Anesthesia and Pain Management in Gynecological Procedures

Admin	
Protocol ID	2023-085
Panel	No Panel Assigned
Student Investigator	XXXXXXXXXXX Signed 09/11/2023 6:39 PM MDT
PI Type	Student
Faculty/Preceptor	Signed 09/12/2023 7:17 AM MDT Benjamin Brooks 04/18/2023 **No COI Reported**
Campus	UT
Faculty/Preceptor Acceptance Status	Accepted 09/12/2023 7:17 AM MDT
Department	MSBS
PI Institution	
External co-PIs	
Exempt Reviewer	Terry Hudgins / Completed / 10/17/2023 5:00 PM MDT
Review Type	Exempt Review
Approval Status	Exemption Approved (2) Tests, Surveys, Interviews
Submitted By	XXXXXXXXXXXX
Date Received	09/12/2023
Date of Completion	10/18/2023
Date Approved	10/18/2023
Approval Expires	*Approved Without Project Report*
Proposed Start Date	08/18/2023
Proposed End Date	10/31/2023
Date Closed	
Type of Research	Student Research
Funding Source	
Sponsor	
Sponsor Contact	
Sponsor Address	
Sponsor Email	
Sponsor Phone	
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Not Requested
Regulatory Agency	None
Subjects	• Minors (under age 18) • Pregnant Women • RVU Employees • RVU Students
Other Subjects Type	
Total Number of Subjects	200
Searchable Keywords	

added by Abigail Fish 3 minutes ago

(2) Tests, Surveys, Interviews Questions

Date Last Updated: 04/18/2023 11:50 AM MDT

What type(s) of instruments/activities will be used (Check all that apply.)

- ☐ Educational tests (cognitive, diagnostic, aptitude, achievement)
- ✔ Questionnaire/survey
- ☐ Interviews
- ☐ Observation of public behavior in which the research *does not participate* in the activities observed (may include audio or video recording)
- ☐ Observation of public behavior in which the research *does participate* in the activities observed (may include audio or video recording)

Will information be recorded in a manner that participants can be identified (e.g., name, social security number, license number, phone number, email address, photograph)?

Answer: Yes

✔No

Will subject responses be recorded?

Answer: Audio

Video

Digital Recording

✔No Recording

Would disclosure of information obtained put participants at risk for civil or criminal liability or damage to their financial standing, employability or reputation (e.g., drug or alcohol use; criminal or other illegal activity)?

Answer: Yes

✔No

Is the information recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects AND disclosure of the information could place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing employability, educational advancement or reputation.

Answer: Yes

✔No

Will your participants include anyone under the age of 18 years old?

Answer: ✔Yes

No

Age Range of subjects to be included:
<18-85+

Describe the source of the subject population:

Answer:

Anybody that has or has had a uterus

Where/How will the survey/interview occur? (describe the location and/or survey tool):

Answer:

Qualtrics

Pre-Protocol Questionnaire	04/18/2023 Pre-Protocol Questionnaire.pdf
Reviewer Notes	10/16/2023 Exempt Reviewer Review Notes.pdf
Student Research Approval Form	09/11/2023 Pain in Gyn Research Approval Signed Form.pdf
Consent Form	09/11/2023 Anonymous Survey Consent Form - Form Only_No Signa...
Survey Instruments	08/10/2023 Gyn pain survey.docx
Notifications	09/13/2023 Revisions Required: IRB #2023-085.pdf 10/18/2023 Exemption Approval: IRB #2023-085.pdf
Approved Application Sections	10/18/2023 Approved Application Sections Start Here.pdf

Personnel

PI

XXXXXXXX (04/18/2023)

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:

RVUCOM-SU

Faculty/Preceptor

Benjamin Brooks

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:

RVUCOM-SU

Project Description

Please upload your signed Student Research Approval Form. It can be found on the RVU iNet at: https://inet.rvu.edu/home/forms-2/student-research-approval-form/

Answer:

Pain in Gyn Research Approval Signed Form.pdf 09/11/2023 (Student Research Approval Form)

Briefly state the objective(s) and procedures associated with this project in the space provided.

NOTE: Incomplete or unclear information will delay IRB review and approval.

Answer:

The survey is a 13 question survey on history of gynecologic procedures, experience with pain, and pain management. The purpose is to investigate whether or not women are facing disparities in pain management during medical procedures. The survey includes age and race, but no other identifiable questions.

DATA COLLECTION METHODS

Will audio taping or videotaping of subjects occur?

Answer:
- Yes
- ✔No

Will any of the following instruments/methods be used?

Answer:
- Interview
- ✔Anonymous Surveys/Questionnaires
- Identifiable Surveys/Questionnaires
- Focus Groups
- Standardized (published) Tests/Assessments
- Not Applicable

Are you planning on using RVU institutional data (e.g. student information, grades, test scores, evaluations, assessment data) for your research?

Answer:
- Yes
- ✔No

Will the records or specimens be collected from RVU?

Answer:
- RVU only
- ✔RVU and other institutions
- Other institutions only
- Study does not involve records or specimen collection

Upload survey(s)/questionnaire(s):

Answer:

Gyn pain survey.docx 08/10/2023 (Survey Instruments)

Project Details

***Specific Aims* – State the specific scientific objectives of the research:**

Answer:

The specific aim of this project to analyze the effects on women in healthcare in gynecologic settings. It is known socially that women experience a lot of pain while getting basic medical procedures. This survey will allow us to quantify this information and hopefully move into a new era where women can receive pain management if the numbers indicate such. According to Healthy Woman.org, A US review of literature on pain management procedures encourages pain control management for patient comfort during gynecological procedures, but the general consensus in online discussions is that women's pain in general has historically been dismissed or undertreated often, leading to gynecological practices that minimize or dismiss the potential for pain during invasive procedures. There isn't a large body of research measuring pain from invasive gynecological procedures, but one UK study found that patients' ratings of pain did not match estimates from clinicians. There is a lack of research from patient perspectives on their pain levels in this setting. Many articles describe pain to be "mild to moderate", however many patients disagree with this notion. This research study is aimed to give patients a voice in their own experiences.

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***Background and Significance* - Briefly sketch the background leading to the present proposal. Describe the contributions that the study will make to the health of human beings and/or to the scientific data base, using documentation from the literature where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research**

project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan or activity.

Answer:

Within gynecological care at this point, the main use of pain management includes NSAIDs. This route of pain control is used in procedures such as IUD insertion, colposcopies, nexplanon insertions, biopsies, ect. This type of pain control is seen nowhere else in medicine. If patients are experiencing a cutting of the skin, insertion of a foreign object, or a biopsy in any other specialty, they are properly anesthetized. With this survey we will be able to quantify this possible variant in medicine.

Preliminary Studies **- Summarize preliminary studies conducted by the investigator pertinent to this proposal. State "none" if applicable.**

Answer:

There are not many studies done on this topic. The main information out their is describing the pain management that is used. All of these include mostly NSAIDs.

Investigator Experience **- Provide a brief synopsis of the Principal Investigator's (and/or faculty mentor's) expertise, experience, and capability to perform this research. Please DO NOT PASTE CV in this answer section. You may attach a copy of the curriculum vitae or research background of the principal investigator on the protocol page by uploading under "Files" at the bottom of the page.**

Answer:

As a woman, I have insight on what it is like to have these procedures done without proper pain management. I also hear from many women in my life, social forums, and other communication that many women struggle with this. I have done research in the past including Manual Labor, Chronic Pain, and the Risk of Opioid Addiction. I was a research assistant in undergrad as well. I know I will be able to get this survey into the hands of many women.

Experimental Design and Methods **- Detailed protocol for this project / subject-related studies.**

Methods and Procedures - Describe the procedure (s) in sequential detail. Clearly identify any experimental element of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.

[The description of investigational medical devices should include information on each important component, ingredient, principle of operation, and anticipated developmental changes in the device. On a separate page describe and address issues associated with the device presenting "Significant Risk" or "Non-Significant Risk"]

Answer:

Create Survey
Provide Survey to women of all ages
Analyze the statistics of the survey
Analyze the data and write an educational paper on the results and findings

Data Analysis and Data Monitoring **- Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).**

Answer:

All information will be anonymous then processed by statistician. The survey is completely anonymous which will protect the safety and welfare of volunteer subjects.

Data Storage and Confidentiality **– Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release.**

Answer:

The data will be completely confidential because the survey through Qualtrics is completely anonymous. There will be no digital footprint of volunteer subjects.

Setting **- Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians offices.**

NOTE: If other institutional review committees (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other involved institutions' IRBs must be obtained before initiation of the project (but are not essential for RVU IRB review to begin).

Answer:

Internet via Qualtrics

Are other IRBs involved in the approval of this project?

Answer: Yes
✔No

Laboratory Methods and Facilities **- Indicate where specific laboratory tests will be performed; e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc. If None, state N/A**

Answer:

None

Estimated Period of Time to Complete the Study **– Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hrs, etc.). Where possible use a table or "bullet-point" format to clearly illustrate the flow of activities and procedures.**

Answer:

Patients will complete the survey within 5 minutes.

Human Subjects **- Describe the characteristics of the research population**

Description of subjects **is to include the projected sample size, plans for the selection of subjects, and inclusion and exclusion criteria.**

Answer:

People that have or have ever had a uterus. People of all ages that have experience with gynecologic procedures.

Sample Size: **Number of subjects to be enrolled in this study at this site. Approximately ____ subjects at ____ sites in the U.S. will be enrolled in the study overall. For Clinical Trial studies, indicate number of subjects to be randomized.**

Answer:

Approximately 200 subjects at the Qualtric sites in the US will be enrolled in the study overall.

Describe both *Inclusion / Exclusion Criteria*. BE SPECIFIC! Also, if children (persons under age 18) are excluded from this study provide scientific justification for such exclusion. Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.

Answer:

Inclusion criteria: people with or previously with a uterus, any age
Exclusion: people with no history of having a uterus, cis gendered males

Describe intended gender or sex, age range, intended racial and ethnic distribution. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities) are included, justification must be provided.

Answer:

Female: ages 1 8 -90 years old

Female: 18-90+

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Identify the source(s) from which you will obtain your study population.

Answer:

Social Media, friends, family, large groups/platforms

Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review. Please upload recruitment materials under the "Files" tab at the bottom of your protocol page.

Answer:

Please fill out this survey if you have or have ever had a uterus.

Risk/Benefit Assessment and Informed Consent:

Describe the level of risk, and if more than minimal, describe how this research holds the prospect of a direct benefit for the subjects. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.

Answer:

A minimal risk of breach of privacy with utilizing online anonymous survey. Survey participants should be aware of possible triggering questions dealing with past history of pain and medical trauma.

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Describe how the anticipated benefit justifies the risk.

Answer:

This research is aimed to provide better pain management in gynecologic procedures. Therefore the benefit out weighs the minimal risk of possible breach in privacy and possible triggering questions regarding previous trauma.

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Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

Answer:

NO risk
The anticipated benefit is favorable in that with participants help, this research could lead to better outcomes regarding pain in medical settings.

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Describe any potential *RISKS OR DISCOMFORTS* in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Be sure to describe any anticipated adverse events that might occur during the course of the study.

Answer:

Risks include possible privacy breach utilizing Qualtrics survey program and possible triggering content with questions regarding previous medical trauma

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***Payment/Compensation* - Describe any financial payments for subject participation (e.g. compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.**

Answer:

No payments

***Subject Costs* - Describe any anticipated costs to research subject. If none, state such.**

Answer:

No costs

***Literature Cited* – If any, the references should be limited to relevant and current literature pertinent to the proposed research.**

Answer:

N/A

Do you ever intend to publish or present (oral, poster, or written) the results of this project?

Answer: ✔Yes. *Please remember to fill out the Attestation form on iNET if you present or publish any of your work.

No

Funding

Indicate the category of the sponsor:

Local Government

State Government

Federal Government

Industry or Pharmaceutical Company

Non-Profit Foundation/Institution

RVU Intramural Grant

Informed Consent

Is a signed Informed Consent document being used?

Answer: Yes

✔No

You have indicated that this is an anonymous survey. Please download the "Anonymous Survey Consent Form.doc" file listed

above, enter your consent script information into that file and then upload that file here:

Answer:

Anonymous Survey Consent Form - Form Only_No Signa... 09/11/2023 (Consent Form)

Will a Certificate of Confidentiality be requested from NIH?

Answer: Yes

✔No

Correspondences

Publicationss

Project Reports

Modifications

Adverse Events

Event / Date	Status / Comments / Files	Submitted By
No Adverse Events Found.		

Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		

Reviewer Comments

Exempt Reviewer: Terry Hudgins, Review Completed, Due date 10/17/2023 5:00 PM MDT

- no review text -