White Paper on Evaluation of Sampling Design Options for the National Children's Study

Appendix H

Detailed Summaries of Sample-Size- and Budget-Constrained Cost Estimates

In order to develop the cost estimates presented in Section 8, a number of assumptions were made in each of the seven major areas of work and for each of the four sampling frames. Section 8.3 introduced those assumptions and provided some discussion regarding potential changes that could be made to those assumptions. This appendix provides additional detail regarding the cost assumptions that were utilized and how those were derived for each of the seven major work areas.

I. Study Design and Start-Up

As noted in Section 8, the Study Design and Start-up area includes all costs involved with planning, designing, and implementing the study up to point when participant recruitment can begin at each Center and within each selected PSU. For costing purposes, these costs are applied to Year 0 (one year before recruitment begins) through Year 2. [In reality, Year 0 (representing all pre-recruitment activities) will likely take a longer period of time than one year.] We assumed there would be start-up costs in Year 1 and Year 2 as Centers and PSUs were established on a flow basis. Year 0 costs include:

- sampling strategy design,
- questionnaire and data collection tool development including pilot studies and focus groups,
- preparing OMB clearance materials and obtaining approval,
- preparing Quality Assurance Project Plans and Standard Operating Procedures,
- preparing training material, and
- selecting study centers, contractors, and other participating organizations.

Years 1 and 2 start-up activities may include:

- preparing IRB materials and participating in IRB reviews,
- delivering training to study personnel, and
- selecting study centers, contractors, and other participating organizations.

Within each major work area, we identified sets of fixed and variable costs. For the study design and start-up activities, the fixed costs represent all costs not linked to specific Centers or PSUs – sampling design, tool development, OMB clearance, developing training material, plan and implement pilot studies, etc. The level of fixed Year 0 study design costs was estimated at $10 million. These costs could be roughly distributed across the following activities as seen below:

Study Design Activity	Estimated Cost
Sampling strategy design	$2 million
Data collection tool development	$2 million
QAPP/SOP development	$.75 million
OMB clearance	$.25 million
Develop training material	$1 million
Develop and implement pilot studies	$4 million

As some of the tool development, sampling design, and pilot study work would continue during the early part of study implementation, we included $5 million for fixed study design costs in Year 1 and $2.5 million in Year 2, simply reducing the previous year's cost by half to address the reduced amount of costs required for the study design and start-up activities.

These fixed study design costs are distributed across the four potential sampling frames according to the percentage of total live births recruited from each of the frames. For example, in design option A1 in which 25 percent of the sample is recruited via a national probability-based sample (PBS), 18 percent via an Area PBS, 54 percent via a PBS of Center patients, and 3 percent via an opportunity sample, the annual fixed study design costs are distributed according to a 25/18/54/3 split among the four frames.

The variable costs for study design and start-up activities reflect specific costs incurred to implement each of the four sampling frames at a particular location – either a Center or PSU. Costs specific to a national PBS are those required to open an office for a selected area and hire employees. The variable costs for the three Center-based frames are calculated on a per-Center basis and distributed across the three frames based on the percentage of all Center-based participants recruited via each frame. These variable costs represent the cost to the government of issuing Requests for Proposal, reviewing proposals, selecting Centers, and potentially conducting separate IRB reviews at each Center. Our initial Year 0 variable cost estimates for establishing the necessary number of PSUs and Centers are $25,000 per PSU and $50,000 per Center. We also included Years 1 and 2 variable costs for training of data collectors and other study workers at a rate of $5,000 per PSU and Center for each of those years. This is an estimate of the cost for 2-3 trainers to perform a 2-3 day training session at each study location separately in both of the first two years. The second session would be to train any newly hired staff and also to review the accuracy of the protocols in use by previously trained staff.

II. Recruitment

Recruitment covers the work involved in selecting participants in each of the sampling frames, recruiting all participants, and operating study offices and centers for an estimated three years of study recruitment. The fixed costs of study recruitment are those required to operate study offices in each selected PSU and study Centers, as well. The Year 1 estimated costs are higher for both PSUs and Centers to account for equipment purchases, hiring costs, possible construction costs, and other costs associated with starting operation of the study in an area. We assumed that operation of national PBS offices would be significantly less expensive than operating at a Center because of potential overhead charges associated with hospitals or universities and the ability to establish National PBS office locations based partially on cost. Fixed costs for Centers are distributed across the three Center-based frames based on the percentage of all Center-based participants recruited via each frame. Estimated fixed costs for operating each PSU and Center are:

	Estimated Fixed Recruitment Costs	
Year	PSU	Center
1	$500,000	$750,000
2	$200,000	$500,000
3	$200,000	$500,000

We estimated the variable costs associated with recruiting participants on a per-live birth basis, i.e., the recruitment cost behind each live birth. These costs represent labor costs of recruiters

attempting to enroll women into the study. We established an estimate of $600 for recruiting a single participant into the national PBS. This was based on an assumption that 12 women will have to be contacted for each one that is recruited and that it will cost an average of $50 per contact. Women who decline participating in the study based on a single telephone call will cost less than the estimated $50, but women who require more follow-up before failing to participate (e.g., after reading the informed consent statement, or after a miscarriage) will likely cost more than $50. Thus, we settled on an initial estimate of $50 per contact.

Enrolling women into an Area PBS may be quite similar to recruitment for the national PBS, except that the association with a well-known medical center in the area may boost recruitment rates somewhat. For this reason, we used a slightly reduced cost of $500 per recruit for the Area PBS, i.e., we assumed it would require only 10 contacts per live birth in this frame. Recruiters are likely to be even more successful enrolling women into a PBS of Center patients because of the patients existing association with the Center. For this reason, we reduced our estimated recruitment costs to $250 per live birth for this group of recruits. For the volunteer sample, we assumed a cost of $50 per live birth based on the notion that only one contact would be required per recruited participant.

Regarding the number of live births per year, we assumed that one-third of all live births targeted for each sampling frame would be recruited in each of the first three years of the study. For simplicity, we did not begin to factor in estimated retention rates during this recruitment period. Thus, in Year 3 of the study, the cost models still have the full number of recruits participating, despite that fact that they would be ranging in age from 0 to 2 years old at that point.

III. Data Collection

The Data Collection cost area composes the majority of the resources required to conduct the study. This major work area includes the operation of study offices and Centers for the approximately 22 years following recruitment of all participants, as well as obtaining biological samples and other medical information, performing environmental assessments, conducting questionnaires and surveys, and performing QA/QC audits of data collection protocols over the approximately 25 years of study implementation.

Regarding fixed costs associated with data collection efforts, we assumed that this would include operating costs for all Centers and national PBS locations for Years 4 through 25 of the study. For Centers, we began with Year 4 operating expenses of $450,000 per Center (slightly lower than Years 2 and 3 because of the completion of recruitment work). These expenses cover labor costs for study coordinators and support staff, purchases of equipment and supplies, and rent or space charges. Following Year 4, we escalated the $450,000 per Center by three percent a year to account for inflation. For each PSU, we estimated $200,000 in Year 4 to operate a study office and pay for a local study coordinator, equipment, supplies, etc. We also factored in a three percent inflation rate in each subsequent year.

	Estimated Fixed Data Collection Costs	
Study Year	PSU	Center
4	$200,000	$450,000
5	$206,000	$463,500
6-25	*Escalated by 3% annually*	
25	$372,059	$837,133

We estimated variable costs for each data collection event, with separate costs specified for questionnaire-related data collection visits and visits for environmental and/or biological sample collection. There are two primary components of these variable costs – the number of data collection events and the cost of each event. To develop an estimate of the annual number of data collection visits, we made the following assumptions regarding the data collection protocol:

1) In each sampling frame, two data collection events occur per participant in each of the first two years in the study (pregnancy through Age 1) – completion of two questionnaires per year and two environmental/biological data collections each year.
2) All participants complete a questionnaire annually after their first 2 years in the study. Note that at Year 25 of the study, remaining participants would range in age from 22 to 24.
3) Environmental/biological sample collection occurs annually from participants third through fifth year in the study or from Age 2 to Age 4. Subsequently, environmental/biological samples are collected every three years.
4) Estimated retention rates reduce the number of participants beginning in Study Year 4 and in each subsequent year.

We assumed that more extensive surveys/questionnaires would be conducted in the beginning of the study as detailed information is collected on a participant's parents and pregnancy. On the other hand, we assumed that the environmental/biological data collection protocol would not change significantly over the course of the study. The table below reports our estimated per visit data collection costs.

	Estimated Data Collection Variable Costs per Event	
Year	Questionnaires/Surveys	Environmental/Biological
1	$200	$500
2	$200	$515
3	$200	$530
4	$100	$546
5-25	*Escalated by 3% annually*	
25	$186	$1,016

These costs include the cost of supplies, labor, equipment, etc. We also made the assumption that these cost estimates are the same for each sampling frame, which may not be the case in reality. The reasoning behind the $100 Year 4 estimate for conducting questionnaires is that the entire process of obtaining a completed questionnaire may take approximately four hours – an hour for scheduling, two hours for the actual visit since it may involve travel to a participant's home, and an hour for completing, processing, and shipping data collection forms associated

with the visit at an estimated $25 per hour. This was doubled to account for the more extensive survey in Years 1 through 3 (although perhaps doubling is unnecessary). Estimating a baseline cost of the environmental and biological data collection is difficult because we are not sure what types and how many samples will be collected. We estimated that $500 would cover environmental sampling at a participant's residence (including dust-wipes, visual assessment of environmental hazards, vacuum dust sampling, and perhaps soil sampling) and also collection of a blood and urine sample.

IV. Retention/Tracking

The Tracking component of this cost area involves maintaining participant addresses and contact information over the course of the study and notifying the appropriate organizations regarding participant moves. These Tracking costs compose the fixed portion of Retention/Tracking costs, in addition to general expenses for maintaining participants' involvement such as preparing newsletters, sending birthday and holiday cards, etc. We assumed that these activities would be performed by a single or small number of organizations for the entire study, and, thus, we distributed the costs across the four sampling frames annually based on the percentage of total participants maintained within each frame. For example, the percentage of the fixed costs allocated to the national PBS decreases over time as participants in this frame drop out at a higher rate. Over the full 25 years costed in the initial model, we estimated a total of $42 million for these activities. These were distributed over the 25 years according to the table below:

Study Year	Estimated Annual Fixed Retention/Tracking Cost
1	$500,000
2	$750,000
3	$1,000,000
4-9	*Escalated by 10% per year*
10-17	$1,948,717
18-20	*Escalated by 10% per year*
21	$2,593,742
22	$2,000,000
23-24	$1,500,000
25	$1,000,000
Total	$42.0 million

Note that we start these costs at a relatively low level and ramp them up over the first three years of the study because we assume all participants are not enrolled until Year 3. We then increased these expenses by 10 percent per year through Year 9 (instead of the standard three percent inflation rate we used for the other major work areas) because of the importance of keeping participants in the study over these early years of the study. If their participation can be maintained for a number of years, they may be more likely to stay in for the entire study. Thus, once we reached Year 10, we assumed a constant cost of nearly $2 million per year until participants start to reach college age. Once they do, tracking efforts likely will increase significantly. Thus, we factor in 10 percent increases over the next three years (Years 18-20 of the study), maintain that level for a year, and then begin to scale back as the combination of participants' maintaining stable college addresses, requiring less general encouragement to

participate, and reaching the end of the study requiring less resources for retention/tracking efforts.

The variable cost component of retention activities is calculated annually on a per participant basis. These variable costs represent incentives provided to participants and potential reimbursement for any expenses incurred such as travel or parking. For purposes of this initial costing model in which variable retention rates were utilized, we assume that the incentive structure is the same across each sampling frame. We assume a three-tiered model of incentives - $100, $150, and $200. Participants receive $100 per year through age 7, $150 per year from age 8 to age 17, and $200 per year from age 18 until they complete the study. The estimated level of expenses each year utilized in the model is listed below:

Study Year	Estimated Annual Incentive Cost (per participant)
1-8	$100
9	$125
10-18	$150
19	$175
20-25	$200

The levels in Year 9 and 19 represent those years when a portion of the cohort is moving to the next incentive level. A participant who maintains involvement in the study for the full possible period included in the cost model (that includes 25 years of implementation), i.e. from pre-birth to Age 24, would receive $3,700 in incentives under this structure. In this initial costing model, in Year 25 of the study, one-third of remaining participants would be age 24, one-third age 23, and one-third age 22.

V. Sample Analysis and Storage

This area is focused on the laboratory analysis of biological (blood, urine, hair, etc.) and environmental (dust, paint, soil, etc.) samples collected from study participants. This includes all chain-of-custody and data management work performed by laboratory personnel while conducting the analyses. The initial cost model for this work area includes only a variable cost component made up of laboratory sample analysis and sample storage. The sample analysis component is calculated on a per data collection visit basis, while the sample storage costs are calculated on a per sample basis. Assumptions related to calculating estimated sample analysis and storage costs include:

1) The number of data collection events occur according to the assumptions specified in the Data Collection work area.
2) The Year 1 cost of performing laboratory analysis of the samples collected per data collection visit is $300 for biological samples and $100 for environmental samples. These costs are escalated by three percent per year in subsequent years to account for inflation (ending up at a total of $813 in Year 25).
3) For storage purposes, we assume that four samples from each data collection visit will be stored.
4) All collected samples will be stored for the entire length of the study.
5) Cost of sample storage is $.10 per sample per year.

To provide an idea of the cost impact of the sample storage assumptions on the overall sample analysis and storage work area, in design option A1, sample storage over the life of the study accounts for $7.7 million out of a total cost of $538 million or about 1.5 percent of the cost in this area. Sample storage accounts for about the same percentage in the other design options as well.

VI. Data Management and Software Development

As noted in Section 8, this work area encompasses 1) development and maintenance of software and database tools required to conduct and manage the study (e.g. a project management system allowing tracking of recruitment and retention), 2) development and maintenance of a study website, 3) data entry and validation of all study data collection forms, 4) development, maintenance, and updating of study databases containing all data gathered over the course of the study, and 5) some initial data processing, analysis, and reporting. The initial cost model accounts for the various development and maintenance activities with the inclusion of a fixed cost component that is distributed across the four sampling frames according to the annual distribution of participants in these frames. This model is based on the assumption that there will be a central group or groups that handles these types of activities, i.e., that they will not be handled by individual Centers or local offices. The other variable activities such as data entry and validation are accounted for using a variable component calculated on a per data collection visit basis.

The fixed cost component is based on the following estimates for the resources needed to perform the various development activities:

Study Year	Estimated Annual Fixed Data Management and Software Development Cost
0	$3,000,000
1	$3,000,000
2	$2,000,000
3-25	*Escalated by 3% per year*
25	$3,947,173
Total	$74.9 million

The higher estimated costs in Study Years 0 and 1 reflect the increased level of effort required to complete the initial development of the various systems and databases needed to support the study. We assumed that by Year 2 of implementation there would be a significant reduction in the development effort.

Because each data collection event generates a set of data collection forms that require data entry and/or data that need cleaning, verification, and loading to study databases, as well as quality control on those processes, the Data Management variable cost component in the initial cost model is calculated on a per data collection event basis. Completion of an annual questionnaire/survey is considered a single data collection event. Similarly, completing environmental and biological sample collection is considered a single data collection event. The assumptions regarding the number of data collection events are detailed in subsection III above,

and include two questionnaire and two environmental/biological sample collection visits per year during the first two years in the study; annual questionnaires in all subsequent years; and annual environmental/biological sample collection visits until age 4 and once every three years subsequently. Our estimate of Year 1 cost of data management per data collection event is $50, which is subsequently escalated by three percent per year to account for inflation (ending at $102 per event in Year 25).

VII. Project Management

Our assumption was that this work area includes the federal government's cost to oversee and manage the study as well as the cost of central coordinating centers or organizations that may assist the government in coordinating all aspects of the study. All of these costs were included within a fixed cost component that was distributed across the four sampling frames annually according to the annual distribution of participants in these frames. For the federal government cost component, we used a base estimate of $5 million for Years 0 and 1. For the central coordinating component we used a base estimate of $2 million beginning in Year 1. We then escalated the combined $7 million Year 1 estimate by three percent in subsequent years, as seen below. The $260.2 million in Project Management costs are included in each design option. As noted in Section 8, this assumes that the different mixes of sampling frames used does not impact the level of project management required, an assumption that can be revised if necessary.

Study Year	Estimated Annual Fixed Project Management Cost
0	$5,000,000
1	$7,000,000
3-25	*Escalated by 3% per year*
25	$14,229,559
Total	$260.2 million

Detailed Summaries of Sample-Size-Constrained Cost Estimates

Sample Size-Constrained Design Option A1 - 100,000 Live Births					
National PBS	0	# of PSUs	0	Sample Sizes:	
Area PBS	0	# Centers	50	Year 5	96,924
PBS of Center Patients	97,000			Year 10	89,775
Volunteer Sample	3,000			Year 20	76,956
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$0.0	$19.9	$0.6	$20.5
Recruitment	$0.0	$0.0	$109.1	$52.9	$162.0
Data Collection	$0.0	$0.0	$1,716.2	$55.2	$1,771.3
Retention/Tracking	$0.0	$0.0	$327.4	$10.6	$338.0
Sample Analysis & Storage	$0.0	$0.0	$593.3	$18.9	$612.2
Data Management	$0.0	$0.0	$299.5	$9.6	$309.2
Project Management	$0.0	$0.0	$252.1	$8.1	$260.2
Total	$0.0	$0.0	$3,317.4	$155.9	$3,473.4

Sample Size-Constrained Design Option A2 - 100,000 Live Births					
National PBS	0	# of PSUs	0	Sample Sizes:	
Area PBS	0	# Centers	50	Year 5	97,300
PBS of Center Patients	50,000			Year 10	90,950
Volunteer Sample	50,000			Year 20	79,400
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$0.0	$10.3	$10.3	$20.5
Recruitment	$0.0	$0.0	$56.3	$46.3	$102.5
Data Collection	$0.0	$0.0	$876.7	$910.9	$1,787.6
Retention/Tracking	$0.0	$0.0	$168.3	$176.0	$344.3
Sample Analysis & Storage	$0.0	$0.0	$305.8	$314.9	$620.7
Data Management	$0.0	$0.0	$153.7	$159.7	$313.3
Project Management	$0.0	$0.0	$127.3	$133.0	$260.2
Total	$0.0	$0.0	$1,698.3	$1,750.9	$3,449.1

Sample Size-Constrained Design Option B3 - 100,000 Live Births					
National PBS	0	# of PSUs	0	Sample Sizes:	
Area PBS	24,000	# Centers	50	Year 5	94,868
PBS of Center Patients	72,000			Year 10	83,800
Volunteer Sample	4,000			Year 20	66,928
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$4.9	$14.8	$0.8	$20.5
Recruitment	$0.0	$33.0	$81.0	$40.0	$154.0
Data Collection	$0.0	$306.2	$1,330.0	$76.8	$1,713.0
Retention/Tracking	$0.0	$50.4	$246.1	$14.3	$310.8
Sample Analysis & Storage	$0.0	$109.7	$440.4	$25.2	$575.3
Data Management	$0.0	$50.5	$227.6	$13.1	$291.3
Project Management	$0.0	$42.0	$206.2	$12.0	$260.2
Total	$0.0	$596.8	$2,546.1	$182.3	$3,325.1

Sample Size-Constrained Design Option B4 - 100,000 Live Births					
National PBS	0	# of PSUs	0	Sample Sizes:	
Area PBS	48,000	# Centers	50	Year 5	92,804
PBS of Center Patients	48,000			Year 10	77,800
Volunteer Sample	4,000			Year 20	56,848
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$9.8	$9.8	$0.8	$20.5
Recruitment	$0.0	$66.0	$54.0	$27.2	$147.2
Data Collection	$0.0	$636.9	$936.2	$81.2	$1,654.4
Retention/Tracking	$0.0	$102.2	$166.8	$14.5	$283.6
Sample Analysis & Storage	$0.0	$219.5	$293.6	$25.2	$538.2
Data Management	$0.0	$103.3	$156.4	$13.6	$273.3
Project Management	$0.0	$92.4	$154.3	$13.5	$260.2
Total	$0.0	$1,230.2	$1,771.2	$176.0	$3,177.4

Sample Size-Constrained Design Option B5 - 100,000 Live Births					
National PBS	0	# of PSUs	0	Sample Sizes:	
Area PBS	72,000	# Centers	50	Year 5	90,740
PBS of Center Patients	24,000			Year 10	71,800
Volunteer Sample	4,000			Year 20	46,768
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$14.8	$4.9	$0.8	$20.5
Recruitment	$0.0	$99.0	$27.0	$14.4	$140.4
Data Collection	$0.0	$1,005.6	$502.8	$87.4	$1,595.7
Retention/Tracking	$0.0	$156.2	$85.3	$14.9	$256.3
Sample Analysis & Storage	$0.0	$329.2	$146.8	$25.2	$501.2
Data Management	$0.0	$159.7	$81.5	$14.1	$255.3
Project Management	$0.0	$155.7	$88.9	$15.6	$260.2
Total	$0.0	$1,920.1	$937.2	$172.4	$3,029.7

Sample Size-Constrained Design Option C6 - 100,000 Live Births					
National PBS	25,000	# of PSUs	50	Sample Sizes:	
Area PBS	18,000	# Centers	38	Year 5	92,551
PBS of Center Patients	54,000			Year 10	77,350
Volunteer Sample	3,000			Year 20	56,871
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$3.7	$11.1	$0.6	$21.5
Recruitment	$50.0	$25.0	$61.4	$30.4	$166.7
Data Collection	$499.4	$230.7	$1,003.0	$58.0	$1,791.0
Retention/Tracking	$46.2	$38.4	$187.7	$10.9	$283.2
Sample Analysis & Storage	$106.0	$82.3	$330.3	$18.9	$537.5
Data Management	$48.0	$38.8	$176.0	$10.2	$273.0
Project Management	$41.6	$34.7	$173.8	$10.1	$260.2
Total	$797.4	$453.5	$1,943.2	$139.0	$3,333.1

Sample Size-Constrained Design Option C7 - 100,000 Live Births					
National PBS	25,000	# of PSUs	50	Sample Sizes:	
Area PBS	36,000	# Centers	38	Year 5	91,003
PBS of Center Patients	36,000			Year 10	72,850
Volunteer Sample	3,000			Year 20	49,311
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.4	$7.4	$0.6	$21.5
Recruitment	$50.0	$49.9	$40.9	$20.6	$161.5
Data Collection	$499.4	$480.0	$706.3	$61.3	$1,747.1
Retention/Tracking	$46.8	$77.7	$127.2	$11.1	$262.8
Sample Analysis & Storage	$106.0	$164.6	$220.2	$18.9	$509.7
Data Management	$49.0	$79.2	$120.8	$10.5	$259.5
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$802.3	$934.4	$1,351.3	$134.2	$3,222.2

Sample Size-Constrained Design Option C8 - 100,000 Live Births					
National PBS	25,000	# of PSUs	50	Sample Sizes:	
Area PBS	54,000	# Centers	38	Year 5	89,455
PBS of Center Patients	18,000			Year 10	68,350
Volunteer Sample	3,000			Year 20	41,751
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$11.1	$3.7	$0.6	$21.5
Recruitment	$50.0	$74.9	$20.5	$10.9	$156.3
Data Collection	$499.4	$758.2	$379.5	$66.0	$1,703.1
Retention/Tracking	$47.5	$118.6	$64.9	$11.3	$242.3
Sample Analysis & Storage	$106.0	$246.9	$110.1	$18.9	$481.9
Data Management	$50.2	$122.2	$62.8	$10.9	$246.0
Project Management	$49.4	$125.4	$72.7	$12.7	$260.2
Total	$808.7	$1,457.2	$714.1	$131.3	$3,111.3

Sample Size-Constrained Design Option D9 - 100,000 Live Births					
National PBS	50,000	# of PSUs	50	Sample Sizes:	
Area PBS	12,000	# Centers	25	Year 5	90,234
PBS of Center Patients	36,000			Year 10	70,900
Volunteer Sample	2,000			Year 20	46,814
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$2.5	$7.4	$0.4	$20.8
Recruitment	$65.0	$16.5	$40.5	$20.0	$142.0
Data Collection	$693.4	$153.1	$665.0	$38.4	$1,549.9
Retention/Tracking	$94.1	$26.1	$128.0	$7.4	$255.5
Sample Analysis & Storage	$212.0	$54.9	$220.2	$12.6	$499.6
Data Management	$98.7	$26.6	$122.3	$7.1	$254.7
Project Management	$92.8	$26.0	$133.6	$7.8	$260.2
Total	$1,266.5	$305.6	$1,316.9	$93.7	$2,982.8

Sample Size-Constrained Design Option D10 - 100,000 Live Births					
National PBS	50,000	# of PSUs	50	Sample Sizes:	
Area PBS	24,000	# Centers	25	Year 5	89,202
PBS of Center Patients	24,000			Year 10	67,900
Volunteer Sample	2,000			Year 20	41,774
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$4.9	$4.9	$0.4	$20.8
Recruitment	$65.0	$33.0	$27.0	$13.6	$138.6
Data Collection	$693.4	$318.4	$468.1	$40.6	$1,520.6
Retention/Tracking	$95.1	$52.7	$86.6	$7.5	$241.9
Sample Analysis & Storage	$212.0	$109.7	$146.8	$12.6	$481.1
Data Management	$100.4	$54.3	$83.7	$7.3	$245.7
Project Management	$99.0	$55.8	$96.9	$8.5	$260.2
Total	$1,275.4	$628.9	$914.0	$90.5	$2,908.9

Sample Size-Constrained Design Option D11 - 100,000 Live Births					
National PBS	50,000	# of PSUs	50	Sample Sizes:	
Area PBS	36,000	# Centers	25	Year 5	88,170
PBS of Center Patients	12,000			Year 10	64,900
Volunteer Sample	2,000			Year 20	36,734
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$7.4	$2.5	$0.4	$20.8
Recruitment	$65.0	$49.5	$13.5	$7.2	$135.2
Data Collection	$693.4	$502.8	$251.4	$43.7	$1,491.3
Retention/Tracking	$96.3	$80.2	$44.1	$7.7	$228.3
Sample Analysis & Storage	$212.0	$164.6	$73.4	$12.6	$462.6
Data Management	$102.5	$83.4	$43.2	$7.5	$236.7
Project Management	$106.6	$90.7	$53.5	$9.4	$260.2
Total	$1,286.5	$978.6	$481.5	$88.5	$2,835.0

Sample Size-Constrained Design Option E12 - 100,000 Live Births					
National PBS	75,000	# of PSUs	50	Sample Sizes:	
Area PBS	6,000	# Centers	13	Year 5	87,917
PBS of Center Patients	18,000			Year 10	64,450
Volunteer Sample	1,000			Year 20	36,757
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$1.2	$3.7	$0.2	$20.0
Recruitment	$80.0	$8.5	$20.9	$10.4	$119.7
Data Collection	$887.5	$77.6	$338.0	$19.5	$1,322.6
Retention/Tracking	$144.6	$13.4	$66.1	$3.8	$227.9
Sample Analysis & Storage	$318.0	$27.4	$110.1	$6.3	$461.8
Data Management	$153.9	$13.9	$64.8	$3.8	$236.4
Project Management	$160.2	$15.1	$80.2	$4.7	$260.2
Total	$1,759.0	$157.1	$683.8	$48.7	$2,648.7

Sample Size-Constrained Design Option E13 - 100,000 Live Births					
National PBS	75,000	# of PSUs	50	Sample Sizes:	
Area PBS	12,000	# Centers	13	Year 5	87,401
PBS of Center Patients	12,000			Year 10	62,950
Volunteer Sample	1,000			Year 20	34,237
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$2.5	$2.5	$0.2	$20.0
Recruitment	$80.0	$16.9	$13.9	$7.0	$117.9
Data Collection	$887.5	$161.6	$238.2	$20.7	$1,307.9
Retention/Tracking	$145.7	$27.0	$44.5	$3.9	$221.1
Sample Analysis & Storage	$318.0	$54.9	$73.4	$6.3	$452.6
Data Management	$155.8	$28.2	$44.1	$3.8	$231.9
Project Management	$167.1	$31.7	$56.5	$5.0	$260.2
Total	$1,768.9	$322.7	$473.1	$46.9	$2,611.6

Sample Size-Constrained Design Option E14 - 100,000 Live Births					
National PBS	75,000	# of PSUs	50	Sample Sizes:	
Area PBS	18,000	# Centers	13	Year 5	86,885
PBS of Center Patients	6,000			Year 10	61,450
Volunteer Sample	1,000			Year 20	31,717
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$3.7	$1.2	$0.2	$20.0
Recruitment	$80.0	$25.4	$7.0	$3.7	$116.1
Data Collection	$887.5	$255.4	$128.1	$22.3	$1,293.3
Retention/Tracking	$146.9	$40.8	$22.5	$3.9	$214.3
Sample Analysis & Storage	$318.0	$82.3	$36.7	$6.3	$443.3
Data Management	$158.0	$43.0	$22.5	$3.9	$227.4
Project Management	$175.0	$50.0	$30.0	$5.3	$260.2
Total	$1,780.2	$500.6	$248.1	$45.6	$2,574.6

Sample Size-Constrained Design Option F15 - 100,000 Live Births					
National PBS	25,000	# of PSUs	100	Sample Sizes:	
Area PBS	18,000	# Centers	38	Year 5	92,551
PBS of Center Patients	54,000			Year 10	77,350
Volunteer Sample	3,000			Year 20	56,871
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$3.7	$11.1	$0.6	$23.3
Recruitment	$85.0	$25.0	$61.4	$30.4	$201.7
Data Collection	$804.8	$230.7	$1,003.0	$58.0	$2,096.4
Retention/Tracking	$46.2	$38.4	$187.7	$10.9	$283.2
Sample Analysis & Storage	$106.0	$82.3	$330.3	$18.9	$537.5
Data Management	$48.0	$38.8	$176.0	$10.2	$273.0
Project Management	$41.6	$34.7	$173.8	$10.1	$260.2
Total	$1,139.5	$453.5	$1,943.2	$139.0	$3,675.2

Sample Size-Constrained Design Option F16 - 100,000 Live Births					
National PBS	25,000	# of PSUs	100	Sample Sizes:	
Area PBS	36,000	# Centers	38	Year 5	91,003
PBS of Center Patients	36,000			Year 10	72,850
Volunteer Sample	3,000			Year 20	49,311
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$7.4	$7.4	$0.6	$23.3
Recruitment	$85.0	$49.9	$40.9	$20.6	$196.5
Data Collection	$804.8	$480.0	$706.3	$61.3	$2,052.4
Retention/Tracking	$46.8	$77.7	$127.2	$11.1	$262.8
Sample Analysis & Storage	$106.0	$164.6	$220.2	$18.9	$509.7
Data Management	$49.0	$79.2	$120.8	$10.5	$259.5
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$1,144.4	$934.4	$1,351.3	$134.2	$3,564.3

Sample Size-Constrained Design Option F17 - 100,000 Live Births					
National PBS	25,000	# of PSUs	100	Sample Sizes:	
Area PBS	54,000	# Centers	38	Year 5	89,455
PBS of Center Patients	18,000			Year 10	68,350
Volunteer Sample	3,000			Year 20	41,751
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$11.1	$3.7	$0.6	$23.3
Recruitment	$85.0	$74.9	$20.5	$10.9	$191.3
Data Collection	$804.8	$758.2	$379.5	$66.0	$2,008.4
Retention/Tracking	$47.5	$118.6	$64.9	$11.3	$242.3
Sample Analysis & Storage	$106.0	$246.9	$110.1	$18.9	$481.9
Data Management	$50.2	$122.2	$62.8	$10.9	$246.0
Project Management	$49.4	$125.4	$72.7	$12.7	$260.2
Total	$1,150.8	$1,457.2	$714.1	$131.3	$3,453.4

Sample Size-Constrained Design Option G18 - 100,000 Live Births					
National PBS	50,000	# of PSUs	100	Sample Sizes:	
Area PBS	12,000	# Centers	25	Year 5	90,234
PBS of Center Patients	36,000			Year 10	70,900
Volunteer Sample	2,000			Year 20	46,814
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$2.5	$7.4	$0.4	$22.5
Recruitment	$100.0	$16.5	$40.5	$20.0	$177.0
Data Collection	$998.8	$153.1	$665.0	$38.4	$1,855.3
Retention/Tracking	$94.1	$26.1	$128.0	$7.4	$255.5
Sample Analysis & Storage	$212.0	$54.9	$220.2	$12.6	$499.6
Data Management	$98.7	$26.6	$122.3	$7.1	$254.7
Project Management	$92.8	$26.0	$133.6	$7.8	$260.2
Total	$1,608.7	$305.6	$1,316.9	$93.7	$3,324.9

Sample Size-Constrained Design Option G19 - 100,000 Live Births					
National PBS	50,000	# of PSUs	100	Sample Sizes:	
Area PBS	24,000	# Centers	25	Year 5	89,202
PBS of Center Patients	24,000			Year 10	67,900
Volunteer Sample	2,000			Year 20	41,774
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$4.9	$4.9	$0.4	$22.5
Recruitment	$100.0	$33.0	$27.0	$13.6	$173.6
Data Collection	$998.8	$318.4	$468.1	$40.6	$1,826.0
Retention/Tracking	$95.1	$52.7	$86.6	$7.5	$241.9
Sample Analysis & Storage	$212.0	$109.7	$146.8	$12.6	$481.1
Data Management	$100.4	$54.3	$83.7	$7.3	$245.7
Project Management	$99.0	$55.8	$96.9	$8.5	$260.2
Total	$1,617.6	$628.9	$914.0	$90.5	$3,251.0

Sample Size-Constrained Design Option G20 - 100,000 Live Births					
National PBS	50,000	# of PSUs	100	Sample Sizes:	
Area PBS	36,000	# Centers	25	Year 5	88,170
PBS of Center Patients	12,000			Year 10	64,900
Volunteer Sample	2,000			Year 20	36,734
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$7.4	$2.5	$0.4	$22.5
Recruitment	$100.0	$49.5	$13.5	$7.2	$170.2
Data Collection	$998.8	$502.8	$251.4	$43.7	$1,796.7
Retention/Tracking	$96.3	$80.2	$44.1	$7.7	$228.3
Sample Analysis & Storage	$212.0	$164.6	$73.4	$12.6	$462.6
Data Management	$102.5	$83.4	$43.2	$7.5	$236.7
Project Management	$106.6	$90.7	$53.5	$9.4	$260.2
Total	$1,628.6	$978.6	$481.5	$88.5	$3,177.2

Sample Size-Constrained Design Option H21 - 100,000 Live Births					
National PBS	75,000	# of PSUs	100	Sample Sizes:	
Area PBS	6,000	# Centers	13	Year 5	87,917
PBS of Center Patients	18,000			Year 10	64,450
Volunteer Sample	1,000			Year 20	36,757
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$1.2	$3.7	$0.2	$21.8
Recruitment	$115.0	$8.5	$20.9	$10.4	$154.7
Data Collection	$1,192.8	$77.6	$338.0	$19.5	$1,628.0
Retention/Tracking	$144.6	$13.4	$66.1	$3.8	$227.9
Sample Analysis & Storage	$318.0	$27.4	$110.1	$6.3	$461.8
Data Management	$153.9	$13.9	$64.8	$3.8	$236.4
Project Management	$160.2	$15.1	$80.2	$4.7	$260.2
Total	$2,101.1	$157.1	$683.8	$48.7	$2,990.8

Sample Size-Constrained Design Option H22 - 100,000 Live Births					
National PBS	75,000	# of PSUs	100	Sample Sizes:	
Area PBS	12,000	# Centers	13	Year 5	87,401
PBS of Center Patients	12,000			Year 10	62,950
Volunteer Sample	1,000			Year 20	34,237
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$2.5	$2.5	$0.2	$21.8
Recruitment	$115.0	$16.9	$13.9	$7.0	$152.9
Data Collection	$1,192.8	$161.6	$238.2	$20.7	$1,613.3
Retention/Tracking	$145.7	$27.0	$44.5	$3.9	$221.1
Sample Analysis & Storage	$318.0	$54.9	$73.4	$6.3	$452.6
Data Management	$155.8	$28.2	$44.1	$3.8	$231.9
Project Management	$167.1	$31.7	$56.5	$5.0	$260.2
Total	$2,111.0	$322.7	$473.1	$46.9	$2,953.7

Sample Size-Constrained Design Option H23 - 100,000 Live Births					
National PBS	75,000	# of PSUs	100	Sample Sizes:	
Area PBS	18,000	# Centers	13	Year 5	86,885
PBS of Center Patients	6,000			Year 10	61,450
Volunteer Sample	1,000			Year 20	31,717
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$3.7	$1.2	$0.2	$21.8
Recruitment	$115.0	$25.4	$7.0	$3.7	$151.1
Data Collection	$1,192.8	$255.4	$128.1	$22.3	$1,598.6
Retention/Tracking	$146.9	$40.8	$22.5	$3.9	$214.3
Sample Analysis & Storage	$318.0	$82.3	$36.7	$6.3	$443.3
Data Management	$158.0	$43.0	$22.5	$3.9	$227.4
Project Management	$175.0	$50.0	$30.0	$5.3	$260.2
Total	$2,122.4	$500.6	$248.1	$45.6	$2,916.7

Sample Size-Constrained Design Option I24 - 100,000 Live Births					
National PBS*	25,000	# of PSUs	50	Sample Sizes:	
Area PBS*	36,000	# Centers	38	Year 5	91,003
PBS of Center Patients	36,000	*5% pre-conception		Year 10	72,850
Volunteer Sample	3,000			Year 20	49,311
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.4	$7.4	$0.6	$21.5
Recruitment	$50.0	$49.9	$40.9	$20.6	$161.5
Data Collection	$493.2	$471.1	$706.3	$61.3	$1,732.0
Retention/Tracking	$46.8	$77.7	$127.2	$11.1	$262.8
Sample Analysis & Storage	$106.0	$164.6	$220.2	$18.9	$509.7
Data Management	$49.0	$79.2	$120.8	$10.5	$259.5
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$796.1	$925.5	$1,351.3	$134.2	$3,207.1

Sample Size-Constrained Design Option I25 - 100,000 Live Births					
National PBS*	25,000	# of PSUs	50	Sample Sizes:	
Area PBS*	36,000	# Centers	38	Year 5	91,003
PBS of Center Patients	36,000	*25% pre-conception		Year 10	72,850
Volunteer Sample	3,000			Year 20	49,311
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.4	$7.4	$0.6	$21.5
Recruitment	$50.0	$49.9	$40.9	$20.6	$161.5
Data Collection	$518.0	$506.7	$706.3	$61.3	$1,792.4
Retention/Tracking	$46.8	$77.7	$127.2	$11.1	$262.8
Sample Analysis & Storage	$106.0	$164.6	$220.2	$18.9	$509.7
Data Management	$49.0	$79.2	$120.8	$10.5	$259.5
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$820.8	$961.1	$1,351.3	$134.2	$3,267.5

Detailed Summaries of Budget-Constrained Cost Estimates

Budget-Constrained Design Option A1 - 76750 Live Births					
National PBS (0%)	0	# of PSUs	0	Sample Sizes:	
Area PBS (0%)	0	# Centers	38	Year 5	74,389
PBS of Center Patients (97%)	74,448			Year 10	68,902
Volunteer Sample (3%)	2,303			Year 20	59,064
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$0.0	$19.2	$0.6	$19.8
Recruitment	$0.0	$0.0	$83.1	$40.2	$123.4
Data Collection	$0.0	$0.0	$1,312.2	$42.2	$1,354.3
Retention/Tracking	$0.0	$0.0	$256.4	$8.3	$264.7
Sample Analysis & Storage	$0.0	$0.0	$455.3	$14.5	$469.8
Data Management	$0.0	$0.0	$246.8	$7.9	$254.7
Project Management	$0.0	$0.0	$252.1	$8.1	$260.2
Total	$0.0	$0.0	$2,625.0	$121.9	$2,746.9

Budget-Constrained Design Option A2 - 75750 Live Births					
National PBS (0%)	0	# of PSUs	0	Sample Sizes:	
Area PBS (0%)	0	# Centers	38	Year 5	73,705
PBS of Center Patients (50%)	37,875			Year 10	68,895
Volunteer Sample (50%)	37,875			Year 20	60,146
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$0.0	$9.9	$9.9	$19.8
Recruitment	$0.0	$0.0	$42.7	$35.1	$77.9
Data Collection	$0.0	$0.0	$665.0	$690.9	$1,355.8
Retention/Tracking	$0.0	$0.0	$130.3	$136.2	$266.5
Sample Analysis & Storage	$0.0	$0.0	$231.7	$238.5	$470.2
Data Management	$0.0	$0.0	$125.3	$130.2	$255.5
Project Management	$0.0	$0.0	$127.3	$133.0	$260.2
Total	$0.0	$0.0	$1,332.0	$1,373.8	$2,705.8

Budget-Constrained Design Option B3 - 80000 Live Births					
National PBS (0%)	0	# of PSUs	0	Sample Sizes:	
Area PBS (24%)	19,200	# Centers	40	Year 5	75,894
PBS of Center Patients (72%)	57,600			Year 10	67,040
Volunteer Sample (4%)	3,200			Year 20	53,542
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$4.8	$14.3	$0.8	$19.9
Recruitment	$0.0	$26.4	$64.8	$32.0	$123.2
Data Collection	$0.0	$244.9	$1,064.0	$61.5	$1,370.4
Retention/Tracking	$0.0	$41.2	$200.2	$11.6	$253.0
Sample Analysis & Storage	$0.0	$87.8	$352.3	$20.2	$460.2
Data Management	$0.0	$42.9	$193.9	$11.2	$248.0
Project Management	$0.0	$42.0	$206.2	$12.0	$260.2
Total	$0.0	$490.0	$2,095.8	$149.2	$2,735.0

Budget-Constrained Design Option B4 - 84000 Live Births					
National PBS (0%)	0	# of PSUs	0	Sample Sizes:	
Area PBS (48%)	40,320	# Centers	42	Year 5	77,955
PBS of Center Patients (48%)	40,320			Year 10	65,352
Volunteer Sample (4%)	3,360			Year 20	47,752
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$9.6	$9.6	$0.8	$20.0
Recruitment	$0.0	$55.4	$45.4	$22.8	$123.6
Data Collection	$0.0	$535.0	$786.4	$68.2	$1,389.7
Retention/Tracking	$0.0	$87.2	$141.8	$12.4	$241.3
Sample Analysis & Storage	$0.0	$184.4	$246.6	$21.2	$452.1
Data Management	$0.0	$91.1	$138.5	$12.0	$241.5
Project Management	$0.0	$92.4	$154.3	$13.5	$260.2
Total	$0.0	$1,055.1	$1,522.6	$150.9	$2,728.5

Budget-Constrained Design Option B5 - 88000 Live Births					
National PBS (0%)	0	# of PSUs	0	Sample Sizes:	
Area PBS (72%)	63,360	# Centers	44	Year 5	79,851
PBS of Center Patients (24%)	21,120			Year 10	63,184
Volunteer Sample (4%)	3,520			Year 20	41,156
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$0.0	$14.5	$4.8	$0.8	$20.1
Recruitment	$0.0	$87.1	$23.8	$12.6	$123.5
Data Collection	$0.0	$884.9	$442.4	$76.9	$1,404.3
Retention/Tracking	$0.0	$138.8	$75.5	$13.2	$227.5
Sample Analysis & Storage	$0.0	$289.7	$129.2	$22.2	$441.0
Data Management	$0.0	$145.9	$74.7	$13.0	$233.7
Project Management	$0.0	$155.7	$88.9	$15.6	$260.2
Total	$0.0	$1,716.7	$839.4	$154.2	$2,710.3

Budget-Constrained Design Option C6 - 77000 Live Births					
National PBS (25%)	19,250	# of PSUs	50	Sample Sizes:	
Area PBS (18%)	13,860	# Centers	29	Year 5	71,264
PBS of Center Patients (54%)	41,580			Year 10	59,560
Volunteer Sample (3%)	2,310			Year 20	43,791
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$3.6	$10.7	$0.6	$21.0
Recruitment	$46.6	$19.1	$46.9	$23.2	$135.8
Data Collection	$454.8	$177.1	$769.4	$44.5	$1,445.8
Retention/Tracking	$36.7	$30.5	$148.6	$8.6	$224.4
Sample Analysis & Storage	$81.6	$63.4	$254.3	$14.5	$413.9
Data Management	$39.8	$32.2	$147.0	$8.5	$227.4
Project Management	$41.6	$34.7	$173.8	$10.1	$260.2
Total	$707.2	$360.5	$1,550.7	$110.0	$2,728.4

Budget-Constrained Design Option C7 - 80000 Live Births					
National PBS (25%)	20,000	# of PSUs	50	Sample Sizes:	
Area PBS (36%)	28,800	# Centers	30	Year 5	72,802
PBS of Center Patients (36%)	28,800			Year 10	58,280
Volunteer Sample (3%)	2,400			Year 20	39,449
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.2	$7.2	$0.6	$21.1
Recruitment	$47.0	$39.6	$32.4	$16.3	$135.3
Data Collection	$460.6	$382.1	$561.7	$48.7	$1,453.2
Retention/Tracking	$38.5	$63.9	$104.2	$9.1	$215.6
Sample Analysis & Storage	$84.8	$131.7	$176.1	$15.1	$407.7
Data Management	$41.8	$67.7	$104.0	$9.0	$222.6
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$723.8	$767.7	$1,114.1	$110.1	$2,715.7

Budget-Constrained Design Option C8 - 83500 Live Births					
National PBS (25%)	20,875	# of PSUs	50	Sample Sizes:	
Area PBS (54%)	45,090	# Centers	31	Year 5	74,695
PBS of Center Patients (18%)	15,030			Year 10	57,072
Volunteer Sample (3%)	2,505			Year 20	34,862
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$10.8	$3.6	$0.6	$21.1
Recruitment	$47.5	$61.6	$16.8	$8.9	$134.8
Data Collection	$467.4	$627.2	$313.3	$54.5	$1,462.4
Retention/Tracking	$40.6	$101.2	$55.3	$9.6	$206.6
Sample Analysis & Storage	$88.5	$206.2	$91.9	$15.8	$402.4
Data Management	$44.3	$108.0	$55.8	$9.7	$217.8
Project Management	$49.4	$125.4	$72.7	$12.7	$260.2
Total	$743.8	$1,240.3	$609.4	$111.8	$2,705.3

Budget-Constrained Design Option D9 - 88500 Live Births					
National PBS (50%)	44,250	# of PSUs	50	Sample Sizes:	
Area PBS (12%)	10,620	# Centers	22	Year 5	79,857
PBS of Center Patients (36%)	31,860			Year 10	62,747
Volunteer Sample (2%)	1,770			Year 20	41,430
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$2.4	$7.3	$0.4	$20.6
Recruitment	$61.6	$14.6	$35.7	$17.6	$129.4
Data Collection	$648.8	$135.2	$587.1	$33.9	$1,405.1
Retention/Tracking	$84.0	$23.3	$113.9	$6.6	$227.8
Sample Analysis & Storage	$187.6	$48.6	$194.9	$11.1	$442.2
Data Management	$90.5	$24.4	$112.6	$6.5	$234.0
Project Management	$92.8	$26.0	$133.6	$7.8	$260.2
Total	$1,175.8	$274.5	$1,185.0	$84.0	$2,719.3

Budget-Constrained Design Option D10 - 91000 Live Births					
National PBS (50%)	45,500	# of PSUs	50	Sample Sizes:	
Area PBS (24%)	21,840	# Centers	23	Year 5	81,174
PBS of Center Patients (24%)	21,840			Year 10	61,789
Volunteer Sample (2%)	1,820			Year 20	38,014
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$4.9	$4.9	$0.4	$20.6
Recruitment	$62.3	$30.2	$24.8	$12.5	$129.8
Data Collection	$658.5	$291.0	$428.1	$37.1	$1,414.7
Retention/Tracking	$87.0	$48.2	$78.9	$6.9	$221.0
Sample Analysis & Storage	$192.9	$99.9	$133.6	$11.5	$437.8
Data Management	$94.0	$50.9	$78.6	$6.8	$230.3
Project Management	$99.0	$55.8	$96.9	$8.5	$260.2
Total	$1,204.2	$580.8	$845.8	$83.7	$2,714.5

Budget-Constrained Design Option D11 - 94000 Live Births					
National PBS (50%)	47,000	# of PSUs	50	Sample Sizes:	
Area PBS (36%)	33,840	# Centers	24	Year 5	82,880
PBS of Center Patients (12%)	11,280			Year 10	61,006
Volunteer Sample (2%)	1,880			Year 20	34,530
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$10.5	$7.3	$2.4	$0.4	$20.7
Recruitment	$63.2	$47.2	$12.9	$6.9	$130.1
Data Collection	$670.2	$476.6	$238.7	$41.5	$1,427.0
Retention/Tracking	$90.6	$75.4	$41.3	$7.2	$214.5
Sample Analysis & Storage	$199.3	$154.7	$69.0	$11.8	$434.8
Data Management	$98.3	$80.0	$41.5	$7.2	$227.0
Project Management	$106.6	$90.7	$53.5	$9.4	$260.2
Total	$1,238.7	$932.0	$459.3	$84.4	$2,714.4

Budget-Constrained Design Option E12 - 104000 Live Births					
National PBS (75%)	78,000	# of PSUs	50	Sample Sizes:	
Area PBS (6%)	6,240	# Centers	13	Year 5	91,434
PBS of Center Patients (18%)	18,720			Year 10	67,028
Volunteer Sample (1%)	1,040			Year 20	38,227
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$1.2	$3.7	$0.2	$20.0
Recruitment	$81.8	$8.6	$21.1	$10.4	$121.8
Data Collection	$910.8	$79.6	$345.8	$20.0	$1,356.1
Retention/Tracking	$147.7	$13.6	$67.1	$3.9	$232.4
Sample Analysis & Storage	$330.7	$28.5	$114.5	$6.5	$480.3
Data Management	$158.2	$14.3	$66.5	$3.9	$242.9
Project Management	$160.2	$15.1	$80.2	$4.7	$260.2
Total	$1,804.3	$161.0	$698.9	$49.6	$2,713.8

Budget-Constrained Design Option E13 - 106000 Live Births					
National PBS (75%)	79,500	# of PSUs	50	Sample Sizes:	
Area PBS (12%)	12,720	# Centers	13	Year 5	92,645
PBS of Center Patients (12%)	12,720			Year 10	66,727
Volunteer Sample (1%)	1,060			Year 20	36,291
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$2.5	$2.5	$0.2	$20.0
Recruitment	$82.7	$17.3	$14.1	$7.1	$121.2
Data Collection	$922.4	$167.6	$246.0	$21.3	$1,357.4
Retention/Tracking	$151.2	$27.9	$45.9	$4.0	$229.0
Sample Analysis & Storage	$337.1	$58.2	$77.8	$6.7	$479.7
Data Management	$162.2	$29.4	$45.8	$4.0	$241.3
Project Management	$167.1	$31.7	$56.5	$5.0	$260.2
Total	$1,837.5	$334.5	$488.6	$48.2	$2,708.9

Budget-Constrained Design Option E14 - 107500 Live Births					
National PBS (75%)	80,625	# of PSUs	50	Sample Sizes:	
Area PBS (18%)	19,350	# Centers	13	Year 5	93,401
PBS of Center Patients (6%)	6,450			Year 10	66,059
Volunteer Sample (1%)	1,075			Year 20	34,096
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$14.9	$3.7	$1.2	$0.2	$20.0
Recruitment	$83.4	$26.1	$7.1	$3.7	$120.2
Data Collection	$931.1	$266.7	$133.0	$23.1	$1,354.0
Retention/Tracking	$154.2	$42.8	$23.5	$4.1	$224.6
Sample Analysis & Storage	$341.9	$88.5	$39.4	$6.8	$476.5
Data Management	$166.0	$45.1	$23.6	$4.1	$238.9
Project Management	$175.0	$50.0	$30.0	$5.3	$260.2
Total	$1,866.4	$522.9	$257.8	$47.3	$2,694.4

Budget-Constrained Design Option F15 - 63000 Live Births					
National PBS (25%)	15,750	# of PSUs	100	Sample Sizes:	
Area PBS (18%)	11,340	# Centers	24	Year 5	58,307
PBS of Center Patients (54%)	34,020			Year 10	48,731
Volunteer Sample (3%)	1,890			Year 20	35,829
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$3.5	$10.5	$0.6	$22.4
Recruitment	$79.5	$15.8	$38.7	$19.2	$153.1
Data Collection	$733.0	$145.5	$632.5	$36.6	$1,547.5
Retention/Tracking	$31.3	$25.9	$126.7	$7.4	$191.2
Sample Analysis & Storage	$66.8	$51.8	$208.1	$11.9	$338.6
Data Management	$34.8	$28.2	$129.3	$7.5	$199.7
Project Management	$41.6	$34.7	$173.8	$10.1	$260.2
Total	$994.7	$305.4	$1,319.6	$93.2	$2,712.8

Budget-Constrained Design Option F16 - 66000 Live Births					
National PBS (25%)	16,500	# of PSUs	100	Sample Sizes:	
Area PBS (36%)	23,760	# Centers	25	Year 5	60,062
PBS of Center Patients (36%)	23,760			Year 10	48,081
Volunteer Sample (3%)	1,980			Year 20	32,545
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$7.0	$7.0	$0.6	$22.5
Recruitment	$79.9	$32.9	$26.9	$13.6	$153.3
Data Collection	$738.8	$316.4	$465.5	$40.4	$1,561.2
Retention/Tracking	$33.0	$54.8	$89.6	$7.8	$185.2
Sample Analysis & Storage	$70.0	$108.6	$145.3	$12.5	$336.4
Data Management	$36.8	$59.7	$92.2	$8.0	$196.7
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$1,011.3	$655.1	$955.0	$94.1	$2,715.5

Budget-Constrained Design Option F17 - 69000 Live Births					
National PBS (25%)	17,250	# of PSUs	100	Sample Sizes:	
Area PBS (54%)	37,260	# Centers	26	Year 5	61,724
PBS of Center Patients (18%)	12,420			Year 10	47,162
Volunteer Sample (3%)	2,070			Year 20	28,808
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$7.9	$10.6	$3.5	$0.6	$22.6
Recruitment	$80.4	$51.4	$14.0	$7.5	$153.2
Data Collection	$744.6	$521.4	$260.8	$45.3	$1,572.1
Retention/Tracking	$34.9	$87.1	$47.7	$8.3	$178.0
Sample Analysis & Storage	$73.1	$170.4	$76.0	$13.0	$332.5
Data Management	$39.1	$95.5	$49.7	$8.6	$193.0
Project Management	$49.4	$125.4	$72.7	$12.7	$260.2
Total	$1,029.4	$1,061.7	$524.4	$96.1	$2,711.6

Budget-Constrained Design Option G18 - 73000 Live Births					
National PBS (50%)	36,500	# of PSUs	100	Sample Sizes:	
Area PBS (12%)	8,760	# Centers	18	Year 5	65,871
PBS of Center Patients (36%)	26,280			Year 10	51,757
Volunteer Sample (2%)	1,460			Year 20	34,174
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$2.4	$7.1	$0.4	$22.1
Recruitment	$91.9	$11.9	$29.3	$14.4	$147.5
Data Collection	$894.0	$111.2	$482.7	$27.9	$1,515.8
Retention/Tracking	$71.9	$19.9	$97.7	$5.7	$195.3
Sample Analysis & Storage	$154.8	$40.1	$160.7	$9.2	$364.7
Data Management	$79.4	$21.5	$99.5	$5.8	$206.1
Project Management	$92.8	$26.0	$133.6	$7.8	$260.2
Total	$1,397.1	$233.0	$1,010.6	$71.1	$2,711.8

Budget-Constrained Design Option G19 - 75000 Live Births					
National PBS (50%)	37,500	# of PSUs	100	Sample Sizes:	
Area PBS (24%)	18,000	# Centers	19	Year 5	66,902
PBS of Center Patients (24%)	18,000			Year 10	50,925
Volunteer Sample (2%)	1,500			Year 20	31,331
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$4.7	$4.7	$0.4	$22.1
Recruitment	$92.5	$25.0	$20.5	$10.3	$148.2
Data Collection	$901.8	$240.0	$353.2	$30.6	$1,525.6
Retention/Tracking	$74.5	$41.3	$67.8	$5.9	$189.6
Sample Analysis & Storage	$159.0	$82.3	$110.1	$9.4	$360.8
Data Management	$82.5	$44.8	$69.7	$6.1	$203.0
Project Management	$99.0	$55.8	$96.9	$8.5	$260.2
Total	$1,421.6	$493.9	$722.8	$71.3	$2,709.6

Budget-Constrained Design Option G20 - 77500 Live Births					
National PBS (50%)	38,750	# of PSUs	100	Sample Sizes:	
Area PBS (36%)	27,900	# Centers	19	Year 5	68,332
PBS of Center Patients (12%)	9,300			Year 10	50,298
Volunteer Sample (2%)	1,550			Year 20	28,469
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$12.3	$7.1	$2.4	$0.4	$22.1
Recruitment	$93.3	$37.9	$10.3	$5.5	$146.9
Data Collection	$911.5	$386.7	$193.0	$33.5	$1,524.7
Retention/Tracking	$77.7	$64.7	$35.5	$6.2	$184.2
Sample Analysis & Storage	$164.3	$127.6	$56.9	$9.8	$358.5
Data Management	$86.4	$70.5	$36.9	$6.4	$200.3
Project Management	$106.6	$90.7	$53.5	$9.4	$260.2
Total	$1,452.1	$785.2	$388.5	$71.2	$2,697.0

Budget-Constrained Design Option H21 - 85500 Live Births					
National PBS (75%)	64,125	# of PSUs	100	Sample Sizes:	
Area PBS (6%)	5,130	# Centers	11	Year 5	75,169
PBS of Center Patients (18%)	15,390			Year 10	55,105
Volunteer Sample (1%)	855			Year 20	31,427
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$1.2	$3.6	$0.2	$21.7
Recruitment	$108.5	$7.2	$17.7	$8.8	$142.1
Data Collection	$1,108.4	$66.1	$287.7	$16.6	$1,478.9
Retention/Tracking	$126.0	$11.7	$57.5	$3.3	$198.5
Sample Analysis & Storage	$271.9	$23.5	$94.1	$5.4	$394.9
Data Management	$138.3	$12.5	$58.7	$3.4	$213.0
Project Management	$160.2	$15.1	$80.2	$4.7	$260.2
Total	$1,930.0	$137.3	$599.6	$42.4	$2,709.3

Budget-Constrained Design Option H22 - 87000 Live Births					
National PBS (75%)	65,250	# of PSUs	100	Sample Sizes:	
Area PBS (12%)	10,440	# Centers	11	Year 5	76,039
PBS of Center Patients (12%)	10,440			Year 10	54,767
Volunteer Sample (1%)	870			Year 20	29,786
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$2.4	$2.4	$0.2	$21.7
Recruitment	$109.2	$14.5	$11.9	$6.0	$141.4
Data Collection	$1,117.2	$139.1	$204.7	$17.8	$1,478.7
Retention/Tracking	$128.9	$23.9	$39.3	$3.4	$195.5
Sample Analysis & Storage	$276.7	$47.7	$63.9	$5.5	$393.7
Data Management	$141.8	$25.7	$40.4	$3.5	$211.5
Project Management	$167.1	$31.7	$56.5	$5.0	$260.2
Total	$1,957.4	$285.0	$419.0	$41.3	$2,702.8

Budget-Constrained Design Option H23 - 89000 Live Births					
National PBS (75%)	66,750	# of PSUs	100	Sample Sizes:	
Area PBS (18%)	16,020	# Centers	11	Year 5	77,328
PBS of Center Patients (6%)	5,340			Year 10	54,691
Volunteer Sample (1%)	890			Year 20	28,228
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$16.6	$3.6	$1.2	$0.2	$21.7
Recruitment	$110.1	$21.9	$6.0	$3.2	$141.0
Data Collection	$1,128.8	$222.7	$111.3	$19.3	$1,482.1
Retention/Tracking	$132.5	$36.8	$20.3	$3.5	$193.1
Sample Analysis & Storage	$283.0	$73.2	$32.7	$5.6	$394.5
Data Management	$146.2	$39.8	$21.0	$3.7	$210.6
Project Management	$175.0	$50.0	$30.0	$5.3	$260.2
Total	$1,992.2	$448.1	$222.4	$40.8	$2,703.4

Budget-Constrained Design Option I24 - 80500 Live Births					
National PBS (25%)*	20,125	# of PSUs	50	Sample Sizes:	
Area PBS (36%)*	28,980	# Centers	30	Year 5	73,257
PBS of Center Patients (36%)	28,980	*5% pre-conception		Year 10	58,644
Volunteer Sample (3%)	2,415			Year 20	39,695
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.2	$7.2	$0.6	$21.1
Recruitment	$47.1	$39.7	$32.4	$16.3	$135.5
Data Collection	$456.6	$376.5	$563.7	$48.9	$1,445.7
Retention/Tracking	$38.7	$64.2	$104.7	$9.1	$216.7
Sample Analysis & Storage	$85.3	$132.5	$177.2	$15.2	$410.3
Data Management	$42.0	$68.0	$104.4	$9.1	$223.5
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$720.8	$763.6	$1,118.1	$110.5	$2,712.9

Budget-Constrained Design Option I25 - 78500 Live Births					
National PBS (25%)*	19,625	# of PSUs	50	Sample Sizes:	
Area PBS (36%)*	28,260	# Centers	29	Year 5	71,437
PBS of Center Patients (36%)	28,260	*25% pre-conception		Year 10	57,187
Volunteer Sample (3%)	2,355			Year 20	38,709
Major Work Area	**NPBS**	**Area PBS**	**Patients**	**Volunteer**	**Total**
Study Design & Start-up	$6.1	$7.1	$7.1	$0.6	$21.0
Recruitment	$46.8	$38.5	$31.4	$15.8	$132.5
Data Collection	$472.3	$393.9	$547.6	$47.5	$1,461.2
Retention/Tracking	$37.9	$62.9	$102.6	$8.9	$212.4
Sample Analysis & Storage	$83.2	$129.2	$172.8	$14.8	$400.1
Data Management	$41.3	$66.9	$102.7	$8.9	$219.8
Project Management	$45.0	$75.5	$128.4	$11.2	$260.2
Total	$732.5	$774.1	$1,092.8	$107.8	$2,707.2