

Version: 1.1

Application Version Date: 8/15/2012

Date: Thursday, February 27, 2014 10:00:04 AM

1. Project Identification Information

1.1. * Type of Submission:

Research Protocol or Study on Human Subjects

Grant/Contract Only

Facilitated Review (NCI CIRB)

USC/CHLA Collaborative Review

1.2. * Full Title of Research Protocol

Does the timing of epidural placement influence outcomes for adult patients with traumatic rib fractures?

1.3. * Short Title

Epidural analgesia for Rib fractures

1.4. * Select which IRB you are requesting review from:

USC-Health Sciences (HSC)

2. Study Personnel

2.1. Study Personnel and their roles:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
View		TRAUMA AND CRITICAL CARE	Principal Investigator		no
View		TRAUMA AND CRITICAL CARE	Study Contact Person		no

2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?

Yes No

2.3. If there are any individual collaborators from other institutions, check here:

2.4. Does this study require Cancer Center Committee (CIC) approval?

Yes No

2.4.1. Are Cancer Patients Involved? Yes No

2.5. Specify the group/organization who has reviewed this study for scientific merit:

Division of Trauma Surgery and Surgical Critical Care

3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted.

3.1. Pending Division/Department Approvals:

Name Division/Department Parent Campus

There are no items to display

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus
TRAUMA AND CRITICAL CARE	Division	USC-Health Sciences (HSC)
SURGERY	Department	USC-Health Sciences (HSC)

3a.3. Other campus committees, services or departments that need to review and approve this protocol:

Committee Name Committee Chair Approval Memo

There are no items to display

3a.4. Will the research be conducted through the CTU?

Yes No

4. Type of Study Review

4.1. Select the type of review that you are requesting for this study:

Full Committee Review

Expedited Review

Exempt Review

Coded Specimens/Data

4.2. Attach the protocol here. For simple, investigator-initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.

name Version Modified

There are no items to display

4.3. Attach the sponsor's template informed consent here.

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There are no items to display

4.4. If any study documents are password protected, enter the passwords here.

4.5. If there is a sponsor protocol number associated with this file, specify it here:

4a. Type of Study Review - Expedited Review

This screen is required if you are requesting an expedited review for this study (Question 4.1.) If this is the incorrect review type, please return to page 4 to make changes.

4a. If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):

Short Description (click for full description)

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

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...

(3) Prospective collection of biological specimens for research purposes by noninvasive means...

(4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves...

(5) Research involving materials that have been collected, or will be collected solely for

nonresearch purposes...

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

(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...

4a.1. Since you checked expedited review category 5, please attach a copy of the data collection forms, if applicable:

name	Version Modified
Epidural_data_collection_sheet.doc	History 0.01 8/4/2012 8:14 PM

5. Study Location(s)

5.1. Select the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

HSC - Health Sciences Associated Locations

UPC - University Park Associated Locations

CHLA

5.2. Are there other sites besides USC/CHLA involved in the research?

Yes No

6a. HSC Location(s)

This screen is required if you indicated HSC - Health Sciences Associated Locations (Question 5.1.)

6a.1. Locations that recruitment, consent, and/or study procedures will be performed: (check all that apply)

Location

LAC+USC Medical Center

LAC+USC Emergency Dept

LAC+USC Outpatient Clinics

LAC+USC 5P21 Building

Keck Hospital of USC Facilities

USC Norris Comprehensive Cancer Center Facilities

Keck School of Medicine of USC

Doheny Eye Institute and Hospital

USC Healthcare Consultation Center I or II

USC Center for Health Professions (CHP)

USC School of Dentistry

El Monte Comprehensive Health Center *

H. Claude Hudson Comprehensive Center *

Roybal Comprehensive Health Center *

Other location (e.g., subjects home, community)

6a.2. Describe other location(s):

6a.3. If you are conducting this research in an LAC+USC location, specify the room numbers:

6a.4. If you are conducting this research at a location marked with an asterisk "*", attach a letter of approval from the medical director.

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There are no items to display

8. Funding Information

8.1. What existing, planned, or pending support will be used for this study? (check all that apply)

CTSI

Department of Defense (DOD) Funds

Departmental/Institutional Funds

Federal Grant/Contract

Foundation Grant/Contract

Industry

Intramural/Internal Grant

Residual Funds

State or Local Grant/Contract

Subcontract from another institution

No Funding

Other

9. Methods and Procedures - Selected Descriptors

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. This study will involve: (check all that apply)

Prospective collection of data/specimens

Use of existing or retrospective data/specimens

9.4. Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?

Yes No

11. Study Summary

11.1. Abstract: Provide a simple explanation of the study and briefly address each of the following points: background and rationale; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; intervention and follow-up; statistics and plans for analysis.

Although epidural analgesia is a widely accepted therapy for the management of traumatic rib fractures, its beneficial effects have not been consistently recognized in the scientific literature. A recent meta-analysis published in the Canadian Journal of Anesthesiology in 2009 demonstrated very little overall benefit to the use of epidural analgesia in adult patients with traumatic rib fractures. One reason for this may be variable timing of epidural catheter placement relative to the time of injury. The purpose of our study is to determine whether early compared to late epidural catheter placement is associated with improved clinical outcomes.

We propose a retrospective analysis of all patients with epidural analgesia used for pain management of rib fractures over a five year period (2006 - 2010). The time from hospital admission to the administration of epidural analgesia will be abstracted. Ventilator days, ventilator-free days, intensive care (ICU) and hospital length of days, as well as use of opiate analgesia will be documented for all the patients. Correlation

between time to admission to drug delivery and various outcomes will be performed.

11.2. Research objectives and background

11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions.

(HSC: refer to specific sections of the protocol/grant, if applicable)

The purpose of our study is to determine whether early compared to late epidural catheter placement is associated with improved clinical outcomes.

11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects.

Include relevant citations. (HSC: refer to specific sections of the protocol/grant, if applicable)

Although epidural analgesia is a widely accepted therapy for the management of traumatic rib fractures, its beneficial effects have not been consistently recognized in the scientific literature. A recent meta-analysis published in the Canadian Journal of Anesthesiology in 2009 demonstrated very little overall benefit to the use of epidural analgesia in adult patients with traumatic rib fractures. One reason for this may be variable timing of epidural catheter placement relative to the time of injury. The purpose of our study is to determine whether early compared to late epidural catheter placement is associated with improved clinical outcomes.

Knowledge gained from this study will help improve patient outcomes by determining the optimal time for this intervention.

References

1: Parris R. Towards evidence based emergency medicine: best BETs from the Manchester Royal Infirmary. Epidural analgesia/anaesthesia versus systemic intravenous opioid analgesia in the management of blunt thoracic trauma. *Emerg Med J.* 2007 Dec;24(12):848-9. Review.

2: Carrier FM, Turgeon AF, Nicole PC, Trapanier CA, Fergusson DA, Thauvette D, Lessard MR. Effect of epidural analgesia in patients with traumatic rib fractures: a systematic review and meta-analysis of randomized controlled trials. *Can J Anaesth.* 2009 Mar;56(3):230-42. Epub 2009 Feb 11. Review.

3: Mohta M, Verma P, Saxena AK, Sethi AK, Tyagi A, Girotra G. Prospective, randomized comparison of continuous thoracic epidural and thoracic paravertebral infusion in patients with unilateral multiple fractured ribs--a pilot study. *J Trauma.* 2009 Apr;66(4):1096-101.

4: Ho AM, Karmakar MK, Critchley LA. Acute pain management of patients with multiple fractured ribs: a focus on regional techniques. *Curr Opin Crit Care.* 2011 Aug;17(4):323-7. Review.

5: Truitt MS, Murry J, Amos J, Lorenzo M, Mangram A, Dunn E, Moore EE. Continuous intercostal nerve blockade for rib fractures: ready for primetime? *J Trauma.* 2011 Dec;71(6):1548-52; discussion 1552

6: Kim YJ, Cho HM, Yoon CS, Lee CK, Lee TY, Seok JP. Thoracic Epidural Anesthesia and Analgesia (TEA) in Patients with Rib Fractures. *Korean J Thorac Cardiovasc Surg.* 2011 Apr;44(2):178-82. Epub 2011 Apr 14.

7: Ford SR, Swanevelder CS, Mills PM. Extended-release epidural morphine (DepoDur) as analgesia for rib fractures. *Br J Anaesth.* 2012 May;108(5):883-4.

8: Yeh DD, Kutcher ME, Knudson MM, Tang JF. Epidural analgesia for blunt thoracic injury-Which patients benefit most? Injury. 2012 Jun 15. [Epub ahead of print]

13. Methods and Procedures - Retrospective Studies/Existing Data

This screen is required if you indicated the use of existing/retrospective data or specimens (Question 9.1.)

13.1. Do the retrospective/existing data involve records/specimens from deceased individuals?

Yes **No**

13.2. Describe the method of collection for the records/specimens and how the data/specimens will be analyzed.

Patients will be identified from medical record query using the institutional trauma registry. Data will be entered into an electronic database on Excel spreadsheets, and analyses will be performed using SPSS.

Patient demographics - age, gender, injury characteristics and comorbidities will be documented. Partial correlation analyses will be performed to identify trends between the time to initiation of epidural analgesia and the outcome variables. Adjustments will be made for the clinical covariates listed above.

13.3. Specify the number of records/specimens you expect to use: 100

13.4. Describe the method(s) by which subject records will be identified.

Patients will be identified from medical record query using the Institutional trauma registry

13.5. Attach the approval/permission letter to access existing data, if applicable. Do not include data use agreements here.

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There are no items to display

22. Special Subject Populations

22.1. Indicate any vulnerable subject populations you intend or expect to enroll in the research: (check all that apply)

Normal Volunteers

Employees or Students

Adults not Competent to Consent (or likely to lose the capacity to consent during the study)

Non-English Speaking Populations

Minors (subjects under 18 years of age)

Pregnant Women / Human Fetuses

Neonates (infants under 30 days old)

Wards

Prisoners/Detainees

None of the above

24. Subject Recruitment and Informed Consent

24.3. Informed Consent and Waivers:

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

Written/signed consent (participants will sign an informed consent document)

An information sheet will be provided and/or verbal consent obtained

Waiver of consent (participants will not be asked to sign a consent document or be given an

information sheet)

Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

24.5. You indicated you are requesting a waiver of consent or a waiver/alteration of one or more elements of informed consent. The following questions are required:

24.5.1. The research involves no more than minimal risk to subjects and the waiver/alteration will not adversely affect the rights and welfare of the subjects because: (check ALL that apply and at least one answer from A at least one answer from B)

A. The study will: (check all that apply)

Only collect retrospective data or be performing secondary data analyses on existing data

Only collect information from observation of public behavior

Only collect information from standard of care procedures

Not contact participants

Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment records, etc.)

Other

B. All Data/Information collected will: (check ALL that apply)

Not contain any identifiable information

Be coded and the key codes kept separately and securely

Be kept in a locked/password protected area accessible only to study staff

Other

24.5.2. Explain why the research could not practicably be carried out without the waiver or alteration: (check ALL that apply)

The data being collected are from existing records. Many of the subjects are lost to follow up, no longer seen at the hospital/facility, or deceased.

Participation in this study does not involve personal contact. The participants are not available to provide informed consent.

The study will be examining records from a large number of subjects. It is not feasible to attempt to contact all of them.

Other

24.5.3. Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation: (check ALL that apply)

There is no foreseeable need to provide information to the subjects. If there is a need, the IRB will be contacted to discuss the specific situation.

The study is observational and any results generated from the study will not be applicable to the subjects or the care of the subjects.

Other

** Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except when the following applies:

- Life-threatening situations, inability to communicate with or obtain legally effective consent from, the subject, insufficient time to obtain consent from the subject's legal representative and no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life, even if research presents more than minimal risk [21CFR50.23];
- OR if the study satisfies the requirements under 21CFR50.24 "Exception from Informed Consent Requirements for Emergency Research". Call the IRB office if you are planning to conduct this type of research as other regulatory

requirements apply.

26. Participant Privacy and Data Confidentiality

- 26.1. Privacy Protections:** Privacy is a participant's ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

Research procedures will be conducted in person in a private setting.

Data will be captured and reviewed in a private setting.

Only authorized research study personnel will be present during research related activities.

The collection of information about participants is limited to the amount necessary to achieve aims of the research.

Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.

Other (specify below)

- 26.2. Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be recorded? (check ALL that apply)

Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)

Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)

Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)

Other (explain below)

- 26.3. How will the research data and/or specimens be protected against inappropriate use or disclosure?** (check ALL that apply)

Locked office

Locked storage unit

Restricted access to authorized study personnel

Secure computer/laptop

Individual ID plus password protection

Encryption of digital data

Network Restrictions

Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study

Restrictions on copying study related materials

Destruction of source data immediately after data collection (to preserve anonymity of participants)

Audio and/or video recordings will be transcribed and then will be destroyed

Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified

Photos or images will be modified to eliminate the possibility that study participants could be identified

Study personnel will sign statements agreeing to protect security and confidentiality of study information

Access rights are terminated when authorized study personnel leave the study

Not Applicable

Other (specify below)

26.4. Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?

Yes No

26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).

Retained for study record keeping purposes per institutional policy.

Retained by the investigator for future research use.

Retained for future research use (create data or tissue repository/bank).

Restricted use data will be destroyed or returned to the source.

No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.

This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

Other (specify below)

26.6. Do you have, or plan to apply for, a DHHS issued Certificate of Confidentiality for this study?

Yes No

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use or disclose protected health information (PHI) in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)

Yes No

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

Yes No

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number

- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a "limited data set". If you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.

name	Version	Modified
There are no items to display		

36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate if these activities fall under the rules for Activities Preparatory to Research, if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting, or if neither option applies.

(CHLA Only) Activities Preparatory to Research
Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants
None of the Above

36.2. If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.

Obtaining HIPAA authorization from participant
Full Waiver of HIPAA Authorization

36.2.1. If you are obtaining authorization from the participant, attach the HIPAA authorization forms here (USC Only). Please [click here](#) to download the HIPAA Authorization template forms from OPRS.

name	Version	Modified
There are no items to display		

38. Waiver or Alteration of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Full or Partial Waiver of HIPAA Authorization (Question 36.1. or Question 36.2.)

If you are applying for a full waiver of authorization or a partial waiver of authorization for the purposes of screening, recruitment, and subject identification, provide justification per 45 CFR 164.

38.1. How will you protect PHI from improper use and disclosure? (check all that apply)

No identifiers or links to identifiers will be recorded during the data collection process.

PHI will be used only for the purposes of assessing eligibility and identifying potential participants.

All research documents containing PHI will be stored in a locked/password protected area accessible only to study staff.

Study data will be coded or de-identified prior to being sent outside the study team.

Other

38.2. How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research? (check all that apply)

No identifiers or links to identifiers will be recorded during the data collection process.

Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.

The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.

The FDA requires that the records be retained for two years following marketing approval for the drug/device or discontinuation of the investigation. After that, the identifiers will be shredded and or purged.

The NIH requires that the records be retained for three years following the completion of the study. After that, the identifiers will be shredded and/or purged.

Other

38.3. By checking the "I Agree" box you are providing assurance that PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

I Agree

38.4. The research could not practicably be conducted without the requested waiver or alteration because: (check all that apply)

PHI is required to identify potential participants who meet the eligibility criteria.

It is not feasible to individually contact the large numbers of participants.

It is not possible to locate many of the potential participants because they have left the area or are otherwise lost to follow up.

Other

38.5. The research could not practicably be conducted without access to and use of the PHI because: (check all that apply)

PHI is required to identify potential participants who meet the eligibility criteria.

The data required for this study is only available in the PHI / medical records.

During the recruitment process, PHI is needed in order to contact potential participants.

Other

38.6. The PHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.

39. Conflict Of Interest Information

39.1. Does the Investigator, Research Personnel or Close Relation have an *ownership interest* (such as stock, stock options or warrants, but not mutual funds or a publicly traded equity interest of less than \$10,000) in:

- The sponsor of the research; or

An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or

- An entity that has an economic interest in the research.

Yes **No**

39.2. Does the **Investigator**, **Research Personnel** or **Close Relation** have a **management role** (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

Yes **No**

39.3. Did the **Investigator**, **Research Personnel** or **Close Relation** receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for **consulting** (such as speakers fees or payments for participation on an advisory board or assistance with protocol design) from

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include salary for services as an investigator/staff on the research study.

Yes **No**

39.4. Attach a **Statement of Outside Interests Related to Research Form** for each person who has a potential conflict to be managed. Please note that uploading forms here does not satisfy the need to submit it to the Office of Compliance. A step by step guide on how to submit a disclosure is available from the USC Office of Compliance website at <http://ooc.usc.edu/step-step-guide-disclosure>.

name Version Modified

There are no items to display

39.5. To the investigator's knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project? *An institutional conflict may occur when a financial interest of the University has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.*

Yes **No**

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.

name Version Modified

There are no items to display

40.2. If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.

99. Instructions for Study Submission

You have reached the end of the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.

1. Click the "**Finish**" button on the top or bottom application navigator bar to return to the study workspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the "**Send Study Ready Notification**" activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the study by using the "**Submit Application to _____**", where _____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The study is submitted. The state indicator in the top left of the study workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.