

Isabella Rosa Nanini

Mr. Speice

Independent Study and Mentorship II- 4A

26 September 2017

### Mentor Visit Assessment 1

Mentor: Dr. Timothy Pirolli

Profession: Pediatric Cardiothoracic Surgeon

Location: Children's Health Dallas 1935 Medical District Dr. Dallas, TX 75235

Date: 25 March 2017

Time: 10:00am to 10:45am

My first mentorship visit of my Independent Study and Mentorship II journey was able to clarify my plans for my mentorship with Dr. Pirolli. Coming into ISM II I knew that I wanted to create something more academically challenging with my original work and final product. With this in mind I have spent my past assessments researching problems and solutions within the pediatric cardiothoracic field from tissue engineering in vascular graft to anaesthesia with the hope of developing an idea of my own.

Coming into this meeting Dr. Pirolli and I had discussed via email of my possible participation on a research at UT Southwestern, and the goal of our meeting was to clarify my participation in this research and how it could fit into my ISM journey and project. He began by discussing what this research was (showing me the protocol). He explained that Dr. Guleserian had plans to complete a research of mitral valvuloplasty and mitral valve replacement, but with her move to another hospital she was unable to complete it so now it has fallen in the hands of

Dr. Pirolli. The goal of this research is to increase the knowledge on mitral valvuloplasty and mitral valve replacements in infants less than one year old by studying the charts of the past 12 years of patients under one year of age who have undergone mitral valvuloplasty or mitral valve replacement. Since mitral valvuloplasty is rarely performed on patients under one year of age the results of surgery and any information on this procedure is limited. By creating a retrospective study on the repairs of congenital mitral stenosis through mitral valvuloplasty or mitral valve replacement we will allow surgeons and other physicians to better understand this procedure.

After understanding the goals of this research, Dr. Pirolli gave me several articles to read up on and study that will be used in our research. These articles will allow me to better understand congenital mitral stenosis and the repairs that come with this defect, and learn of the past studies related to mitral valvuloplasty and mitral valve replacement. With his assistance and the assistance of another pediatric cardiothoracic surgical fellow we will begin to work on this research. I am extremely excited to grow from this experience and this research. It is not very common for high school students to have the opportunity to participate in research at a prestigious medical center like UT Southwestern. Not only will I have to learn the process of a scientific/medical research, but of the process of getting an article published on a peer reviewed journal and I will grow my understanding of my ISM topic it self.

The benefits that come with working on this research are endless and I am prepared to be challenged. The only questions that arise are if I can fit this project as my original work and final product and if I will have to look for a different original work idea. These questions will be answered through a discussion with Mr. Speice and other ISM teachers in FISD. I hope to work

on creating research assessments through the articles Dr. Pirolli sent me, and continue to communicate with Dr. Pirolli to move forward on this project.

The University of Texas Southwestern Medical Center at Dallas

Institutional Review Board

Protocol

**Title:** Outcomes of Mitral Valvuloplasty and Mitral Valve Replacement in Infants Less Than One Year Old

**1. Purpose:** This study has been designed to determine the outcomes following re-intervention, transplant, and death rates for patients undergoing a mitral valvuloplasty and mitral valve replacement.

**2. Background:** Congenital mitral stenosis (MS) is an anomaly frequently associated with additional left heart obstructions. Treatments for MS include mitral valvuloplasty and mitral valve replacement. Mitral valvuloplasty is rarely performed in patients under one year old. Since mitral valvuloplasty is rarely performed in pediatric patients, the results of the surgery compared to mitral valve replacement are not well evaluated.

**3. Concise Summary of Project:** This is an exploratory study by retrospective chart review of all patients since January 2004, who have had either a mitral valvuloplasty or mitral valve replacement at Children's Medical Center Dallas. Intra-operative conditions and clinical outcomes will be examined for this study. Group characteristics will be delineated based on the following parameters: early and late survival, transplant, re-intervention/re-operation. Medical

charts between January 1, 2004 and October 31, 2016 will be reviewed. A maximum of 150 charts will be reviewed. Study completion is expected in 1 years' time.

**4. Study Procedures:** A list of all patients who were under 1-year old and had mitral valve repair or replacement at CMC between January 1, 2004 and October 31, 2016 will be generated from an in-house database for cardiothoracic surgery patients (CardioAccess). Medical charts for each patient will be reviewed for the set of clinical data listed below. The research dataset will be formed, and patient identifiers will be destroyed. Descriptive statistics with central tendencies statistics will be run on the variables in this dataset. The results of the analysis will be presented at appropriate conferences and published in appropriate peer reviewed journals.

**5. Criteria for Inclusion of Subjects:** Infants who underwent mitral valvuloplasty or mitral valve replacement at Children's Medical Center between January 1, 2004 and October 31, 2016 within the first year of life.

**6. Criteria for Exclusion of Subjects:** Patients who do not meet the inclusion criteria

**7. Sources of Research Material:** The sources of research material will be existing medical records at Children's Medical Center and an in-house cardiothoracic surgery database. Patient names, medical record numbers, date of birth, diagnoses, surgical history, intraoperative parameters, surgical outcomes, medical history, laboratory results, imaging results (x-rays, echocardiograms), cardiac catheterization reports, and neurological exams results will be reviewed and compiled into the research dataset.

**8. Recruitment Methods and Consenting Process:** This project includes retrospective data review of elements previously collected for standard of care, quality and operational purposes. The only potential minimal risk is the loss of confidentiality which is no greater than the risk

posed in standard of care. The scientific analysis in this project requires the inclusion of all applicable subjects. Consent cannot reasonably be obtained due to the retrospective nature of the project.

**9. Potential Risks:** The only potential risk is the loss of confidentiality of participants. Results of this research will be presented in aggregate only without identification of individual subjects.

The study does not exceed the limits of minimal risk to the patient that would not otherwise be incurred if the patient were not a participant in this study. While some of the information obtained from the charts is of sensitive or of a personal nature that would lead to a moderate level of expected risk, these data points are already on hand as part of the medical record. In order to protect the study patient's private health information from potential harm, the information will be stored securely and kept confidential. Only the researchers will have access to the data..

**10. Procedures to Maintain Confidentiality:** The data will need to be identifiable to ensure that data has been collected on all subjects prior to statistical analysis. Once the search is complete, only study investigators will access the patient medical record to record the above mentioned data. Before statistical analysis, the data will be de-identified by deleting the associated names, medical records, date of birth, and any other identifiers. Electronic data will be password protected and paper records maintained in a locked file cabinet in a locked office.

**11. Potential Benefits:** There are no direct benefits to participation in this study. The information produced from this study may benefit future patients who require mitral valvuloplasty or mitral valve replacement.