Cover Page

Buffered Lidocaine in Paracervical Blocks

NCT 03107754

Most recently updated July 2, 2018

Approved by University of Hawaii Institutional Review Board August 2, 2018

Protocol Title: Buffered Lidocaine for Paracervical Block to Decrease Injection Pain During First Trimester Surgical Abortions

Protocol Type: Unified IRB Form

Date Submitted: 01/30/2017

Approval Period: Draft

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* * * Personnel Information * * *

Starred items indicate required fields whenever that section is completed.

Is this a student led research?* N

Principal Investigator

UH defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.				
Name of Principal Investigator*		**Degree (MD/PhD/BSN/etc.)**		**Title**
Soon, Reni		MD, MPH		Asst Prof
Email*		**Phone**		**Fax**
rsoon@hawaii.edu		808-203-6548		808-697-3626
Research Department		**UH Status Check ALL that apply***		**Mailing Address**
University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	X	**Faculty**		
		Staff		
		Other		1319 Punahou Street Suite 824 Honolulu, HI 96826
ALL research personnel are required to complete Human Subject Research training.				
Which human subjects research training was completed for this protocol?*				CITI
See memo regarding appropriate human subjects training.				
The Research Compliance Office will verify the last date of completion below.				
Attach file of NIH training certificate in Attachments Section.				
NIH Completion Date				
Training Details				
No training data is available.				

Other Investigator(s)

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Name of Other Investigator	Degree (MD/PhD/BSN/etc.)	Title	Research Department	Type of Investigator
Chin, Jennifer	MD	Ob/Gyn Resident	University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	Co-Investigator
Kaneshiro, Bliss	MD, MPH	Assoc Prof, Fam Plan Fellowship Prog Dir	University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	Co-Investigator
Salcedo, Jennifer	MD, MPH, MPP	Asst Prof	University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	Co-Investigator
Raidoo, Shandhini	MD	Family planning fellow	University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	Co-Investigator
Moayedi, Ghazaleh	DO	Family planning fellow	University of Hawaii at Manoa, Obstetrics, Gynecology and Women's Health	Co-Investigator

Administrative Contact

Name of Administrative Contact, Project Director, or Lab Coordinator	Degree (MD/PhD/BSN/etc.)	Title
Email*	**Phone**	**Fax**
Research Department	**Mailing Address**	

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* * * Subject Checklist * * *

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Subject Checklist

Select All That Apply :

- [ ] Children and/or students under 18 years of age (including neonates)
- [X] Pregnant women/ fetuses
- [ ] Prisoners
- [ ] Military personnel
- [ ] Adult Volunteers
- [ ] Economically/educationally disadvantaged
- [ ] Mentally Ill
- [ ] University students
- [ ] University employees
- [ ] Illiterate
- [ ] Homeless
- [ ] Public officials/candidates for public office
- [ ] Institutionalized patients/residents
- [ ] Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
- [ ] Healthy Individuals
- [ ] Other (please specify):

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* * * Study Location * * *

Study Location

Select All That Apply - NOTE: Check "Other" and input text: 1.) If your study location is not listed, or 2.) If you would like to list details of your already-checked location (e.g., specific school within a school district)

- [ ] University of Hawaii, Manoa
- [ ] University of Hawaii, Hilo
- [ ] University of Hawaii, West Oahu
- [ ] University of Hawaii Community Colleges

- [ ] School/School District
  - [ ] Hawaii Public School
  - [ ] Hawaii Charter School
  - [ ] Private school
- [ ] Medical Health Care Facility
  - [ ] Queens Medical Center (QMC)
  - [ ] Hawaii Pacific Health (HPH)
  - [ ] Castle Medical Center

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Shriners Hospitals for Children - Honolulu

X Other (please specify)

Women's Options Center - faculty practice sites

Has this protocol or proposal been or will it be submitted to any Institutional Review Board(s) or ethics review committees other than the UH IRB? N

Is this a multi-site project? (A multi-site study is one where different PIs at different institutions are conducting the same study or aspects of the same study.) N

If this study also involves site(s) outside UH, will UH function as the coordinating center or lead institution?(Check N/A for studies done solely at UH.) Yes No X N/A

Please attach any and all non-UH IRB approval correspondence or letters of permission / support from external study sites, if applicable, in the Attachment section.

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* * * General Checklist * * *

General Checklist

Select All That Apply, unless otherwise indicated :

Section 1: If you are requesting that UH cede IRB authority to another IRB, stop here, do not use this application. Instead, submit the following materials to the Human Studies Program Office at uhirb@hawaii.edu.

Request to have UH IRB be the Relying IRB:In addition to completing the application, please also include in the Attachment section the following required materials:(1) Memorandum requesting to designate UH IRB as the relying IRB with justification(2) IRB Authorization Agreement signed by the other institution's Institutional Official (template can be found by clicking the HELP button In the top right corner of this page).

Section 2: Biomedical Research

Industry-Sponsored Clinical Trial

Human blood, cells, tissues, or body fluids (Institutional BioSafety)

Tissues to be stored for future research projects

Tissues to be sent out of this institution as part of a research agreement (Material TransferAgreement (MTA))

Human Embryos

Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.

Use of Patient related equipment? If Yes, specify what equipment is being used.

Radioisotopes/radiation-producing machines, even if standard of care (Radiation Safety)

Investigational Device

This study involves drugs or devices regulated by FDA

Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).

Investigational drugs, reagents, or chemicals

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)

Section 3: Methodologies

X Interview

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Questionnaire/Survey

Blood Draw

Section 4: For Student-led research

Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval (if available) in Attachments section.)

Class Project

Section 5: Other

X This study is or will be posted on ClinicalTrials.gov

If checked, specify the number in the field to the right: TBD

Protocol involves studying potentially addicting drugs.

X Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.

X HIPAA Authorization

Waiver or Alteration of Authorization

Activities Preparatory to Research

Limited Data Set and Data Use Agreement

Use and Disclosure of Decedents PHI without Authorization

Specify any other (use the text box to the right)

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* * * Funding * * *

X NONE--This project does not have any funding. If you want to add Funding for the study, please uncheck "NONE."

Funding

Add external and internal grant funding source(s) below: Federal Government, Other Gov. (i.e., State, local), Foundation or Other. Select "None" above if there is no external funding for the study.

Funding for this study has been secured by the UH Office of Research Services (ORS)

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* * * Application Type Checklist * * *

Application type checklist

Not Human Subjects Research/Undefined Research/Training or Infrastructure Grant

Exempt

X Expedited/Full Board

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* * * Expedited Paragraphs * * *

PLEASE READ: For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.

Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application.If none of the expedited criteria are appropriate for your project, please move to the next screen WITHOUT checking any of these criteria; your protocol will be reviewed by the full IRB. Note: The IRB will make the final determination if your protocol is eligible for expedited review.

Select one or more of the following paragraph(s):

Check all that apply	Category	Description
	1.	Clinical studies of drugs and medical devices when an IND or IDE application is not required by the FDA.
	2a.	Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds.
	2b.	Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from other adults and children, considering the age, weight and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
	3.	Prospective collection of biological specimens for research purposes by non-invasive means.
	4.	Collection of data through non-invasive procedures, not involving general anesthesia or sedation, routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
	5.	Research involving materials, such as data, documents, records, or specimens, that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis.
	6.	Collection of data from voice, video, digital, or image recordings made for research purposes.
	7a.	Research on individual or group characteristics or behavior, including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
	7b.	Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance.

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* * * Summary, Purpose, Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

Buffered Lidocaine for Paracervical Block to Decrease Injection Pain During First Trimester Surgical Abortions

Proposed Start Date: 02/01/2017 **Proposed End Date:** 06/30/2019

Protocol Title: Buffered Lidocaine for Paracervical Block to Decrease Injection Pain During First Trimester Surgical Abortions

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1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

First trimester surgical abortions are one of the most common outpatient procedures worldwide. Approximately 42 million are performed annually. Many different techniques have been used for pain control during this procedure. Some providers use conscious sedation, general anesthesia, or listening to music. Most providers use the paracervical block, a numbing injection into the cervix, either alone or in combination with other pain control techniques. The paracervical block has been shown to decrease pain during the procedure especially at earlier gestations. Some studies have shown a decrease in pain with four site injection paracervical blocks rather than the conventional two site injection. Some providers believe that a waiting period after the paracervical injection decreases pain. Some providers use buffered lidocaine due to a belief that it decreases pain. Others use plain lidocaine. At our clinics, the standard pain management protocol is using 20 cc of 1% plain lidocaine in a two site injection. Few studies have compared buffered versus nonbuffered lidocaine for paracervical blocks during first trimester surgical abortions. This study seeks to determine if buffered lidocaine decreases injection pain versus plain lidocaine for paracervical blocks.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

The purpose of this study is to see if using buffered lidocaine for the standard paracervical block will decrease the injection pain normally associated with the plain lidocaine solution we use as our standard protocol. Plain lidocaine is commonly used for paracervical blocks. However, some studies have suggested that buffered lidocaine may decrease the pain associated with the injection of the medication, but few studies have looked specifically at using buffered lidocaine for paracervical blocks during first trimester outpatient surgical abortions. Our hypothesis is that using buffered lidocaine for the paracervical block during first trimester surgical abortions will decrease injection pain as compared to using plain lidocaine.

b) What do the investigators hope to learn from this project?

Primary objective: To assess if buffered lidocaine reduces pain from injection more effectively than plain lidocaine for paracervical blocks during first trimester surgical abortions

Secondary objectives: To evaluate if buffered lidocaine is more effective than plain lidocaine at reducing pain during dilation and postoperative pain from first trimester surgical abortions

3. Procedures

a) Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

Potential participants will be identified at their office visits to the University Women's Health Specialists either at Kapi'olani or Queen's. If a patient desires surgical termination of a first trimester pregnancy or management of a failed pregnancy in the first trimester, they will first receive standard counseling and provide informed consent for the procedure. Next, the patient's eligibility for our study will be assessed. If the patient is eligible, she will be asked by a member of the research team if she is interested in participating. If she is, the study will be explained to her and written consent will be obtained after she is given the opportunity to have all of her questions answered. The patient will then complete a written questionnaire to collect demographic data.

This prospective randomized control trial will consist of two study arms. As participants are enrolled they will be randomly assigned to Arm 1, where a paracervical block will be administered with 20 cc of 1% lidocaine, which is our standard office protocol, or to Arm 2, where a paracervical block will be administered with 20 cc of 1% lidocaine buffered with 8.4% sodium bicarbonate.Patients will be randomly assigned to either Arm 1 or Arm 2 of the study. Prior to the start of the study, study assignments will be generated in a 1:1 ratio. A statistician not involved with the conduct of the study will use a computer random number generator to generate random permuted blocks. The random permuted blocks will also be randomly varied in sizes of 4, 6, & 8. This statistician will place allocation assignment cards in sequentially numbered, sealed, opaque envelopes. A different randomization scheme will be used for each location, one at the Kapi'olani office and one at the Queen's office.

A clinic staff member not involved with the conduct of the study will be trained specifically in the opening of the allocation envelopes. The clinic staff member will be trained to pull envelopes individually in a sequentially numbered order. The staff member will be trained to open the envelope and remove the study card to read the allocation group: buffered lidocaine or plain lidocaine. The staff member will be trained to not tell anyone involved in the study of the allocation assignment. The clinic staff member will then draw up the buffered lidocaine or plain lidocaine in an unlabeled syringe, and give it to the procedural physician or surgical assistant for study administration.

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All patients who consent to the study will receive standard counseling prior to their procedure. The procedure will start with a bimanual exam by the provider. Next, the provider will place a speculum, cleanse the cervix with betadine solution, and place a single-tooth tenaculum on the anterior lip of the cervix. At this point, participants assigned to Arm 1 will receive a paracervical block loaded with 20 cc of 1% lidocaine with 10 cc injected at the 4 and 8 o'clock positions of the cervicovaginal junction. Participants assigned to Arm 2 will receive a paracervical block loaded with 18 cc of 1% lidocaine and 2 cc of 8.4% sodium bicarbonate in the same fashion. The research assistant will ask the patient to verbally report their level of pain based on the 100 mm visual analog scale at the following points of the procedure:
1)Prior to the start of the procedure (baseline)
2)After speculum placement
3)After paracervical block
4)After cervical dilation
5)After suction curettage
6)Fifteen minutes postoperatively

i) **Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.**

Our current standard of care is to use 20 cc of 1% plain lidocaine for the paracerical block. We are experimenting using a paracervical block loaded with 18 cc of 1% lidocaine and 2 cc of 8.4% sodium bicarbonate to see if this decreases injection pain.

b) **Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).**

Abortion care providers will perform the dilation and curettage at University Women's Health Specialists either at the Kapi'olani or Queen's location. The research portion will take place on the same day as the dilation and curettage procedure and will add an additional 20 minutes to the patient's standard office visit. No additional visits are required for this research study. Data will be collected in person and recorded on paper then transferred to a secure electronic database.

i) **Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**

All instruments used are in the public domain.

c) **For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and nonsubjects will be located during the activities.**

N/A

d) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section**

N/A

e) **Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the tapes/photographs (e.g., shown at scientific meetings, erased, etc.).**

N/A

f) **Will the proposed research involve the use of existing data/specimens? If so, check all that apply:**

- **i. The research involves data from publicly available sources**
- **ii. That data will be recorded by the investigator in such a manner that subjects cannot be identified.**
- **iii. Any link to identifying information has been destroyed**
- X **iv. N/A**

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* * * Background and additional procedures * * *

4. Background and additional procedures

a. Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

A small number of studies have addressed this research question with conflicting results.

A multiphase study was published in 1995 using various techniques of the paracervical block for surgical abortions. Using a 10 cm visual analog scale (VAS), the study found a statistically significant decrease in injection pain when using buffered lidocaine as compared to plain lidocaine and bupivacaine. However, the pain immediately after the injection decreased from 3 cm to 2 cm on the 10 cm VAS, which may not be a clinically relevant difference. Several pain studies have found that a 30% or 13-20mm difference on a 100mm VAS is clinically meaningful for patients.

Another study compared buffered lidocaine versus plain lidocaine for paracervical blocks for surgical abortions. Using an 11 point scale, the investigators found an 8% decrease in pain from injection when using buffered lidocaine versus plain lidocaine. Although this difference was statistically significant, the author concluded that this was most likely not clinically significant and thus not worth the extra cost of preparing the buffered solution.

Buffered lidocaine versus plain has been looked at in non-gynecological procedures as well. One randomized controlled study compared buffered lidocaine versus plain lidocaine for patients undergoing bilateral periocular surgery. Investigators found a 51% decrease in injection pain when using buffered lidocaine versus plain lidocaine, which was both statistically and clinically significant.

Another study compared 1% lidocaine with epinephrine versus 1% lidocaine buffered with 8.4% sodium bicarbonate for patients undergoing loop electrosurgical excision procedure (LEEP) procedure. Using a 100 mm Likert scale, the study found an eight-point decrease in procedural pain when using buffered lidocaine; however, this was not statistically significant.

Loma Linda University conducted a study comparing pain using 1% lidocaine with epinephrine versus 1% lidocaine with epinephrine buffered with 8.4% sodium bicarbonate for patients undergoing eyelid surgery. Using a 10 cm visual analog scale, investigators found a trend toward decreased pain from injection when using buffered lidocaine; however, this was not statistically significant.

Two studies found no difference when using buffered lidocaine versus plain lidocaine. A dental study comparing buffered lidocaine versus plain lidocaine for maxillary injections found no difference in pain with 5% buffered, 10% buffered, and nonbuffered lidocaine. Another study compared buffered versus plain lidocaine for patients undergoing incision and drainage for pulpal necrosis. No significant difference in pain was found.

Thus, very few studies have specifically looked at buffered lidocaine versus plain lidocaine for paracervical blocks during first trimester surgical abortions. The studies that have been conducted have conflicting results. Some have found benefit by reducing pain from injection or procedural pain. Other studies have found no difference in pain.

It is important to determine the ideal anesthesia for first trimester surgical abortions since it is one of the most common outpatient procedures worldwide. Buffered lidocaine for paracervical injections may have benefit for patients. However, it is more expensive to prepare and requires more planning due to a shorter shelf life. Thus, buffered lidocaine should only be used if there is a definite benefit. It is therefore important to determine if buffered lidocaine decreases injection pain during paracervical blocks for first trimester surgical abortions.

We have decided to select our study population from patients at University Women's Health Specialists offices due to the high volume of patients seeking surgical terminations of pregnancy or surgical management of miscarriages. We believe our selected patient population will reflect the diversity of Hawai'i.

b. Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).

Based on previous research showing that a clinically relevant decrease in pain on a 100 mm VAS is at least 15 mm, we need to enroll 88 patients (44 in each group) to show this difference with 80% power and alpha of 0.05. Inflating this number by 10% to account for potential dropout (which is unlikely due to the lack of longitudinal follow-up), we obtain a total sample size of 98 patients (49 in each group).

Based on the typical volume of patients seen in our office practice, we anticipate that enrollment will take approximately 6-8 months.

We will assess the primary objective by comparing the mean pain score after paracervical block from participants receiving buffered

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We will assess the primary objective by comparing the mean pain score after paracervical block from participants receiving buffered lidocaine versus the mean pain score after paracervical block from participants receiving plain lidocaine. To assess our secondary objectives, we will compare the mean pain score after cervical dilation between participants assigned to Arm 1 and Arm 2 as well as compare postoperative pain between the two arms. All analyses will assume a statistical significance level of 0.05. In addition, we will monitor the extra costs of preparing buffered lidocaine solutions and how the preparation of buffered lidocaine impacts clinic flow and staffing.

c. **Alternative Procedures. Describe any alternatives to participating in the research. (e.g., standard of care treatment, etc.). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.**

If a participant decides to withdraw from the study, she will receive our standard of care which is to administer a paracervical block using 20 cc of 1% plain lidocaine prior to the procedure.

d. **Will subjects be followed after their active participation is complete?** N

If yes, explain why and describe how:

e. **Will subjects have access to the study treatment/procedure after completing the study?** N

If yes, explain why and describe how:

f. **Do any of the following apply.**

i. **Will subjects be audio recorded?** N

ii. **Will subjects be videotaped?** N

iii. **Will subjects be photographed?** N

If yes to i, ii or iii, explain the collection process and use in the context of this research of such media

(Explicit consent must be obtained for use of these methods for Expedited and Full Board studies.)

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* * * Subject Population (a-f) * * *

5. Subject Population

a) **How many subjects do you intend to enroll and/or how many subject records do you intend to access?**

i. **At this site**

# of subjects 98

# of records N/A

ii. **At all sites** X **N/A**

# of subjects

# of records

b) **Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)**

i. **Identify inclusion criteria.**

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•Pregnant women 14 years and older
•Desiring surgical termination of pregnancy or surgical management of a miscarriage
•Gestational age up to 13 weeks and 6 days to be established by best dating (i.e. LMP or earliest ultrasound)
•Treatment plan involves outpatient surgical termination
•Participant able to provide informed consent in English and willing to participate in the study

ii. **Identify exclusion criteria.**

•Unable to read, speak, or understand English
•Unable to provide informed consent
•Currently incarcerated
•Under the age of 14 years
•Contraindications to receiving lidocaine or buffered lidocaine

c) **What is the rationale for studying the requested group(s) of participants?**

We believe that our inclusion criteria select for a group of participants that will be able to provide informed consent and reflect a diverse population of patients requesting dilation and curettage either for termination of a pregnancy or surgical management of a miscarriage. Thus, we will ensure the safety of our participants as well as collect valuable data from our participants.

d) **If your participants include pregnant women, human fetuses, neonates, children, adults with diminished capacity, and/or prisoners, describe the protocol-specific safeguards used to protect the rights and welfare of this study population:**

This study will recruit two possibly vulnerable populations: pregnant women and minors. This could raise the possibility of additional risk to the pregnant woman or the fetus due to the pregnancy. However, women coming to either clinic are already choosing to terminate their pregnancies and thus there are no additional risks to either the women or the fetus due to enrolling in this study. Also, this study will recruit patients who are below the age of 18. Patients below the age of 18 will require patient assent and parental consent.

e) **Provide a clear compelling rational for excluding women, minorities, or minors, if they are intentionally excluded from the research.** X **N/A**

f) **State if any of the subjects are students, employees, or laboratory personnel. Please explain how subjects will be protected from coercion and undue influence** X **N/A**

g) **Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training). Also, explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).**

My co-investigators and I have extensive experience and training in providing abortion care. I completed a reproductive health externship in medical school, attended the Abortion Training Institute, and have completed my family planning rotation in residency. My co-investigators have completed fellowships in family planning and conducted numerous research projects in family planning, some specifically related to pain control. Because this research project does not alter the actual procedure being done, local community attitudes, cultural norms, and cultural sensitivities should not hinder our project. In general, Honolulu is a city that supports a woman's right to choose; thus, this project should not meet too much resistance.

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* * * Subject Population (g-j) * * *

5. Subject Population

g) **Will bilingual or multilingual subjects be recruited?** N

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h) Will non-English speaking subjects be recruited? N

If yes, state language(s) spoken (other than English):

i) Will subjects be less than 18 years of age? Y

Age Ranges:

- 0-7
- 8-13
- X 14-17

j) Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire) in the Attachment Section (#16).

We plan to collect demographic data including age, race, marital status, highest education level, level of menstrual symptoms, previous pregnancies and outcomes, medications, pre-existing conditions, and any previous cervical procedures.

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* * * Recruitment Process, Subject Compensation and Costs * * *

6. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how.**

Potential participants will be identified at their office visits to the University Women's Health Specialists either at Kapi'olani or Queen's. If a patient desires surgical termination of a first trimester pregnancy or management of a failed pregnancy in the first trimester, they will first receive standard counseling and provide informed consent for the procedure. Next, the patient's eligibility for our study will be assessed. If the patient is eligible, she will be asked by a member of the research team if she is interested in participating. If she is, the study will be explained to her and written consent will be obtained after she is given the opportunity to have all of her questions answered.

b) Planned Subject Identification Methods:

	N/A		Direct advertising
	Chart/database review		Living conditions (e.g., nursing home residents)
	Class participants	X	From PI's own practice/clinic
	Organization mailing lists		UH Participant Recruitment Pool(e.g.,SONA)
	Circumstance (e.g., homelessness)		

If referrals, explain how much they will be compensated for referrals if compensation is given.

Other (please specify):

c) Planned Recruitment Materials/Methods:

	N/A		Flyers/posters
	Phone Scripts		Letters to providers/schools/organizations
	Television ads		Newspaper ads

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	Letters to prospective subjects		Radio ads
	Oral Scripts		PowerPoint presentations
	Internet ads/postings		Email
X	Face to face interactions		UH Subject Pool
	Other (please specify):		

(All advertising must be submitted for review in its final printed/recorded form)

Note: Attach copies of ALL recruitment materials in the Attachment Section

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? N

Total amount (in dollars or equivalent)

b) Form of Compensation:

	Cash		Voucher
	Check		Course/extra credit
	Gift card/certificate		Reimbursement only
	Other (please specify):		

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

d) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.

e) Will subjects or their health care providers be required to pay for any study related procedures or products?

i. If yes, explain:

f) Who is responsible for costs incurred due to injury/harm?

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* * * Risks * * *

8. Risks

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

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a) **PI's evaluation of the overall level of Risk. (Please check one: minimal or minimal.)**

X Minimal (everyday living)

Minimal (greater than everyday living)

b) **Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risk(s) associated with each research procedure or test.**

This study poses minimal risk to the research participants. Paracervical blocks are commonly performed in gynecological procedures both in the office and in the operating room and are generally well tolerated. Routine care in our practice is to administer paracervical blocks with 20 cc of 1% plain lidocaine. There is no evidence to suggest that adding the buffering agent would present any additional risks to the patient. Therefore risks of participating in this study are commensurate with the risks associated with having a surgical abortion. Potential risks associated with enrollment in our study include the potential loss of privacy of medical information. However, we are taking steps to mitigate these risks as outlined below.

c) **Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

Patient's medical information will be protected to the best of our ability using password protection and limiting access to investigators and research staff. In addition, data will be de-identified prior to statistical analysis. If, during the study, new information is available that would affect the safety of participants, they will be informed and the study will be modified to reflect this information.

d) **How will subjects be assessed for adverse events?**

All investigators will protect and monitor the rights, safety, and welfare of all participants. All participants will be informed to report any adverse events or severe adverse events. Investigators will review these reports and follow all adverse events until they resolve. Any severe adverse events will be reported to the principal investigator within 24 hours as well as to the IRB and to the FDA if appropriate.

If a participant is withdrawn from the study due to a severe adverse event, the participant will be referred for or provided appropriate medical follow up.

e) **Is there a plan to monitor study data for subject safety?** Y

If yes, discuss who will monitor the study data and describe the monitoring plan:

Investigators will meet regularly to review study progress, adverse events, severe adverse events, and any necessary changes to study protocol. If at any point the study is suspected to place participants at unnecessary risk, the study may be unblinded and terminated.

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* * * Benefits * * *

9. Benefits

a) **Discuss any potential benefits that would justify involvement of subjects in this study. Compensation is not considered a benefit.**

i. **Direct benefits to subjects (if applicable)**

There is a potential medical benefit to participants who receive the buffered lidocaine for their paracervical injection due to a possible decrease in injection pain.

ii. **Indirect benefits to society**

Participants will also benefit from their ability to contribute to the improvement of medical care.

b) **Explain how the potential benefits justify the potential risks involved in participation in this research.**

It is important to determine how to decrease pain during one of the most common outpatient procedures worldwide. The potential risks to the participants are minimal and commensurate with the risks associated with having the planned procedure. Thus the

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potential benefits justify the potential risks.

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* * * Procedures to Maintain Confidentiality * * *

10. Procedures to Maintain Confidentiality or Anonymity

Will your research involve any of the following types of data listed below? Y

Which of the following types of data will you work with:

X **IdentifiableInformation is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person or investigator could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).**

AnonymousData are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

De-identifiedIf the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means). Note: This also applies if the source of the data is identifiable but the data collected is not.

CodedThis refers to data that have been stripped of all direct subject identifiers, but in this case each record has its own study ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the study team (e.g. the PI) or it could be held by someone outside of the study team (e.g. researcher at another institution). A coded data set may include limited identifiers under HIPAA. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

a) If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.

•Government or university staff may have access to patient information for review.
•Providers and other healthcare staff of University of Hawaii may have access for direct patient care.
•Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, and the National Institutes of Health may have access to patient information for research purposes.

b) Explain how you will protect subjects' privacy. Note: Privacy refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interest's people want to control:

- **The time and place where they give information.**
- **The nature of the information they give.**
- **The nature of the experiences that are given to them.**
- **Who receives and can use the information.**

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center that is clearly identified as such by signs on the front of the building. Please keep this definition in mind as you respond to this item.

Both of our clinic locations share space with other Ob/Gyn practitioners. Thus, patients are not clearly identified as seeking abortion care when they walk through our doors. Once a patient is seen, she will receive counseling for the procedure and information about the research project, if she is interested, in a private, confidential setting.

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c) **Describe how you will maintain the confidentiality of subjects' information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.**

Data will initially be recorded in a paper chart and then entered into an online database on a password protected computer. Only study investigators and research staff will be allowed to access data. Data will be de-identified prior to analysis.

d) **Who will have access to study records or specimens? (Please identify specific team members by name.)**

All co-investigators will have access to study records, including Drs. Soon, Chin, Kaneshiro, Salcedo, Raidoo, Moayedi, and Mary Tschann.

e) **If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the IRB application submission. It includes data or specimens collected for research and non-research activities.**

N/A

f) **How will subjects be asked to provide their permission for release of identifiable data collected as a part of this proposed research (e.g., pictures, recordings, responses to research questions), now or in future? Explain and include appropriate statements in consent materials.**

Subjects will sign a written consent form, which will be explained by a member of the research team and all questions answered.

g) **If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?**

N/A

h) **If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.**

N/A

i) **Explain why, where, in what format, and for how long data/specimens will be retained.**

Data will be kept electronically on a password protected computer for seven years after study completion in order to access information if needed.

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* * * Consent Information * * *

11. Consent Information

11 a & b only apply to exempt applications

a) **How will subjects be informed of procedures, intent of the study, and potential risks to them?**

b) **How will subjects be informed they may withdraw at any time without penalty?**

Note: Attach, in the Attachments Section, written and/or verbal instructions the subject will receive.

See sample consent forms at https://manoa.hawaii.edu/researchcompliance/templates

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c) Click Add to answer consent process questions and provide the consent forms.

Informed Consent

Title	Consent Type	Attached Date
Consent	Consent	02/28/2017
Parental Consent	Consent	02/28/2017

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* * * Assent Background * * *

12. Assent Background

(Complete if applicable)

Assent Document: A form or script of the information that will be conveyed to the child about the study. In general, researcher must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of hildren, more than one assent form may be needed (i.e., an assent from suitable for a 17 year old is not usually suitable for a 7 year old child).

Assent Waiver: No child assent will be sought at all. This means that the IRB is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefits that is important to the health or well-being of the child.

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

See sample consent/assent forms at https://manoa.hawaii.edu/researchcompliance/templates/

Click Add to attach the Assent forms and provide assent process background information for each Assent Form, Alteration Form and Waiver.

Assent Background

Title	Assent Information Type	Attached Date
Assent Form	Assent Form	01/29/2017

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* * * HIPAA * * *

13. Health Insurance Portability and Accountability Act (HIPAA)

If you are using PHI and this page is not active you must return to the General Checklist and check the box regarding the use of PHI in this research.

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes.

The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement Authorization).

Is Your Research Covered by HIPAA's Privacy Rule? - Decision Tree

HIPAA /Privacy Rule Authorization Template

Protected Health Information (PHI) is health information with one or more of the following identifiers. For more information see: https://www.hawaii.edu/researchcompliance/human-studies or consult HIPAA Privacy Rule for Research

Research which involves the use of de-identified data is exempt from HIPAA requirements. In order to be de-identified data. NONE of the subject identifiers listed below can be collected, used, reviewed, recoded, accessed or disclosed.

Please review the following list and indicate if any of the information will be collected from any medical records for the purpose of this research project.

1. X Names
2. X Social Security Numbers
3. X Telephone Numbers
4. X All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census;
   - i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
   - ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
5. X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
6. Fax Numbers
7. Electronic Mail Addresses
8. Medical Record Numbers
   - You must attach a data collection sheet identifying the data points being collected from the MRN
9. X Health Plan Beneficiary Numbers
10. X Account Numbers
11. Certificate/License Numbers
12. Vehicle Identifiers and Serial Numbers, including License Plate Numbers
13. Device Identifiers and Serial Numbers
14. Web Universal Resource Locations (URLs)
15. Internet Protocol (IP) Address Numbers
16. Biometric Identifiers, including Finger and Voice Prints
17. Full Face Photographic Images and any Comparable Images
18. Any other unique identifying number, character, or code (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

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to code the research data)

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* * * Drugs and Devices * * *

14. Drugs and Devices

Drugs

Name	IND Number (if applicable)	Type of Research
lidocaine		Therapeutic

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* * * Potential Conflict of Interest * * *

15. Potential Conflict of Interestrr

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

a) N Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

b) N Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

c) N Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) N Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) N Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) N Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) N Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) N Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

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Minimizing Risks and Disclosure to Subjects

i) N Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) **What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?**

If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

By submitting this form, you are attesting that you have read the UH HRPP Policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Link to UH's Conflict of Interest Policy: https://manoa.hawaii.edu/.

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* * * Attachments * * *

16. Attachments

Attach relevant documents here. These could include:

- NIH/ CITI Training Certificate
- Advertisements
- Bibliography
- Conflict of Interest Information
- Cooperating Institution(s) Approval
- Data Collection Sheet
- Explanatory diagram (Sequence of events)
- Grant proposal
- Impact Statement
- Information Sheets/Brochures
- Investigators Brochure
- Material Safety and Data Sheet
- Package Inserts
- Phone Scripts
- Program Project Grant/List
- Questionnaires
- Recruitment Material (e.g., flyers, e-mail text)
- Recruitment Statement
- Protocol
- Protocol Modification Requests
- Training Grant/List
- Other files associated with the protocol (you can upload most standard file formats: xls, pdf, jpg, tif, etc.)

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Please be sure to attach all documents associated with your protocol. Failure to attach the files associated with the protocol may result in this protocol being returned to you for completion prior to being reviewed.

Students: Be sure to attach the Methods section of your thesis or dissertation proposal. If this protocol is associated with a grant proposal, please remember to attach your grant.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Attachment Name	Attached Date	Submitted Date
Protocol	Chin_Protocol_Jan29	01/30/2017	01/30/2017
Data Collection Sheet	Chin_Procedure_data_form_Jan29	01/30/2017	01/30/2017
Other	Chin_SAE_form_Jan29	01/30/2017	01/30/2017
Other	Chin_AE_form_Jan29	01/30/2017	01/30/2017
Other	Chin_Eligibility_Jan29	01/30/2017	01/30/2017
Other	JS - CITI HSR	01/31/2017	02/01/2017
Other	JS - CITI IPS	01/31/2017	02/01/2017
Other	RS - CITI HSR	01/31/2017	02/01/2017
Other	RS - CITI IPS	01/31/2017	02/01/2017

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* * * Obligations * * *

Obligations

Obligations of the Principal Investigator include the following:

Provide all subjects a copy of the signed consent form, if applicable.

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel.Training must be updated every three (3) years.

Final Report - The IRB will be notified when the study is complete.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the UH IRB.

I agree to not enroll any subjects or collect any data intended only for research use prior to issuance of an IRB approval.

I understand that I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all of the applicable policies and regulations.

This study will not begin until the investigator receives written final approval or determination of exemption.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

Submit the Continuing Review Form in order to maintain active status of the approved protocol. This form must be submitted to the IRB at least 30 days (AHSIRB) or 45 days (SSIRB) prior to the date of expiration.

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Submit the Protocol Violation Form to report protocol Deviations/Violations or the Event Reporting Form to report Adverse Events (AEs) or Unanticipated Problems that occur in the course of the protocol.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

"blue"Please click "Check for Completeness" to your left to continue to the next step. If the protocol is complete and ready for submission, please click "Submit Form" to your left to submit your protocol for IRB Review.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Consent Forms	Letters
01/29/2017	NEW FORM CREATED			
01/30/2017	NEW FORM SUBMITTED	Y		
01/31/2017	NEW FORM RETURNED			
02/01/2017	NEW FORM RESUBMITTED	Y		
02/01/2017	NEW FORM RETURNED			
02/01/2017	NEW FORM RESUBMITTED	Y		
02/03/2017	NEW FORM PANEL ASSIGNED			
02/06/2017	NEW FORM REVIEWER(S) ASSIGNED			
02/27/2017	NEW FORM CONTINGENT			