**Pre-Approval (FRONT END):**

**JHS CTO Application:** The purpose of the form is to obtain general information about the study, such as study title, PI Name, study IRB #, primary coordinator, enrollment target, JHS location, services, duration of the study etc.

**JHS Study Calendar:** The purpose is toindicate the study schedule of events, which will be performed at JHS. It is JHS Medicare Coverage Analysis (MCA) and should mirror UM’s MCA.

**JHS Research Request form for JHS’ Electronic Medical Record access:** The purpose is to obtain information from the requestor (DOB, 4 last digits of SSN#, IRB studies) to grant access to JHS’ Electronic Medical Record.

**Pathology By-Pass Letter**: The purpose is to waive the pathology requirements of handling the tissue for research purposes under the specified conditions in the protocol, i.e tissue placed immediately in ice to maintain viability.

**Pathology Research Fee Schedule:** The purpose is to provide a copy to study team to select the tissue services that will be requested during the study. This will aid in the budget development. These fees are now included in the rate sheet provided to ORA.

**WORKFLOW**: The purpose is to indicate the location of the services and personnel performing the services either at JHS or UM. Serves as a guide when developing the budget and communicating with the nursing/other area teams for feasibility.

**Pre-Submission Feasibility/Budget Request**: The purpose is to list questions necessary to input the ticket request, which will be fulfilled by IT. IT needs to understand the scope of work required.

**Retrospective Chart Review Data Request Questionnaire**: The purpose of this questionnaire is to obtain details about the study (inclusion/exclusion criteria etc) and its data request; the information is necessary in order for IT to fulfill the request.

**Post-Approval (BACK END):**

**Monthly Enrollment Report Form**: The purpose is to list all participants who screened, enrolled and/or are off study/withdrawal in the trial. It serves to cross-reference with the consents received and to maintain billing compliance. It also serves to un-flag the participants in JHS’ Electronic Medical Record. Study team is responsible to submit this form to CTO at the beginning of the month. CTO shall review the form and communicate with study team if any discrepancy.

**PACS. Research Request Form**: The purpose is to request study images for JHS approved studies. The form provides patient information needed to prepare CD’s (usually anonymized) by the JHS PACS Administration team. The CTO receives the request, CTO verifies that it is JHS approved with all consents received (if applicable) and send’s verification to PACS Admin for fulfillment of the services.

**Pathology Research Fee Schedule**: The purpose is for the study team to request the services from the JHS Pathology Department. The form contains details for the study and pathology services. Pathology department will notify CTO of the services. CTO will review form and study folder in order to determine if pathology services are in the contract. Once this is confirmed CTO will invoice for services.

**Patient Chart Review Form**: The purpose is to list all patients whose charts were reviewed for the research purpose. The form includes the name, MRN, date accessed, observations, and the study details. Study team is responsible to submit this form to CTO at the beginning of the month. CTO shall review the form and communicate with study team if any discrepancy. JHS requires this form to be submitted monthly.

**Research Encounter Ticket (RET):** The purpose is to reflect all study services during the clinical trial and to aid in scrubbing the patient’s accounts based on CMS guidelines. The RET is the baseline to invoice for all clinical trial services performed at JHS. CTO is tasked with placing the required modifiers and codes on the claim in place for the routine and non-routine care that takes place within the context of any research protocol or clinical trial.