

Charleston Research Institute

Policy Memorandum

Title: Study Start-Up Agreement Policy
Reviewed by: Board of Directors
Implementation Date: February 8, 2016
Revision Date: April 24, 2019
Next Scheduled Review Date: April 24, 2022
Approval: Amanda C. LaRue, Ph.D., Chairperson

Policy Statement:

Prior to the negotiation of a Cooperative Research and Development Agreement (CRADA) and following execution of a Confidential Disclosure Agreement (CDA), Charleston Research Institute (CRI) will require industry sponsors to execute a Study Start-Up Agreement (SSUA) to provide for the provision and payment of regulatory submission services in connection with a sponsor's study. Sponsor's payment will cover the Institutional Review Board's fee and the study coordinator's time to prepare and submit regulatory documentation.

Background:

CRI has a board-approved Extramural Schedule of Fees ("Schedule") that applies to all industry-sponsored studies. Included in that schedule are IRB fees and study start-up fees to cover regulatory submission of protocols. CRI will apply the Schedule to the SSUA.

Guidelines:

Following execution of a CDA and site selection, CRI will provide the sponsor with a copy of the SSUA. If the sponsor modifies the SSUA, CRI will forward the modifications to VA Office of General Counsel Specialty Team Advising Research (STAR) for review and approval.

Per the terms of the SSUA, should Ralph H. Johnson VA Medical Center, CRI, and the Sponsor fail to enter into a CRADA, the Sponsor, in consideration for the provision of the services outlined in the SSUA, will pay CRI non-refundable regulatory submission fees in accordance with the Schedule within thirty (30) days of receipt of invoice.