The Clinical Research Center Research Practice Manual

Guidelines for Developing Budgets for Clinical Research – RPG-13

Guideline

Purpose

The purpose of this document is to provide Investigators with guidelines for developing clinical research study budgets to ensure costs needed to properly conduct the research are considered. Included is information on a variety of direct costs, indirect costs, determination of staff efforts, contractual costs, and consultants.

Definitions

Direct Costs: Costs in a grant or contract that support a project or program including personnel, equipment, supplies, patient care costs.

Modified Direct Costs: Used to calculate the Indirect Costs and excludes items from the Direct Costs such as: some equipment, student tuition, research patient care costs, and some subcontract costs.

Indirect Costs: Costs associated with the general operation of an institution and the conduct of its research activities like facilities and administrative costs; calculated by applying a specified rate to the Modified Direct Costs.

Total Costs: Total allowed costs, both direct and indirect, incurred by a grantee to carry out a project or activity.

Procedure

The following section outlines the procedures to be followed when developing a budget. Refer to the ***Research Policy and Procedure Manual's*** *Direct and Indirect Costs Policy* for institutional policies regarding the development of research budgets.

Person Responsible for Determining Staffing needs and other costs

The type of staff and amount of time budgeted for staff each year will vary depending on the nature and scope of work proposed and the study timeline, i.e. specific tasks that are expected to be implemented each year. (See Attachment I for an example of a study timeline that may be included in a grant.)

In general,

- The first year or start-up time involves final protocol development; staff hiring and training; development of case report forms and study manuals; database development and programming of forms.
- The follow-up years or study implementation years involve primarily study subject recruitment, study management, intervention implementation, data collection, data entry, data cleaning and data management activities as well as DSMB reporting and interim data analyses as required by the study.
- The last year or close out period involves primarily preparation of analytical data sets for final statistical analyses, abstract and manuscript preparation.

Components of the Study Budget

The following is a description of the types of costs that might be included in a research study.

Direct Costs incurred to conduct the research may include:

Personnel effort (salary and fringe):

All personnel efforts are described as percent efforts (Full Time Equivalents or F.T.E.'s) or calendar months for NIH grants. When converting percent effort in a year to calendar months per year, multiply the percent effort by 12. For example 10% effort is 1.2 calendar months, 20% effort is 2.4 calendar months and so on.

Budgeting staff efforts for various activities depends on the scope of work and complexity of the project. In general, for the average single site study, budgeting for the following personnel is critical to the successful implementation of the study. These include the PI, Co-Investigators, project manager and/or clinical research coordinator, data manager, applications developer, statistician, and data entry staff. In some small studies, staff can assume dual roles. For example, a junior CRC may also perform data management activities. In contrast, in very large studies, one may need both a senior project director and junior CRC. The amount of effort to be budgeted for each person should be carefully matched to the responsibilities of the individual and the scope of work of the study. In addition, investigators should be aware of and adhere to any salary caps or effort minimums or maximums that must be followed for various sponsors or funding mechanisms. For example, NIH has a maximum salary that must be used for senior investigators whose salary may exceed this amount, and this amount is announced on a yearly basis.

An example of how to calculate FTE's (Full Time Equivalent) for a data entry clerk is as follows:

A PI anticipates enrolling 200 subjects who will each complete 7 study visits over a 24-month period (1400 visits). It is estimated that there will be 12 CRFs per visit, and it will take 5 minutes to data enter the 12 CRFs for each of the 1400 visits; therefore, the PI estimates s/he will need 120 hours of primary data entry effort over the course of the 24

months or 60 hours over 12 months. (1400 visits x 5 minutes = 7000 minutes / 60 minutes = 116.6 hours rounded to 120 hours). The FTE's/year would then be 60 hours/2080 hours/year=.028, or about 3% effort per year for data entry support.

This estimate does not include any double data entry (DDE) that is sometimes employed for all or a lower percentage of CRFs to identify and resolve keystroke errors that may occur. If every CRF is entered twice, the time required for data entry should be doubled,

i.e. 240 hours, and the FTE's would then double to 6% per year.

Office Supplies and Equipment:

Office Supplies must have a direct benefit to the project and it must be documented that there is a "significantly greater amount…required for a project" than ordinary office supplies. They must also meet any sponsor guidelines.

Equipment: According to the CHB ***Research Policy and Procedure Manual's*** Direct and Indirect Costs Policy, CHB defines equipment "as items with a useful life of at least 3 years and an acquisition cost of $5,000 or more. Equipment that meets this definition and is used specifically for the benefit of the sponsored project may be budgeted on the sponsored project according to the sponsor specific guidelines. General equipment such as copiers and computers for use on multiple projects should not be budgeted for by a specific project. This type of equipment is included as part of the cost reimbursed through the indirect cost rate."

Examples of study-specific supplies or equipment may include laptops, scales, stadiometers, dinamaps, or human specimen related processing and shipping supplies etc.

Postage/Photocopies

Postage and Photocopies are allowable direct charges only if it can be documented that there is a direct benefit to the study (such as a survey mailing or photocopying). Other charges to consider are FEDEX charges for mailing of human samples to research laboratories.

Printing

Printing costs may be budgeted for manuals, case report forms, recruitment materials, or intervention materials. This should be justified by the number of pages and the cost per page. Binders may also be included in this line item. For example, the costs of subject binders to store all forms may be budgeted as 100 subjects x $12.50 per binder X 1 binder per subject = $1250.00

Patient Care Costs

The costs for patient care such as inpatient room charges, patient travel, patient interviews, and office visits all should be included in the budget.

Patient Care Costs are determined through charge codes/cpt. For industry-sponsored trials, the PI works with the ***Clinical Trials Office (CTO)***, to determine the correct

costs to budget

For NIH supported or foundation supported studies, the PI works with the Office of Sponsored Programs (OSP) to calculate clinical costs. OSP will work in conjunction with the CTO to determine the correct costs.

Lab Tests and Procedures

Lab tests, MRI's, X-rays, echocardiograms, etc, that are budgeted are allowable direct costs as defined by the sponsor guidelines. Many sponsors, such as NIH, limit the amount of money that can be budgeted for these expenses. For sponsored research that includes patient care costs, such as clinical studies, it is important that the PI consult with the CTO or OSP as directed above to ensure that the correct patient care costs are used in the budget. These costs can also be found at ***CTO*** for corporate sponsored studies, and at ***OSP*** for NIH sponsored studies.

Study start-up and close-out fees

For industry sponsored studies, this is calculated by the PI/Research Team by estimating the amount of resource time in preparing primary documents, up front study preparation and management and closing out the study (non-patient care related activities, including document receipt, budget meeting and review, contract meeting and review, submission administration, etc.). Typically, start-up and close-out costs range between $1,000 and $5,000.

The IRB Review Fee

The IRB Review Fee is a non-negotiable item for **industry** funded clinical research. This fee is **$2,500**.

Clinical and Translational Study Unit (CTSU) Services

This is the core clinical research facility for inpatient and outpatient nursing. Clinical protocols will need to be submitted for separate review by the CTSU before any services can be provided. For any Corporate sponsored studies, there is a non-negotiable of $2,500 fee to cover protocol review. **This fee is for industry-initiated studies only**. It does not apply to NIH, foundation, or investigator-initiated studies. The fee covers the cost of CTSU review. Additionally, industry sponsored trials pay for all costs associated with research performed in the CTSU. The study PI should contact CTSU for cost estimates.

Pharmacy Fee

The Pharmacy Fee is a non-negotiable item for any **industry sponsored** clinical research that utilizes the pharmacy. The fee is **$2,000**, and it may be waived for PI initiated studies that are internally funded.

Translation Services

Translational services in studies where there may be greater than minimal risk and where there may be non-English speaking subjects, funds to translate consent documents and other study materials such as recruitment material, intervention

materials, and forms should be included. Such costs are often based on the number of words in the document, for example $0.25/word. Costs should be budgeted for forward and back translation.

Study Monitoring

If the research is being conducted under an investigator initiated IND or IDE, studies need to budget for monitoring which is done through the ***Education and Quality Improvement Program (EQUIP)***. With the assistance of EQUIP, the monitoring fees can be determined.

Professional Meetings and Travel

In general, NIH usually allows costs for 1-2 professional meetings at which the PI and/or others on the research team can present interim or final results. Travel costs, which include transportation (airfare and ground travel), lodging, per diem, mileage, and incidentals, must meet both the CHB travel guidelines set by ***Research Finance*** and the travel guidelines in ***OASC-3 Appendix E (IX)(B)(43)***. For industry funded research, travel guidelines from the sponsor must also be followed. Budgeting for projects must use the most current institutional, sponsor, and/or federal rates.

Patient Incentives and Patient Reimbursements

Incentives should be modest to avoid any issue of human subject protections, i.e. they should be commensurate with the time and effort study participants are being asked to give and yet not be seen as coercing or overly enticing individuals to participate. Reimbursements for patient costs for travel, lodging, and parking should be budgeted; especially when it is expected that subjects will be traveling any extended distance for participation in the study. Specific guidelines may be found on the ***Committee on Clinical Investigation (CCI) website under guidelines and policies***.

Database Software Technologies

Most Studies will require a study database or Electronic Data Capture Tool. The Clinical Research Informatics Core Services a variety of tools that may be free or available at a fee to cover licensing costs. This one time fee per study may range from $500 to $10,000, depending on the complexity of the tool required by the study or sponsor. All PI's should consult with Clinical Research Center and Clinical Research Informatics Core on what to budget for use of these institutionally administered technologies.

Contractual Direct Costs and Consultants

PI's should work with OSP on the development of contractual agreements with organizations and consultants. CHB requires that subcontractors submit a budget through OSP that details the amount of money they are requiring. Some funding sources limit the total dollar amount for contractual and consulting agreements to ensure that the majority of the work is being performed by the applicant.

"Consultant costs should be reviewed for reasonableness and compliance with sponsor guidelines. The compensation should be clearly stated as: $50/hour for 20 days or 5 days/$350 per day."

Indirect Costs

Indirect Cost Rates vary by funding agency and are determined by the institution. Please see the ***Research Policy and Procedure Manual's*** *Direct and Indirect Costs Policy* for further information on how to calculate the indirect costs using total direct costs or modified total direct costs when subcontracts, patient care, or other excluded costs are budgeted. Corporate sponsored clinical research overhead should be confirmed with Clinical Trials Office (CTO) and applied to study budget.

Indirect rates will change over time and therefore they must be confirmed and the most current rate used.

Components of the Budget Justification

The budget justification provides a narrative description to justify the direct costs and usually includes the following:

- All personnel responsibilities
- All the expenses and how they were determined including any rates used to obtain the amounts;
- Quotes for major equipment;
- Letters of support from consultants; and
- Subcontract agreements and justifications.

Related Content

• Study Timeline Example

TASK	Year 01	Year 02	Year 03
Finalize Study Protocol /IRB Approval	**X**		
Hire and Train Personnel	→		
Develop CRFs and Study Manuals	**X**		
Develop Study Database	**X**		
Recruitment and Randomization	→	→	
Intervention Implementation	→	→	→
Data Collection at Study Visits	→	→	→
Data Cleaning	→	→	→
DSMB Meetings/Reports	**X**	**X** **X**	**X**
Final Analysis and Manuscripts/Study Closeout			→

Personnel Responsibilities Template

Each PI should customize this template as appropriate to the work scope of their study and include specific names, titles, and degrees of the staff proposed.

PRINCIPAL INVESTIGATOR

- Oversees the scientific and administrative aspects of the study
- Leads the scientific design and implementation of the study
- Provides financial oversight of the project
- Provides overall direction and leadership to the project staff
- Participates in the analysis and interpretation of the data
- Prepares manuscripts for publication
- Leads meetings and conference calls

SENIOR BIOSTATISTICIAN (Doctoral Level)

- Provides scientific input on all aspects of the statistical design including sample size and power calculations and randomization and analysis methods
- Conducts interim analyses to assess safety and efficacy
- Directs data analyses and participates in the interpretation of results
- Provides oversight of the work of the Master's level statistician or statistical analyst
- Assists with the preparation of manuscripts for publication
- Participates in all meetings and conference calls

STATISTICAL ANALYST (Master's level)

- Prepares the study data for statistical analysis
- Performs data analysis under the direction of the senior biostatistician
- Creates final data sets for archival purposes as applicable
- Participates in manuscript preparation

PROJECT MANAGER/DIRECTOR

- Oversees all aspects of study implementation, including recruitment, intervention, and data collection and data management activities.
- Conducts training of project staff
- Coordinates project meetings and supervises the tasks of staff involved in the project
- Develops the data collection forms and study manuals of operation
- Assists the application developer in the design and testing of the data management system
- Monitors study progress including recruitment status, subject drop-out or losses, study form completion, and intervention compliance, and performs quality assurance of data collection methods

- Conducts site visits to ensure standard implementation of the study protocol
- Oversees the accuracy and completeness of the data entry and the resolution of data entry errors

CLINICAL RESEARCH COORDINATOR (CRC)

- Assists Principal Investigators (PIs) in planning and implementing clinical research studies as assigned.
- Coordinates preparation of protocol applications for submission to the IRB, sponsor, regulatory authority, etc.
- Corresponds with the IRB, study sponsors, clinical research organizations, study participants, and referring physicians.
- Responsible for recruitment of study participants for enrollment in clinical trials.
- Organizes study procedures and schedules study participants for study visits. Assists the PI during patient visits. Performs study procedures designated for the Study Coordinator.
- Completes record abstraction of source documents, conducts required study measurements, and completes study Case Report Forms in accordance with best practice methods. Maintains regulatory binders, case report forms, source documents, and other study documents.

DATA MANAGER

- Manages data flow for study.
- Designs and validates databases.
- Develops or assists with development of CRFs and data management and data quality procedures.
- May perform descriptive statistical analysis.
- May supervise junior data managers.
- Assists with the development of study case report forms.
- •Performs data entry.

RESEARCH ASSISTANT (May also be doing the DATA ENTRY tasks listed below)

- Conducts literature searches on behalf of research team

Assists with testing of the study database under the direction of the CRC Project Manager

DATA ENTRY CLERK

- Conducts accurate and timely data entry of all study forms
- Resolves data entry errors
- NIH Budget Example

BUDGET JUSTIFICATION

All salaries and fringe benefits have been calculated with a 3% annual increase and 30% fringe benefit rate (for this example only, find current rates on the OSP website). The total costs per year may increase at a rate greater than 3% because of increased patient and control enrollment.

1. PERSONNEL:

M.D., M.P.H. Co- Principal Investigator is Professor of Pediatrics at Harvard Medical School and XXX in the Department of Cardiology at Children's Hospital, Boston. Together with Dr. XXX, Co-Principal Investigator, she will provide oversight of the research proposal, and will develop and implement all policies, procedures, and processes. In these roles, Drs. XXX and XXX will be responsible for the implementation of the scientific agenda, the leadership plan, and the specific aims, and they will ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including those related to human research. Dr. XXX will oversee Specific Aims 3 and 4. She will coordinate and supervise the various study co-investigators; will be responsible for the smooth functioning of data coordinating center personnel, including the statistician, programmer, data manager, and financial administrator; and will be responsible for implementation of human subjects research and approvals. She will also be responsible for assessing medical history and factors related to neurodevelopmental outcome. Dr. XXX will rotate with Dr. XXX (odd and even grant years, respectively) as Chair of a Steering Committee of key personnel that meets monthly to monitor study progress and address problems as "contact PI". She will chair weekly meetings of data coordinating center personnel to monitor study progress and to address problems. She will be responsible for overseeing data analysis, manuscript preparation, and dissemination of study findings at national meetings. Her time commitment will be 1.8 calendar months in Years 1-5. Her salary is based on an annual rate of $191,300.

M.D., Co-Principal Investigator is Associate Professor of Neurology at Harvard Medical School and XXX at Children's Hospital Boston. He served as the Principal Investigator at Children's Hospital Boston for the landmark NIH sponsored "MRI Study of Normal Brain Development in Children". Together with Dr. XXX, Co-Principal Investigator, he will provide oversight of the research proposal, and will develop and implement all policies, procedures, and processes. In these roles, Drs. XXX and XXX will be responsible for the implementation of the scientific agenda, the leadership plan, and the specific aims, and they will ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including those related to human research. Dr. XXX will oversee Specific Aims 1 and 2. He will be responsible for oversight of all brain MRI imaging in this study. He will participate in and supervise MRI scanning sessions. Such supervision will be both scientific and medical. He will perform and also supervise the MRI research assistant and Drs. XXX and XXX in post-imaging data analysis in both volumetric and diffusion tensor imaging domains. He will ensure quality of compiled data, their analyses and interpretation. He will ensure that all protocols used in the study are

safe, comfortable for children and well tolerated by them. He will ensure quality of neuroimaging data in all publications resulting from this work. Dr. XXX will rotate with Dr. XXX as Chair of a Steering Committee of key personnel that meets monthly to monitor study progress and address problems as "contact PI". His time commitment will be 1.8 calendar months throughout the grant period. His salary is based on an annual rate of $191,300.

Ph.D., Co-Investigator in Neuropsychology is Professor of Neurology at Harvard Medical School. He has made seminal contributions to our understanding of the developmental impact of early insults to the central nervous system, including lead poisoning and the neurodevelopmental effects of open heart surgery in infants and children with congenital heart defects. He will serve as leader for the Neuropsychology component of evaluation. In addition to participating in neuropsychology testing, he will be responsible for the training and supervision of a research assistant, who may perform some of the exams. He will take responsibility for the collaborative effort of co-investigators in psychology and neuropsychology and will ensure quality of compiled data, their analyses and interpretation. He will ensure that the neuropsychologic tests used in the study flow smoothly and that the testing protocol is well tolerated by study subjects. Finally, he will ensure quality of all publications related to neuropsychologic outcomes resulting from this work. His time commitment will be 1.2 calendar months throughout the grant period, and his salary is based on an annual rate of $139,050.

M.D., Co-Investigator in Psychiatry is Professor of Psychiatry and Pediatrics at Harvard Medical School and XXX at Children's Hospital Boston. He was the psychiatry consultant to the Department of Cardiology for 28 years, and has made seminal contributions to understanding the emotional adjustment of children with heart disease. Dr. XXX will lead the Psychiatry component of the protocol and will be responsible for training and supervising a research assistant, who will conduct most of the assessments. He will also be available to conduct assessments should the research assistant be unavailable. His time commitment will be 0.6 calendar months throughout the grant period. His salary is based on an annual rate of $191,300.

M.D. Co-Investigator in Developmental Pediatrics is Professor of Pediatrics at Harvard Medical School and XXX at Children's Hospital Boston. Dr. XXX will be involved in the recruitment of normal control patients through the large clinical pediatric practice of which he has been a member. He will also provide important guidance on issues of overall study conduct, data analysis planning, interpretation, and manuscript preparation. His time commitment will be 0.36 calendar months throughout the grant period, and his salary will be covered by departmental funds.

M.D., Co-Investigator in Genetics is Assistant Professor of Pediatrics at Harvard Medical School and XXX for the Department of Cardiology at Children's Hospital Boston. Dr. XXX will be responsible for the coordination of all genetics aspects of the protocol, including performing genetics exams, interpreting chromosomal microarrays, and maintaining the DNA biorepository. She will devote 0.6 calendar months throughout the grant period and salary is based upon an annual rate of

$168,000.

M.D., Co-Investigator in Neuroradiology is Associate Professor of Radiology at Harvard Medical School and Clinical Chief, Department of Radiology, at Children's Hospital Boston. Dr. XXX will be responsible for interpretation of neuroanatomic aspects of the brain MRI's. He will devote 0.36 calendar months throughout the grant period, and salary is based upon an annual rate of $191,300.

Ph.D., Co-Investigator in Biostatistics is Associate Professor of Pediatrics at Harvard Medical School and XXX at the XXX. Dr. XXX has special expertise in the area of pediatric cardiovascular disease. He has collaborated with members of the investigative team for more than a decade and has been a leader in the design, conduct, and analysis of clinical research hospital-wide. He will be responsible for supervising statistical aspects in the final development of forms, database development, data quality and checking, preliminary data analyses, annual reports, final data analyses, and preparation of all reports and scientific publications. His time commitment will be 1.8 calendar months in Year 1, 1.2 calendar months in Years 2-4, and 3 calendar months in Year 5. His salary is based on an annual rate of $142,397.

MR Physicist is fully trained in magnetic resonance physics. He has worked with nuclear magnetic resonance (NMR) methodologies since the early 1980s when he utilized NMR tools to identify structural and dynamic properties of solids. His work in NMR applications in medicine includes the development of methods for quantitative tissue relaxation measurement, including Carr-Purcell-Mieboom-Gill (CPMG) imaging sequences. He successfully modified the sequence to demonstrate its potential for fast imaging and developed an imaging technique now referred to as Fast Spin Echo (FSE) or Turbo Spin Echo (TSE) for which he received the prestigious Distinguished Contribution in MR Imaging Award from General Electric in 1991. Dr. XXX has continued to design, implement and test new MR methods for both imaging and spectroscopic application of MR in medicine, including recent developments in the field of diffusion imaging. His interests and accomplishments in tissue relaxation measurement and interpretation, fast high quality clinical imaging and improved diffusion imaging techniques make him exceptionally qualified to serve on the current proposal. He has worked closely with Dr. XXX in other projects including the NIH funded studies, Pediatric Study Centers for MRI Study of Normal Brain Development, Outcomes in Adolescence after Repair of d-TGA and SCCOR in Pediatric Heart Development and Disease. In addition, he, Dr. XXX, and Dr. XXX (see below) have worked closely in the implementation of fMRI and DTI at Children's Hospital. Working closely with Dr. XXX, Dr. XXX will supervise implementation and maintenance of MR pulse sequences used in this study and he will maintain a quality control program to ensure consistent image quality throughout the project covering diffusion tensor, volumetric, and functional imaging applications. His time commitment will be 1.2 calendar months throughout the grant period. Salary is based on an annual rate of $125,000.

Computer Engineer is the lead computer scientist in XXX at Children's Hospital. He has degrees in Mechanical Engineering with special expertise in geometric modeling, computer aided design and development of the algorithms involved in three dimensional and multidimensional geometry. He possesses knowledge about design, installation and implementation of computer hardware and software including software for the analysis of MR spectroscopic and dynamic contrast data. Dr. XXX's work experience has included segmentation of brain volume MR data, implementation of algorithms to analyze diffusion tensor imaging data, installation of software for analysis of MRI data sets, and computer hardware and software support. Dr. XXX works closely with Dr. XXX in other projects including the NIH funded Pediatric Study Centers for MRI Study of Normal Brain Development, Outcomes in Adolescence after Repair of d-TGA and SCCOR in Pediatric Heart Development and Disease. He, Dr. XXX, and Dr. XXX have worked closely in the implementation of fMRI at Children's Hospital. For the current proposal, Dr. XXX will interact with the Research Technician in the analysis of diffusion tensor imaging data sets. In addition, he will ensure the quality of the research technician's contribution to this area of the project. His time commitment will be 0.84 calendar months throughout the grant period. Salary is based on an annual rate of $87,737.

Ph.D., Clinical Psychologist is an Instructor in Psychology in the XXX at Children's Hospital Boston. Dr. XXX will be responsible for conducting neuropsychological and psychiatric assessments for subjects who choose to come in on the weekend. Weekends are frequently the only time that adolescents can come in for testing. Her time commitment will be 1.8 calendar months in Years 1-3, 1.2 calendar months in Year 4, and 0.6 calendar months in Year 5. Her salary is based on an annual rate of $70,000.

Financial Administrator will execute the administrative details of the study. She will be responsible for preparing the budget, projecting personnel expenditures and other costs (e.g., supplies and patient care), and initiating, approving and maintaining files on all purchases. She will manage a significant amount of patient related expenses (e.g., reimbursing families for travel); coordinate annual progress reports and DSMB conference calls; prepare and submit IRB reports, and assist in manuscript preparation. She will manage and maintain all paperwork for personnel associated with the project. She will work closely with Research Finance staff to ensure accurate financial reporting. Her time commitment will be 1.2 calendar months throughout the grant period. Her salary is based on an annual rate of $38,000.

Data Coordinator has coordinated neurodevelopmental studies within the Department of Cardiology at Children's Hospital Boston, for over two decades. She will be responsible for making hotel and air travel arrangements for patients and their families and coordinating other logistical aspects of the evaluations. She will be responsible for ensuring that data forms are correctly completed and promptly transmitted. She will maintain a patient log for outstanding forms, errors and omissions, for each form and investigator. Finally, she will enter the data. Her time

commitment will be 6 calendar months throughout the grant period. Her salary is based on an annual rate of $63,944.

M.S., Programmer will be responsible for formatting, database management, and programming needs, as well as report generation throughout the grant period. Her time commitment will be 3 calendar months in Year 1, 1.8 calendar months in Years 2-4, and 3 calendar months in Year 5. Her salary is based on an annual rate of $72,605.

MRI Research Technician (to be named) will carry out duties in MRI data acquisition, in post-imaging data processing, and in data archiving. The technician will participate in the scan session and will be responsible for scan preparation, the positioning of subjects into the scanner and (with Dr. XXX) will acquire the MR data from each subject. In addition, the research technician will work under the guidance of both Drs. XXX and XXX in preparation of the atlas required for segmentation analysis of data acquired from the adolescent subjects. Subsequently, the research technician will perform the post-imaging segmentation analysis of each subject's data set for determination of the cortical gray matter, subcortical gray matter, white matter, and cerebrospinal fluid volumes. The technician will work with Drs. XXX and XXX in the analysis of diffusion tensor data sets. Finally, the technician will be responsible for the archiving and maintenance of all processed MRI data. These duties will occupy a dedicated research technician fully over the course of the project during which time Dr. XXX will supervise his work. Time commitment will be 12 calendar months throughout the grant period. Salary is based on an annual rate of $30,000.
Neuropsychological Research Assistant (to be named) will assist Dr. XXX in the conduct of the neuropsychological assessments, and Dr. XXX in medical record review. The time commitment will be 6 calendar months throughout the grant period. Salary is based on an annual rate of $30,000.

2. CONSULTANT COSTS: None

3. EQUIPMENT: None

4. **SUPPLIES:**

a.) Developmental Testing Materials (year 1 only)

Developmental Testing Materials	**Total Pkgs**	**Total Cost**
Wechsler Individual Achievement Test-2nd Edition, complete kit		$417
- record forms/response booklets (25 pkg @ $77)	9	$693
Wechsler Intelligence Scale for Children-4th Edition complete kit		$950
- response booklet #1 (25/pkg @ $65)	9	$585
- record forms (25/pkg @ $107)	9	$963
Conners' Continuous Performance Test II Version 5 complete kit		$699
Delis-Kaplan Executive Function System™ complete kit		$775
- record forms (25 pkg @ $75)	9	$675
- Trail-Making Test response form (25 sets/pkg @ $35)	9	$315
- Design Fluency response form (25 sets/pkg @ $35)	9	$315
Children's Memory Scale complete kit		$560
- record forms, 9-16 year olds (25/pkg @ $32)	9	$288
Behavior Rating Inventory of Executive Function™ introductory kit		$220
- parent form questionnaires (25/pkg @ $52)	9	$468
- teacher form questionnaires (25/pkg @ $55)	9	$495
- parent form scoring summary forms (50/pkg @ $36)	5	$180
- teacher form scoring summary forms (50/pkg @ $38)	5	$190
Test of Visual Perceptual skills, Third Edition complete kit		$155
- record forms (25/pkg @ $32))	9	$288
Children's Depression Inventory (CDI) complete kit		$126
- CDI quick score forms (25/pkg @ $55)	9	$495
Stress Index for Parents of Adolescents kit		$130
- SIPA booklets (25/pkg @ $47)	9	$423
- SIPA answer sheet/profile forms (25/pkg @ $47)	9	$423
PedsQL 4.0		
- teen report (25/pkg @ $15)	9	$135
- parent of teen proxy report (25 pkg @ $15)	9	$135

Conduct Disorder Scale (CDS) introductory kit - CDS summary/response forms (50/pkg @ $48)	 5	$106 $240
Conner's Rating Scale (Revised) - CRS User's Manual - CRS Technical Manual - Complete parent, teacher and adolescent user package CADS ADHD/DSM-IV Scales quick score forms: - parent forms (25/pkg @ $40) - teacher forms (25/pkg @ $40) - adolescent forms ($25/pkg @ $40) CADS ADHD/DSM-IV Scales Feedback forms - parent forms (25/pkg @ $40) - teacher forms(25/pkg @ $40) - adolescent forms(25/pkg @ $40)	 9 9 9 9 9 9	 $49 $76 $276 $360 $360 $360 $360 $360 $360
TOTAL COST OF DEVELOPMENTAL SUPPLIES		$14,005

b) MRI Supplies:

Computer Workstation**:** A computer workstation is requested for the research technician to use in organization and analysis of data collected in the project. The research technician will use this workstation for all data management related to the proposed project.

Year 1: 2000 (Year 1 only)

DVD-RW Discs: Request is made for 100 DVD R/W discs per year for each year of the proposed project. These discs will be used for data storage. Further, they provide an alternate form of data back-up to for each subject scanned. DVDs will be maintain for each scanned conducted in the project.

Year 1: $100
Year 2: $103
Year 3: $106
Year 4: $109
Year 5: $113

Data Back-up Tapes: Fifteen Fujifilm LTO Ultrium 3 400/800gb data back-up tapes are requested per year of the project. These tapes are critically important for

back-up of data produced in the proposed project. An effective data back-up system is already in place in Dr. XXX's lab for which these tapes serve as the principal back-up medium. Request is made for 15 tapes/ year at the cost of $40/tape.

Year 1:	$600
Year 2:	$618
Year 3:	$637
Year 4:	$656
Year 5:	$675

External RAID System: Data storage related to the proposed project will require a dedicated RAID server beginning in the second year of the project. The RAID server will permit on-line availability to all project-related MRI data. Request is made for a $4,000 unit to accommodate 2 TB of data storage. This cost has been distributed across Years 2-5 of the proposed project.

Year 2:	$1000
Year 3:	$1000
Year 4:	$1000
Year 5:	$1000

E-prime software: Request is made for the one time purchase of E-prime software.
This software will be invaluable for fMRI activation paradigm development, planning and maintenance. A one-time request of $995 is made in the first year of the proposed project.

Year 1:	$995 (Year 1 only)

c) Office supplies

There will be a significant amount of record keeping, mailing costs, and office supplies related to the project (e.g., patient binders, printer/FAX cartridges, copier/fax supplies, and miscellaneous office supplies.).

Printer/Fax cartridges: $500/yr
Mailing costs: $500/yr
Record keeping supplies (e.g., binders/folders): $500/yr
Misc. office supplies: $500/yr

Year 1:	$2000
Year 2:	$2060
Year 3:	$2122
Year 4:	$2185
Year 5:	$2251

5. P.I. TRAVEL:

We estimate that investigators will, in total, travel to two national meetings per year, $1,500/meeting.

Year 1:	$3000
Year 2:	$3090
Year 3:	$3183
Year 4:	$3278
Year 5	$3377

6. OUTPATIENT CARE COSTS:

MRI scanning costs We have estimated that 210 children (160 XXX patients, 50 controls) may undergo structural MRI scans during this study, and an additional 45 children will undergo functional MRI in the latter two years of the study.

a) Structural MRI costs: While data should be easily and comfortably gathered from each child well within a 1 hour scanning session, 225 imaging sessions have been budgeted to allow for re-scanning children whose data sets may be marred by movement artifact. We have a negotiated rate of 25% of charges for MRIs funded by research grants from the NIH. Given the technical charges of $2,786 from brain MRI without contrast in 2008, our research rate per MRI scanning session is $697 in Year 01:

Year 1:	$697/patient x 49 =	$34,153
Year 2:	$718/patient x 65 =	$46,670
Year 3:	$739/patient x 65 =	$48,035
Year 4:	$762/patient x 46 =	$35,052

b) Functional MRI costs: Children will return for their functional MRIs in years 4 and 5. A total of 35 XXX patients will undergo functional MRI in Years 4 and 5. We will use previously-gathered data from control patients using a similar paradigm. Because some XXX subject's datasets may be marred by movement artifact, we have budgeted for 45 MRIs. The charge for functional MRI is $3,054 per study, and the NIH discounted rate (25%) will be $764/study in the current fiscal year. Assuming 3% inflation per year, we estimate costs as follows:

Year 4:	$835/patient X 20 =	$16,700
Year 5	$860/patient X 25 =	$21,500

c) Genetic testing: Each XXX patient will have a genetic testing that will comprise a chromosomal microarray (discounted cost): $664, Phlebotomy fee (GCRC): $16/person x3 (subject and parents): $48, and DNA extraction and storage

$24/sample x 3 (subject and parents): $72. Thus, the cost for genetic testing per subject will be $784/XXX subject. Microarrays will be done at the first evaluation, in an estimated 30 XXX patients in Year 1, 51 in Year 2, 50 in Year 3, and 29 in Year 4. Assuming a 3% increase in cost per year, calculations are as follows:

Year 1	$784/patient X 30 =	$23,520
Year 2	$808/patient X 51 =	$41,208
Year 3	$832/patient X 50 =	$41,600
Year 4	$857/patient X 29 =	$24,853

7. OTHER EXPENSES:

a) Patient Travel: We estimate that we will evaluate 30 XXX patients in Year 1, 51 in Year 2, 50 in Year 3, and 29 in Year 4 for the first part of the evaluation, involving structural MRI, neuropsychological evaluation, and genetics evaluation. Approximately 36% of patients will have to travel to Boston via air. The remaining patients reside in New England or New York State, and approximately half will require overnight stays at a local hotel. From our experience, we have estimated that the average airfare will be $700, hotel cost will be $168/night (2 nights), food allowance per day will be $55/person (one parent and child), and taxi from Boston Logan airport will be $40 each way. Costs for patients traveling by car from a distance are assumed to include two nights at a hotel; two days of food allowance; mileage (estimate 120 miles round trip @ $.585/mile); parking at $8/day (2 days); and all patients will receive a $100 stipend.

We estimate patient travel costs for the first visit as follows:

Year 1:	Air travel	11 pts x $2355/pt:	$25,906
	Land travel	19 pts x $961/pt:	$18,265
		Total:	$44,171
Year 2:	Air travel	18 pts x $2426/pt:	$43,668
	Land travel	33 pts x $990/pt:	$32,670
		Total:	$76,338
Year 3:	Air travel	18 pts x $2499/pt:	$44,982
	Land travel	32 pts X $1020/pt:	$32,640
		Total:	$77,622
Year 4:	Air travel	10 pts X $2574/pt:	$25,740
	Land travel	19 pts X $1050/pt:	$19,950
		Total:	$45,690

An additional 20 patients in Year 4 and 25 patients in Year 5 will come in for a few hours in the day for functional MRI. Because this is a brief visit, we have

budgeted for these patients as though they were traveling a short distance by car ($100 stipend, $8 parking, $15 mileage):

Year 4:	20 pts x $123/pt	= $2453
Year 5:	25 pts x $126/pt	= $3150

Control Group. A group of 75 adolescents will be recruited from a local pediatric practice. Each of these 75 adolescents will be paid $100 to participate in the two-day evaluation, as well as reimbursement for mileage ($35); parking for two days ($16) and lunch for child and parent for two days ($40).

Year 1:	25 pts x $191/pt	= $4778
Year 2:	20 pts x $197/pt	= $3940
Year 3:	20 pts x $203/pt	= $4060
Year 4:	10 pts x $209/pt	= $2090

b) Computing Costs: To update computer software for database management, and graphics (e.g., Stata, SAS, Sigma Plot)

Year 1:	$2000
Year 2:	$2060
Year 3:	$2122
Year 4:	$2185
Year 5:	$2251

c) Publication Costs: (cost of publication, graphic art, slides, presentations will increase in Years 4-5)

Year 1:	None
Year 2:	$ 500
Year 3:	$ 515
Year 4:	$1500
Year 5:	$2000

Personnel	Role	Base	Salary	Fringe	12/1/2009-11/31/2010 % Effort Yr 1	Year 1	12/1/2010-11/31/2011 % Effort Yr 2	Year 2	12/1/2011-11/31/2012 % Effort Yr 3	Year 3	12/1/2012-11/31/2013 % Effort Yr 4	Year 4	12/1/2013-11/31/2014 % Effort Yr 5	Year 5	
A	Co-PI	$191,300	$28,695	$8,609	15%	$37,304	15%	$37,304	15%	37,304	15%	37,304	15%	37,304	
B	Co-PI	$191,300	$28,695	$8,609	15%	$37,304	15%	$37,304	15%	37,304	15%	37,304	15%	37,304	
C	Co-Investigator in Neuropsychology	$139,050	$13,905	$4,172	10%	$18,077	10%	$18,619	10%	$19,177	10%	19,753	10%	20,345	
D	Co-Investigator in Psychiatry	$191,300	$9,565	$2,870	5%	$12,435	5%	$12,435	5%	12,435	5%	12,435	5%	12,435	
E	Co-Investigator in Developmental Pediatrics	$191,300	$5,739	$1,722	3%	$0	3%	$0	3%	0	3%	0	3%	0	
F	Co-Investigator in Genetics	$168,000	$8,400	$2,520	5%	$10,920	5%	$11,248	5%	$11,585	5%	11,933	5%	12,291	
G	Co-Investigator	$191,300	$5,739	$1,722	3%	$7,461	3%	$7,461	3%	$7,461	3%	$7,461	3%	$7,461	
H	Co-Investigator in Biostatistics	$142,397	$21,360	$6,408	15%	$27,767	10%	$19,067	10%	$19,639	10%	20,228	25%	52,087	
I	MR Physicist	$125,000	$12,500	$3,750	10%	$16,250	10%	$16,738	10%	$17,240	10%	17,757	10%	18,290	
J	Computer Engineer	$87,737	$6,142	$1,842	7%	$7,984	7%	$8,224	7%	$8,470	7%	8,724	7%	8,986	
K	Clinical Psychologist	$70,000	$10,500	$3,150	15%	$13,650	15%	$14,060	15%	$14,481	10%	9,944	5%	5,121	
L	Financial Admin	$38,000	$3,800	$1,140	10%	$4,940	10%	$5,088	10%	$5,241	10%	5,398	10%	5,560	
M	Data Coordinator	$63,944	$31,972	$9,592	50%	$41,563	50%	$42,810	50%	$44,095	50%	45,418	50%	46,780	
N	Programmer	$72,605	$18,151	$5,445	25%	$23,597	15%	$14,583	15%	$15,020	15%	15,471	25%	26,558	
O	RA	$30,000	$30,000	$9,000	100%	$39,000	100%	$40,170	100%	$41,375	100%	42,616	100%	43,895	
P	RA	$30,000	$15,000	$4,500	50%	$19,500	50%	$20,085	50%	$20,688	50%	21,308	50%	21,947	
Total Personnel Costs						**$317,753**		**$305,195**		**$311,514**		**$313,054**		**$356,364**	**$1,603,880**
Consultant						$0		$0		$0		$0		$0	
Equiptment						$0		$0		$0		$0		$0	
Supplies															
Developmental testing materials						$14,005		$0		$0		$0		$0	$14,005
MRI supplies						$3,695		$1,721		$1,743		$1,765		$1,788	$10,712
Misc office supplies						$2,000		$2,060		$2,122		$2,186		$2,252	$10,620
PI travel						$3,000		$3,090		$3,183		$3,278		$3,377	$15,928
Outpatient care costs															
MRIs						$34,153		$46,670		$48,035		$51,752		$21,500	$202,110
Genetics costs (microarray)						$23,520		$41,208		$41,600		$24,853		$0	$131,181
Other expenses															
Patient travel						$48,948		$80,278		$81,682		$50,233		$3,150	$264,291
Computing costs						$2,000		$2,060		$2,122		$2,185		$2,251	$10,618
Publication costs						$0		$500		$515		$1,500		$2,000	$4,515
Total direct costs						**$449,075**		**$482,782**		**$492,516**		**$450,805**		**$392,682**	**$2,267,860**
Indirect Costs (MTDC)															
Indirect Cost Base						$391,402		$394,904		$402,881		$374,200		$371,182	
	71% 10/1/09-9/30/10					231,579									
	72% 10/1/10-9/30/11					46,968		236,943							
	74% 10/1/11-9/30/12							48,705		$298,132		276,908		274,675	
Total Indirect Costs						**278,547**		**285,648**		**298,132**		**276,908**		**274,675**	**$1,413,910**
Total Costs (Direct and Indirect)						**$727,622**		**$768,430**		**$790,648**		**$727,713**		**$667,356**	**$3,681,770** **$ 3,674,844** **$ (6,926)**

Corporate Research Example

Protocol Title: A Phase 2 Trial
Company/Sponsor: Company B
PI: Dr. Name
SC/RN: Study Coordinator Name
Site Number: 051

VISIT DATE	Screening & Baseline	Day 1	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	TOTAL
Informed Consent	$ 75	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 75
Medical History	$ 100	$ 25	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 125
Complete PE	$ 150	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 150	$ -	$ -	$ 150	$ -	$ 450
Limited PE		$ 100	$ -	$ -	$ -	$ 100	$ -	$ 100		$ 100	$ 100		$ 100	$ 600
12-lead ECG	$ 100	$ 100	$ -	$ -	$ -	$ -	$ -	$ -	$ 100	$ -	$ -	$ 100	$ -	$ 400
Vital Signs (HR,BP,RR,Temp, Wt)	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 325
Safety Blood Draws	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 30	$ 390
Urine collection	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 260
MRI: R (Ferriscan) +T2* (cardiac and abdominal) & LVEF	$ 2,110	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 2,110	$ -	$ -	$ 2,110	$ -	$ 6,330
Principal Investigator	$ 200	$ 150	$ 75	$ 75	$ 75	$ 75	$ 75	$ 75	$ 200	$ 75	$ 75	$ 75	$ 100	$ 1,325
Study Nurse	$ 175	$ 120	$ 120	$ 120	$ 120	$ 140	$ 120	$ 120	$ 150	$ 120	$ 120	$ 150	$ 120	$ 1,695
Study Coordinator	$ 250	$ 100	$ 50	$ 50	$ 50	$ 100	$ 50	$ 50	$ 100	$ 50	$ 50	$ 100	$ 200	$ 1,200
Subtotal	**$ 3,235**	**$ 670**	**$ 320**	**$ 320**	**$ 320**	**$ 490**	**$ 320**	**$ 420**	**$ 2,885**	**$ 420**	**$ 420**	**$ 2,760**	**$ 595**	**$ 13,175**
Overhead (25%)	$ 809	$ 168	$ 80	$ 80	$ 80	$ 123	$ 80	$ 105	$ 721	$ 105	$ 105	$ 690	$ 149	$ 3,294
Patient costs	$ 50	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 25	$ 350
Total	**$ 4,094**	**$ 863**	**$ 425**	**$ 425**	**$ 425**	**$ 638**	**$ 425**	**$ 550**	**$ 3,631**	**$ 550**	**$ 550**	**$ 3,475**	**$ 769**	**$ 16,819**

Direct Costs:

Start up fee	$ 4,000.00
IRB Fees	$ 2,500.00
CTSU Fee	$ 2,500.00
Pharmacy Set up	$ 2,000.00
Pharmacy Dispensing	$ -
Close out fee	$ -
TOTAL	**$ 11,000.00**

References

Document Attributes

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