Date: Thursday, October 13, 2016 12:26:50 PM

Print Close

**IRB_00071740** **Created:** 2/12/2014 4:47 PM

**PI:** IRB Administrator **Submitted:** 2/19/2014

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

# 1. Contacts and Title

**1. Principal Investigator:**

IRB Administrator

| Email | Training | CoI Date |
|---|---|---|
| irb@hsc.utah.edu | | |

**a. Position of Principal Investigator:**

- (●) **Faculty**
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

**If Other, describe:**

**b. Will the Principal Investigator consent participants?** ( ) Yes (●) **No**

**2. Contact Person(s) (if different from the PI):**

| Name | Email | Training |
|---|---|---|

There are no items to display

**3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):**

| Name | Email | Training | Obtaining Consent | CoI Date |
|---|---|---|---|---|

There are no items to display

**4. External Sub-Investigator(s) (Investigators outside the University of Utah):**

| Last Name | First Name | Affiliation |
|---|---|---|

There are no items to display

**5. Faculty Sponsor (if needed):**

**6. Guests:**

| Last Name | First Name | E-Mail |
|---|---|---|

There are no items to display

**7. What type of application is being submitted?**

New Study Application (or Amendment/Continuing Review)

**8. Title Of Study:**
EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

**9. Study Purposes and Objectives:**

**The purpose of this study is to allow for secondary analyses of previously collected clinical data (standard of care) on patients treated by the investigators on this application according to the study objectives listed below.**

**This is a submission for an umbrella protocol that will cover all secondary data analyses conducted by the investigators on this application. The umbrella protocol meets the criteria for the University of Utah IRB Exemption Category #7: "Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded AND:**

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**i.Research is not subject to FDA regulations**

**ii.Research is not federally funded**

**iii.Research is not contractually or otherwise subject to federal research requirements, including but not limited to research conducted under the Department of Veterans Affairs or under an NIH Certificate of Confidentiality.**

**iv.Research does not involve prisoners as participants**

**Research meets the University's ethical standards governing the conduct of the research, including appropriate provisions for the protection of privacy and confidentiality when identifiable and coded information are used.**

**Study Objectives:**

1. **Review and report on the clinical outcomes of patients that have received treatment for upper extremity pathologies.**
2. **Studying the value of care provided by assessing quality, outcomes and the cost of standard of care treatments for upper extremity pathologies**

***As per the agreement with EDW, the data will remain in the EDW with users gaining access to it through various web-based tools and SQL.*

**10. Background and Introduction:**

**Secondary data analysis allows for the acquisition of clinical data for the purposes of understanding outcomes and recommending improvements for patient care. It facilitates the identification of clinically relevant trends that may lead to changes in the way patient care is managed or provide evidence that supports current clinical care pathways.**

**Understanding the outcomes of treatment for upper extremity pathologies and the costs associated with those treatments are fundamental steps in improving the care for these patients.**

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

Site Name Other Site Site Investigator Sponsor Contact Information Investigator/Main Contact

## 2. Study Location and Sponsors

1. **Department:**
   ORTHOPEDIC SURGERY
2. **Location of Study:**

   University of Utah's Covered Entity (Health sciences, hospitals, and clinics)
3. **Is this a Multicenter Study (i.e., the study involves other sites with other PIs):**

   ○ Yes ◉ **No**

   a. **If yes, are you the lead investigator of this study, or is this the central location for the study?**

      ○ Yes ○ No
4. **Indicate other locations that are participating in the study for which you, as the PI, are responsible:**

   | Site Name | Other Site | Site Investigator | Investigator/Main Contact |
   |---|---|---|---|

   There are no items to display

   a. **How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?**
5. **Indicate the source(s) of funding obtained or applied for to support this study.**

   | Sponsor | Sponsor Type | Sponsor Contact Information |
   |---|---|---|

   There are no items to display
6. **Does this study have functions assigned to a Contract Research Organization (CRO)?**

   ○ Yes ◉ **No**

   **If yes, CRO Contact Information:**
7. **Does this study involve use of the Utah Population Database (UPDB)?**

   ○ Yes ◉ **No**

## 3. Participants

1. **Ages of Participants:**

| | |
|---|---|
| Less than 7 years old | (Parental permission form needed) |
| 7 to 17 years old | (Parental permission and assent form needed) |
| 18 and older | (Consent form needed) |

2. **Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**
   0-100

3. **Indicate any vulnerable participant groups (other than children) included:**

   None

   **If "Other", please specify:**

   **If "None" and no children are involved, answer the following question.**
   **Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?**
   ○ Yes ○ No

4. **Number of participants to be enrolled during the entire study:**

   **At Utah:** 100,000

   **All Centers:**100,000

5. **Characteristics of Participants/Inclusion Criteria:**

   **We will secondarily analyze archived clinical and cost data on all upper extremity patients, regardless of gender, race, and age at the University of Utah Covered Entity.**

6. **Participant Exclusion Criteria:**

   None

7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**

   ○ Yes ◉ **No**

## Vulnerable Populations

**Justification Requirements for the Inclusion of Vulnerable Populations**

1. **How does the nature of the research require or justify using the proposed subject population?**
   The research involves the review and analysis of secondary data and inclusion of all patients is needed to provide generalizability of the results.
2. **Would it be possible to conduct the study with other, less vulnerable subjects?**
   ○ Yes ◉ **No**

   **If yes, justify the inclusion of vulnerable subjects:**
3. **Is this population being included primarily for the convenience of the researcher?**
   ○ Yes ◉ **No**

   **If yes, explain:**
4. **Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?**

   ◉ **Yes** ○ No

# 4. Study Information

1. **Design of Study (select all that apply):**
   Secondary/Archival Data Analysis
   **If Other, describe:**

2. **Does your study involve the use of any placebo?**
   ○ Yes ◉ **No**

3. **Length of entire study, from initiation through closeout:** 100 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**
   Written or electronic record review

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   **Eligible participants will be identified using the University's enterprise data warehouse as well as the clinical and surgical databases of the investigators.**

5. **How will consent be obtained?**
   Waiver or Alteration of Informed Consent

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

   **We will query data from the previously mentioned sources to obtain a list of patients that meet particular criteria for the outcome measure in review. Data may be confirmed via chart review of both paper and electronic medical records. The content of the data will include information on medical comorbidities, social habits, socioeconomic, educational, and demographic status, review of systems, general health status, pain status, psychological status, musculoskeletal status and quality of life status. Data collected as standard of care including patient and provider reported outcomes, procedures, laboratory and pathology results, histology results, radiological data, surgical/rehabilitation/treatment data, implant component data, patient satisfaction assessments and the cost of care data may be reviewed. Once the outcome measures have been obtained and all the study variables collected and reviewed the data analysis will begin.**

   ****The data will remain in the EDW with users gaining access to it through various web-based tools and SQL.**

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ◉ **Yes** ○ No

   **If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):**

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ◉ **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   **Statistical methods will depend on the particular question for the study. Studies will use the appropriate parametric and/or non-parametric statistics for analysis. The investigators, to ensure the data is accurate, may review outliers identified in the analysis process. Commercially available statistical software will be used for the analysis.**

**IRB_00071740** **Created:** 2/12/2014 4:47 PM

**PI:** IRB Administrator **Submitted:** 2/19/2014

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

| | Date Created | Type of Request | Purpose of Waiver Request |
|---|---|---|---|

# Request for Waiver or Alteration of Consent

**Requested Waivers**

| | Date Created | Type of Request | Purpose of Waiver Request |
|---|---|---|---|
| View | 2/13/2014 | Waiver of Informed Consent | Review and analysis of secondary data conducted by the investigators on this application according to the study objectives. |

**PI:** IRB Administrator

# Request for Waiver or Alteration of Consent

**Submitted:** 2/19/2014

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

1. **Purpose of the Waiver Request:**
   Review and analysis of secondary data conducted by the investigators on this application according to the study objectives.

2. **Type of Request:**
   Waiver of Informed Consent

   a. **Will deception be used?** ○ Yes ◉ **No**

   **If yes, provide the rationale and describe the debriefing procedures:**

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).**
   Names. MRN, Address (to identify geographic locations), Dates of visits and procedures, DOB

4. **Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":**
   If consent were a requirement, the investigators would be unable to obtain consent approximately 50% of participants. This is an estimate based on prior studies performed at the University of Utah Orthopaedic Center. Additionally some of these patients are located outside of the local geographical area and it would be difficult if not impossible for them to return to the clinic to complete the consenting process. There are also patients who meet the criteria for enrollment who have been lost to followup or who are deceased.

5. **Explain why the research and privacy risk of the research are no more than *minimal:***
   Because the main risk of this study is a breach of confidentiality and procedures are in place such as keeping data on secure computers to make sure breaches are very unlikely.

6. **Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects:***

   The Rights and welfare of the participants will not be adversely affected because all information was collected for clinical care, and the research will not change the treatment any individual received.

7. **Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate *"Not applicable":***
   Not Applicable

# 5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   **Select all that apply:**

   The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

   **Other or additional details (specify):**

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   **Select all that apply:**

   Storing research data on password protected computers or in locked cabinets or offices

   **Other or additional details (specify):**

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ◉ **No**

   **If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):**

4. **How will study data and documentation be monitored throughout the study?**

   **Select all that apply:**

   Periodic review of the transfer/transcription of data from the original source to the research record

   Other or additional details (specify):

   **Other additional details (specify):**
   The study team will maintain a record of all specific projects and analyses that are conducted under this protocol, including documentation that each is conducted in accordance with the procedures and provisions described in this umbrella application. A report of the specific, individual projects/analyses will be submitted annually to the IRB via the ERICA Report Form for acknowledgement. This report will include the name of the investigators who conducted the specific project, the date the project began and ended (if ended), the actual or estimated number of patients whose data were/will be analyzed, and a short description of the specific aims and procedures for the projects.

   The PI will ensure that any substantial amendments to the umbrella protocol, including changes in co-investigators, will be submitted to the IRB via an amendment application. The PI will also ensure that all possible unanticipated problems or instances of non-compliance related to any individual projects under this umbrella will be reported to the IRB according to standard IRB reporting policies.

5. **Who will be the primary monitor of the study data and documentation?**

   **Select all that apply:**

   Principal Investigator

   Study Coordinator or Research Nurse

   Independent Physician, Faculty or Staff Member

   **Other or additional details (specify):**

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
   Annually

## 6. Risks and Benefits

1. **Describe the reasonable foreseeable risks or discomforts to the participants:**

   **Risks include possible breach of confidentiality for all participants. The research involves the collection or study of existing data, and documents from the University of Utah's Covered Entity and it's electronic medical records.**

2. **Describe the potential benefits to society AND to participants (do not include compensation):**

   **No direct benefits to participants. Societal benefits include increased knowledge about musculoskeletal disorders and the costs associated with the treatment of those disorders. This could lead to improved treatment and care pathways and lower the cost of the treatment of these disorders.**

3. **Are there any costs to the participants from participation in research?**

   ○ Yes ◉ **No**

   **If yes, specify:**

4. **Is there any compensation to the participants?**

   ○ Yes ◉ **No**

   a. **If yes, answer the following:**
      **Specify overall amount:**

   b. **Specify when participants will be paid (e.g. at each visit, at end of study, etc.):**

   c. **If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):**

   d. **If applicable, explain plan for prorating payments if participant does not complete the study:**

## 7. HIPAA and the Covered Entity

**1. Does this study involve Protected Health Information (PHI) or de-identified health information?**

(●) **Yes** ( ) No

**a. If yes, select the method(s) of authorization that will be used:**

Waiver or Alteration of Authorization

**If needed, select De-Identification Form:**

**b. If yes, will PHI be disclosed outside the Covered Entity?**

( ) Yes (●) **No**

**If so, to whom?**

**And for what purposes?**

**2. Does this study involve any of the following:**

**a. The investigational use of a drug?**

( ) Yes (●) **No**

**b. The investigational use of a medical device?**

( ) Yes (●) **No**

**c. Is this an investigator-initiated drug or device trial lead by the Principal Investigator?**

( ) Yes (●) **No**

**d. Exposure to radioisotopes or ionizing radiation?**

( ) Yes (●) **No**

**e. Does the study involve cancer patients and/or address a cancer question?**

( ) Yes (●) **No**

**f. Obtaining data or information from the UUHSC Enterprise Data Warehouse (EDW) in a query outside of the Utah Population Database (UPDB)?**

(●) **Yes** ( ) No

**g. Any component of the Center for Clinical and Translational Science (CCTS)?**

( ) Yes (●) **No**

**The Clinical Services Core (CSC)?**

( ) Yes (●) **No**

**h. A Humanitarian Device Exemption (HDE)?**

( ) Yes (●) **No**

**i. Genetic testing and/or analysis of genetic data?**

( ) Yes ( ) No

**j. Creating or sending samples to a tissue bank/repository?**

( ) Yes (●) **No**

**k. The use of human subjects and biological agents (e.g., staphylococcus aureus, adenovirus), the collection of samples from individuals infected with biological agents (e.g., blood or tissue samples from hepatitis B virus-positive patients), or the deliberate transfer of recombinant DNA vectors/plasmids (recombinant DNA, or DNA or RNA derived from recombinant DNA) or synthetic DNA into human research participants?"**

( ) Yes (●) **No**

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

# Request for Waiver or Alteration of Authorization

**Request for Waiver of Authorization for Recruitment Only**

*This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.*

**Other Requests for Waivers of Authorization:**

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

| | Date Created | Type of Request | Purpose of Waiver Request |
|---|---|---|---|
| View | 2/13/2014 | Waiver of Authorization | Review and analysis of all secondary data collected during routine office visits and standard of care practices by the investigators on this application according to the study objectives. |

**PI:** IRB Administrator

# Request for Waiver or Alteration of Authorization

**Submitted:** 2/19/2014

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

1. **Purpose of the Waiver Request:**
   Review and analysis of all secondary data collected during routine office visits and standard of care practices by the investigators on this application according to the study objectives.

2. **Type of Request:**
   Waiver of Authorization

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).**
   Names, MRN, Address (to identify geographical locations), Dates of visits and procedures, DOB.

4. **Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:**
   The identifiers are needed for the merging of databases and the reviewing of medical records to confirm the data is accurate. Location variables may be needed to report on trends by geographical area.

5. **Explain why the research could not practicably be conducted without the waiver of authorization.** *For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."*
   For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."
   If authorization were a requirement we would not be able get authorization from approximately 50% of the patient population. This number is based on prior analysis at the Orthopaedic Center where authorization has been limited to approximately 50% of our patients in prospective registries. Additionally, some of these patients are located outside of the local geographical area and returning to the Orthopaedic Center to provide authorization would be difficult and impractical for these patients. There are also patients who may be eligible for this study but are currently lost to followup or are deceased.

6. **Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:**
   The PHI for this study will be stored on password-protected computers. Access to the data will be limited to study team members who need the files for data entry or analysis.

7. **The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:**
   Each individual project under this umbrella protocol will used identifiable information for the duration needed to review the data and ensure the analysis is accurate. Identifiers may be retained while publication is being sought, such that results can be verified. PHI will not be used beyond this point.

8. **Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:**
   The data files generated for this study will be kept confidential on password protected computers and will not be transferred outside the covered entity unless the files have been de-identified. Only study team members, working under this umbrella application, who need access to complete the study will use and review PHI. The IRB and those entities required by law may also be given access to the data.

## 8. Resources and Responsibilities

1. **State and justify the qualifications of the study staff:**

   **All investigators and staff are experienced researchers who have conducted multiple retrospective studies.**

2. **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   **All staff and investigators will or have performed CITI training or equivalent, as well as HIPAA training through the institution.**

3. **Describe the facilities to be used for the research activities (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.):**
   The University of Utah Covered Entity, including the University of Utah Orthopaedic Center and its affiliated clinics.

4. **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   Not Applicable.

**IRB_00071740** **Created:** 2/12/2014 4:47 PM

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| Name | Version | Date Created | Date Modified |
|---|---|---|---|

## Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

**Naming Documents:** Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document (Highlighted Changes)

Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.

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**Print View: IRB Draft Protocol Summary**

**eProtocol Summary:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Parental Permission Documents:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Assent Documents:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**VA Consent Documents:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Surveys, Questionnaires, Interview Scripts, etc.:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|
| There are no items to display | | | |

**IRB_00071440** **Created:** 2/12/2014 4:47 PM

**PI:** IRB Administrator **Submitted:** 2/19/2014

**Title:** EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for upper extremity pathologies.

**Grant Application:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Literature Cited/References:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Principal Investigator's Scholarly Record (CV/Resume):**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Faculty Sponsor's Scholarly Record (CV/Resume):**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Other Stamped Documents:**

*Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.*

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Recruitment Materials, Advertisements, etc.:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

**Other Documents:**

| Name | Version | Date Created | Date Modified |
|---|---|---|---|

There are no items to display

## Finish Instructions

**Finish Instructions**

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   **You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.**
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**