Protocol Title: *The Impact of Meditation on Anxiety and Post-Operative Pain in Pediatric Patients Undergoing Urological Surgery*

Principal Investigator: *Bradley Morganstern, M.D.*

1. Objectives

Describe the purpose, specific aims, and hypothesis:

1. The aim of this study is to assess anxiety in pediatric patients preoperatively, perioperatively, and postoperatively and whether meditation reduces anxiety in the days before, during, and after the surgery.

2. The second aim of this study is to see if longitudinal meditation is associated with decreased postoperative pain by examining whether the group prescribed meditation has reduced pain medication intake, measured by the frequency of liquid analgesic medicine intake.

4. Number of Subjects/Records/Samples Collected

Indicate the total number of subjects to be accrued/records reviewed/samples collected across all sites:
60, including 30 controls and 30 study subjects.

5. Recruitment Methods

Describe when, where, and how potential subjects will be recruited:

Patients will be identified from the Urology clinic. Pediatric patients between the ages of 6 to 18 who will be undergoing urological surgery will be selected for this study along with their parents. Recruitment will begin in the clinic after surgery is scheduled.

6. Multiple Site ☒ N/A

A site is defined as an institution/organization/university that is collaborating with Augusta University

If this research involves multiple sites, specify the lead site and describe the roles of each site in the study.

If Augusta University will serve as the lead site, indicate that all required approvals are already obtained or will be obtained at each site prior to project implementation. In addition:

Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?

Describe the mechanisms you have in place to ensure that all local site investigators conduct the study appropriately and that engaged participating sites safeguard data as required by local information security policies. Please confirm that all non-compliance and /or unanticipated problems associated with the study protocol or applicable requirements will be reported in accordance with local policy.

Click here to enter text.

7. Reliance Agreements/Single IRB ☒ N/A

Reliance agreements (i.e. IRB Authorization Agreement (IAA), Individual Investigator Agreement (IIA), etc.) are formal arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research. Investigators working at multiple institutions, each having an IRB, may choose to have one IRB become the IRB of record over some or all participating sites. This means that the AU IRB is either the reviewing IRB (IRB of Record) or is relying on another IRB for IRB oversight of the research activity.

has eleven questions on a five-point scale ranging from "Not at all" to "A lot". An example of the meditation video questionnaire is linked here:
https://augusta.qualtrics.com/jfe/form/SV_3DeFFKdJVupMJQq (experimental group)
https://augusta.qualtrics.com/jfe/form/SV_2b2DZ9x16jY9IzQ (PeSSKi questionnaire)
The PeSSKi questionnaire will be in this form on another page for the meditation group. The control group will receive just the PeSSKi questionnaire.

Data will be collected from medical records.

c. *Data Types and Source Records:*

Briefly describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.

Data will be collected from electronic medical records, and the study questionnaires. Data collected from the EMR will include type of surgery, demographics, prior diagnoses and meditation experience, vital signs, and pain medication usage.

d. *Describe the procedures performed to lessen the probability or magnitude of risks:*

All data will be managed in a secure format and according to all applicable regulatory guidelines. Subjects will be assigned a study ID number. All medical records information will be entered into the secure database by the PI or designated study team members. A key linking the patient identifiers and the study ID will be stored separately from the data collection form. Only the approved investigator or study team members with username/password access will review medical records and the study information that is collected and stored on the secure drive. The original signed informed consent documents will be secured in a locked cabinet that is accessible only to members of the study team. Surveys will be labeled with a subject ID.

All data will be stored on an AU Secure HUMAN Box folder with access only given to study team members approved by the IRB.

e. *Describe the duration of an individual subject's participation in the study and the time involved also include the overall duration of the project:*

Active participation in the study will last for about one month, this includes three weeks pre-operatively and one week post-operatively. Total duration of the project is approximately two years.

v. *How long will the data and/or specimens be stored?*

According to AU and GA BOR policy

vi. *Describe whether, and how, subjects can request withdrawal or destruction of their information or biospecimens.*

Subject must contact the PI as indicated on the consent form to request withdrawal of their information.

vii. *Who will have access to the data or specimens?*

Only approved study team members

viii. *Who is responsible for receipt or transmission of the data and/or specimens? X N/A*

Click here to enter text.

ix. *How will data and/or specimens be transported? X N/A*

Click here to enter text.

10. Provisions to Monitor the Data to Ensure the Safety of Subjects ☒ N/A

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

a. *Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.*

Click here to enter text.

b. *Describe what data are reviewed, including safety data, untoward events, and efficacy data.*

Click here to enter text.

c. *Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*

Click here to enter text.

d. *Describe the frequency of data collection, including when safety data collection starts.*

Click here to enter text.

e. *Describe who will review the data.*

Click here to enter text.

f. *Describe the frequency or periodicity of review of cumulative data.*

Click here to enter text.

g. *Describe any conditions that trigger an immediate suspension of the research.*

Click here to enter text.

13. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research.

There is the potential for reduction of anxiety using meditation. No benefits can be guaranteed.

14. Confidentiality

Describe the procedures for maintenance of confidentiality.

Patients will be assigned a study ID for entry into the data collection sheet. A key linking the patient identifiers and the study ID will be stored separately from the data collection form and will be destroyed at the conclusion of the study. Both documents will be stored on the secure drive provided by IT specifically for the study and will be available only to study team members with username/password access. No identifiable participant information will be used in any publication or presentation materials. All study information will be kept confidential per HIPAA regulations. All investigators have undergone proper research training for evaluation and handling of patient information through CITI.

15. Incomplete Disclosure, Authorized Deception, or Deception ☒ N/A

See the Deception Policy on Augusta University Website.
If the study will use incomplete disclosure or deception, describe the incomplete disclosure or deception, and provide a rationale explaining why it is necessary to the research.
Click here to enter text.

Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.
Click here to enter text.

experience conducting human subject research. The PI and all study members' education and credentials are listed on their linked CV and CITI training

a. *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

n/a

b. *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

Each of the research team members, Ali Abolhassani, Ana-Sophia Chung, Luke Guy, Alleigh Wettstein, and Charlyn Shue have been involved in the development of the protocol for "The Impact The Impact of Meditation on Anxiety and Post-Operative Pain in Pediatric Patients Undergoing Urological Surgery". Each member of the research team understand their roles in data collection and interpretation. The research team will meet 1 week prior to data collection for a final review the protocol.