NON-INDUSTRY "FEE SCHEDULE" / SITE BUDGET GUIDANCE DOCUMENT

Introduction and Purpose

The scope and purpose of this Guidance Document is to provide a starting point for analyzing site costs associated with participating in non-industry funded clinical trials. The following considerations limit to the scope of the guidance provided herein:

- Department/division standard practices differ, making it important to understand internal policies.
- Each protocol has differing needs. As such, not all examples listed in this document are applicable to every trial.
- The list of examples does not include every item that could be a cost of participation in a clinical trial.

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

CMS: Centers for Medicare & Medicaid Services
CTSI: Clinical and Translational Science Institute
FTE: Full-time Equivalent
IDS: Investigational Drug Services
IND: Investigational New Drug
IRB: Institutional Review Board
PI: Principal Investigator
SOC: Standard of Care

Procedure

1. Budget Edits

Non-industry funded protocol budgets are typically considered non-negotiable, or 'take it or leave it.' However, some funding agencies do have flexibility and take into consideration a site's requested budget edits.

1.1. It is important to ask the funding agency whether the site is able to request budget edits prior to contract/grant execution.

2. Cost/Budget Analysis

If budget edits are not allowed (i.e., budget is non-negotiable), the site will still need to create a cost/budget analysis in order to:

2.1. Allow the department/PI to understand how much it will cost for the site to complete protocol-required tasks.

2.2. Allow financial staff/PI to understand which expenses will post to the project in

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management reports and how expenses will post.

2.3. Follow clinical research billing compliance standards.

3. Reimbursement Approach

Determine whether funding agency is reimbursing the site using an *FTE approach* or a *capitated/milestone approach*.

3.1. *FTE Approach* - Example: Funding agency offers 0.1 FTE to account for PI effort & 0.5FTE to account for coordinator effort.

3.1.1. An advantage of the FTE Approach is that the site receives funds regardless of site enrollment.

3.1.2. However, may not be ideal if the protocol-mandated tasks require more effort than is offered by the funding agency.

3.2. *Capitated/Milestone Approach* - Example: Funding agency offers set amount per enrollment and/or completed visit.

3.2.1. Site typically only receives payment if enrollment occurs.

3.2.2. Payments are typically inclusive of the PI effort, coordinator effort, procedures, etc. that are required to complete milestone.

3.2.3. May not be ideal if funding agency is not offering funding outside of visit milestones. Effort for startup, IRB submissions, etc. are sometimes not accounted for.

3.3. Note that many funding agencies are moving away from the FTE approach and offering the capitated/milestone approach for non-industry clinical trials.

4. 'Routine/SOC' Procedures

If the sponsor/funding agency states that "all procedure are performed as routine care/standard of care," the site still needs to create a cost budget/analysis.

4.1. When protocol required tasks are being routed to an insurance/third party payer, the site will also need to perform a thorough Centers for Medicare & Medicaid Services (CMS) Coverage Analysis to ensure the site engages in proper clinical research billing compliance practices.

5. Budget Categories

Determine applicable budget categories, as follows:

5.1. One-time costs: For example, how much will startup, closeout, etc. cost site?

5.2. Milestone costs: For example, how much will each visit/enrollment cost site?

5.2.1. Cost estimation should include study procedures per protocol, clinical research unit, subject reimbursement, study team effort, etc.

5.3. Contingent costs (i.e., per occurrence/unit): For example, how much will IRB

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submission prep, maintenance, pre-screening costs, etc. cost site?

6. Personnel Costs vs. "Set Charges"

Non-industry cost budgeting is often derived from the amount of time and effort needed from the study team in order for the site to participate in the clinical trial. Some fees that are generally charged to an industry sponsor might not be charged as a fee to a non-industry sponsor. Instead, the fee would be recouped through indirect costs. This is because non-industry sponsored research typically has a higher indirect rate when compared to industry. As such, the indirect costs generally cover those fees.

To help determine which items are personnel costs vs. "set charges", Sections 6.1 and 6.2 provide examples of the most common types of costs/charges for each. This is not an exhaustive list.

6.1. Personnel Costs; Examples:

- 6.1.1. Administrative Start-up
- 6.1.2. Training
- 6.1.3. IRB (initial, amendment, annual, closeout)
  - 6.1.3.1. Local IRB submission fees are a great example of fees that are charged to industry sponsors but are covered by a higher indirect rate for non-industry sponsored research. However, researchers should consider the effort required by regulatory personnel to prepare document for submission.
- 6.1.4. CMS Coverage Analysis
- 6.1.5. Monitoring Visit
- 6.1.6. Remote Based Monitoring
  - 6.1.6.1. Depending on the protocol, set charges may be applicable for remote monitoring. Ex. Printing, shipping, document retrieval, etc.
- 6.1.7. Pre-screening/Recruitment
- 6.1.8. Quality Assurance/Auditing (internal or external)
- 6.1.9. Participant Re-consent
- 6.1.10. Safety Event Reporting and Follow-up
- 6.1.11. Pregnancy Follow-up
- 6.1.12. IND External Safety Reports
- 6.1.13. Ancillary Services Sponsor Required Protocol Training
- 6.1.14. Site Closeout

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6.2. Set Charges; Examples:

Researchers should request a quote for service(s).

6.2.1. Research Facility Fee

6.2.1.1. Researchers should determine location of study visits. For example, CTSI will provide quote for services including an infrastructure per hour charge.

6.2.2. CTSI (nursing, infrastructure, application submission and startup)

6.2.2.1. Request quote from CTSI.

6.2.3. Foreign Language Translation

6.2.3.1. $250 (1-3 consent documents) or $0.065/word for any other document.

6.2.3.2. Request quote from Office of Research Translation and Interpretation.

6.2.4. IDS Pharmacy (setup, drug destruction, protocol amendment, maintenance, special drug handling, treatment plan development, special monitoring, additional paperwork, satellite site transfer, closeout)

6.2.4.1. Request quote from IDS Pharmacy.

6.2.5. Radiology (setup, maintenance, phantom imaging)

6.2.5.1. Request quote from Research Imagining.

Document Approval

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Revision History

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