# Resident/Student Research Project Process Form

*The resident or student is responsible for completing this form, the REDCap form and obtain approval prior to initiating the IRB process for each resident/student initiated research project. Name and save the current file such that it includes the date of submission, last name of who is submitting and version # (example: "01012017\_last name\_verX"). Please transfer the following information and upload the current form into REDCap using the following link:* [*http://j.mp/2lIbUlZ*](http://j.mp/2lIbUlZ)*.*

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| **Project Title:** |  | **Date:**  |
| **Faculty Advisor:** |  | **Email:** |
| **Resident Investigator(s)** |  |
| **Student Investigator** | 1. | 2. | 3. | 4. |
| **Project contact email** |  |
| **Study Design** |   1. Case study  2. Retrospective chart review  3. Randomized clinical trial   4. Other |
| **Project Abstract**: IN 300 words or fewer, Please provide a brief background on this topic. Include relevant literature WITH APPROPRIATE CITATIONS and specifiy the gap in knowledge to be addressed. |
|  |
| **Research question(s)** (Resource: <http://twp.duke.edu/uploads/media_items/research-questions.original.pdf>). CREATE A NUMBERED LIST OF ALL RESEARCH QUESTIONS. EACH RESEARCH QUESTION SHOULD HAVE ONLY 1 OUTCOME. |
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| **HYPOTHESIS** – A declarative statement predicts the relationship between a predictor variable and an outcome. THERE SHOULD BE A HYPOTHESIS ASSOCIATED WITH EACH OF YOUR RESEARCH QUESTIONS. CREAT A NUMBERED LIST OF THE HYPOTHESE THAT CORRESPONDS TO YOUR NUMBERED LIST OF RESEARCH QUESTIONS.  |
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| **Primary outcome**- Provide name OF YOUR PRIMARY OUTCOME (**THIS MUST BE A SINGLE VARIABLE**) AND THE unit of measure and HOW IT WILL BE CALCULATED WHEN APPLICABLE (example: length of hospital stay, DAYS, calculated as date of discharge - date of admission) |
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| **Secondary outcome(s)** - Provide name(s), unit of measure, and how EACH VARIABLE WILL BE calculated WHEN APPLICABLE (example: KOOS Pain Score (NUMERICAL SCORE) at 6 weeks post TKA). LIST ALL SECONDARY OUTCOMES AND TIME POINTS OF MEASUREMENT. |
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| **Other variables of interest**- Possible confounders or modifiers (e.G., age, SEX, KL GRADE, CHARLSON COMORBIDITY INDEX). Provide name, unit of measure and how THE VARIABLE WILL BE calculated (when applicable)  |
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| **Data Source** |  Redcap (Dr. Dasa patients) Redcap (Dr. Krause patients) Louisiana Trauma Database REACHNet  Other publicly available dataset (HCUP, CMS, Medicaid) LSU Allscripts Ochsner EPIC  UMC EPIC CHNOLA EMR Other |
| Have you confirmed that all data listed previously ARE **available** in the above listed data source?  |

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| **REsources-** The department offers Drs. Leonardi and BRONSTONE's time to assist you with statistical analysis and project/manuscript development. Note: THeir assistance is typically not needed for Case Studies. Which of the following resources is needed? |
|  Dr. Amy Bronstone- project/manuscript development Dr. Claudia Leonardi - project/manuscript development/dATA cOLLECTION AND ANALYSIS Lab Software OtherIf any funding is required, please submit budget form found at the end of this document. |
| Do you intend to submit this project for any external grant funding? |
|   Yes No |
| What is the **level of evidence** assignable to this project? (<http://journals.lww.com/jbjsjournal/Pages/Journals-Level-of-Evidence.aspx>) |
|  Level I Level II Level III Level IV Level V |
| **Anticipated IRB submission category (**[**http://www.lsuhsc.edu/administration/academic/ors/irb.aspx**](http://www.lsuhsc.edu/administration/academic/ors/irb.aspx)**)** |
|  EXEMPT EXPEDITED FULL BOARD REVIEW |
| **AUTHORSHIP CRITERIA**1a. Substantial contributions to study conception and design1b. Substantial contributions to acquisition of data1c. Substantial contributions to analysis and interpretation of data2. Drafting the article or revising it critically for important intellectual content3. Final approval of the version of the article to be publishedIndividuals must meet criteria 1 (1a, 1b, and/or 1c), 2, and 3 below to qualify for authorship. Please indicate below the aspects of the work for which each author had responsibility.Anticipated author order: |
| 1. 2. 3.4. 5. 6.  |
| targeted conference and adbstract submission deadline? <https://www.medschool.lsuhsc.edu/orthopaedics/annual_meetings.aspx> |
|  |
| **Project Milestones and target dates** |
| IRB Submission: \_\_\_\_\_\_\_\_\_\_\_ Data Collection Start: \_\_\_\_\_\_\_\_\_\_\_Data Collection End: \_\_\_\_\_\_\_\_\_\_\_ Data Analysis: \_\_\_\_\_\_\_\_\_\_\_\_Abstract Submission: \_\_\_\_\_\_\_\_\_\_\_\_ Manuscript Submission: \_\_\_\_\_\_\_\_\_\_\_\_ |

**IRB approval required prior to proceeding.**

**LSUHSC Department of Orthopaedics Research Budget**

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| **DETAILED BUDGET**  | FROM (Date) | THROUGH (Date) |

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| --- | --- |
| **PERMANENT EQUIPMENT** *(Itemize)* |  |
| **CONSUMABLE SUPPLIES** *(Itemize)* |  |
| **ANIMALS AND ANIMAL CARE** (Purchase and Housing) |  |
| **ALL OTHER EXPENSES** *(Itemize)* |  |
| **TOTAL COSTS FOR BUDGET PERIOD**  |  |

**Budget JUSTIFICATION**: