TBK1-selective inhibitor [TBK1i]) or DMSO will be added accordingly: 2uM TAK1i, 2uM TBK1i, 2uM TAK1i + 2uM TBK1i, DMSO only. Cells will be returned to incubator for an additional 24h before being collected for flow cytometry.

[2] To determine the effect of <u>TAK1/TBK1 parallel blockade</u> on human AML cells, 1.0 x 10<sup>6</sup> human AML cells (MOLM-13, MV4-11, HL-60, THP-1, U-937) will be seeded in triplicate on a 12-well plate. Cells will be incubated at 37°C/5% CO<sub>2</sub>/100% humidity for 24h, then TAK1i and/or TBK1i or DMSO will be added accordingly: 2uM TAK1i, 2uM TBK1i, 2uM TBK

### **Clinical Examples**

#### **Research design and methods**

A retrospective cohort will be identified based on ICD-10 codes for supervision of pregnancy (e.g. 233.1, 234.2) who attended Loyols' WHCA. Postpartum care attendance will similarity be identified by ICD-10 codes (239.X) in up to 6-months post birth. Exclusion criteria are: miscarriage/termination of pregnancy, delivery at outside institution. The two prediction models to be evaluated include variables of: mother's age, gestational age at first PNC visit, number of PNC visits, insurance status, and parity. Additional variables to be queried include: race/ethnicity, ZIP code, marital status, comorbidities (gestational diabetes, precelampsia).

#### Statistical Analysis

Descriptive statistics will be reported for the sample. The published risk prediction tools will be applied to calculate predicted probabilities of non-attendance. For <u>aim\_1</u>, the accuracy of each model will be evaluated using the area under the curve (AUC), a measure of model discrimination. Receiver operating characteristic (ROC) curves will be plotted for each model, and between-model comparisons of the AUC will be made using non-parametric U statistics. Subgroup-specific AUC will be calculated with 95% confidence intervals. Calibration plots will be constructed for both models, and decision curve analysis will be used to describe model performance in practice, illustrating the net benefit for a range of threshold probabilities.<sup>4</sup> For <u>aim\_2</u>, the Acquitas toolbox will be employed to evaluate false discovery rate, false omission rate, false positive rate, and false negative rate in sub-groups. Parity in the false negative, false omission rate, would indicate fairness of the tool in terms of allocating resources/interventions.

#### Sample size

Based on a query of the clinical research database, we anticipate a sample size 2700 over 5 years. Estimates of post-partum care visit nonatendance are 31-37% in the source studies.<sup>1,5</sup> Precision and power were determined for accepatble discriminative ability as assessed by the AUC. AUC values close to 0.50 indicate overlapping risk distributions and models that perform no better than a coin flip, and increasing AUC indicates better discriminative ability with perfect prediction for AUC=1. Should performance of these models be similar to the model development studies, the precision of an AUC=0.7 will be  $\pm$ 0.08. Subgroup sample sizes 07.800 or greater will have  $\pm$ 80% power to reject the null hypothesis H0:AUC=0.06 [poor discrimination] in favor of alternative hypothesis H1:AUC=0.7 [good discrimination] using a two-side z-test at significance level =0.05.

#### Research design and methods

Inclusion Criteria: All patients with a new or pre-existing ICD10 diagnosis of HTN (BP > 140/90 mmHg) seen at one of 14 Loyola outpatient primary care clinics during calendar years 2019-2020.

Exclusion Criteria: Patients with evidence of end stage renal diseases or renal transplant, or patients residing in long term care facility during the measurement period.

Exposures: use of automated office BP measurement (AOBP), prescription of fixed-dose combination therapy (e.g. lisinopril + hydrochlorothiazide, telmisartan + amlodipine, lisinopril + amlodipine, telmisartan + hydrochlorothiazide), prescription of thiazide diuretic therapy, scheduled follow-up within 4 weeks.<sup>6</sup>

Study Endpoint: Physician BP control rate, defined as % of patients with a diagnosis of HTN with BP <140/90 mmHg at their most recent follow up, stratified into tertiles at the individual provider level.

Confounders: Possible confounders include patient demographics and co-morbidities (e.g. diabetes, heart failure, chronic kidney disease, and smoking status), body mass index, marital status, and insurance status.

Statistical Analysis: Patient and provider level data from our retrospective patient cohort of 21,861 patients with an ICD10 diagnosis of HTN who were seen in one of 14 Loyola primary care outpatient clinics during calendar years 2019-2020 will be queried and analyzed using STATA (StataCorp. College Station, TX).

Physicians will be stratified into "BP control" tertiles based on % of patients with a diagnosis of HTN who achieve a target BP of <140/90 mm Hg based on vital signs at the last clinic visit during the study period (2019-2020).

Exposures will be compared across provider tertiles while accounting for differences in demographics, comorbidities, and insurance status for provider patient panels. Descriptive characteristics of patient panels by clinician BP control tertiles will be examined using means, medians (IQR) or proportions, where appropriate. A p-value <0.025 will be considered statistically significant to account for comparing two upper tertiles to the lowest tertile. Data will be analyzed using mixed effects modeling in STATA statistical software (StataCorp. College Station, TX) to control for patient level factors and individual clinic.

# Data Collection, Analysis Plans, and Anticipated Results

# DataAnalysis Plan

- Select statistical tests that align with study aims and data type (e.g., t-tests, regression analysis).
- Define primary and secondary outcomes and how they'll be measured.
- Identify software (e.g., SPSS, R, STATA) for data handling and statistical analysis.
- Ensure access to necessary tools and team familiarity with chosen software.

## **Anticipated Results**

- Summarize expected outcomes based on your hypothesis.
- Describe how results will contribute to the field or clinical practice.

## Interpretation and Potential Implications

- Discuss how findings could impact future research or patient care.
- Address how the results will fill gaps identified in the background.
- Anticipate possible limitations in data interpretation (e.g., small sample size, confounding factors).

# What methods should I beusing?

- What is the best way to and what tools do I need to answer the question in my hypothesis? should come from a discussion with your PI!
- o The more specific you can be, the better!
- o Will you be using any analysis tools?
  - Applied Biosystems QuantStudio 3 Real-Time PCR System / RStudio
- Explain experiments as if the person reading was going to repeat them (time points, drug doses, protein names, exact assays, etc)
- Ex: Chart review to collect provider level factors (use of AOBP, prescribing thiazides and combination medication, and use of follow-up visits)

# **Common Challenges in Methodology Design & How to Avoid Them**

### **Determining Appropriate Cohort Size**

- Selecting a cohort that's too small can lead to inconclusive or unreliable results.
- Larger-than-necessary cohorts can waste resources and time.
- Aim to define the minimum cohort size needed to answer your research question reliably.

### Importance of Calculating Study Power

- Power analysis helps ensure your study can detect meaningful effects if they exist.
- Properly powered studies reduce the risk of Type II errors (false negatives).

### Performing a Power Analysis

- Use statistical software (e.g., G\*Power, SPSS) to determine sample size based on effect size, alpha level, and desired power (typically 80-90%).
- Consult prior research to estimate effect sizes relevant to your study.

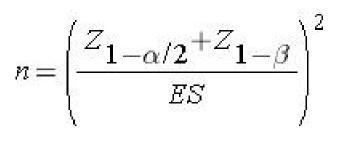
# MOST COMMON REASON FOR REJECTION!!!

# **POWER ANALYSIS - a quick overview**

- o Statistical power is the likelihood of detecting an effect or difference between groups when there actually is one
- The point is to determine the sample size needed for a study for the protection of the enrolled subjects
- o Helpful website!!!
- o <u>https://sphweb.bumc.bu.edu/otlt/mph-modules/bs/bs704\_power/bs704\_power\_print</u> <u>.html</u>
- o Power Tables
- https://www.semanticscholar.org/paper/Using-Power-Tables-to-Compute-Statistical Power-in-Konstantopoulos/931245ecaf252517b43085d6900e30f6f9a3e6ed

# **POWER ANALYSIS - a quickoverview**

- o Sample size(n)
- o Degree of significance ( $\alpha$ ) 0.05
- o Power ( $\beta$ ) **0.8**
- o Effect size (ES)
- o Meanfor observed groups  $(\mu)$
- o Standard deviation of groups ( $\sigma$ )



Effect Size = 
$$ES = \frac{\mu_1 - \mu_0}{\sigma}$$

https://sphweb.bumc.bu.edu/otlt/mph-modules/bs/bs704\_power/bs704\_ power\_print.html

# RESOURCES



# Loyola-Specific Links

Program Overview:

https://www.luc.edu/hsc/researchser vices/studentresearch/starprogram/

InfoReady Submission Site:

https://luc.infoready4.com/#competit ionDetail/1952019

# **Statistics Helpful Links**

Power Analysis: https://www.youtube.com/watch?v=VX\_M 3tlyiYk

How to choose a statistical test: https://www.youtube.com/watch?v=ruIIUA N0U3w

Excel Statistics Help: https://www.youtube.com/watch?v=\_g5ro KHj95o

Statistics Intro 30min BOOTCAMP: https://www.youtube.com/watch?v=kyjlxsLW1Is

# **LUC BIOSTATISTICS CORE**

The LUC Biostatistics Core will provide \*free\* stats assistance for students participating in the STAR program! You can request a meeting through their online form linked below.

Request Form: <u>https://hscrc.luc.edu/redcap/surveys/?s=ETAXFKLEXNKW8TJ8</u>

Biostatistics Main Site: https://www.luc.edu/hsc/cro/biostatistics/

Director: Cara Joyce, PhD cjoyce6@luc.edu





# **IRB Links and Resources**

LUC IRB Main Page: <a href="https://www.luc.edu/hsc/researchservices/committees/irb/">https://www.luc.edu/hsc/researchservices/committees/irb/</a>

LUC IRB HSC Deadlines

Cynthia Tom - Director of Human Research Protection Program <a href="mailto:ctom@luc.edu">ctom@luc.edu</a>