



Georgetown-Howard Universities  
Center for Clinical and Translational Science

# Study Budgets and Contract Negotiations

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# Objectives

- Identify key components of the study budget
- Identify how standard of care and research are determined in advance to ensure appropriate billing
- Identify three major areas of a clinical trial agreement



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# Study Budget

## Commercial

- Staff Costs
- Start-up Costs
- Study-related procedures/study visit costs
- Equipment/Supplies
- Overhead

## Federal/Non-Commercial

- Staff Costs
- Study-related procedures/study visit costs
- Equipment/Supplies
- Travel
- Subs/Consultants
- Overhead



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# Staff Costs

## Commercial

- Base compensation
- Fringe benefits
- Productivity factor
- Overtime
- Investigator meetings

Note, these costs are usually rolled into a rate, but must be calculated for each billable event

## Federal/Non-Commercial

- Base compensation
- Fringe benefits
- Percent of Effort
- Number of Months
- Salary Cap (?)
- PostDoc/Student Stipend caps (?)



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# Start-up Costs

## Commercial

- Preparation of IRB submission
- IRB Fees
- Advertising
- Investigator meetings
- Preparation of regulatory binder
- Site-initiation visit (SIV)
- Pharmacy start-up

## Federal/Non-Commercial

- Any fees that are related to a staff member's time should be calculated into that particular staff members' percent of effort
- Advertising
- Travel



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# Study-Related Procedures and Study Visit Costs

## Commercial

- Routine vs. research procedures – how do you determine?
- Study assessments (histories and physicals)
- Ancillary Services/Labs
- IRB Maintenance Fees
- Patient stipends

## Federal/Non-Commercial

- Any fees that are related to a staff member's time should be calculated into that particular staff members' percent of effort
- Ancillary Services/Labs
- Patient stipends



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## Commercial

- Monitor Visits
- Screen Failures
- Record Storage
- Facility fees
- Adverse Event reporting
- CRF completion
- Query resolution
- Drug/Device Procurement
- Overhead

# Other Costs

## Federal/Non-Commercial

- Project Materials & Supplies
- Equipment
- Travel
- Subcontractors
- Consultant Services
- Publication Expenses
- Tuition
- Animal Costs
- Drug/Device Procurement
- Overhead



# Contract Negotiations

## Commercial

- Injury language
- Participant compensation
- HIPAA/confidentiality
- Indemnification
- Intellectual property
- Publication rights
- Reporting Requirements

## Federal/Non-Commercial

- Notice of Grant Award or Foundation Grant Terms
- Federal Acquisitions Regulations (FAR)
- NIH Grants Policy Statement
- Public Access Policy
- Reporting Requirements





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# Other Resources

- NIH YouTube:

<https://www.youtube.com/user/NIHgrants>

- NIH Salary Cap:

[https://grants.nih.gov/grants/policy/salcap\\_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm)

- NIH Postdoc/Student Stipends:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-003.html>



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# References

- NIH Budget Development Web Page:  
<https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#personnel>
- Developing an investigator site budget for clinical trials. J Oncology Practice. 3(2): 94-97, 2007
- Fautsch, M and Klous, D. How to develop a clinical study site budget. RCRI White Paper, 6/23/2011
- Neal, JP. Eight Steps to Create a winning Clinical Research Study Budget. Premier Clinical



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# Questions

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