



## Strong Site CTAs and Budgets Negotiations

CTA and budget negotiations often feel impossible to navigate. Below are common site practices to ensure your site secures safe and productive clinical trial contracts and budgets for financially responsible healthy performances. Contact CRPN today if you'd prefer to access our professional negotiation services.

### Clinical Trial Agreements (CTAs)

- 1) No holding back.**  
Do not allow "withholding" or "holdback" penalties. Make this an institutional SOP and quality standard.
- 2) Require monthly payments.**  
If you need enhanced and routine cash flow, make monthly payments your institution's standard.
- 3) Do not allow short Invoiceable Windows of Opportunity (IWOs)**  
Many CTAs will build in "use it or lose it" invoiceable windows, such as 30-60 days post-occurrence. To avoid forfeiting revenue for services performed, do not agree to a timeline that your institution cannot meet.
- 4) DO NOT perform extended work without a contract.**  
Regulatory and operations teams will try to file documents before an agreement is in place. Perform as much as possible parallel to negotiations, however NEVER submit to external parties without an executed legal agreement.
- 5) Know how to contact the sponsor directly.**  
Its important during trial escalations to communicate directly with sponsors. If possible, obtain and maintain relevant contact information of both sponsor and CRO representatives.
- 6) Monitor responsibly.**  
Ensure all monitoring visits are subject to "mutually-agreeable business hours" and understand expectations for monitoring frequency and remote monitoring possibilities. Do NOT authorize full and unrestricted access to site electronic systems.

### Budgets

- 1) Time matters. Budget for it.**  
Budget amendments are rare. Therefore, what you negotiate today will likely be the resources available to perform the trial. Assess trial duration as a cost factor to ensure negotiated rates last anticipated inflation over time.
- 2) Be direct about indirect costs.**  
Maintain an updated overhead justification letter template. Customize indirect costs or overhead rates for every trial by duration, requirements, sponsor reputation, and contractual provisions.
- 3) Limit screen fail ratios.**  
Every unpaid screen failure you allow only adds risk to your trial's performance and quality. In fact, every service performed should be fully funded. Do not approve high screen fail ratios that that allow for excessive unpaid work.
- 4) Create a master invoice list.**  
Know your site and its customized invoiceable needs. Maintain a master list of all require invoiceable items required by your site's operations. Update this list routinely as you identify unfunded trial performance activities.
- 5) Document. Itemize. JUSTIFY.**  
Actively manage detailed justification documents for budget requests, with data, evidence, and case studies. Understand before signing an agreement when justification is required for invoiceable items.
- 6) Set an expiration date.**  
When possible, establish a "good until" not-to-exceed timeline for agreed-upon rates to ensure continued fundability.

