

## How to Submit a Research Application to the USC IRB for a Novice Applicant

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**Learner Audience:** medical students/residents

**Background:** Anecdotally, it has been shown that students and residents have struggled to navigate the IRB application process due to the vast amount of paper work and the poor organization and guidance from the institution to support the novice.

**Needs Assessment:** In order to stimulate change, a new document needs to be drafted to promote ease of use.

**Hypothesis:** Based on previous attempts at organizing the information and the 400 page complete body of policies and procedures, an approximately 10 page document entailing the most important details with appendices of templates and instructions compiling the necessary pieces of the application will improve success.

**Curriculum Design:** It will touch on the basics of human research subjects, cover tips and recommendations for writing a sound, feasible protocol, ancillary study documents and application. It also provides information regarding IRB study review types, investigator roles and possible outcomes. Finally the document compiles instructions and templates of protocol, study documents and applications in a list of appendices. The specific templates include a protocol template, instructions and screen shots of the online application entry site, informed consent instructions and template, patient bill of rights instruction and template, HIPAA disclosure instructions and template, and samples of a drug inventory form, laboratory agreement, budget, study staff instruction, timeline flowchart, and data collection form.

**Outcome:** Has yet to be assessed, as the document is in the final drafting stages with the cooperation of the USC IRB. In the coming months, an examination of approval rates and document usage will be assessed.