SAINT LOUIS UNIVERSITY
EST. 1818

**ClinicalTrials.gov**

Study ID 26976

Official Title: NSAID Use in Postpartum Hypertensive Women

NCT02902172

Document date: 6.9.17

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| | |
|---|---|
| **Protocol Title:** | NSAID use in postpartum hypertensive women |
| **Protocol Status:** | CLOSED |
| **Date Submitted:** | 06/09/2017 |
| **Approval Period:** | Draft |
| **Important Note:** | This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details. |

## * * * Continuing Review * * *

### Continuing Review Request

**WHAT TO UPLOAD WITH YOUR CONTINUING REVIEW APPLICATION**

For studies where research activities are limited to data analysis, upload subject safety information and publications (e.g., manuscripts, abstracts) since the last IRB approval, if applicable.

NOTE: if activities are limited to data analysis of de-identified/anonymous data (data that can no longer be linked to subject identifiers directly or through use of a code with master list kept), the study can likely be closed via the Final Report Form. See the SLU IRB Guidance for Closure of Human Subjects Research Studies.

For all other studies, upload:

- Subject safety information including the most current Serious Adverse Event (SAE) cumulative table and data safety monitoring reports since the last IRB approval, if applicable.
- Any publications (e.g., manuscripts, abstracts) since the last IRB approval.

Any changes, updated and/or new study materials should be uploaded and questions 19 - 24 of this form should be completed.

1. **Please indicate the status of the study:**

a) **The study has not started but will become active.**
**Please explain why the study has not started.**

b) X **The study is ACTIVE (please check the appropriate box below):**
X **Study is open to accrual.**
**Study is on hold or halted.**
**Please explain what needs to occur before accrual can resume.**

**Study is permanently closed to accrual.**

i. Have all subjects completed all research related activities/interventions?
ii. Will the research only remain active for long-term follow-up of

subjects?

iii. Are remaining research activities limited to data analysis only? (See instructions above).

iv. For studies that are closed to subject accrual, do any subjects need to be re-consented (to inform them about changes to study procedures, study risks, study personnel, etc.)?

**For IRB office use: * may qualify for expedited review**

c) **The study has expired and needs to be re-initiated.**
**Explain any research activities occurring during lapse in IRB approval.**

2. **Date the study was initially approved by the IRB:** 07/05/2016

3. **Approval date of previous continuing review:**

4. **Total number of participants/records/specimens you are approved to enroll.** 160

5. **Total number of subjects that have given consent (verbal or written) to date.** 17

6. **Total number of subjects that failed screening (if not applicable, state N/A).** 0

7. **Total number of participants accrued since the beginning of the project.** 17

8. **For multi-center studies, number of subjects approved for accrual study-wide (SLU site plus all other sites).**

9. **For multi-center studies, number of subjects enrolled study-wide (SLU site plus other sites).**

10. **Number of withdrawals from the research (since last approval date) and explanation/reasons for withdrawals.**
none

11. **Description and number of:**

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a) Reportable Protocol Deviations/Violations since the last approval date:

none

b) Unanticipated Problems (UPs) since the last approval date:

none

c) Serious Adverse Events (SAEs) since the last approval date:Note: Information here should be consistent with the cumulative table, which should also be attached in section #16.

none

12. Have there been any complaints about the research during the last year? N

If yes, please describe.

13. Briefly describe the progress of the study to date. Provide a status of participants in study, for example, where is the most recently accrued participant in terms of timeline in the study? If participants are in long-term follow-up, explain what this consists of in terms of data collection and/or intervention. Provide any new information in regard to risks. Summarize or attach publications or presentations.

Enrollment continues

14. Is there a Data Safety Monitoring (DSM) plan for this study?

No

Yes, a copy of the DSM report(s) for the last approval period is attached.

Y Yes, but a copy of the DSM reports(s) for the last approval period is not attached. Please explain below.

The DMSB does not generate minutes/reports unless there are SAEs to review. No SAEs have been reported for this protocol.

15. FDA Regulated Studies

Is this a Food and Drug Administration (FDA) Regulated Study, (i.e., involves drugs, devices, biologics)? If yes, please answer the following questions: Y

a) Have there been any changes in the FDA status of any drug or device used in the study? N

If yes, please explain:

b) Have any of the investigational drugs or devices used in this study received FDA approval? N

If yes, please explain:

c) Have any new alternative drugs or devices been approved for treatment of the study condition that may affect subjects willingness to participate? N

If yes, please explain:

Have current subjects been notified? Please explain:

d) Has there been a change in the standard care that may be considered as an alternative to the investigational drug or device or that would affect the original study design? N

If yes, please explain:

Have current subjects been notified? Please explain:

e) Is there any new information that might affect the risk/benefit ratio and the willingness of current study subjects to participate or to continue to participate in the research? N

If yes, please explain:

Have current subjects been notified? Please explain:

f) Does the study include an investigator's brochure (IB)? N

If yes, what is the current version date?

(If study has multiple IBs, attach current versions in Attachments section (#16))

16. Provide a summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

nothing to report

17. Have there been any significant amendments or revisions to the N

protocol during the past approval period? (Significant amendments include changes in study design or risk level including those that resulted in a change in consent).

If yes, please briefly summarize the changes:

18. Y The consent materials attached to this eIRB application (including consent documents, assent documents, recruitment statements or other materials used to obtain consent) are the versions being used in the conduct of this study and all enrolled subjects have signed consent forms on file, if required. (If the requirement to obtain consent was waived or if no participants have enrolled since last continuing review, check N/A).

NOTE: The IRB routinely monitors consent document usage and may request copies of redacted participant consent forms.

19. Are any changes (amendments) requested with this Continuing Review?

Y Yes, please complete the remainder of this form.

No, form is complete. Please submit.

20. Summarize the proposed changes to the protocol in lay terms, including the type of change AND what the change involves.

If this is a change in PI a new Department Chair review is required. Please upload the signed document in the Attachments section.

Duties for Kayleigh Dittes will be updated to include consenting.

21. Provide justification/explanation for the proposed changes.

Kayleigh Dittes will assist with consenting.

22. Will currently accrued subjects need to be notified of changes? N

If no, please justify why not.

Changes do not affect accrued subjects.

If yes, please explain how AND when notification or re-consenting will occur.

23. Does the SLU IRB Protocol need to be modified? Y

24. Are consent documents modified? N

Proceed to the appropriate section(s) of the protocol and make your changes. Also make necessary changes in the Consent Form(s), Assent Form(s), Recruitment Statement, Questionnaire, or other attachments, as applicable. Upload any revised IRB materials. Please provide the entire revised document (not just revised pages). Use track changes or highlight (in yellow) changes to documents being revised. Please upload a

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tracked/highlighted copy of each revised document to be stamped upon IRB approval. NOTE: Upload a clean copy (changes or highlights removed) of documents in file formats other than Microsoft Word (i.e., the IRB will remove the tracked changes/highlights on uploaded Word documents).

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in the Funding section of the protocol (this information will appear on the approval letter).

**List of changed sections:**
Personnel Information
Informed Consent (13)
Attachments (16)

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## * * * Personnel Information * * *

**Study Personnel Roles:**
-Principal Investigator: accepts responsibility for study, must sign obligations, can edit protocol and submit to IRB
-Administrative Contact: additional study contact, may or may not also be member of research team, can edit/prepare protocol and submit to IRB
-Key Personnel (Research Team): SLU member of research team, can view protocol (not edit)
-Non-SLU Collaborator: member of research team from another institution or organization outside of SLU, has no access to system, must be provided with PDF of protocol. NOTE: SLUH/SSM employees who collaborate regularly may obtain a guest SLU account if access to system is needed.
-Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

**IMPORTANT NOTE: Human Subjects Protection Training is mandatory for all research team personnel.**

**Principal Investigator (PI) Mandatory**

**PI must be SLU affiliate.**

| Name of Principal Investigator (Faculty, Staff or Student) | Degree (MD/PhD) | Title |
|---|---|---|
| Goldkamp, Jennifer | MD | MFM Fellow |
| **Email** | **Phone** | **Fax** |
| jgoldka2@slu.edu | 314-977-2090 | |
| **Department Name** | | |
| Ob/Gyn-Maternal/Fetal | | |
| **Human Subjects Training Completed? class=MARK>*** | | Y |

**WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.**

**Research Experience** ***?HELP?***

Dr. Goldkamp has 6 years of research experience including protocol design, consenting, data collection and analysis and has completed training in human subject research and HIPAA.

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**Research Team Member Duties Picklist**

| | | | | | |
|---|---|---|---|---|---|
| 1. | X | Recruitment | 2. | X | Obtains consent |
| 3. | X | Determine Subject Eligibility for Accrual | 4a. | | Subject Physical Examinations |
| 4b. | X | Follow-up Visits including physical assessments | 5. | | Perform study procedures or Specimen Collection |
| 6a. | | Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed) | 6b. | | Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |
| 7. | X | Subject Randomization or Registry | 8. | X | Collection of Subject Data |
| 9. | X | Report Data (CRFs, e-CRFs, Spreadsheets) | 10. | X | Data Analysis |
| 11a. | | Review Adverse Events | 11b. | | Treat and Classify Adverse Events |
| 12. | | Other (Please insert explanation below.) | | | |

| UserID | CourseCompletionDate | Course |
|---|---|---|
| jgoldka2 | 08-09-2008 | CITI Biomedical Research Basic Training |
| jgoldka2 | 01-05-2018 | Good Clinical Practice (GCP) |

**Administrative Contact**

| Name of Administrative Contact | Degree | Title |
|---|---|---|
| Thompson, Judy | RN | Research Nurse |
| Mathews, Katherine | MD | Associate Professor |
| Miller, Collin | MSW | Research Coordinator |
| Siegrist, Dana | BA | Research Coordinator |

**Key Personnel (Research Team)**

| Name of Key Personnel (Research Team) | Degree | Title | Department Name |
|---|---|---|---|
| Vricella, Laura | MD | Assistant Professor | Ob/Gyn-Maternal/Fetal |
| Buchanan, Christopher | MD | MFM Fellow | Ob/Gyn-Maternal/Fetal |
| Malik, Shubhra | MD | Student | Ob/Gyn-Maternal/Fetal |
| Perez, William | MD | MFM Fellow | Ob/Gyn-Maternal/Fetal |
| Patel, Nileema | MS1 | Student | Ob/Gyn-Maternal/Fetal |
| Kraus, Elena | MD | OB, GYN Resident | Ob/Gyn-General |
| Dittes, Kayleigh | MS | Student | Ob/Gyn-Maternal/Fetal |

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## Department Chair Mandatory

**The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.**

| Name of Department Chair | Degree | Title |
|---|---|---|
| McLennan, Mary | MD | Professor |

| Email | Phone | Fax |
|---|---|---|
| mclennan@slu.edu | (314) 781-1031 | |

**Department Name**
Ob/Gyn-Administration

**Is this individual also a member of the research team? class=MARK>*** N

**Human Subjects Training Completed? class=MARK>***
**WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.**

**Research Experience** ***?HELP?***

**Research Team Member Duties Picklist**

| | | | |
|---|---|---|---|
| 1. | Recruitment | 2. | Obtains consent |
| 3. | Determine Subject Eligibility for Accrual | 4a. | Subject Physical Examinations |
| 4b. | Follow-up Visits including physical assessments | 5. | Perform study procedures or Specimen Collection |
| 6a. | Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed) | 6b. | Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |
| 7. | Subject Randomization or Registry | 8. | Collection of Subject Data |
| 9. | Report Data (CRFs, e-CRFs, Spreadsheets) | 10. | Data Analysis |
| 11a. | Review Adverse Events | 11b. | Treat and Classify Adverse Events |
| 12. | Other (Please insert explanation below.) | | |

| UserID | CourseCompletionDate | Course |
|---|---|---|
| mclennan | 01-26-2018 | Good Clinical Practice (GCP) |
| mclennan | 01-19-2018 | CITI Biomedical Research Refresher Training |
| mclennan | 01-11-2001 | Protecting Study Volunteers in Research |

## Research Team Roles

| Name(s), Degree | Department | Experience | Duties |
|---|---|---|---|
| Goldkamp, Jennifer, MD | Ob/Gyn-Maternal/Fetal | Dr. Goldkamp has 6 years of research experience including protocol design, | Recruitment, Obtains consent, Determine Subject Eligibility for |

| | | | |
|---|---|---|---|
| | | consenting, data collection and analysis and has completed training in human subject research and HIPAA. | Accrual, Follow-up Visits including physical assessments, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis |
| Thompson, Judy , RN | Ob/Gyn-Research Faculty | Has over 27 years of research experience including design, development, consenting, data collection and analysis, and has completed training in human subject research and HIPAA. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices , Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets) |
| Miller, Collin, MSW | Ob/Gyn-Research Faculty | Has 5 years of research experience, including consenting, data collection and analysis, and has completed training in human subject research and HIPAA. | Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis |
| Vricella, Laura, MD | Ob/Gyn-Maternal/Fetal | Faculty, has over 19 years of research experience including design, development, consenting, data collection and analysis, and has completed training in human subject research and HIPAA. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Review Adverse Events, Treat and Classify Adverse Events |
| Buchanan, Christopher, MD | Ob/Gyn-Maternal/Fetal | Dr. Buchanan has 4 years of research experience including design, consenting, data collection and analysis, and has completed training in human subject research and HIPAA. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data |

| | | | |
|---|---|---|---|
| | | | (CRFs, e-CRFs, Spreadsheets) |
| Malik, Shubhra, MD | Ob/Gyn-Maternal/Fetal | Limited but will be mentored by the experienced staff | Recruitment, Obtains consent, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets) |
| Perez, William, MD | Ob/Gyn-Maternal/Fetal | Dr. Perez has 4 years of research experience including design, consenting, data collection and analysis, and has completed training in human subject research and HIPAA. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets) |
| Patel, Nileema, MS1 | Ob/Gyn-Maternal/Fetal | Limited clinical research experience, but will be mentored by the PI and the research team. | Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets) |
| Kraus, Elena, MD | Ob/Gyn-General | Dr. E Kraus has 2 years of research experience including consenting and protocol implementation. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis |
| Dittes, Kayleigh, MS | Ob/Gyn-Maternal/Fetal | Kayleigh has over 1 year of clinical research experience working as a Clinical Research Coordinator for an infectious disease study at the University of Minnesota. She has experience with patient recruitment and obtaining informed consent, taking skin cultures, data collection and analysis. | Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets) |



## * * * Subject Population * * *

**Subject Population(s) Checklist**

**Select All That Apply :**

X Adults

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Cognitively Impaired Subjects
Employees (specifically targeted)
Fetuses
X Minors (under 18)
X Neonates
Non-English Speaking Subjects
Pregnant Women
Prisoners
Students (specifically targeted)
Terminally Ill Subjects
Wards of the State
Other (any population that is not specified above)

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## * * * Study Location * * *

### Study Location(s) Checklist

**Indicate where the study will be conducted. Select all that apply:**

Saint Louis University, Medical Center Campus
Saint Louis University, Frost Campus
Saint Louis University, Madrid Campus
X Saint Louis University, UMG Practice Locations
X SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
Cardinal Glennon Children's Medical Center
Saint Louis University Hospital (SSM Health- SLU Hospital)
SLU-SSM Cancer Center Research Alliance Sites
Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB.) Please refer to the Guidance for involving non-SLU institutions in human subject research.

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## * * * General Checklist * * *

### General Checklist

**Select All That Apply :**

Collection of Specimens
Data collection via e-mail or the Internet
Deception/Incomplete Disclosure
Dietary Supplements, Vitamins, and Other Food Agents

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| | |
|---|---|
| | FDA Approved Device |
| X | FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products |
| | Genetic Testing |
| | HIV Testing |
| | Human blood, cells, tissues, or body fluids |
| | International Research or Research on International Populations |
| | Investigational drugs, reagents, chemicals, or biologic products |
| | Investigational Device |
| X | Investigator Initiated Study *?HELP?* |
| X | Medical Records |
| | Photography, Video, or Voice-Recording Subjects |
| X | Questionnaires and/or tests |
| | Radioisotopes/radiation-producing machines, even if standard of care |
| | rDNA/Gene Transfer Therapy |
| | Registry(ies) |
| | Specimens to be stored for future research projects (must be in consent form) |
| | Study of existing data or specimens |
| X | University Indemnified Study (SLU is responsible for liability coverage) *?HELP?* |
| | Other (clarify in text box to the right) |

Single Use. Provide a brief summary and justification for the Single Use Therapy. Note: This application will refer to research. For Single Use applications it is understood that 'research' will mean 'therapy'.



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## * * * Funding * * *

### Funding Checklist

**NONE**

### Funding - Other

| Name of Other Funding source | SLU eRS # |
|---|---|
| Department of Ob, Gyn | 62528 |

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**NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).**

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## * * * Expedited Paragraphs * * *

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.



1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

**a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)**

**b) Research on medical devices for which**

(i) An investigational device exemption application (21 CFR Part 812) is not required; or

**(ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

**a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or**

**From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.**

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

**EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.**

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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

**EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.**

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. 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) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.

   a) Previously approved research where
      (i) The research is permanently closed to the enrollment of new subjects;
      (ii) All subjects have completed all research-related interventions; and

(iii) The research remains active only for the long term follow-up of subjects.

b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.

c) Previously approved research where the remaining research activities are limited to data analysis.

9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## * * * Background, Purpose, Study Procedures * * *

**Title**

NSAID use in postpartum hypertensive women

**Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate. Do not leave any required sections blank.**

**1. Background**

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

a) **Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. *<a href="javascript:showPopUpdata('HELP','Application Consideration:**

**In this question the IRB requires a brief introduction with supporting background information to describe your study. Do not include overly lengthy descriptions.**

**Investigator Initiated studies (i.e., the Principal Investigator has conceived, designed, and is conducting the research) are required to cite references in the response or should upload a referenced bibliography in the Attachments section.')">?HELP?***

Nonsteroidal anti-inflammatory drugs (NSAIDs) are the most common medication used for pain relief in the postpartum period in the United States. For pain relief of uterine involution, NSAIDs have shown to be superior to placebo, and equivalent or superior to narcotics (1). In 2013 the American College of Obstetricians and Gynecologists (ACOG) discouraged the use of NSAIDs in women with pre-eclampsia due to concerns for inadvertently increasing blood pressure (2). This recommendation is based on non-obstetrics literature, which tended to show a small increase of blood pressures in patients who use NSAIDS. However the literature is mixed, particularly on ibuprofen which is the most common NSAID used in the postpartum. Of the two meta-analysis that are commonly referenced, Pope et al found a decrease of -0.3 (+/- 2.57) mmHg in mean arterial pressure (MAP) in patients with hypertension treated with ibuprofen (3), and Johnson et al identified an average of 5mmHg increase in blood pressure with ibuprofen use (4). A large study of 18,325 patients who were treated with NSAIDS or COX-2 inhibitors, found an average of a 2.1 (+/- 0.5) mmHg increase in blood pressure with ibuprofen administration (5).

There are two articles available in the obstetrics literature on the topic of NSAIDS in women with hypertension disorders in the postpartum period. The first is by Makis et al, and is a case series of six women, with discussion of two cases. The explanations are limited and possible alternate diagnoses are not discussed (6). The second by Wasden et al is a retrospective study of women who had the diagnosis of severe hypertension disorders in pregnancy. The patients were matched 2:1 for women exposed to NSAIDs versus those who did not receive NSAIDs. MAPs were compared, and there was no difference found between the two groups (7). This second study is better designed and is likely representative of the true outcome of NSAID use in pre-eclamptic women, as the general literature shows a small, non-clinically significant change in blood pressure readings.

1. Deussen AR1, Ashwood P, Martis R. Analgesia for relief of pain due to uterine cramping/involution after birth. Cochrane Database Syst Rev. 2011 May 11;(5).
2. American College of Obstetricians and Gynecologists. Task Force on Hypertension in Pregnancy. 2013. ISBN 978-1-934984-28-4.
Pg 1 - 89. 9. American College of Obstetricians and Gynecologists.
3. Pope JE, Anderson JJ, Felson DT. A meta-analysis of the effects of nonsteroidal anti-inflammatory drugs on blood pressure. Arch Intern Med. 1993 Feb 22;153(4):477-84.
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Please save frequently

**b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.**

N/A

**2. Purpose of the study**

**a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.**

Women who have the diagnosis of hypertension (pre-pregnancy and pregnancy induced) and deliver an infant via vaginal delivery will be placed into two groups in the postpartum period. One group will receive Ibuprofen for pain control and the other group will be given Tylenol. Blood pressures during the postpartum period will then be collected and compared in order to see if NSAIDs use increases blood pressure.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

**Protocol Title:** NSAID use in postpartum hypertensive women

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b) **List your research objectives (specific aims & hypotheses of the study).**

To determine if NSAIDS in the postpartum period raise blood pressure in women with a hypertensive disorder.

Please save frequently

c) **Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.**

The patients who have a vaginal delivery and have the diagnosis of hypertension in pregnancy will be randomized to either Ibuprofen use or acetaminophen use during the postpartum period. Standard blood pressure monitoring in the postpartum period will be followed to help determine if there is a significant rise in the women who use NSAIDS in the postpartum period versus those that use acetaminophen.

Groups will be divided into women with chronic hypertension, women with chronic hypertension with superimposed preeclampsia, women with preeclampsia without severe features, women with preeclampsia with severe features, women with gestational hypertension without severe range blood pressures, and women with gestational hypertension with severe range blood pressures.

Recruitment will last 36 months. Patients will be monitored during their postpartum stay (typical 2 days) and then again at 1 week and 6 weeks (standard practice of care) with blood pressure measurements. An additional 12 months will be needed for data analysis and publication.

d) **If subjects will be given placebo, please justify placebo use. *?HELP?***

N/A



## 3. Study Procedures

a) N Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?

Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.

Will the SLU site be participating in all parts/procedures/arms of the study?

**If No, explain what SLU will NOT participate in:**

Please save frequently

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

b) **Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and**

**which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).**

The patients will be screened for inclusion/exclusion criteria when admitted to labor and delivery or in the clinic. They will then be consented and randomized around time of admission.
During the postpartum period the patient will receive either Ibuprofen 600mg every 6 hours prn or acetaminophen 650mg every 6 hours prn. All groups will have oxycodone 5mg as a backup pain medication for pain (this is standard of care). Oxycodone will be given upon the patient's request for additional pain medication, pain scores and physician's orders. The oxycodone is given "as needed" and usually is given as a single dose followed by the return to the patient taking ibuprofen or acetaminophen. Acetaminophen or Ibuprofen will not be given in combination with oxycodone. Total acetaminophen dosing will not exceed 3000mg/24 hours. This portion of the protocol is research.
Blood pressures will be monitored per standard protocol, which is normally every 15 minutes following delivery for 2 hours and then every 4 hours when moved to the postpartum unit. Additional blood pressures may be requested at the discretion of the care team. Blood pressures every 4 hours will be continued until discharge from the hospital. This is standard of care. The attachment in section 16 "Nurse Instructions" will be given to the floor staff to provide consistency in the taking of BP and steps to take if abnormal, reinforcing SOC.
A posted reminder for the staff will be placed in the patient's room to remind staff to take BP's every 4 hours and to keep intake and output-this is standard of care and would be done even if the patient were not in the study. If a reminder is posted outside the room then "NSAID Participant" will be removed.
Women will also be asked to complete a survey of the pain management during admission. The survey is not standard of care.
The patient will then have an appointment to check their blood pressure within the first week after delivery and again at 6 weeks postpartum. These visits are both standard of care.

The research team will also review and collect information about the patient and their infant from the maternal medical record.This will include information regarding the course of this pregnancy.



c) **If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

Interim analysis will be completed in order to ensure safety. The 1st interim analysis will be after the first 60 patients are enrolled to look at safety and the objective of this protocol.

d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

Continuous variables will be expressed as means and standard deviations or medians and ranges. Categorical variables will be reported as numbers and percentages. Student's t-test and/or Mann-Whitney U will be utilized to compare continuous variables depending on the normality of the distribution. Chi-square and/or Fischer's exact test will be used to compare categorical variables. Analysis may also include other pertinent statistical tests.

The proposed sample size is based on mean differences in postpartum systolic blood

pressures between the two groups with an alpha level of .05 and a level of power of .80. Utilizing a mean difference of 5 points and a standard deviation of 15 points, 80 women would be needed in each group. Groups included are women with chronic hypertension, chronic hypertension with superimposed preeclampsia, women with preeclampsia without severe features, women with preeclampsia with severe features, women with gestational hypertension without severe range blood pressures, and women with gestational hypertension with severe range blood pressures.

Please save frequently

e) State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). <a href=http://www.slu.edu/Documents/research/irb/Deception_Incomplete.doc target=_blank > See IRB Deception Guidelines.

f) Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. *?HELP?* Y

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

Ibuprofen 600mg every 6 hours prn or acetaminophen 650mg every 6 hours prn, this is standard or care. .All groups will have oxycodone 5mg as a backup pain medication for pain (this is standard of care).
Acetaminophen or Ibuprofen will not be given in combination with oxycodone 5mg.

g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). N

If yes, please describe and include whether there are plans to share findings with study participants.

h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.

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## * * * Radioisotopes or Radiation Machines * * *

**You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.**

### 4. Radioisotopes or Radiation Machines

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur first, even before submission to IRB. For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.



a) **If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)**

b) **Total estimated research radiation dose * :** _____

* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

NOTE: Informed Consent Radiation Exposure Risk Statement- The applicant must insert the appropriate Informed Consent Radiation Exposure Risk Statement template language into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

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## * * * Devices * * *

### 5. Devices

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a) Please list in the space below all investigational devices to be used on subjects during this study.

b) Please list in the space below all FDA approved devices to be used on subjects during this study.

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## * * * Drugs, Reagents, Chemicals, or Biologic Products * * *

### 6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents

| | | | |
|---|---|---|---|
| Pilot | Phase I | | Phase II |
| Phase III | Phase IV | X | Not Phased |

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

&nbspb) Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).

&nbspc) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).

FDA Approved Drugs, Reagents, Chemicals, Biologic Product

| Drug Name | Manufacturer | Source (e.g., Pharmacy, Sponsor, etc.) | Dosage |
|---|---|---|---|
| ibuprofen | varies | pharmacy | 600mg/6hours PRN |
| acetaminophen | varies | pharmacy | 650mg every 6 hours PRN |
| oxycodone | varies | SSM Pharmacy | 5mg PRN |

&nbspd) Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.

Please read the IND Statements.

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## * * * Other Levels Of Review * * *

## 7. Other Levels Of Review

### 1. University Radiation Safety

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

X **Not Applicable**

**Yes, study involves radioactive materials (per instructions, submit to RSC before IRB)**

### 2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

X **Not Applicable**

**Yes, study requires Institutional Biosafety review**

### 3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmsluh.com for more information.

X **Not Applicable**

**Yes, study requires PTNT review**

### 4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including inpatient or outpatient services and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This effort is coordinated through the Clinical Trials Office via eRS. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible,

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or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh.research@ssmsluh.com or the SLU Clinical Trials Office at 977-6335 or clinical-trials-office@slu.edu for more information.

X **Not Applicable**

**Yes, study requires Saint Louis University Hospital review**

**5. SSMSL**

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

**Not Applicable**

X **Yes, study requires RBR review**

6. **  Does this project require registration on ClinicalTrials.gov, and/or is this project subject to the NIH GCP Training Requirement? (Select "Yes" if either apply)** Y

**Registration may be required if any of the following apply: 1) The project meets the FDAAA definition of an "<a href=https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf target=_blank>Applicable Clinical Trial", which requires registration on ClinicalTrials.gov.; 2) As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policies require personnel on NIH "Clinical Trials" to take GCP Training every three years.; 3) Registering may be required for Journal Publication (ICMJE). Please review relevant definitions <a href=http://slu.edu/Documents/research/IRB/NIH_Clinical_Trial_Definition.docx target=_blank>here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/training-and-education target=_blank>Training page of the IRB website for information on NIH GCP Training requirements.**

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## * * * Subject Population * * *

**8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)**

a) **Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).**

14-50 years old

**Protocol Title:** NSAID use in postpartum hypertensive women

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b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).** 160

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

c) **Number of evaluable subjects to be accrued study wide. *?HELP?*** 160

d) **If including vulnerable populations (<a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>minors, <a href=https://www.slu.edu/Documents/research/IRB/Pregnant_Women_Fetuses.docx target=_blank>pregnant women and fetuses, <a href=https://www.slu.edu/Documents/research/IRB/Neonates.docx target=_blank>neonates, <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>non-English speaking, economically or educationally disadvantaged, <a href=https://www.slu.edu/Documents/research/IRB/Prisoner_Research.doc target=_blank>prisoners, <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/general-guidelines target=_blank>SLU Guidelines containing additional considerations and strategies for mitigating risks.**

Pregnant women is the population that is being studied, and are the only group that develops disease such as preeclampsia and gestational hypertension.
Women are considered emancipated in the state of Missouri once pregnancy is achieved.

e) **If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. *?HELP?***

N/a

f) **If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See <a href=https://www.slu.edu/Documents/research/IRB/Students_Employees.docx target=_blank>SLU Guidelines for additional considerations and strategies for mitigating risks.**

g) **Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#16). Important to remember: potential subjects cannot be contacted before IRB approval. NOTE: The use of SLU owned websites in an approved SLU format (e.g., Cancer Center website, etc.) are always approved methods of recruitment.**

Women will be screened for admission/exclusion criteria when admitted to labor and delivery. Some women will also be recruited in clinic if a diagnosis of a hypertensive disorder has been made previously.

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**Protocol Title:** NSAID use in postpartum hypertensive women

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## * * * Subject Population * * *

**8. Subject Population (continued)**

**Page numbers from a sponsor's protocol/grant may be referenced in 8h.**

**h) Inclusion and Exclusion Criteria.**

**Identify inclusion criteria.**

Vaginal delivery
Diagnosis of chronic hypertension, chronic hypertension with superimposed preeclampsia, preeclampsia without severe features, preeclampsia with severe features, gestational hypertension without severe range blood pressures, or gestational hypertension with severe range blood pressures.
Singleton pregnancies

**Identify exclusion criteria.**

Cesarean delivery
No diagnosis of hypertensive disorder
Chronic or acute renal disease
Allergy to Ibuprofen or acetaminophen or Oxycodon
Lupus
Multiple order pregnancies (twins, triplets)
Narcotic addiction/ in treatment for substance abuse/ current prescription drug user / current use of illegal drugs.



**i) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.**

Patients who participate in this study will be compensated for their time. They will receive a $20.00 gift card at the time of completion of the final survey.

**j) Describe who will cover study related costs. Explain any costs that will be charged to the subject.**

The only related cost is that of paper which will be covered by the OB/GYN department.
The proposed medications are medicines that are standard of care and readily available.

**k) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.**

Each patient will be involved for approximately 6 weeks, from the time of delivery until their 6 week postpartum exam.
Estimates for total time include 3 years for recruitment, and an additional 1 year for analysis and publication.

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## * * * Risks * * *

**9. Risks**

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There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.

1.    Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.

2.    Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

3.    Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

Ibuprofen
Incidence Greater than 1%
(but less than 3%)

The most frequent type of adverse reaction (bad side effect) is:

GASTROINTESTINAL
Nausea*, 3% to 9%
epigastric (upper central region of the abdomen) pain*,3% to 9%
heartburn*,3% to 9%
diarrhea, <3%
abdominal distress,<3%
nausea and vomiting, <3%
indigestion,<3%
constipation, <3%
abdominal cramps or pain,<3%
fullness of GI tract (bloating and flatulence[gas]) <3%
Gastric or duodenal ulcer with bleeding and/or perforation (a hole)<1%
gastrointestinal hemorrhage (bleeding in the bowels), <1%
melena (dark tarry stools), <1%
gastritis (inflammation of the stomach) <1%
hepatitis (inflammation of the liver), <1%
jaundice (yellow skin),<1%

abnormal liver function tests ( abnormal blood work); <1%
pancreatitis (inflammation of the pancreatitis)<1%

CENTRAL NERVOUS SYSTEM
Dizziness*, 3% to 9%
headache, <3%
nervousness <3%
Depression <1%
insomnia (can't sleep) <1%
confusion<1%
mood swings <1%
somnolence (drowsy)<1%
aseptic meningitis (swelling of the brain) with fever and coma <1%

DERMATOLOGIC
Rash* (red skin, raised bumps), 3% to 9%
pruritus (itching) <3%
Vesiculobullous eruptions (blisters),<1%
urticaria (a rash of round, red welts on the skin that itch intensely),<1%
erythema multiforme (lesions and redness around the lesions), <1%
Stevens-Johnson syndrome (flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), <1%
alopecia (hair loss)<1%

SPECIAL SENSES
Tinnitus (ringing in your ears) <3%
Hearing loss, <1%
amblyopia (blurred and/or diminished vision, <1%
scotomata (a blind spot in your visiom) and/or changes in color vision) <1%
Conjunctivitis (eye infection),<1%
diplopia (double vision),<1%
optic neuritis (inflammation of the optic nerve),<1%
cataracts (a clouding of the lens in the eye leading to a decrease in vision)<1%

METABOLIC/ENDOCRINE
Decreased appetite <3%
Gynecomastia (enlargement of a man's breasts), <1%
hypoglycemic reaction (low blood sugar),<1%
acidosis (a condition in which there is too much acid in the body fluids) <1%

CARDIOVASCULAR
Edema (Swelling of body tissues) , <3%
fluid retention <3%
Congestive heart failure in patients with marginal cardiac function,(when your heart muscle doesn't pump blood as well as it should) <1%
elevated blood pressure,<1%
palpitations (feel your heart beat)<1%
Arrhythmias (fast or slow heart rate) <1%

HEMATOLOGIC
Neutropenia (low white blood cell count), <1%
agranulocytosis (lowered white blood cell count),<1%
aplastic anemia (your body stops producing enough new blood cells) <1%
hemolytic anemia (sometimes Coombs positive-red blood cells are destroyed and removed from the bloodstream before their normal lifespan is over.)<1%
thrombocytopenia (a low blood platelet count), <1%
decreases in hemoglobin and hematocrit (your red blood cell count)<1%
Bleeding episodes, throwing up blood or heavy periods<1%.

ALLERGIC
Syndrome of abnormal pain, fever, chills, nausea and vomiting;<1%
anaphylaxis (allergic reaction); bronchospasm (constriction of the air passages of the lung), <1%
Serum sickness, ( a self-limited immune complex disease caused by exposure to foreign proteins or haptens, much like a delayed allergic reaction) <1%
lupus erythematosus syndrome (disease in which the body's immune system mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain, and other organs)<1%
Henoch-Schonlein vasculitis, (a hemorrhagic disease characterized by extravasation (leaking) of blood into the tissues, under the skin, and through the mucous membranes, and producing spontaneous bruises, ecchymoses (A purplish patch caused by extravasation (leaking) of blood into the skin, larger than petechiae), and petechiae (small hemorrhagic spots) on the skin.) <1%
angioedema (is swelling of the blood vessels below the skin, which may be painful and accompanied by redness. It often appears on the face, tongue, hands or genitals)<1%

RENAL
Acute renal failure, <1%
decreased creatinine clearance, (blood test that reflects kidney function) <1%
polyuria,(Excessive urination) <1%
azotemia, (an increase in nitrogen-based waste products in the blood stream)<1%
cystitis,(irritation of the bladder)<1%
hematuria (blood in the urine) <1%
Renal papillary necrosis (the death of tissue in the kidney) <1%

MISCELLANEOUS
Dry eyes and mouth,<1%
gingival ulcer, (ulcers on the gums)<1%
rhinitis (running nose)<1%

Clinical trials have shown an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal.



Acetaminophen
Severity: Major

Rare:
Bloody or black, tarry stools
bloody or cloudy urine
fever with or without chills (not present before treatment and not caused by the condition being treated)
pain in the lower back and/or side (severe and/or sharp)
pinpoint red spots on the skin
skin rash, hives, or itching
sore throat (not present before treatment and not caused by the condition being treated)
sores, ulcers, or white spots on the lips or in the mouth
sudden decrease in the amount of urine
unusual bleeding or bruising
unusual tiredness or weakness
yellow eyes or skin
If any of the following symptoms of overdose occur while taking acetaminophen, get emergency help immediately:

If any of the following symptoms of overdose occur while taking acetaminophen, get emergency help immediately.
Symptoms of overdose:
Diarrhea

increased sweating
loss of appetite
nausea or vomiting
stomach cramps or pain
swelling, pain, or tenderness in the upper abdomen or stomach area

General
In general, acetaminophen is well-tolerated when administered in therapeutic doses.

Hepatic
Alcoholic patients may develop hepatotoxicity (liver toxcity) after even modest doses of acetaminophen.

Gastrointestinal
Gastrointestinal side effects have included nausea (34%) and vomiting (15%). Cases of acute pancreatitis (inflammation of the pancreas) have been reported rarely.

Renal
Renal side effects are rare and have included acute renal failure (kidney failure), acute tubular necrosis (death of kidney), and interstitial nephritis (inflammation of the kidney).

Hypersensitivity
Hypersensitivity side effects including anaphylaxis (allergic reaction) and fixed drug eruptions have been reported rarely in association with acetaminophen use.

Hematologic
Hematologic side effects including rare cases of thrombocytopenia (low platelet count) associated with acetaminophen have been reported.

Dermatologic
Dermatologic side effects including erythematous (red rasied rashes)skin rashes associated with acetaminophen have been reported, but are rare.
Very rare potentially fatal skin reactions: Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP).

Respiratory
Respiratory side effects have included dyspnea (shortness of breath) and a case of acetaminophen-induced eosinophilic pneumonia (a disease in which an eosinophil, a type of white blood cell, accumulates in the lung. These cells cause disruption of the normal air spaces (alveoli) where oxygen is extracted from the atmosphere).

Cardiovascular
Cardiovascular side effects including hypertension (high blood pressure) and hypotension (low blood pressure) have been reported following the administration of acetaminophen.

Metabolic
hypokalemia (low levels of potassium in the blood).
metabolic acidosis have been reported following a massive overdose of acetaminophen.

In the case of metabolic acidosis, causality is uncertain as more than one drug was ingested. The case of metabolic acidosis followed the ingestion of 75 grams of acetaminophen, 1.95 grams of aspirin, and a small amount of a liquid household cleaner. The patient also had a history of seizures which the authors reported may have contributed to an increased lactate level indicative of metabolic acidosis.

Nervous system
Headache (10%),
insomnia (difficultly falling/or staying asleep) (7%),

fatigue.

Musculoskeletal
Musculoskeletal side effects associated with acetaminophen IV have included muscle spasms and trismus (lockjaw).

Psychiatric
Psychiatric side effects associated with acetaminophen IV have included anxiety.

Acetaminophen has been associated with acute liver failure, at times resulting in liver transplant and death. Liver toxicity is usually associated with excessive acetaminophen intake and often involves more than one product that contains acetaminophen. An overdose of acetaminophen can damage your liver or cause death.

oxycodone
Serious Reaction
Respiratory depression is the chief hazard from all opioid agonist preparations. Respiratory depression occurs most frequently in elderly or debilitated patients, usually following large initial doses in non-tolerant patients, or when opioids are given in conjunction with other agents that depress respiration.

Oxycodone has been detected in breast milk. Withdrawal symptoms can occur in breastfeeding infants when maternal administration of an opioid analgesic is stopped. Ordinarily, nursing should not be undertaken while a patient is receiving oxycodone hydrochloride tablets since oxycodone may be excreted in milk.
Oxycodone exposes users to the risk of addiction, abuse, and misuse, potentially leading to overdose and death.

Less serious
> 3%. In descending order of frequency they were:
nausea
constipation
vomiting
headache
pruritus (itching)
insomnia (difficulty falling asleep)
dizziness
asthenia (weakness, lack of energy)
somnolence.(sleepy, drowsy)

< 3% of patients involved in clinical trials with oxycodone:
Body as a Whole:
abdominal pain,
accidental injury,
allergic reaction,
back pain,
chills and fever,
fever,
flu syndrome, (flu like symptoms)
infection,
neck pain,
pain,
photosensitivity reaction, (eyes are sensitive to light)
sepsis.(a life-threatening illness caused by your body's response to an infection)

Cardiovascular:
deep thrombophlebitis, ( a blood clot the forms ina vein deep in the body)

heart failure,
hemorrhage, (bleeding)
hypotension, (low blood pressure)
migraine, (severe headache)
palpitation, (you can feel your heart beat)
tachycardia.(fast heart rate)

Digestive:
anorexia, (eating disorder)
diarrhea,
dyspepsia,(indigestion)
dysphagia, (difficulty swallowing)
gingivitis, (inflammation of the gums)
glossitis,(inflammation of the tongue)
nausea and vomiting.

Hemic and Lymphatic:
anemia (low red blood counts)
leukopenia. (low white blood count)

Metabolic and Nutritional:
edema, (swelling)
gout, (a kind of arthritis)
hyperglycemia, (high blood sugar)
iron deficiency anemia (your body doesn't have enough of the mineral iron)
peripheral edema. (swelling of the arms and legs)

Musculoskeletal:
arthralgia, (joint pain)
arthritis, ( inflammation of one or more of your joints. )
bone pain,
myalgia (muscle pain)
pathological fracture.(a break that occurs in an area of weakened bone)

Nervous:
agitation,
anxiety,
confusion,
dry mouth,
hypertonia, ( too much muscle tone causing stiffness in your arms or legs)
hypesthesia,(an increased sensitivity to the stimuli. )
nervousness,
neuralgia, (nerve pain)
personality disorder, (a type of mental disorder in which you have a rigid and unhealthy pattern of thinking, functioning and behaving)
tremor,
vasodilation.( Widening of blood vessels that results from relaxation of the muscular walls)

Respiratory:
bronchitis,
cough increased,
dyspnea, (shortness of breath)
epistaxis, (nose bleeds)
laryngismus, (laryngeal spasm caused by the sudden contraction of laryngeal muscles)
lung disorder,
pharyngitis, (inflammation of the pharynx, a region in the back of the throat)
rhinitis, (inflammation of the nose)
sinusitis.(inflammation of the sinuses)

Skin and Appendages:
herpes simplex, (cold sores)
rash,
sweating,
urticaria.(hives)

Special Senses:
amblyopia.(lazy eye)

Urogenital:
urinary tract infection (bladder infection)

**4.    Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.**

**5.    Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).**

There will be no procedures performed outside of routine blood pressure monitoring.
The group treated with Ibuprofen may experience an elevation in blood pressure that would cause their ibuprofen to be stopped, and switch to a different pain medication besides a NSAID, blood pressure medication to be started, or an increase in blood pressure medication.
The SOC protocol for treatment of elevated BP is attached in section 16 (Elevated BP procedure).

**6.    Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).**

**7.    Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially better than standard of care or other common alternatives. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form. *?HELP?***

We will be comparing blood pressures from medications that are used as the standard of care

postpartum (NSAIDS/Ibuprofen) to acetaminophen which is at a lower risk for increasing blood pressures and is currently used as an alternative to Ibuprofen. If this study shows there is not significant difference then women with hypertensive disorders can continue to use NSAIDS without concerns postpartum.

8.   **Describe any psychological, social, or legal risks the subject may experience. *?HELP?***

No more than minimal risk, which does include loss of confidentiality.

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

9.   **Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**

Women's blood pressures will be screened at least every 4 hours, which is the standard of care at our institution. If a woman's blood pressure is consistently elevated to 150/100 or higher, transitioning to a different pain medication or starting an antihypertensive medication/adjust a previously started medication may be required.

10.   **Reproductive Risks.**

a.   **Please list the pregnancy category of any drugs or N/A.**

N/A

   **Please describe any reproductive risk associated with any part of the research study. Include any data from other studies (animal or human).**

N/a

   **Data Safety Monitoring**

**Protocol Title:** NSAID use in postpartum hypertensive women

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nbsp&n
bsp&nb
sp&nbs
p 
&nbsp1
1.

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Please refer to <a href=http://www.slu.edu/Documents/research/IRB/Data_Safety_Monitoring.doc target=_blank > SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

a. Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist).
A DSM charter can be referenced for all items except for "f) who is reviewing SAEs in real time."

If no, please justify why not.

| Please see DSMP |
|---|

&nb  &nbspIs there a Data Safety Monitoring Plan (DSMP)? Y
sp&
nbs
p&n
bsp
&nb
sp&
nbs
pb.

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).

| a BPs-noted in the patient's medical record, SAEs-medical record and study record |
|---|

**Protocol Title:** NSAID use in postpartum hypertensive women

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b.Goldkamp, MD, MFM Fellow, PI will be monitoring patient's BP and care while in the study
Gross, M.D. MFM Director-Independent
Vricella, M.D,, MFM-research staff
Childress, M.D. MFM-Independent
Said, D.O. MFM Fellow-research staff
Buchanan, M.D. MFM Fellow-research staff
Perez, M.D. MFM Fellow-Independent
Myles, M.D. MFM-Independent
Amon, M.D. MFM-Independent
Thompson, R.N. Research-research staff
c. Twice a month
d.PI and research staff
e. There will be no procedures performed outside of routine blood pressure monitoring.
The group treated with Ibuprofen may experience an elevation in blood pressure that would cause their ibuprofen to be stopped, a switch to a different pain medication besides a NSAID, blood pressure medication to be started, or an increase in blood pressure medication.

**If no, please justify why not.**

**12.   In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.**

**a.   State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.**

**b.   Will there be language barriers and if so, how will they be addressed?**
**Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.**

         &nbspNOTE: Export control laws include the transfer of technical information and data, as well as information
         &nbspand technology to foreign nationals. If this study has international components, contact the <a href=http://www.slu.edu/general-counsel-home/compliance/export-controls target=_blank > SLU Export           <a href=http://www.slu.edu/general-counsel-home/compliance/export-controls target=_blank >Control Officer for direction on whether export control policies apply.

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*** * * Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy * * ***

10. Benefits/Alternatives

**Protocol Title:** NSAID use in postpartum hypertensive women

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a)  **Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.**

This study will allow us to determine if NSAID use should be limited in those with with postpartum hypertensive disorders. There is no direct benefit to the patients, however it may change management in the future.

b) **Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.**

The alternative is to not participate. The patient will have routine postpartum care.

## 11. Procedures to Maintain Confidentiality and Privacy

**Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.**

Confidentiality

**To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).**

**For the questions below, please use the following definitions:**

**    &nbspAnonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to     &nbspindividual identities;**

**    &nbspCoded: data in which (1) identifying information, such as name or social security number, has been replaced     &nbspwith a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists     &nbspenabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept     &nbspseparately from coded data; AND/OR**

**    &nbspIdentifiable: data that includes personal identifiers (e.g., name, social security number), such that information     &nbspcould be readily connected to respective individuals.**

a)  **Electronic (Computer) Data**

**Click "Add" to enter data security information for each type of electronic data that will be created in the**

study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

| Type of Data | Storage Location | Data Transmission Outside of SLU | Supplemental information related to above items can be entered here or leave blank: |
|---|---|---|---|
| Coded | SLU ITS network storage (T: drive (shared drive), U: drive (personal drive)); Collection or Storage of data in SLU REDCap | Not Applicable, I will not be sending/sharing electronic data outside of SLU | NA |

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

| Type of Data | Storage Location | Transported Data Security | Supplemental information related to above items can be entered here or leave blank: |
|---|---|---|---|
| Coded | SLU Locked Room/Office; SLU Locked Suite | Not being shared | NA |

c)  If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.

Patients will be assigned an ID number which will be attached to their data sheets. The key for the ID numbers will be kept in a separate location.

The Master List will be kept separate and destroyed after publication

d)  If data or specimens are being shared outside of the research team, indicate who will receive the material and specifically what they will receive (data or specimens).

N/A

e) If samples or data will be provided from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected.

N/A

f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).

g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).

h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable".

A reminder for the staff to take BP every 4 hours and to do I/O's X 48 hours will be placed at the participant's bedside. The procedures are SOC and this serves as a reminder.-attached "Doorflier" in section 16.

Pharmacy will put a note in the patient's chart regarding their randomized number. This is only displayed as a note and will not be in the problem list.

i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. N

If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

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Privacy refers to persons having control over the sharing of oneself with others.

 &nbspj)   Please indicate how participant privacy will be protected in this study (select all that apply):

X Discussion of health related and/or personal information in a private room/area

X Research interactions/interventions are conducted in a private room/area

Use of drapes or other privacy measures

X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):



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## * * * Potential Conflict of Interest * * *

### 12. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

1) X No equity interest and/or Financial Interest less than or equal to $5K
2) Any equity interest and/or Financial Interest exceeding $5K but not exceeding $25K in the past year or expected in the current year
3) Financial Interest exceeding $25K in the past year or expected in the current year

Check all those that apply:

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**Consulting**
**Speaking Fees or Honoraria**
**Gifts**
**Licensing agreement or royalty income**
**Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors**
**Other fees/compensation**

If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.
   has been approved for all investigators for this study
   is pending
   has not been initiated

2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:



**Note to Investigator(s) Reporting a Potential Conflict of Interest**

**Investigator(s) must have:**

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.

   . This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.

2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.

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## * * * Informed Consent * * *

### 13. Informed Consent

**Federal regulations require that informed consent be obtained from individuals prior to their participation in**

research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) How is consent being obtained? When and where will the discussion take place? If the study involves a non-English Speaking participant/population, please include details about plans for translated materials and interpreters to be used (see <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>SLU Guidelines for Involving Non-English Speaking Subjects for more details).

Consent will be obtained from a trained research personnel. Consent will occur in clinic or at admission to labor and delivery. For those patients who are in active labor, they will be approached once they are comfortable and stable (Mom and baby are tolerating labor).

2) If the study involves adults unable to consent for themselves (whether diminished capacity to consent is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See <a href=https://www.slu.edu/Documents/research/IRB/LAR_Guidelines.docx target=_blank>SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>SLU Guidelines for Adults Unable to Provide Consent for additional detail.

n/a

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

| Title | Consent Type | Attached Date |
|---|---|---|
| Approved_CR2017_Main consent Ver 6 | Consent | 06/22/2017 |

* * * Assent * * *

14. Assent

**Protocol Title:** NSAID use in postpartum hypertensive women

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**Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.**

1. **Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of consent should be added for IRB review. See <a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>SLU Guidelines for Research Involving Minors for additional detail.**

   Pregnant minors in the state of Missouri are considered emancipated and are therefore included.

2. **If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.**

   NA

3. **How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.**

   NA

**Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.**



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## * * * HIPAA * * *

### 15. HIPAA

**Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.**

1. **Will health information be accessed, received or collected?**

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

2. **Which personal identifiers will be received or collected/recorded?**

   No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

   Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

appropriate, below.

City/State/Zip codes

Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

Age (if subjects are 90+ years)

At least one direct identifier will be received or collected/recorded.

X Names

Social Security numbers

Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

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: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

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

Fax numbers

Electronic mail addresses

X Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

**If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.**

**3. Sources of Protected Health Information:**

X Hospital/medical records for in or out patients

X Physician/clinic records

X Laboratory, pathology and/or radiology results

Biological samples

X Interviews or questionnaires/health histories

Mental health records

Data previously collected for research purposes

Billing records

X Other

**Please describe:**

Maternal medical record for infant information

4. **If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.**

X Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. **HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.**



**HIPAA Documents**

| HIPAA Documents | Title | Attached Date |
|---|---|---|
| HIPAA Authorization | Approved_HIPAA ver 3 | 08/29/2016 |

## * * * Attachments * * *

### 16. Attachments

**In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.**

**Possible documents for this protocol could include:**

- **Bibliography**
- **Cooperating Institution's IRB Approval**
- **Data Collection Sheet**
- **Debriefing Script**

- Device Information/Documentation
- Grant Proposal/Sub-Contract
- Human Subjects Training Certificate/Proof of Training
- Information Sheet/Brochure
- Interview/Focus Group Questions
- Investigator's Brochure
- Letter of Agreement/Cooperation
- IND Application Letter
- Package Insert
- Patient Diary Form
- Questionnaire/Survey
- Recruitment Material (e.g., flyers, ads, e-mail text)
- Safety Information (DSM Information)
- Scientific/PPC Review or Department Chair Review
- Sponsor's Protocol
- Sponsor's Protocol Amendment
- Study Design Chart/Table
- Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)

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

| Document Type | Document Name | Attached Date | Submitted Date |
|---|---|---|---|
| Package Insert | Ibuprofen Tablets USP, 600 mg | 06/09/2016 | 06/18/2016 |
| Package Insert | Acetaminophen | 06/18/2016 | 06/18/2016 |
| Package Insert | Oxycodone | 07/19/2016 | 07/28/2016 |
| Other | Nursing instructions 8-18-16 | 08/18/2016 | 08/18/2016 |
| Other | Approved_ElevatedBPprotocol | 08/29/2016 | 08/29/2016 |
| Other | Approved_room Fliers 8-18-2016 | 08/29/2016 | 08/29/2016 |
| Questionnaire/Survey | Approved_PPHTNNSAIDsPtsatsifactionpain | 08/29/2016 | 08/29/2016 |
| Committee Approvals | Approval Letter.Goldkamp SLU#26976 (1) | 10/19/2016 | 12/20/2016 |
| Human Subjects Training Certificate/Proof of Training | Nilema Patel - CITI Training Completion Report (1) | 12/14/2016 | 12/20/2016 |
| Data Collection Sheet | Approved_Data collection sheet REVISED | 02/22/2017 | 02/22/2017 |

**Protocol Title:** NSAID use in postpartum hypertensive women

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## * * * PI Obligations * * *

### PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. It also indicates that you have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Saint Louis University's assurance with the Department of Health and Human Services. The PI assures that if members of the SLU research team access protected health information (PHI) from a covered entity in order to seek consent/authorization for research or to conduct research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver. PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).

1) Have you completed the annual Conflict of Interest in Research Disclosure Form? Y

You can only select N/A if you are not currently listed on any externally funded research projects nor listed on any proposals for externally funded research support.



NOTE: An annual disclosure must be completed by all faculty, staff and students involved in the design, conduct or reporting of externally funded research applications and awards.

2) Have your financial interests changed significantly since you completed the annual disclosure form? N

The PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at SLU has a conflict of interest or if a conflict of interest does exist, that an appropriate management plan is in place.

According to the Saint Louis University Conflict of Interest in Research Policy, as PI, it is your responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of externally sponsored research of their requirement to complete a Conflict of Interest in Research Disclosure Form.

**Protocol Title:** NSAID use in postpartum hypertensive women

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X **I accept this responsibility.**

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

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## * * * Event History * * *

### Event History

| Date | Status | View Attachments | Letters |
|---|---|---|---|
| 01/11/2018 | CLOSED | | |
| 01/11/2018 | FINAL FORM APPROVED | Y | Y |
| 01/09/2018 | FINAL FORM REVIEWER(S) ASSIGNED | | |
| 01/04/2018 | FINAL FORM PANEL REASSIGNED | | |
| 01/03/2018 | FINAL FORM SUBMITTED | Y | |
| 12/12/2017 | FINAL FORM CREATED | | |
| 12/12/2017 | AMENDMENT 9 FORM DELETED | | |
| 12/04/2017 | REPORT 6 FORM APPROVED | Y | Y |
| 11/20/2017 | REPORT 3 FORM APPROVED | Y | Y |
| 11/20/2017 | REPORT 4 FORM APPROVED | Y | Y |
| 11/17/2017 | REPORT 6 FORM REVIEWER(S) ASSIGNED | | |
| 11/17/2017 | REPORT 6 FORM PANEL REASSIGNED | | |
| 11/17/2017 | REPORT 6 FORM SUBMITTED | Y | |
| 11/17/2017 | REPORT 6 FORM CREATED | | |
| 11/06/2017 | REPORT 5 FORM APPROVED | Y | Y |
| 11/01/2017 | REPORT 5 FORM REVIEWER(S) ASSIGNED | | |
| 11/01/2017 | REPORT 5 FORM PANEL REASSIGNED | | |
| 10/31/2017 | REPORT 5 FORM RESUBMITTED | Y | |
| 10/31/2017 | REPORT 5 FORM RETURNED | | |

| | | | |
|---|---|---|---|
| 10/30/2017 | REPORT 5 FORM SUBMITTED | Y | |
| 10/27/2017 | REPORT 4 FORM REVIEWER(S) ASSIGNED | | |
| 10/27/2017 | REPORT 3 FORM REVIEWER(S) ASSIGNED | | |
| 10/27/2017 | REPORT 3 FORM PANEL MANAGER REVIEW | | |
| 10/27/2017 | REPORT 4 FORM PANEL MANAGER REVIEW | | |
| 10/13/2017 | REPORT 5 FORM CREATED | | |
| 10/11/2017 | REPORT 4 FORM PANEL REASSIGNED | | |
| 10/11/2017 | REPORT 3 FORM PANEL REASSIGNED | | |
| 10/06/2017 | REPORT 3 FORM REVIEWER(S) ASSIGNED | | |
| 10/06/2017 | REPORT 4 FORM REVIEWER(S) ASSIGNED | | |
| 10/05/2017 | REPORT 4 FORM PANEL MANAGER REVIEW | | |
| 10/05/2017 | REPORT 3 FORM PANEL MANAGER REVIEW | | |
| 10/05/2017 | REPORT 3 FORM PANEL REASSIGNED | | |
| 10/03/2017 | REPORT 4 FORM SUBMITTED | Y | |
| 10/03/2017 | REPORT 4 FORM CREATED | | |
| 10/03/2017 | REPORT 1 FORM APPROVED | Y | Y |
| 10/03/2017 | REPORT 2 FORM APPROVED | Y | Y |
| 09/20/2017 | REPORT 1 FORM REVIEWER(S) ASSIGNED | | |
| 09/20/2017 | REPORT 3 FORM REVIEWER(S) ASSIGNED | | |
| 09/20/2017 | REPORT 1 FORM PANEL REASSIGNED | | |
| 09/20/2017 | REPORT 1 FORM PANEL REASSIGNED | | |
| 09/20/2017 | REPORT 3 FORM PANEL REASSIGNED | | |
| 09/19/2017 | REPORT 3 FORM SUBMITTED | Y | |
| 09/19/2017 | REPORT 1 FORM SUBMITTED | Y | |
| 09/15/2017 | REPORT 2 FORM REVIEWER(S) ASSIGNED | | |

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|---|---|---|---|
| 09/15/2017 | REPORT 2 FORM PANEL REASSIGNED | | |
| 09/14/2017 | REPORT 2 FORM SUBMITTED | Y | |
| 09/07/2017 | REPORT 3 FORM CREATED | | |
| 09/07/2017 | REPORT 2 FORM CREATED | | |
| 09/07/2017 | REPORT 1 FORM CREATED | | |
| 08/16/2017 | AMENDMENT 9 FORM CREATED | | |
| 07/25/2017 | AMENDMENT 8 FORM DELETED | | |
| 07/10/2017 | AMENDMENT 8 FORM CREATED | | |
| 06/22/2017 | CONTINUING REVIEW 1 FORM APPROVED | Y | Y |
| 06/13/2017 | CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED | | |
| 06/13/2017 | CONTINUING REVIEW 1 FORM PANEL MANAGER REVIEW | | |
| 06/09/2017 | CONTINUING REVIEW 1 FORM PANEL REASSIGNED | | |
| 06/09/2017 | CONTINUING REVIEW 1 FORM SUBMITTED | Y | |
| 06/07/2017 | CONTINUING REVIEW 1 FORM CREATED | | |
| 06/07/2017 | AMENDMENT 7 FORM APPROVED | Y | Y |
| 06/06/2017 | AMENDMENT 7 FORM REVIEWER(S) ASSIGNED | | |
| 06/01/2017 | AMENDMENT 7 FORM SUBMITTED | Y | |
| 05/26/2017 | AMENDMENT 7 FORM CREATED | | |
| 05/08/2017 | AMENDMENT 6 FORM APPROVED | Y | Y |
| 05/05/2017 | AMENDMENT 6 FORM REVIEWER(S) ASSIGNED | | |
| 05/03/2017 | AMENDMENT 6 FORM SUBMITTED | Y | |
| 05/02/2017 | AMENDMENT 6 FORM CREATED | | |
| 04/10/2017 | AMENDMENT 5 FORM APPROVED | Y | Y |
| 04/07/2017 | AMENDMENT 5 FORM REVIEWER(S) ASSIGNED | | |

| | | | |
|---|---|---|---|
| 04/04/2017 | AMENDMENT 5 FORM SUBMITTED | Y | |
| 04/04/2017 | AMENDMENT 5 FORM CREATED | | |
| 02/22/2017 | AMENDMENT 4 FORM APPROVED | Y | Y |
| 02/21/2017 | AMENDMENT 4 FORM REVIEWER(S) ASSIGNED | | |
| 02/16/2017 | AMENDMENT 4 FORM SUBMITTED | Y | |
| 02/13/2017 | AMENDMENT 4 FORM CREATED | | |
| 02/08/2017 | AMENDMENT 3 FORM APPROVED | Y | Y |
| 02/07/2017 | AMENDMENT 3 FORM REVIEWER(S) ASSIGNED | | |
| 02/06/2017 | AMENDMENT 3 FORM SUBMITTED | Y | |
| 01/17/2017 | AMENDMENT 3 FORM CREATED | | |
| 01/09/2017 | AMENDMENT 2 FORM APPROVED | Y | Y |
| 01/09/2017 | AMENDMENT 2 FORM REVIEWER(S) ASSIGNED | | |
| 12/20/2016 | AMENDMENT 2 FORM SUBMITTED | Y | |
| 12/14/2016 | AMENDMENT 2 FORM CREATED | | |
| 09/08/2016 | AMENDMENT 1 FORM APPROVED | Y | Y |
| 09/07/2016 | AMENDMENT 1 FORM REVIEWER(S) ASSIGNED | | |
| 09/02/2016 | AMENDMENT 1 FORM PANEL REASSIGNED | | |
| 08/30/2016 | AMENDMENT 1 FORM SUBMITTED | Y | |
| 08/29/2016 | AMENDMENT 1 FORM CREATED | | |
| 08/29/2016 | NEW FORM APPROVED | Y | Y |
| 08/29/2016 | NEW FORM REVIEWER(S) ASSIGNED | | |
| 08/23/2016 | NEW FORM SUBMITTED (CYCLE 3) | Y | |
| 08/18/2016 | NEW FORM SUBMITTED (CYCLE 2) | Y | |
| 08/05/2016 | NEW FORM REVIEWER(S) ASSIGNED | | |

**Protocol Title:** NSAID use in postpartum hypertensive women

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|---|---|---|
| 07/28/2016 | NEW FORM SUBMITTED (CYCLE 1) | Y |
| 07/07/2016 | NEW FORM CONTINGENT | |
| 06/24/2016 | NEW FORM REVIEWER(S) ASSIGNED | |
| 06/22/2016 | NEW FORM PANEL MANAGER REVIEW | |
| 06/20/2016 | NEW FORM PANEL ASSIGNED | |
| 06/18/2016 | NEW FORM SUBMITTED | Y |
| 06/17/2016 | NEW FORM PREREVIEWED | |
| 06/10/2016 | NEW FORM PREAPPROVAL | |
| 03/01/2016 | NEW FORM CREATED | |