



# Site Invoiceables Toolkit Preview

A Resource for Research Sites to Understand Common Invoiceable Items & Services



Full Guide Available to SCRS Members

# Section 1: Introduction

## About This Resource

SCRS developed the Site Invoiceables Toolkit to assist sites in their understanding of key components to protocol budgets. Understanding these components and ensuring sites consider them for each trial budget is essential to the financial foundation of the site to ensure sustainability throughout the lifecycle of each protocol they undertake.

**Section 2** provides a quick reference table of common Invoiceable Items & Services and the usual billable unit and/or frequency.

**Section 3** provides detailed information on each of these Invoiceable Items & Services beginning with a justification for each expense as an activity directly related to the conduct of the trial. Following each description are helpful hints for calculating individual site costs associated with that Invoiceable Item and/or Service. It also discusses alternatives to charging individually for the Invoiceable Item or Service and other important notes are included for consideration.

**Section 4** provides a conclusive summary, with a cut/paste-friendly version of the same information to ease the inclusion of the Invoiceable Items & Services into study budgets. It also provides a placeholder for the site to input their charges.

### This resource has a two-fold purpose:

- **Short term:** Enhance a site's ability to identify and demonstrate protocol costs in a manner that justifies budget requests, and improve protocol success through transparent dialogue with sponsors and CROs regarding the true cost of conducting their protocols.
- **Long term:** Provide a foundation for the normalization of these "hidden costs" such that they become standard line-items in initial budget templates.

## Using This Resource

This resource is not all-inclusive but highlights most common Invoiceable Items & Services. It is important to note that costs will vary by site, by protocol, by other variables and can change over time. Nevertheless, adequate site budgeting is dependent upon a thorough analysis of operational and financial impact and securing an adequate budget with the initial Clinical Trial Agreement (CTA).

Securing additional funding following CTA execution can be difficult and creates additional work for the site and the sponsor/CRO. Thus, a best practice is to secure a budget that can sustain the lifecycle of the protocol at the time of initial CTA execution.

Not every line-item within this document will be relevant to every protocol nor to every site. This document means to serve as a guide. Sites must consider each trial individually and determine which line-items are applicable to the protocol. Blindly adding line-items to budgets that are not relevant to the protocol nor to the site will only serve to discredit the site.

As many previous budgets do not account for these Invoiceable Items & Services, it may take effort from both the site and the sponsor/CRO to gain a clear understanding of each Invoiceable Items & Services and determine how and where to capture them within each budget.

## Section 2: Quick Reference Tables

<b>Invoiceable Items &amp; Services Related to Protocol Start-Up</b>	<b>Typical Billable Unit</b>
<b>Non-Refundable Start-Up Fee</b>	One Time
<b>IRB/REB/EC Initial Submission Preparation Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Insurance (i.e. Medicare/Medicaid) Coverage Analysis Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Third-Party Vendor/Software Integration Fee</b>	Per Vendor (Or Bundled in Start-Up Fee)
<b>Subject Document Translation Fee</b>	Per Page or Per Document (Or Bundled in Start-Up Fee)
<b>Mock Subject Quality Assurance Run-Through Fee</b>	Per Mock Run (Or Bundled in Start-Up Fee)
<b>Protocol-Required Test Scan Fee</b>	Per Test Scan (Or Bundled in Start-Up Fee)
<b>Source Document Development Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Pharmacy Set-Up Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Lab Set-Up Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Sponsor Required Training Fee</b>	Per Hour or Lump Sum (Or Bundled in Start-Up Fee)
<b>Non-IRB/REB/EC Committee Interface (For Protocol Start-Up Issues) Fee</b>	One Time (Or Bundled in Start-Up Fee)
<b>Transcribe Provided Information To Sponsor/CRO Custom Form Fee</b>	Per Form or Per Page (Or Bundled in Start-Up Fee)

<b>Invoiceable Items &amp; Services Related to Inter-Protocol Events</b>	<b>Typical Billable Unit</b>
<i>Recruitment/Retention/Safety Related</i>	
<b>Recruitment Activity (Site Staff Time) Fee</b>	Per Hour
<b>Recruitment Activity (Third-Party Vendor) Fee</b>	Per Invoice
<b>Translation/Interpreter Services Fee</b>	Per Unit of Service
<b>Third-Party Transportation Fee</b>	Per Invoice

<b>Diagnosis &amp; Treatment for Protocol-Related Injury Fee</b>	Per Service
<b>Unscheduled Subject Visit Fee</b>	Per Visit
<i>Monitoring / Audit Related</i>	
<b>Scheduled On-Site Monitoring Visit Fee</b>	Per Time Unit (e.g., Per Half-Day)
<b>Scheduled Remote Monitoring Visit Fee</b>	Per Time Unit (e.g., Per Half-Day)
<b>Regulatory or Sponsor/CRO Audit Visit Fee</b>	Per Time Unit (e.g., Per Half-Day)
<b>Unscheduled Monitoring Inquiry Response Fee</b>	Per Time Unit (e.g., Per Hour)
<b>Change of Monitor Fee</b>	Per Change
<i>Protocol Change Related</i>	
<b>Protocol Amendment Review &amp; Set-Up Fee</b>	Per Amendment
<b>Subject Reconsenting Due to ICF Change Fee</b>	Per Subject
<b>Contract / Budget Change Fee</b>	Per Change
<i>Training and Quality Assurance Related</i>	
<b>Post-Startup Meeting/Training Fee</b>	Per Staff / Per Meeting
<b>Periodic Protocol Maintenance Fee</b>	Annually, although can be more or less frequently)
<i>Regulatory Requirement Related</i>	
<b>Safety Report Review Fee</b>	Per Report
<b>Certified Copy of Electronic Health Record Fee</b>	Per Record or Per Page
<b>Interim/Continuing IRB/REB/EC Filing Fee</b>	Per Filing
<b>Non-IRB/REB/EC Committee Interface (For Post-Protocol Start-Up Issues) Fee</b>	Per Report/Fee
<i>Non-Site Vendor Management Related</i>	
<b>Non-Site Vendor Issue Resolution Fee</b>	Per Hour
<b>Subject Helpdesk Fee for Non-Site Provided Technology</b>	Per Hour
<i>Other Protocol-Related</i>	
<b>Dry Ice (UN 1845)</b>	Per Unit Of Service

<b>Invoiceable Items &amp; Services Related to Protocol Close Out</b>	<b>Typical Billable Unit</b>
Protocol Close-Out Fee	One Time
IRB/REB/EC Close-Out Submission Preparation Fee	One Time (Or Bundled in Protocol Close-Out Fee)
Pharmacy Close-Out Fee	One Time (Or Bundled in Protocol Close-Out Fee)
Lab Close-Out Fee	One Time (Or Bundled in Protocol Close-Out Fee)
Investigational (and/or Control) Product Return/Destruction Fee	One Time (Or Bundled in Protocol Close-Out Fee)
Record Packaging Fee	One Time (Or Bundled in Protocol Close-Out Fee)
Protocol Record Storage Fee	One Time (Or Bundled in Protocol Close-Out Fee)

Records Destruction and Electronics Recycling Fee	One Time (Or Bundled in Protocol Close-Out Fee)
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Miscellaneous Invoiceable Items & Services	Frequency
<b>Unexpected Cost Allotment Fund</b>	Per Event
<b>Post-Close-Out Record Retrieval Fee</b>	Per Event
<b>Subject Stipend IRS-1099 Determination &amp; Filing (U.S. Sites) Fee</b>	Per Subject
<b>Cancelled Protocol Fee</b>	Per Cancelled Protocol
<b>Subject Transfer Fee</b>	Per Transfer
<b>Special Requested Added Staff Fee</b>	Per Hour or Per Month

## Section 3: Activities with Annotations

### Key Concepts

**Billable Hourly Rate:** This is the fully loaded hourly rate of an employee that is billed to a customer, not solely the hourly/salary rate of the employee. This is generally equivalent to Salary + Benefits + Overhead + Reasonable Margin. Often this is equal to twice the hourly/salary rate but may vary by site.

**Inflation Adjustments:** While everyone generally understands that \$100 in the future is not worth as much as \$100 is worth today, many fail to quantify that amount and negotiate this into multi-year budgets. This decrease in value in reimbursement of a site's costs is not difficult or time consuming to calculate. There are websites that can do this but recommendations are that budget professionals learn the Present Value (PV) and Future Value (FV) functions in finance calculators or software like Excel for better analysis and budget planning.

Note that cost-of-living rates vary over time (the U.S. average 2010-2019 was 1.7%, however 2022 inflation has been over 8%) and we do not know what they will be in the future, so predictive estimates must be made. In the examples below, it is important to note that these are not budget increases but the same budget numbers across three years with a cost-of-living adjustment based on the current expected inflation rate.

- Example 1: Have defined step increases in the budget based on an agreed inflation estimate: If the parties agree on a 5% annual rate increase, the budget would list Y1 at \$1,000, Y2 at \$1,050 and Y3 at \$1,102.50 to make the payments a constant value in present day money.
- Example 2: Have defined step increases in the budget based on a publicly available statistic: Instead of agreeing on a rate, the parties would agree on a relevant published statistic. The

budget would list Y1 at \$1,000 and then indicate that each year there will be an increase based off of a mutually agreed upon independent statistic (e.g. the Consolidated U.S. Consumer Price Index or the published healthcare components of that index which may more accurately reflect a site's expense).

- Example 3: Maintain a constant rate, accounting for inflation. If the expected inflation would be 5% then the parties could agree to set Y1, Y2 and Y3 at ~\$1050.83 to average out the inflation over the three years (i.e.  $(\$1,000 + \$1,050 + \$1,102.5)/3$ ).

**Mixing Costs Among Line-Items:** When the parties are unable to negotiate the necessary amount for a certain line-item, one mitigation strategy is to negotiate higher reimbursement in other line-items in an effort to break even. While the net effect may be to successfully cover the site's overall trial expense, the artificially altering of the documented fair market value (FMV) for those line-items impacts future negotiations. This practice can lead to a negative impact, not only for the site, but also for other sites across the globe as well when they attempt to negotiate based upon actual expense associated with the respective line-item.

While a short-term solution may be obtainable via this method, this practice is discouraged as it invalidates the integrity of the FMV defense. Rather, for the long-term benefit for the industry to achieve better consensus around each line-item and ensure fair market values based on valid and related costs, we encourage open dialogue to educate all parties regarding each expense and maintain the integrity of the line-items and their FMV.

**Third-Party Invoice Management Costs:** The costs of many line-items may involve third-party fees to which the site is paying the third-party and promised reimbursement from the sponsor or CRO upon invoice. Two key factors come into play when this occurs:

- (1) While the site may predict the initial cost of the invoice amount for budgeting purposes, the site is cautioned on the risks of hardwiring in a number into the CTA as opposed to leaving it open ended (e.g. "\$2,500 USD" instead of "Paid Upon Invoice") as with the former, the site bears the cost of any increases in the third-party pricing over time.
- (2) While the site's full Overhead percentage amount is usually not applied to third-party invoiced amounts, there is administrative cost borne by the site (that would not be borne by the site if the sponsor or CRO contracted with the third-party directly instead of the asking the site to do it). This often includes but is not limited to:
  - (i) the generation/review/execution of the contract with the third-party (which can be burdensome especially if between healthcare providers where Stark and Anti-Kickback laws apply);

- (ii) the set up the third-party in the site's accounting systems;
- (iii) the processing of the third-party's invoice(s), and (iv) the invoicing of and collecting or reimbursement from the sponsor/CRO.

There is also the time value of the money lost on the financial float, meaning the time between when the site pays the invoice and the time the site receives reimbursement for it. This cost should be either budgeted for in an "Administrative Processing Fee for Third-Party Invoices" or elsewhere.

### *Sample Fees Included from Site Invoiceables Guide:*

Non-Refundable Start-Up Fee	
Description	<ul style="list-style-type: none"> <li>• This fee covers protocol costs related to the site's completion of protocol start-up activities that are required prior to opening of enrollment at the site. This fee should include all costs not otherwise provided for by the sponsor/CRO or compensated as a pass-through reimbursement (e.g. paid in full upon third-party invoice such as IRB/REB/EC fees).</li> </ul>
Calculating the Costs	<ul style="list-style-type: none"> <li>• In general, this includes, at a minimum, the Billable Hourly Rate of the staff required to complete the items and/or services multiplied by the respective hours necessary to complete the task. While it is possible to charge Billable Hourly Rates for the various staff in an open-ended manner, most agreements settle on a single amount based on a good faith estimate of the total cost specific to the protocol.</li> <li>• This fee often includes numerous costs such as Confidentiality Agreement (CDA) completion, feasibility questionnaire (FQ) completion, investigator/site meeting attendance, IRB/REB/EC preparation and submission, budget and contract review and completion, vendor set-up, staff training, supply procurement, regulatory setup and many more. Depending on the site preference and/or sponsor requirements, the site may invoice these activities as separate line-items or bundle them into this single Non-Refundable Start-Up Fee.</li> <li>• Also important for consideration when calculating start-up expense are the costs associated with the use of any and all third-party vendors the site must purchase items and/or services from (e.g., commercial IRB fees, insurance (i.e. Medicare/Medicaid) coverage analysis by an independent party, use of a third-party hospital that invoices a protocol set-up fee). If the sponsor is not agreeing in the contract to pay these third-party fees directly to the third-party provider, the site should include Third-Party Invoice Management Costs</li> </ul>

	into the calculation of the total costs within this Non-Refundable Start-Up Fee or as a separate invoiceable line-item (e.g. "Administrative Processing Fee for Third-Party Invoices").
Alternatives to Charging This as A Line-Item	<ul style="list-style-type: none"> <li>• Although this is often a single line-item, it is acceptable to charge individually for each item and/or service associated with start-up activities.</li> <li>• For start-up services directly provided by the sponsor/CRO, there should be a resultant decrease/removal of this expense from this Non- Refundable Start-Up Fee (e.g. the sponsor is providing the insurance (i.e. Medicare/Medicaid) coverage analysis or paying the IRB/REB/EC fees directly). Direct sponsor/CRO payment for a third-party service should be specified in the CTA as a sponsor/CRO obligation to avoid future dispute as to whose responsibility it is to pay the vendor.</li> <li>• There are few alternatives a site has to this charge other than to be underfunded for this item and/or service. Attempts to reallocate these costs into other areas of the budget are not optimal.</li> </ul>
Important Notes	<ul style="list-style-type: none"> <li>• It is important to ensure the Non-Refundable Start-Up Fee is in the CTA as unambiguously non-refundable reimbursement for the start- up costs and not in any way dependent upon future performance of the site (i.e., it is not an advance payment or other cash advance that the sponsor/CRO deducts from future payments).</li> <li>• It is intentional and important that the term "Non-Refundable" is included in the line-item title in the event the sponsor or CRO cancels or indefinitely delays the protocol prior to site initiation.</li> <li>• A site may develop tiered charging options based on protocol complexity such as a lower Non-Refundable Start-Up Fee (Post- Marketing Observational protocol) and a higher Non-Refundable Start-Up Fee (Phase 3 protocol). sites can delineate as many of these tiers as they like such as Non-Refundable Start-Up Fee (IDE protocol without Hospitalization) versus the higher Non-Refundable Start-Up Fee (IDE protocol with Hospitalization).</li> </ul>

### Unscheduled Monitoring Call/Inquiry Response Fee

Description	<ul style="list-style-type: none"> <li>• This fee covers the protocol costs related to the time it takes the various site staff to be available to the protocol monitor (whether remotely or on-site) at unscheduled times.</li> </ul>
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Calculating the Costs	<ul style="list-style-type: none"> <li>In general, this includes, at a minimum, the Billable Hourly Rate of the staff required to complete the items and/or services multiplied by the respective hours necessary to complete the task. While it is possible to charge Billable Hourly Rates for the various staff in an open-ended manner for the amount of time the monitoring inquiry takes to resolve, most agreements settle on a “per inquiry” estimate. The estimate for this Item can be a challenging number to derive as the impact of the unscheduled inquiry can vary widely thus the expense can have a wide margin. The site may need to revisit line-items such as this more often than other line-items. This would likely include at a minimum (i) investigator time for dialogue with the monitor and (ii) regulatory professional and research coordinator time for responding to the inquiry.</li> </ul>
Alternatives to Charging This as A Line-Item	<ul style="list-style-type: none"> <li>One alternative to this line-item is to contractually or otherwise document an agreement that no (or limited, such as imminent safety related issues) monitoring communications will be responded to outside of scheduled monitoring visits. This protects the site from these hidden costs and business/workflow interruptions as well as the sponsor/CRO from receiving invoices due to sporadic monitoring inquiries that could be handled during scheduled monitoring visits.</li> </ul>
Important Notes	<ul style="list-style-type: none"> <li>Note that some monitoring can occur without much need for staff time. For example, if the monitor can access necessary documents in their native environment via technology in a manner that does not require time with site staff, this would arguably not trigger a charge unless the sponsors/CROs are requiring resending or re-uploading into other viewing portals for the monitoring inquiry. The intent of this line-item is to capture the expense for staff time when interrupted from other activities to support the monitoring function. This is a related but not a duplicative charge to the Expedited Issue/Query Resolution Fee; however, requests may invoke both charges.</li> </ul>

<b>Lab Close-Out Fee</b>	
Description	<ul style="list-style-type: none"> <li>This fee covers the protocol costs related to the site’s lab management costs affiliated with closing out their infrastructure surrounding protocol-specific lab supplies and infrastructure. It allows for the proper disposal of remaining protocol-specific laboratory supplies and the closing of any protocol-specific lab related operations.</li> </ul>

Calculating the Costs	<ul style="list-style-type: none"> <li>• In general, this includes, at a minimum, the Billable Hourly Rate of the staff required to complete the items and/or services multiplied by the respective hours necessary to complete the task. While it is possible to charge Billable Hourly Rates for the various staff in an open-ended manner, most agreements settle on a single amount based on a good faith estimate of the total cost.</li> <li>• If non-local labs are used (e.g. a central lab or a community lab) then this may invoke invoiceables that need to be paid along with Third-Party Invoice Management Costs.</li> <li>• Also important for consideration when calculating this cost are the costs associated with the use of any and all third-party vendors from whom the site must purchase items and/or services. If the sponsor is not agreeing in the contract to pay these third-party fees directly to the third-party provider, the site should include Third-Party Invoice Management Costs into the calculation of the total costs of this line- item or as a separate invoiceable line-item (e.g. “Administrative Processing Fee for Third-Party Invoices”)</li> </ul>
Alternatives to Charging This as A Line-Item	<ul style="list-style-type: none"> <li>• In lieu of charging this as a separate line-item, this can be included in a bundled “Protocol Close-Out Fee”.</li> <li>• There are little alternatives a site has to this charge other than be underfunded in this area. Attempts to reallocate these costs into other areas of the budget are difficult and not optimal.</li> <li>• This may possibly be bundled as a unified “Lab Set-Up and Close-Out Fee” as both activities will need to occur.</li> </ul>

## Appendix 1: A Site’s Cut and Paste Table (Preview)

This appendix presents no new information but provides a cut/paste-friendly version of the same information to ease the inclusion of the Invoiceable Items & Services into study budgets. It also provides a placeholder for the site to input their charges.

### Invoiceable Items & Services Related to Protocol Start-Up

**Non-Refundable Start-Up Fee:** \_\_\_\_\_

This fee covers protocol costs related to the site’s completion of protocol start-up activities that are required prior to opening of enrollment at the site. This fee should include all costs not otherwise provided for by the sponsor/CRO or compensated as a pass-through reimbursement (e.g. paid in full upon third-party invoice such as IRB/REB/EC fees).

## Invoiceable Items & Services Related to Inter-Protocol Events

### **Third-Party Transportation Fee:** \_\_\_\_\_

This fee covers the protocol cost related to cover the third-party transportation needs of the protocol subjects; specifically, transportation companies (taxi, ride apps, etc.) that the sponsor/CRO asks the site to advance the payment to (and be reimbursed upon invoice) in lieu of the sponsor/CRO compensating the vendors directly. This is not to be confused with a patient stipend which is invoiced by the site separately.

## Invoiceable Items & Services Related to Protocol Close-Out

### **IRB/REB/EC Close-Out Submission Preparation Fee:** \_\_\_\_\_

This fee covers the protocol cost related to the site's preparation of the Final Report (a.k.a. Close-Out Report) and other requirements the site must deliver to the IRB/REB/EC. This is a regulatory requirement of conducting the protocol. This is also not including the cost of the IRB/REB/EC fees that the site invoices separately.

## Other Invoiceable Items & Services

### **Post-Close-Out Record Retrieval Fee:** \_\_\_\_\_

This fee covers the protocol costs related to the site's staff time and any third-party fees necessary for retrieving documents requested by the sponsor/CRO after the close-out visit has occurred.

## Want the Full Guide?

The Site Invoiceables Toolkit includes 40+ fully annotated invoiceable items, with:

- Detailed cost-calculation guidance for every line-item
- Alternatives to charging and when to use them
- Important negotiation notes grounded in real site experience
- A ready-to-use cut-and-paste budget table you can bring directly to CTA negotiations

SCRS members get full access to this resource and the complete SCRS resource library developed for sites. Learn more and join the community at [myscrs.org](https://myscrs.org).