

Budgeting Template



The following information is provided to support the process and structure for EFS budget development.

1. Study Information

- **Study Name:**
[Insert Study Name]
- **Sponsor:**
[Insert Sponsor Name]
- **Clinical Protocol:**
[Insert Number and Version]
- **Site Name:**
[Insert Site Name]
- **Principal Investigator:**
[Insert PI Name]
- **Study Start Date:**
[Insert Date]
- **Estimated Study Completion Date:**
[Insert Date]

Note: if budget is attached to the clinical trial agreement (CTA), this information may be omitted.

2. Budget Overview

2.1. Protocol-required Tests Fees

Sponsor first should list all required tests and follow-up schedule from clinical protocol utilizing [Table 1](#) format. It is recommended that such required tests/schedule should also be aligned with case report forms.

Next, Sponsor to work with the site to:

- 1) Indicate what tests/procedures are Standard of Care (SOC) vs. have to be completed for Research (R) purposes at specific time points (e.g., follow-up visits).

For all R tests/procedures, add fair market value amounts (FMV). FMV will vary across sites. It is typical to observe regional and site-specific variability.

Note: Any SOC test that is repeated per study-specific requirements must be converted to R payment. For example: if echocardiographic imaging is SOC at baseline but it has to be completed per study-specific acquisition protocol that differs from SOC or has to be repeated due to tight compliance window required per clinical protocol that does not align with SOC.

Table 1. Protocol-required Tests Fees – extend table as needed to accommodate all study visits.
 Include study related costs at each required timepoint. Standard of Care (SOC) will have some variation across sites.

Budget Item	Baseline	Procedure	Discharge	Follow Up 1	Follow Up 2	Follow Up 3
Informed Consent	R - \$\$					
Inclusion/Exclusion	R - \$\$					
Medical History	R - \$\$			R - \$	R - \$	R - \$
Physical Exam	R - \$\$	R - \$\$	R - \$\$	R - \$\$	R - \$\$	R - \$\$
Medication Log	R - \$		R - \$	R - \$	R - \$	R - \$
Questionnaire 1	R - \$		R - \$	R - \$	R - \$	R - \$
Questionnaire 2	R - \$		R - \$	R - \$	R - \$	R - \$
6 Minute Walk Test	R - \$\$			R - \$\$		R - \$\$
Imaging E.g. echo, CT... (one per line - add lines as needed)	R - \$\$\$		R - \$\$\$	SOC	R - \$\$\$	R - \$\$\$
Add lines as needed						
12-Lead ECG	SOC		R - \$	SOC	R - \$	R - \$
Pregnancy Test	\$					
Blood work e.g. CBC, PT/PTT (one per line - add lines as needed)	SOC		R - \$	R - \$	R - \$	R - \$
Pre CMS approval procedure/ hospitalization costs		R - \$\$\$\$				
Research Coordinator (RC) Fees*						
Principal Investigator (PI) Fees*						

* Includes time required to complete listed above activities per each visit and data entry/signing of corresponding case report forms (CRFs). Some sites prefer to combine RC and PI fees into one line item.

Post CMS approval

- **Category A** – Medicare can be billed for procedure and hospitalization. Investigational device must be provided at no cost.
- **Category B** – Medicare can be billed for procedure, hospitalization and the investigational device.

Private payors may not align reimbursement with CMS determinations. Pre-authorization for services may be required.

2.2. Potential Study Candidate Identification/Screening Fees

To ensure proactive and efficient study recruitment, consider adding potential study candidate identification/screening fees as outlined in [Table 2](#).

Table 2. Potential Study Candidate Identification/Screening Fees

Budget Item	Description
Pre-consent Pre screening*	<p>Sponsor may choose to ask for designated number of charts to be reviewed by RC per week in effort to identify study candidates. Consider estimating the number of hours spent per week or month on such pre-screening activity (e.g., 20 hours/month of RC time).</p> <ul style="list-style-type: none">• A cap on hours is suggested to manage expectations and enhance productivity.• A log of de-identified screen failure potential participants with reasons for exclusion must be submitted to the Sponsor (suggest monthly) for reimbursement.• Sponsor may want to specify pre-screen to enroll ratio (e.g. per each 20 pre-screen failed patients at least 1 acceptable candidate must be identified) to ensure effectiveness of activity.• Modifications to the cap of hours or ratio can done with Sponsor's written approval.• Quarterly or biannual invoicing is recommended.
Post consent screen failures	Reimburse sites for research (R) activities completed per Table 1 .
Preparation of Screening Committee presentation	Intended to cover time spent by RC and/or PI to prepare PowerPoint slides and/or summaries required for potential study candidate presentation to Screening Committee. Payment per participant/ per presentation is recommended.

The alternative approach for pre-screening is to provide a one- time fee reimbursed at study commencement. This approach decreases the administrative burden but may not align compensation with the actual work.

2.3. One-Time and Annual Fees

All institutional review board (IRB) fees should be charged as pass through. The cost at the beginning of the study can be obtained during the site qualification visit (SQV); however, **they are subject to change throughout the study and are non-negotiable**. These fees include:

- IRB initial review fees
- IRB annual review fees
- IRB amendment fee
- Additional IRB fees (e.g., serious adverse event (SAE) review, unanticipated adverse device effect (UADE) review, etc.)

It is recommended that budgets either exclude specific IRB fees—given their variability—or include estimated amounts with a note acknowledging that these fees are subject to change and will be treated as pass-through costs.

Additional one-time and annual fees are listed in [Table 3](#). All fees related to first year of study at a given site (defined as one year post CTA/budget execution) should be fixed. However, since some studies may require long-term follow-up, the budget must accommodate changes in annual fees that are expected at a later stage of the study.

Table 3. One-time and Annual Fees

Budget Item	Description	Amount (\$)
Study start-up fee	Covers time required to activate the site inclusive of training	
Coverage Analysis	These are <i>optional</i> but common fees required by most sites in United States (US) for assessment of fair market value of each study-specific tests/procedures.	
IRB preparation fees		
Initial review ¹	Preparation of initial study submission to local or reliance IRB. This fee also includes time required to address any IRB follow-up questions in order to receive initial study approval.	
Annual review	Preparation of study annual review submission to local or reliance IRB.	
Other	Site specific – determined at SQV	
Research pharmacy fees (only applicable to combination products or study drugs)		
Start-up	Covers site activation and meeting with Sponsor representatives to finalize logistics for drug/combo device receipt if used per protocol.	
Annual	Covers annual cost associated with maintaining the study at the site's pharmacy.	
Other	These fees are varies per site and may include dispensing fees, documentation fees, etc.	
Storage/Archiving fee ²	Storage of study materials/data.	
Study close-out fee	Final data submission, any gap analysis required to ensure proper completion of the study at a given site.	

¹If IRB preparation for initial study review is included in study start-up fees (that is common), this line item is not applicable.

²Storage fee for US sites typically is limited to two years post study completion as required by CFR 812. However, if study protocols may require longer storage/archiving of the study documentation, then budget must be adjusted accordingly.

2.4. Per Occurrence Fees

Once a study is initiated, sites may incur additional, often unpredictable work to maintain compliance (e.g., adverse event reporting, image transfer, protocol amendments, reconsenting). Because the frequency of these activities—particularly in EFS—cannot be reliably predicted in advance, it is recommended they be budgeted and reimbursed on a “per occurrence” basis. This approach provides flexibility for both sites and Sponsors. Table 4 lists recommended per-occurrence fees for EFS.

Because per-occurrence fees add budget uncertainty, they should be limited where possible, especially for EFS sponsored by small startups with constrained resources.

Table 4. Per Occurrence Fees

Budget Item	Description	Unit Cost (\$)
Protocol amendment ¹	Covers administrative activities required to implement a protocol amendment at the site, including any necessary revisions to the informed consent form (ICF).	
Protocol & device training after site activation ²	On site - sponsor mandated: <ul style="list-style-type: none"> Investigator - protocol and/or device re-freshers - up to a maximum of 4 hours for an agreed upon total to train the team of investigators. Invoice shall contain date, first & last name of attendee and topic of training. Study staff - consider hourly or a one time fee to cover all team members Off site (may consider reimbursing): <ul style="list-style-type: none"> Investigator - daily fee Coordinator - daily fee 	
CTA and/or Budget amendment	Includes administrative support required to implement changes to CTA and/or budget per Sponsor request. <u>Note:</u> changes required per site (e.g., PI change) shall not be charged to the Sponsor.	
Reconsenting	In the event of ICF changes, re-consenting may be required. This is charge per patient/consent.	
SAE/UADE submission fee	Includes preparation of the SAE/UADE related documentation required for Sponsor and/or IRB notification.	
Death certificate	Upon request	
Image submission (optional)	If required per clinical protocol or requested by Sponsor, intended to cover RC time to de-identify and submit images to Sponsor, Core Laboratory, Institutional Fees. This is charged per image.	
Monitoring Visit		
In-person visits	Covers RC time supporting in-person monitoring visits. Hourly billing based on actual time spent is recommended; however, if time tracking across multiple staff is impractical, a flat per-visit fee may be negotiated.	
Remote visits	Covers RC support for remote monitoring visits. Due to variability in time required, hourly billing is recommended.	
Audit/Inspection	Covers site staff time (e.g., RC, PI) for regulatory inspections. Hourly billing is recommended; a per-day rate may be used if preferred. <u>Note:</u> for cause audits are not chargeable to the Sponsor.	
Source documentation collection & submission (optional)	If required by Sponsor, intended to cover RC time to review, compile and de-identify source documentation. This is charge per requested set of source documentation per patient. <u>Note:</u> many Sponsors underestimate the amount of time required for such task.	
Return of explanted study device (optional)	Covers shipment of explanted study devices using required biohazard procedures; charged per shipment.	

¹Protocol amendment may necessitate an update to the CTA and/or budget.

²Training due to site’s staff turnover or non-compliance cannot be charged to the sponsor.

2.5. Participant Reimbursement

Especially for studies with elderly patients, it is critical to offer participants reimbursement for accommodations required to ensure compliance with protocol's follow-up schedule. These costs may include but may not be limited to:

- Transportation reimbursement: travel costs for participants to get to and from site that can be either taxi, car service or reimbursement of car mileage.
- Hotel accommodation (for long-distance travel or multi-day visits).

Since there is a great variability in patient situations and geographical locations relative to site, it is strongly recommended to offer pass-through receipt-based reimbursement. Sponsor pre-approval above a set rate may be appropriate (especially in high-cost regions). Alternatively, patient stipends can be offered instead; however, careful analysis must be completed to ensure that stipend is intended to reimburse actual expenses and not induce patients to participate in the study via compensation. Additionally, **participant reimbursement must be clearly outlined in the ICF.**

3. Considerations for Budget Negotiation

1. Ensure Predictability

- Clarify protocol guidance to reduce unnecessary charges.
- Be clear relaying payment terms i.e. one-time payment versus annual versus per occurrence
- Aim to limit “per occurrence” fees where possible.

2. Minimize Administrative Delays

- Schedule early discussions with key sites before finalizing the clinical protocol.
- Use phone discussions rather than email for faster resolution.

3. Plan for Amendments & CMS Approval

- If CMS approval was not yet obtained for EFS, include pre-CMS and post-CMS budget versions.
Note: if CMS approval is not received, the study index procedures (e.g., implant) must be covered by Sponsor and added as a separate line item to [Table 1](#).
 - Clearly define amendment processes to allow flexibility; consider allowing additional study-related tests fees to be approved by Sponsor via email (as addition to agreed budget).

4. Payment Schedule & Terms

It is critical for the Sponsor to determine institutional overhead during SQV:

- Discuss what items overhead should be applied for.
- Add overhead fees to budget (e.g., [Table 1](#), etc.)

The start-up fees should be paid by Sponsor as one-time, non-refundable administrative fee payable within sixty (60) days of CTA/budget execution. Protocol required fees should be reimbursed per completed CRF. For all other services unless clearly delineated, the site should be held responsible for invoicing Sponsor on a quarterly basis. The payment terms should specify where invoices shall be sent and include the following information:

- Bank name:
- Account name:
- Routing #
- Account #
- Tax ID: