Administrative Review of Research

All research affiliated with or conducted, in whole or in part, at Boone Hospital Center should undergo the process of Administrative Review and Approval. This includes a thorough review by hospital administration to assess any budgetary concerns, legal aspects and overall biomedical facets of the research. Following review, if identified concerns can be addressed, hospital administration will grant approval for the research to be conducted within our facility. The steps in this review process are broken down here. Please note that your application to Washington University IRB (WU IRB) may be started in tandem with legal review; however, you will require senior administrative approval via a signed assurance document to proceed with submission. If you need assistance in any step of this process please call the Boone Hospital Clinical Research Office at (573) 815 5132.

### Medical Review

Every study that involves Boone Hospital Center, including study-related tests or procedures, has to be approved by a Senior Medical Authority, such as the Chief Medical Officer (Dr. Robin Blount), Chief Nursing Officer (Monica Smith), or, if requesting deferral to outside IRB oversight, by the Medical Director for IRB matters at BHC (Dr. Michael Hauan). The review consists of an email submission of the research summary/protocol (when available), along with any other relevant information. A call/discussion with the Study PI/representative is also acceptable.

### BUDGETARY Review

Following medical review any research affiliated with or involving Boone Hospital Center facilities should begin with a review of the budget. Research coordinators and investigators should work together, along with their sponsor, to assemble a budget review of their study based on Revenue and Expense metrics related to the study. Please contact Brian Winn, Financial Services Advisor at Brian.Winn@bjc.org, for assistance with pricing for tests and procedures performed at BHC. The final approval should be between your site/PI and the sponsor of your research, if applicable. For studies involving billing for research procedures performed at Boone Hospital Center you will need to create an RCAST form and verify billing routing before the procedure takes place. For details about the RCAST form, please contact Tiffany Hamilton in the BJC Compliance Office, tiffany.hamilton@bjc.org

### LEGAL Review

After medical review and budgetary review, legal review for Boone Hospital Center is performed by Kate Pitzer, Kathleen.Pitzer@bjc.org, Boone Hospital In-House Counsel. Included in this review are the Confidentiality Disclosure Agreement (CDA) (if applicable), followed by the Clinical Trial Agreement (CTA). The final budget is usually added to the CTA before its execution (signatures of PI and sponsor generally are required, and BHC may be a signatory). In addition, a Facility or Service Agreement may be required between your site (if outside of BHC) and Boone Hospital Center. This agreement should specify the study-specific procedures or testing to be performed at Boone Hospital Center, as well as the funding source for performing these procedures or testing.

### SENIOR Approval

Finally, every study submitted to WU IRB requires an assurance document signed by the Principal Investigator of the study and by a Boone Hospital Center Medical Authority, such as the Chief Medical Officer (Dr. Robin Blount) or Chief Nursing Officer (Monica Smith). The signed assurance document is generated by the myIRB system at the time of a new project submission and after printed and signed, it needs to be uploaded back in the system in order to be able to submit. Staff in the Clinical Research Office can assist you with obtaining this signature.

### IRB Review

You are now ready to submit to WU IRB!