

## Pre-Study Work Flow: Investigator Initiated Clinical Trials Research

<b>Grant Funded</b>	If grant funded <b>RSP</b> will handle contract & budget negotiations.	If your study involves billable services /procedures <b>RSP</b> will send to <b>JCCTR</b> to conduct Medicare Coverage Analysis ( <b>MCA</b> ) and identify which services are billable to insurance/CMS vs. which services need to be <b>covered by the grant</b> .	<b>Important Reminder!</b> All billable services / procedures <b>MUST</b> be covered either by the grant or be billable to insurance/ CMS per <b>MCA</b>
<b>Un-funded</b>	No contract/budget negotiations.	If your study involves billable services /procedures <b>IRB</b> will send to <b>JCCTR</b> to conduct Medicare Coverage Analysis ( <b>MCA</b> ) and identify which services are billable to insurance/CMS <b>ALL services not billable would need to be picked up by PI/department</b> .	

**Important Reminder!**  
**No free services are allowed on any unfunded projects.** If you have items/services that are billable you cannot provide to patients free of charge. You need to reimburse with departmental funds or have another funding source.

- Research Staff** completes IRB application and submits to local IRB
- IRB:** reviews, approves or requires modifications to application, consent, or protocol
- PI:** If meets NIH clinical trial definition or if publishing data you need to upload onto **Clinicaltrials.gov** prior to enrolling your first subject.

