

1 Funding tables, worksheets, and checklists

Table 1.1 Questions when deciding whether to respond to an RFA or RFP (QuesRFP.Tab)

When: When considering whether to respond to an RFA or RFP after issue

Who: The person responding

Purpose: To understand what is involved in doing what is proposed and in helping to decide whether one should respond

Answer questions "yes" or "no" by checking (_y) or (_n). Any "no" answer should be pause for concern. Three or more "nos" should be sufficient for you to stand down from replying.

Definitions

request for application (RFA) - A document prepared and distributed by a sponsoring agency to solicit applications pertaining to an area of work detailed in the request; especially such a document prepared and distributed by an agency of the federal government and in which said work is to be supported by grants. rt: request for proposal **Usage note:** From the NIH perspective, both RFAs and RFPs are used as vehicles for identifying and selecting investigators and centers in trials. As a general rule, investigators have more control over the activity proposed under the NIH RFA mode of initiation and grant support than under the NIH RFP mode of initiation and contract support. The emphasis in an RFA is on a scientific question or issue. The focus in an RFP is on a defined task and on deliverables related to that task.

request for proposal (RFP) - A document prepared and distributed by a sponsoring agency to solicit proposals for execution of a specified task, especially such a document prepared and distributed by an agency of the federal government and in which said work is to be supported by contracts. rt: request for application **Usage note:** Not to be confused with request for application.

A. Identifying information

1. RFA/RFP name: _____
2. Form completed by: _____
3. Date completed (day-month-year) ____-____-____

B. General questions

Career goals

- Is the role proposed compatible with your goals and interests? (_y) (_n)
- Do you have sufficient time for the work? (_y) (_n)
- Do you enjoy multicenter collaboration? (_y) (_n)
- Will there be opportunities for writing and authoring papers in the project? (_y) (_n)
- Do you function well in committee settings and are you willing to accept the dictates of committees and sponsors in the execution of the study? (_y) (_n)

Table 1.1 Questions when deciding whether to respond to an RFA or RFP

Environment

- Are stipulations in the RFA or RFP compatible with policies of your institution? . . . (y) (n)
- Are personnel recruitment practices, pay scales, and promotion criteria of your institution compatible with those needed for the work proposed? (y) (n)
- Is the business office of your institution capable of administering the funding if awarded?
- Is the work compatible with the goals of your department? (y) (n)
- Are colleagues in your institution likely to view your activities in the work in a favorable light?
- Will you be able to obtain the necessary signatures from administrative personnel in your institution to submit a response? (y) (n)
- Will you have the active support of your chief if you are funded? (y) (n)
- Will there be adequate space and facilities to do the work if you are funded? (y) (n)
- Do you believe you will be able to acquire the people needed for the project? (y) (n)

C. Specific questions concerning the RFA or RFP

- Is the problem posed worthy of investigation? (y) (n)
- Are you willing to be a party to randomizing persons to the treatments proposed for study?
- Is there sufficient time to prepare an adequate response? (y) (n)
- Is the project likely to achieve its stated aims? (y) (n)
- Does the project have a realistic timetable and, if not, do you believe the sponsor is willing to modify it? (y) (n)
- Does the sponsoring agency desire scientific input in the way the work is designed and carried out? (y) (n)
- Will there be adequate time for development of the study protocol and data forms before the study is launched? (y) (n)
- Are staffing guidelines realistic? (y) (n)
- Are funding levels realistic? (y) (n)
- Are the duties of the project officer compatible with your role in the trial? (y) (n)
- Is the reporting schedule for progress summaries during the trial reasonable? (y) (n)
- Are the policy and procedures proposed for treatment effects monitoring and data sharing acceptable? (y) (n)
- Will investigators have autonomy in paper writing and publication? (y) (n)

Table 1.2 Proposed budget by center (BudSum.Tab)

When: As a prelude to submission of an investigator-initiated multicenter proposal

Who: The study chair or director of the coordinating center

Purpose: To summarize funding requested by type of center and essential functions and to provide summary tables for inclusion in the funding request

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) _____

4. Dollar cost by center (direct costs)

	<u>Yr 1</u>	<u>Yr 2</u>	<u>Yr 3</u>	<u>Yr 4</u>	<u>Yr 5</u>	<u>Total</u>
4.a. Clinics	_____	_____	_____	_____	_____	_____
4.b. Coord center	_____	_____	_____	_____	_____	_____
4.c. Other centers	_____	_____	_____	_____	_____	_____
4.d. Total direct	_____	_____	_____	_____	_____	_____

5. Fractional costs of total direct cost by center

5.a. Clinics						
Item 4.a ÷ 4.d	_____	_____	_____	_____	_____	_____
5.b. Coord center						
Item 4.b ÷ 4.d	_____	_____	_____	_____	_____	_____
5.c. Other centers						
Item 4.c ÷ 4.d	_____	_____	_____	_____	_____	_____
5.d. Total	1.00	1.00	1.00	1.00	1.00	1.00

6. Total personnel costs (direct costs: salaries + fringe benefits)

6.a. Clinics	_____	_____	_____	_____	_____	_____
6.b. Coord center	_____	_____	_____	_____	_____	_____
6.c. Other centers	_____	_____	_____	_____	_____	_____
6.d. Total	_____	_____	_____	_____	_____	_____

Table 1.2 Budget summary tables

	<u>Yr 1</u>	<u>Yr 2</u>	<u>Yr 3</u>	<u>Yr 4</u>	<u>Yr 5</u>	<u>Total</u>
7. Fraction of budget devoted to personnel costs						
7.a. Clinics Items 6.a ÷ 4.a	_____	_____	_____	_____	_____	_____
7.b. Coord center Items 6.b ÷ 4.b	_____	_____	_____	_____	_____	_____
7.c. Other centers Items 6.c ÷ 4.c	_____	_____	_____	_____	_____	_____

Table 1.3 Budget analysis (BudAnal.Tab)

When: As a prelude to submission of an investigator-initiated multicenter proposal

Who: The study chair or director of the coordinating center

Purpose: To assess the adequacy of allocation of funding

A. Identifying information

1. Study name: _____
2. Form completed by: _____
3. Date completed (day-month-year) _____

B. Budget analysis

4. Years of support requested as represented in Table 1.2 _____
5. Funds requested (direct costs only)
 - 5.a. Clinics (fr Table 1.2, item 4.a) _____
 - 5.b. Coordinating center (fr Table 1.2, item 4.b) _____
 - 5.c. Other centers (fr Table 1.2, item 4.c) _____
 - 5.d. **Total** (fr Table 1.2, item 5.d) _____
6. Projected sample size (fr WS 1.1, item 5) _____
7. Cost per person enrolled
 - 7.a. Clinic (item 5.a ÷ item 6) _____
 - 7.b. Coordinating center (item 5.b ÷ item 6) _____
 - 7.c. Other centers (item 5.c ÷ item 6) _____
 - 7.d. **Total** (item 5.d ÷ item 6) _____
8. Unit of followup time (check one)
 - () Day
 - () Week
 - () Month
 - () Year

Table 1.3 Budget analysis

() Other (specify)

9. Projected person units of followup time (expected median length of followup per person enrolled x projected sample size) _____

10. Cost per person unit of followup time

10.a. Clinic (item 5.a ÷ item 9) _____

10.b. Coordinating center (item 5.b ÷ item 9) _____

10.c. Other centers (item 5.c ÷ item 9) _____

10.d. **Total** (item 5.d ÷ item 9) _____

11. Expected number of data collection visits (fr item 13; WS 1.1)

. _____

12. Cost per data collection visit

12.a. Clinic (item 5.a ÷ item 11) _____

12.b. Coordinating center (item 5.b ÷ item 11) _____

12.c. Other centers (item 5.c ÷ item 11) _____

12.d. **Total** (item 5.d ÷ item 11) _____

13. Personnel cost (fr item 6, Table 1.2)

13.a. Clinic _____

13.b. Coordinating center _____

13.c. Other centers _____

13.d. **Total** _____

14. Proportion of cost devoted to personnel

14.a. Clinic (item 13.a ÷ item 5.a) _____

14.b. Coordinating center (item 13.b ÷ item 5.b) _____

Table 1.3 Budget analysis

14.c. Other centers (item 13.c ÷ item 5.b) _____

14.d. **Total** (item 13.d ÷ item 5.d) _____

C. Budget assessment

15. Is the allocation of funding, as represented in Table 1.2, consistent with the effort required?

() Yes

() No; adjustments are necessary.

16. If clinics are to be paid by person enrolled or completed data collection visits per person, is the amount to be paid consistent with FTE requirements as detailed in Budget Checklist (CL 1.1)?

() Yes

() No; level of funding inadequate for effort required

17. Is percentage of funds devoted to data center activities less than 10%?

() Yes; level of funding likely inadequate

() No

WS 1.1 Budget worksheet (Budget.WS)

When: Preparing a funding initiative

Who: A senior investigator

Purpose: To provide a set of reminders for construction of budget in a funding request

A. Identifying information

1. Study name: _____
2. Form completed by: _____
3. Date completed (day-month-year) ____-____-____

B. Specifications

4. Treatment groups
 - Test-assigned groups _____
 - Control-assigned groups _____
 - Total number of treatment groups _____
5. Sample size goals
 - Number per test-assigned group _____
 - Number per control-assigned group _____
 - Total planned sample size _____
6. Proposed timetable
 - Start up _____ Mos
 - Enrollment and treatment _____ Mos
 - Treatment and followup _____ Mos
 - Close out of data collection _____ Mos
 - Wind up _____ Mos
 - Total anticipated time _____ Mos

WS 1.1 Budget worksheet

7. Close out design

() Anniversary (specify period of followup) _____ Mos

() Common close date (specify range of followup)

Min: _____ Mos Max: _____ Mos

8. Trial type (check all that apply)

() Treatment

() Prevention

() Phase I/II

() Phase III

() Phase IV

() Parallel treatment design

() Crossover design

C. Screening and enrollment

9. Primary method of recruitment

() Referral

() Screening

() Record review

() Mailings

() Other (specify)

10. Expected screening rate per person enrolled

() > 10 to 1

() 7 - 10 to 1

() 6 - 4 to 1

() 3 to 1

() < 3 to 1

D. Data collection schedule

11. Screening and baseline data collection visits

Expected number of screenees per enrollee _____

12. Treatment and followup data collection visits

Expected number per person enrolled _____

WS 1.1 Budget worksheet

13. Total number of expected visits per person enrolled (sum of values in items 11 and 12)

..... _____

14. Total number of expected data collection visits (item 5 x item 13) _____

E. Number of study centers

Clinics _____

Coordinating centers _____

Other centers _____

Total number of centers _____

WS 1.2 Funding specification worksheet (FundMode.WS)

When: Early in the design phase of the trial and prior to the start of enrollment

Who: Study chair and director of the coordinating center, independent of one another to reveal areas of confusion or uncertainty

Purpose: For multicenter trials to make clear the mode of funding and mechanism of funding for the various centers in the trial

Definitions

direct funding - A mode of funding in which money flows to the point of use directly from a sponsor.

indirect funding - A mode of funding in which money flows to the point of use from an intermediary of a sponsor, e.g., with centers in a multicenter trial funded via another center in the trial as in consortium funding.

A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) _____

B. Funding sources and vehicles

4. Number of funding sources?

() One (specify)

() Two or more (specify; list in descending order by amount)

5. Primary funding vehicles for clinics and coordinating center

Clinics

() Grant

() Cooperative agreement

() Contract

() Fixed amount per person enrolled (specify amount) \$ _____

WS 1.2 Funding specification worksheet

() Fixed amount per completed visit (specify amount) \$ _____

() Other _____

Coordinating center

() Grant

() Cooperative agreement

() Contract

() Other _____

C. Funding route

6. Route of money from funding agency to clinics

() Direct, i.e., direct from funding agency to individual clinics

() Indirect, i.e., via an intermediary to clinics (e.g., to the coordinating center from the funding agency and then from the coordinating center to clinics); indicate the intermediary

() Mixed; some direct and other indirect (explain)

7. Route of money from funding agency to data center/coordinating center

() Direct

() Indirect (specify)

8. Other study centers?

() No

() Yes

If yes, list and indicate whether direct or indirect funding by writing D or I in the space at the right

Center

_____ _____

_____ _____

_____ _____

WS 1.2 Funding specification worksheet

 9. Funding awards

Number direct from funding agency to centers _____

Number indirect _____

Total number _____

D. Funding agreement and period of funding

10. Funding agreements

Clinics (check all that apply)

- Fixed cost
 Cost reimbursement
 Per person enrolled
 Per person with complete followup
 Other (specify)
-

Coordinating center (check one)

- Fixed cost
 Cost reimbursement
 Other (specify)
-

11. Period of funding

- ≤ 2 years
 3 years
 4 years
 5 years
 > 5 years

CL 1.1 Budget checklist (Bud.CL)

When: Preparing a funding initiative

Who: A senior investigator

Purpose: To provide a set of reminders for construction of budget in a funding request

A. Identifying information

1. Study name: _____
2. Form completed by: _____
3. Date completed (day-month-year) _____

B. Personnel

4. Full time equivalent personnel (check all that apply and indicate aggregate number of FTEs for 1st year of funding, middle year of funding, and end year of funding)

Note

Contrary to expectation personnel support remains relatively flat over the course of the trial including for the coordinating center. Duties may change but personnel support remains fairly constant.

	1st yr FTEs	Middle yr FTEs	End yr FTEs
() Center directors			
() Deputy directors			
() Study physicians			
() Clinic coordinators			
() Laboratory technicians			
() Biostatisticians			
() Programmers			
() Data coordinators			

CL 1.1 Budget checklist

	<u>1st yr</u> <u>FTEs</u>	<u>Middle yr</u> <u>FTEs</u>	<u>End yr</u> <u>FTEs</u>
() Data entry personnel	_____	_____	_____
() Research/administrative assistants	_____	_____	_____
() Other support personnel	_____	_____	_____
Total FTEs	_____	_____	_____
5. Estimated personnel cost			
5.a. Median salary of study personnel			\$ _____
5.b. Median fringe benefit cost as percentage of median salary			_____ %
5.c. Total median salary expense (item 5.a + (item 5.a x item 5.b))			\$ _____
5.d. Inflation factor relative to 1st yr			
Middle yr			_____ %
End yr			_____ %
5.e . Total personnel cost			
1st yr (item 5.c x 1st year total FTEs in item 4)			\$ _____
Middle yr (item 5.c x middle year total FTEs x middle yr inflation factor)			\$ _____
End yr (item 5.c x end year total FTEs x end yr inflation factor)			\$ _____
6. Consultants (persons paid on a retainer or fee-for-service basis; typically not associated with any center in the trial)			
() To provide expert advice in the diagnosis, classification, or treatment of patients in the trial			\$ _____
() To perform a specialty function, such as reading ECGs, biopsy material, etc.			\$ _____
() To provide expert advice to a resource center in the trial, such as to the data coordinating center for data analysis			\$ _____
() To serve as an expert advisor to the study leadership or sponsor of the trial			\$ _____
() To serve as voting members of the treatment effects monitoring committee			\$ _____

CL 1.1 Budget checklist

7. Other personnel (list)

_____	\$ _____
_____	\$ _____
_____	\$ _____

C. Equipment (purchase or lease)

8. Study clinics

()	General office equipment*	\$ _____
()	Furniture for examining and waiting rooms*	\$ _____
()	Dedicated equipment needed for data collection, e.g., fundus photography camera or spirometer; justification should indicate why existing equipment will not meet the needs of the study; requests for standard equipment, regarded as essential to any clinic setting not generally approved	\$ _____
()	Other (specify)		
	_____	\$ _____
	_____	\$ _____
	_____	\$ _____

9. Data center/coordinating center

()	General office equipment*	\$ _____
()	Computing equipment for receiving, processing, and analyzing data	\$ _____
()	Computing software packages for database management and analyses	\$ _____
()	Mailing equipment	\$ _____
()	Machines for assembling and binding reports	\$ _____
()	Paper shredders	\$ _____
()	Other (specify)		
	_____	\$ _____
	_____	\$ _____
	_____	\$ _____

CL 1.1 Budget checklist**D. Supplies**

10. Clinics

- () Office supplies (paper, pencils, notebooks, file folders, postage, photocopy supplies, telephone line charges, etc.) \$ _____
- () Drugs, syringes, laboratory reagents and supplies, patient information brochures, postage for patient mailings, etc. \$ _____
- () Other (specify)
- _____ \$ _____
- _____ \$ _____
- _____ \$ _____

11. Data center/coordinating center

- () Office supplies (paper, pencils, notebooks, file folders, postage, photocopy supplies, telephone line charges, etc.) \$ _____
- () Computer supplies, printer supplies, electronic storage mediums, etc. \$ _____
- () Other (specify)
- _____ \$ _____
- _____ \$ _____
- _____ \$ _____

E. Travel

12. Clinic

- () Local (Mileage charges for study related travel to a study site, for patient recruitment, for home visits, etc.) \$ _____
- () Study related (Travel and living expenses for meetings of research group and study committees) \$ _____
- () Other (specify)
- _____ \$ _____
- _____ \$ _____
- _____ \$ _____

CL 1.1 Budget checklist

13. Data center/coordinating center
- () Local (Mileage charges for local travel) \$ _____
- () Study related (Travel and living expenses for meetings of research group and study committees) \$ _____
- () Travel and living expenses for study site visits \$ _____
- () Other (specify)
- _____ \$ _____
- _____ \$ _____
- _____ \$ _____
14. Meetings of treatment effects monitoring committee
- () Travel and living expenses for TEMC members \$ _____
- () Travel of data center personnel to meetings of the TEMC \$ _____
15. Other travel
- () National (Travel and living expenses incurred in conjunction with study meetings, site visits, and for study-related professional meetings) \$ _____
- () International (Travel and living expenses for study and related activities and for selected professional meetings related to the needs and goals of the study) \$ _____
- F. Patient care costs***
16. Pay for study-related procedures not covered by 3rd party payers \$ _____
17. Other expenses (specify)
- _____ \$ _____
- _____ \$ _____
- _____ \$ _____
- G. Alterations and renovations***
- () Renovations of a clinic area \$ _____
- () Renovations to accommodate special items of equipment needed in the trial . \$ _____

CL 1.1 Budget checklist

() Other expenses (specify)

_____ \$ _____

_____ \$ _____

_____ \$ _____

H. Consortium/contractual costs

Funds to cover payments to individuals or groups outside the investigator's institution who have formal agreements to perform specified functions in the trial \$ _____

I. Other expenses

- () Patient travel to and from clinic \$ _____
- () Equipment maintenance charges \$ _____
- () Telephone installation and monthly usage charges \$ _____
- () Copying and reproduction charges \$ _____
- () Data entry charges \$ _____
- () Study insurance \$ _____
- () Books and journals \$ _____
- () Journal page and reprint charges \$ _____
- () Charges for printing and distributing study forms, manuals, etc. \$ _____
- () Fee-for-service charges, such as for laboratory determinations, reading ECGs, etc., if not covered under a consultant or contractual agreement \$ _____
- () Space rental \$ _____
- () Moving charges \$ _____
- () Indirect costs or associated contractual services included in item 8 \$ _____
- () Purchase of study drug \$ _____
- () Packaging and distribution of study drug \$ _____

CL 1.1 Budget checklist

() Other expenses (specify)

_____ \$ _____

_____ \$ _____

_____ \$ _____

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* Generally not allowed

