BUDGET JUSTIFICATION

PERSONNEL

An organizational chart for the Clever Name Study team is shown in Figure 5 on page 72.

Jane Best, MD, PhD, Principal Investigator (30% Effort Year 1 & 5, 20% Effort Years 2-4) is faculty in the departments of Excess Curiosity and Medicine. She is the PI for the Clever Name Study. She has the majority of her time allocated for research. For this project, she will partner with Dr. Great, who will function as co-PI to direct all aspects of study operation. They are both located at the Center for Clever Research and will work closely with the investigator team and study staff. Dr. Great will provide a very high level of day-to-day supervision given the complexity of the study, and Dr. Best will have ultimate responsibility for conduct of the study. Dr. Best has expertise in using clinical diagnostic tools, such as ultrasound and CGH for genetic testing, in the context of research. She also has extensive experience from multiple studies in developing systems for abstraction of both office and hospital records from multiple practice sites which requires methods that assure both detail and uniformity of methods across varied record formats. She will be responsible for abstractor training and oversight. She has designed and supervised imaging protocols for [purposes identical to the Clever Name Study], including training and quality control protocols. She also has significant experience in community-based recruitment of study participants. She will oversee all aspects of finalizing study protocols and implementing the proposed research including training, quality control metrics, and maximizing utilization of study data. The latter will include involving graduate and postdoctoral trainees from [relevant programs]. With Dr. Great, she will lead twice monthly investigator team meetings, participate in weekly staff and data quality meetings, and coordinate the team of investigators for analysis of the data and publication of results.

Michelle F. Great, PhD, Co-PI (40% Effort Year 1 & 5, 25% Effort Years 2-4) is faculty in the department of Excess Curiosity and in the Really Good Stuff Imaging Institute. She directs the Methods Core for the Center for Clever Research and has collaborated with Dr. Best for more than three years. She will orchestrate the array of activities required for this study, including coordination of posting positions and hiring new staff, participant recruitment, data management, and quality assurance checks. She will have ready, daily access to Dr. Best as required. Dr. Great will work with the Senior Data Manager to finalize adaptation of the existing web-based diary and reminder system and will interface with the Survey Research Unit to monitor the telephone audio computer assisted survey interview (T-ACASI) system. She will be responsible for surveillance of study quality metrics in collaboration with the Senior Data Manager. Over the course of the study, she will have primary responsibility for finalizing operational definitions related to [dangerous substance] exposure including constructing cumulative exposure window "dose" estimates, creating data-driven definitions of patterns of exposure, and for conducting analysis of the reliability of recalled [dangerous substance] use. Dr. Great will be the primary interface between the Clever Name Study and the Outstanding Department regarding preparation and analysis of tissue specimens and with the [Name] Core Lab for a biomarker validation substudy of self-reported [dangerous substance] exposure. She will also continue substantive involvement with graduate student trainees. She will chair weekly meetings of key staff and bi-weekly data quality meetings. With Dr. Best, she will lead the team of investigators for the analysis of the data and publication of results.

Arthur V. Senior, PhD, Co-Investigator (5% Effort Year 1, 2% Effort Years 2-4, 10% in Year 5) is faculty in the School of Public Health, and division chief of Clever Methods. He is a nationally recognized researcher in [relevant content area] with substantial experience in the study of [this study's exposure and outcomes]. He will provide guidance as needed with troubleshooting challenges that could arise, consultation at critical decision nodes, and additional expertise related to statistical analysis of Aim 3. He will provide review of final standardized operating procedures and participate in twice monthly investigator meetings and in data quality control meetings. His time on the study is weighted to assure ample involvement in the early phases and in fully examining the wealth of data that will be available as the conclusion of the study approaches. He will be directly involved in analysis of data and publication of results.

Amy B. Awesome, PhD, Co-Investigator (20% Effort Year 1, 5% Effort Years 2-4, 30% Effort Year 5) is faculty in Biostatistics. She will provide statistical guidance and expertise regarding study sampling methods, procedures, and analysis. In Year 1, she will assist with design and implementation of the computerized probability-based sampling system to be used to over-sample likely [dangerous substance] users relative to their proportion among callers screened for the study. She will also advise on refinements to the tracking system and data linkage structures. She will oversee analysis of data, including interim quality and consistency checks. Ultimately, she will assist with taking into account consideration of design effects, including proper

calculation of variance associated with repeated measures and re-enrollments, and selecting appropriate models for addressing aspects of longitudinal data. She will also assist with fitting splines for flexible modeling of covariate effects and address issues that may arise due to missing data. She will be directly involved in analysis of data and publication of results. Her time on the study is also weighted to assure ample involvement in the early phases and the fullest possible use of the wealth of data obtained during the study.

Christina Marvel, MPH, Study Manager (45% Effort Year 1; 30% in Years 2-5) has 12 years' experience in public health research and practice. She will work under the direction of the Principal and Co-Investigators and will be responsible for overseeing the day-to-day administration of this study. This includes: 1) finalizing study documents including questionnaires, data collection forms, and process tracking systems, and preparing and revising as needed all written data collection and management protocols; 2) supervising field staff; 3) keeping all co-investigators apprised of the study status, including preparation of a monthly update for all investigators; 4) coordinating co-investigator activities so that study priorities are clear and protocols are thoroughly reviewed by appropriate individuals; 5) coordinating and overseeing field activities at each clinic site; 6) supervising financial management of the project including contact with all university budget and grant offices as needed; 7) serving as the primary contact with the university and study site institutional review boards; and 8) scheduling and keeping notes of study staff and investigator meetings.

Dave Thoughtful, Senior Data Manager (65% Effort Year 1, 15% Effort Years 2-4, 50% Effort Year 5) has more than 11 years' experience as the lead programmer for large prospective studies. Mr. Thoughtful will finalize the design the data architecture and user interface for the web-based diary and automated reminder system currently in use in our pilot work. He will subsequently oversee implementation and testing of the system. He will coordinate necessary changes to our computerized study tracking system for the Clever Name Study. As needed, he will develop, refine, and monitor methods for data collection, entry, and transfer from the study sites to the study office, integrate data streams as they are established, and have responsibility for working with investigators in the construction of variables and data analysis. He will have primary responsibility for assuring the highest possible quality of data documentation. He will be the primary liaison between Clever Name and Excellent Institute to ensure that data transfer is timely and secure. He will assist the Study Manager with preparation of monthly progress and data QC reports and participate in both staff and investigator meetings.

Diana Most, MPH, Study Coordinator (80% Effort in Year 1, 100% Effort Years 2-4, 50% Effort in Year 5) has three years of human participant research experience, including work on the Clever Name pilot phase. She will implement the study protocol in the 15-county study region. She will work under the direction of the Study Manager and with the assistance of the entire study team to enroll 64 women per month by telephone, log information in the study tracking system, oversee consent and enrollment, coordinate imaging with the staff, and maintain relations at a local level with care providers. She will be responsible for managing all correspondence, maintaining study files, formatting study instruments (questionnaires, data forms, etc.), distributing materials to investigators and staff, purchasing supplies, and processing travel forms. She will work with the research assistants to align imaging and telephone interview schedules and coordinate other activities such as record review and study outreach. Ms. Most will also prepare and distribute the participant newsletter to current and past participants and a study newsletter to all collaborating clinics, businesses, and interviewing staff based at Excellent Institute.

Jude Wonder, Recruitment Specialist (100% Effort for 8 months in Year 1, 100% Effort Years 2-4, 0% Effort Year 5) will work under the direction of the study coordinator. She will meet with 16 participants per week (on average) to obtain signed informed consent and acquaint them with the daily diary system. She will distribute promotional materials to medical practices, drug stores, other retail outlets and community organizations such as library, YMCA, day care centers, nursing lounges at local hospitals and so forth. She will assist with production of the study newsletters and with preparation of recruitment reports. When the study is notified of a loss with an available specimen, she will collect specimens for processing.

Erika Honor, Research Assistant (80% in Year 1, 100% in Years 2-4, 50% in Year 5) will staff the screening and enrollment phone line, including conducting the intake interview. With approximately 300 women completing diaries on any given day, a significant portion of her time will be dedicated to positively engaging and encouraging the minority of participants who are not optimally reporting diary data. She will be responsible for tracking imaging documentation and for verifying attendance at appointments as scheduled. She will oversee prompt return of faxes and imaging originals and verify legibility and completeness of materials including photo documentation and cloud upload as they are logged. She will assist with data entry of imaging

results and with preparation of monthly imaging reports. In addition, she will assist with recruitment support in the surrounding communities.

TBN, Programmer (40% in Year 1, 65% in Years 2-3, 70% in Year 4, 80% in Year 5). The study programmer will be responsible for setting up the telephone-based diary system, managing the data flowing from both the phone and web-based systems, and monitoring regular backup procedures. Under the direction of the Senior Data Manager, the programmer will implement changes to and maintenance of the tracking system, screening, enrollment, intake and positive pregnancy test interviews. The programmer will assist with implementation and testing of the final web-based diary system and ensure that it has adequate capacity for the number of participants who are enrolled at any given time. The programmer will have primary responsibility for developing reports to track participant progress and recruitment targets as well as ongoing data cleaning and quality assurance checks.

Crystal Kleer, Research Imaging Technician (50% Effort for 6 months in Year 1, 50% Effort Years 2-4, 50% Effort for 2 months in Year 5) will conduct imaging for study participants. She will oversee imaging scheduling across the imaging sites including cross-coverage of staff and sites as required by changes in recruitment volume and by vacation and leave schedules. She will be responsible for initiating an additional imaging site in the western counties of the extended study region, which includes securing both site agreements and equipment leases. She will implement imaging-related coding, reporting, and calibration activities, and will coordinate the annual imaging technician training and calibration technique meeting. She will assist as needed with cleaning and verifying imaging data.

Sophia Determined, MD, MPH, Medical Record Abstractor (0% Effort Year 1, 10% Effort Years 2-4, 20% Effort Year 5) is a retired physician with four years of experience conducting and supervising abstraction of medical records, including both outpatient and inpatient records, and hospital records for emergency visits. She will go to the hospitals and private clinics and abstract patient records related to pregnancy losses using a computerized medical records abstraction form which we are currently piloting in two hospitals and our own clinics.

Fringe Benefits vary by job classification and are noted in each individual's salary support calculations. Fringe includes combined social security and retirement plus the institutional contribution to health insurance coverage, weighted for effort. Fringe benefits for Dr. Best are mandated to include an additional 5.5% of salary and $1,800 per year for supplemental insurance.

CONSULTANTS

Donna D. Clever, MPH, PhD, Co-Investigator (Unpaid Consultant) is a Senior Epidemiologist at the National Institute of Environmental Health Science. She has a longstanding interest and special expertise in the study of exposures and outcomes being investigated in the Clever Name Study. Dr. Clever will consult on refinements and additions to interviews, contribute to design of an algorithm to classify categories of outcomes, contribute to analysis of daily diary reporting, and consult on aspects of data analyses. She has particular interest in methodologic aspects of exposure to [dangerous substance] as well as multivariable survival modeling and in analysis of longitudinal data. She will participate in twice-monthly investigator meetings and be directly involved in preparation of publications (see letter of support).

EQUIPMENT: None

SUPPLIES

Photocopying costs for study forms and internal study communication are $50 per month in each year of the study. (Costs associated with printing recruitment materials are described below.)

Computer Supplies for the study will require upgrade of hardware and software at $600 per year for maintaining the study administration database for use by the study coordinator. $3400 in Year 1 for 2 computers for study staff use.

Pregnancy Test Kits will be purchased in bulk at a price of $1.50 each for use prior to imaging. Based on projected enrollment in each year, we will require approximately 1023 kits in Year 1, 1890 kits in Year 2, 1890 in Year 3, and 1497 kits in Year 4.

TRAVEL

An investigator will make one trip to a meeting that includes the sponsoring institute to discuss progress and present preliminary results in Years 1-4. In order for multiple investigators to present final results in Year 5, four trips are included. Costs are estimated at Airfare: $1,200 per trip; Hotel/per diem: 2 days at $100/day = $200 plus $100 for ground transportation for a total of $1,250 in Years 1-3, $3,000 for two trips in year 4 and $6,000 for four trips in Year 5.

The cost of travel to obtain written informed consent from participants is estimated based on an average of 37 miles round trip X $0.405 per mile X 341 new participants in Year 1, 630 in Years 2 & 3, and 499 in Year 4. The cost of travel to physician offices to abstract medical records for women with losses is estimated based on an average of 1.5 offices with related records per loss X 37 miles round trip on average X $0.405 per mile x 30 participants with a loss in Year 1, 142 in Year 2, 146 in Years 3 & 4, and 20 in Year 5. An additional 10 trips per month (120 per year) are included in Years 1-4 for recruitment-related activities.

OTHER

Communication: Communication charges include $120 per month for dedicated Clever Name recruitment phone lines including digital toll-free lines, conventional fax, and postage for corresponding with participants including incentive and pregnancy test mailings. In Years 1-4, eight phone lines connected to the TACASI (Telephone Audio Computer-Assisted Survey Interview) system at the survey research unit will be supported for phone-based diary reporting at a cost of $30/line/month. In Year 5, we will reduce the number of phone lines to four in the first two months and then discontinue the phone lines entirely when all of the participants have completed the daily diaries.

Recruitment Costs: Our recruitment needs will include consultation with Recruitment Co, a research-oriented media marketing firm who have been involved in the pilot phase of the Clever Name Study. They will assist in design of additional materials specifically created to enhance recruitment of a diverse cohort. Successful community-based recruitment is essential for this study, and additional assistance will also be sought from Dr. Carol Hometown, an expert in community recruitment. Materials cost will include printing of modified versions of study brochures, posters and items such as post-it note pads for outreach; recruitment costs also include advertising on area websites, bus banners and benches, bathroom advertising displays, and limited radio advertising as required to tailor recruitment focus. Other venues include local print publications, movie theatres, and public relations items for study marketing. Based on our experience with recruitment in Right Here, USA, we have projected $30,000 in Year 1, $20,000 in Year 2, $10,000 in Years 3-4, and $0 in Year 5.

Imaging Equipment Leases: Two [what kind of] machines will be leased for the Distant and Far Away County locations at a rate of $550/mo for nine months in Year 1, 12 months in Years 2-4 and two months in Year 5.

Incentives: Participants will receive $5 each week if they complete at least 6/7 diary entries each week and another $10 for completing the exposure risk survey module. Participants with exposures who continue in the subcohort will receive an additional $5 diary incentive per week for another 8 weeks. Participants will receive a $10 incentive for completing the imaging and another $20 for the first Computer Assisted Telephone Interview (CATI). At the end of 20 weeks, we will ask participants to return a brief questionnaire that confirms their address and confirms or updates their usual care provider and whether or not they used emergency or hospital care. Upon return, participants will receive $5.

Year 1

Type of Incentive	Number of Participants	N events per participant	Amount per Event	Total Cost
Daily diary incentive (per week)	341	12*	$5	$20,460
Exposure risk reporting incentive	156	1	$10	$1,557
Sub-cohort diary incentive (per week)	156	8	$5	$6,240
Imaging incentive	156	1	$10	$1,557
CATI incentive	127	1	$20	$2,543
Care status incentive	74	1	$5	$371
TOTAL (YEAR 1)	**1,010**	**24**	**$55**	**$32,728**

Year 2

Type of Incentive	Number of Participants	N events per participant	Amount per Event	Total Cost
Daily diary incentive (per week)	630	12*	$5	$37,800
Exposure risk reporting incentive	361	1	$10	$3,610
Sub-cohort diary incentive (per week)	361	8	$5	$14,440
Imaging incentive	361	1	$10	$3,610
CATI incentive	359	1	$20	$7,188
Care status incentive	352	1	$5	$1,760
TOTAL (YEAR 2)	**2,424**	**24**	**$55**	**$68,408**

Year 3

Type of Incentive	Number of Participants	N events per participant	Amount per Event	Total Cost
Daily diary incentive (per week)	630	12*	$5	$37,800
Exposure risk reporting incentive	362	1	$10	$3,619
Sub-cohort diary incentive (per week)	362	8	$5	$14,480
Imaging incentive	362	1	$10	$3,619
CATI incentive	362	1	$20	$7,237
Care status incentive	362	1	$5	$1,809
TOTAL (YEAR 3)	**2,440**	**24**	**$55**	**$68,564**

Year 4

Type of Incentive	Number of Participants	N events per participant	Amount per Event	Total Cost
Daily diary incentive (per week)	499	12*	$5	$29,925
Exposure risk reporting incentive	315	1	$10	$3,146
Sub-cohort diary incentive (per week)	315	8	$5	$12,600
Imaging incentive	315	1	$10	$3,146
CATI incentive	336	1	$20	$6,716
Care status incentive	362	1	$5	$1,809
TOTAL (YEAR 4)	**2,142**	**24**	**$55**	**$57,342**

Year 5

Type of Incentive	Number of Participants	N events per participant	Amount per Event	Total Cost
Daily diary incentive (per week)	0	12*	$5	$0
Exposure risk reporting incentive	7	1	$10	$65
Sub-cohort diary incentive (per week)	7	8	$5	$280
Imaging incentive	7	1	$10	$65
CATI incentive	15	1	$20	$310
Care status incentive	50	1	$5	$249
TOTAL (YEAR 5)	**86**	**24**	**$55**	**$969**
TOTAL (ALL YEARS)	**8,102**	**120**	**$275**	**$228,011**

Biostatistical Computer Service Maintenance: The cost of this service is standardized by the Department of Biostatistics at $3,991 per FTE per year for Dr. Amy Awesome. Related costs for this proposal are:

Year 1: 20% FTE X $3,991 = $798
Years 2-4: 5% FTE X $3,991 = $200
Year 5: 30% FTE X $3,991 = $1,197

CONTRACTUAL AGREEMENT

A subcontract with Excellent Institute will be established. Excellent Institute will modify the existing pilot CATI instrument (English) and create and Spanish version. They will pilot test the final version and ensure accurate electronic updating link to the Clever Name Study Tracking and Reporting System. A detailed budget is enclosed.