Development and Management of D2d budget

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Principles

Goal: Manage total D2d budget

- In a conservative, efficient, dynamic way that meets study goals

- Proportional to sites' efforts
  - Recognizing that each site's needs are unique
  - Remain consistent and fair among all sites

Principles, cont.

- *Approach:* Hybrid model with 2 parts:
  - Core
  - Performance-based payments
- Details of model may vary from year to year
  - Study-wide
  - Within sites
- Receive the entire proposed budget <u>only</u> if all participants enrolled

Core payments

Year 1	Half of personnel (~35% of year 1 budget) “Original Core”
Years 2-3	40% of total yearly budget Flexible allocation: personnel or non-personnel “New Core”
Years 4-5	Core adjusted based on final site enrollment

- ✓ Sites invoice Tufts Medical Center quarterly for core-related expenses based on actual expenses.
  - ✓ Invoices may vary from quarter to quarter

Example: Core for site that successfully enrolls and follows

all 150 participants to completion

	Year 1	Year 2	Year 3	Year 4	Year 5	TOTAL
BUDGET PROPOSED FOR 150 ENROLLED PARTICIPANTS						
Personnel	174,400	174,400	149,920	135,070	135,070	
Non-Personnel	49,177	68,208	39,074	37,178	19,368	
Total Direct Costs Budget	**223,577**	**242,608**	**188,994**	**172,248**	**154,438**	**981,865**

REVENUE FROM TUFTS MC FOR 150 ENROLLED PARTICIPANTS

"Original Core"	87,200					
"New Core"		97,043 (40% of total)	75,597 (40% of total)	68,899 (40% of total)	60,026 (40% of total)	**388,765**

Direct costs only—each site will receive full F&A in accordance with the current federally negotiate agreement on file

Performance-based payments

- Linked to successful enrollment *and* retention
- = total 5 year budget *minus* original core (all 5 years) divided by target enrollment

✓ Payments are made by Tufts Medical Center quarterly based on randomizations and follow-up visits

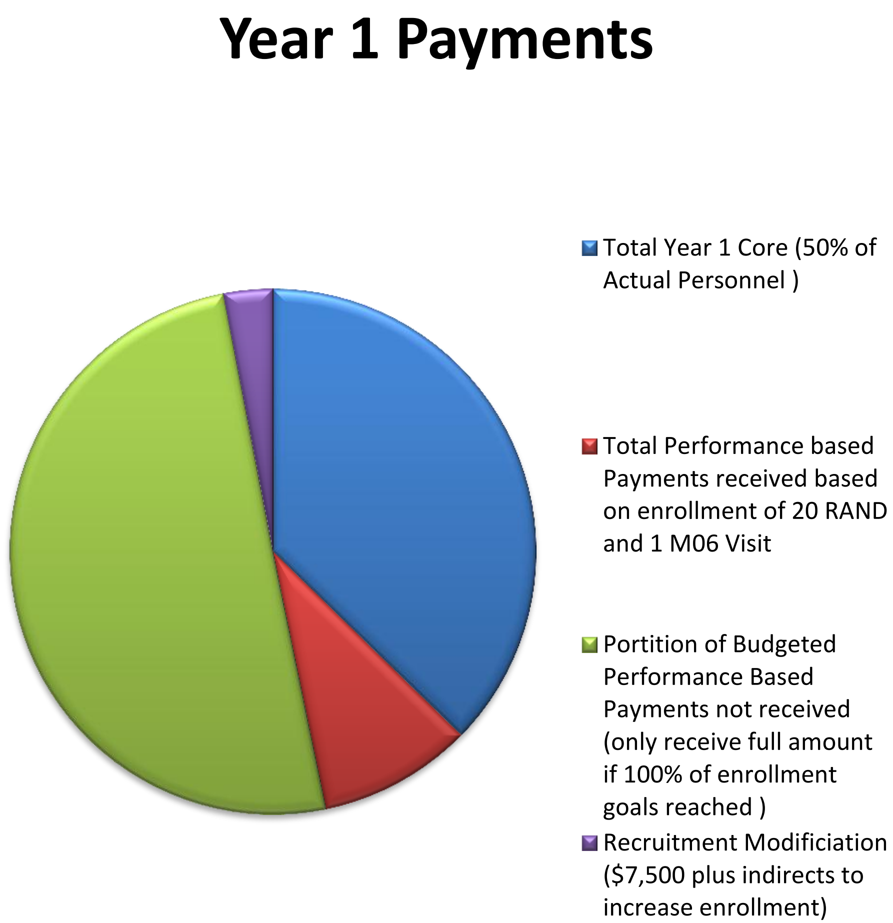
  ✓ Invoices will vary from quarter to quarter

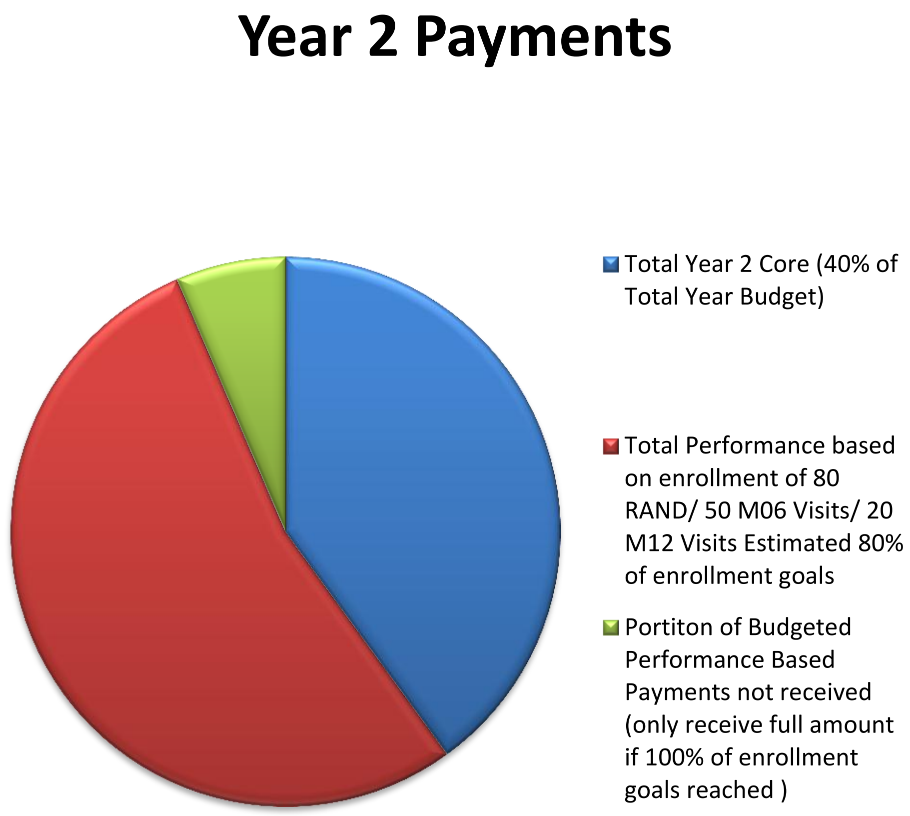
Example: Performance-based for site that successfully enrolls and follows all 150 participants to completion

	Year 1	Year 2	Year 3	Year 4	Year 5	TOTAL
BUDGET PROPOSED FOR 150 ENROLLED PARTICIPANTS						
Personnel	174,400	174,400	149,920	135,070	135,070	
Non-Personnel	49,177	68,208	39,074	37,178	19,368	
Total Direct Costs Budget	**223,577**	**242,608**	**188,994**	**172,248**	**154,438**	**981,865**
REVENUE FROM TUFTS MC FOR 150 ENROLLED PARTICIPANTS						
"Original Core"	87,200	87,200	74,960	67,535	67,535	
"New Core"		97,043 (40% of total)	75,597 (40% of total)	68,899 (40% of total)	60,026 (40% of total)	**388,765**
Target Enrollment			**150**			
Per Participant Cost = Budget-Original Core/ Target Enrollment			3,954			**593,100**
Total # actual Enrollment			**150**			
Performance-based revenue over 5 Years			**593,100**			

Variance, Actual Payments vs. Budget: 0

Example: Year 1 vs. Year 2





The payment structure is likely to vary from year to year, depending on a variety of factors and may also vary from site to site depending on performance.