

PI: [REDACTED]	Title: [REDACTED] [REDACTED]	
Received: 02/04/2014	FOA: PAR11-258	Council: 10/2014
Competition ID: FORMS-C	FOA Title: PREGNANCY IN WOMEN WITH DISABILITIES (R01)	
[REDACTED]	Dual:	Accession Number: 3663032
IPF: [REDACTED]	Organization: [REDACTED]	
Former Number:	Department: Disability, Health and Employm	
IRG/SRG: ZRG1 HDM-T (50)R	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A)	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Year 1: 352,941		
Year 2: 368,850		
Year 3: 374,585		
Year 4: 379,396		
Year 5: 358,253		
<b>Senior/Key Personnel:</b>		
<b>Senior/Key Personnel:</b>	<b>Organization:</b>	<b>Role Category:</b>
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

APPLICATION FOR FEDERAL ASSISTANCE  
**SF 424 (R&R)**

3. DATE RECEIVED BY STATE | State Application Identifier

1. TYPE OF SUBMISSION\*  
 Pre-application     Application     Changed/Corrected Application

4.a. Federal Identifier  
 b. Agency Routing Number

2. DATE SUBMITTED  
 2014-02-04

Application Identifier  
 [REDACTED]

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION Organizational DUNS\*: [REDACTED]

Legal Name\*: [REDACTED]  
 Department:  
 Division:  
 Street1\*: [REDACTED]  
 Street2:  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province:  
 Country\*: [REDACTED]  
 ZIP / Postal Code\*: [REDACTED]

Person to be contacted on matters involving this application  
 Prefix:      First Name\*: [REDACTED]      Middle Name:      Last Name\*: [REDACTED]      Suffix:  
 Position/Title: [REDACTED]  
 Street1\*: [REDACTED]  
 Street2: [REDACTED]  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province:  
 Country\*: [REDACTED]  
 ZIP / Postal Code\*: [REDACTED]  
 Phone Number\*: [REDACTED]      Fax Number [REDACTED]

6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)\* [REDACTED]

7. TYPE OF APPLICANT\*      H [REDACTED]  
 Other (Specify): [REDACTED]       Women Owned       Socially and Economically Disadvantaged

8. TYPE OF APPLICATION\*  
 New       Resubmission       Renewal       Continuation       Revision  
 If Revision, mark appropriate box(es).  
 A. Increase Award       B. Decrease Award       C. Increase Duration  
 D. Decrease Duration       E. Other (specify) :

Is this application being submitted to other agencies?\*       Yes       No      What other Agencies?

9. NAME OF FEDERAL AGENCY\*  
 [REDACTED]

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT\*  
 [REDACTED]

12. PROPOSED PROJECT  
 Start Date\*      Ending Date\*  
 [REDACTED]      [REDACTED]

13. CONGRESSIONAL DISTRICTS OF APPLICANT  
 [REDACTED]

**14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

Prefix:            First Name\*: [REDACTED]            Middle Name:            Last Name\*: [REDACTED]            Suffix: [REDACTED]  
 Position/Title: [REDACTED]  
 Organization Name\*: [REDACTED]  
 Department: [REDACTED]  
 Division:  
 Street1\*: [REDACTED]  
 Street2:  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province:  
 Country\*: [REDACTED]  
 ZIP / Postal Code\*: [REDACTED]  
 Phone Number\*: [REDACTED]            Fax Number: [REDACTED]

**15. ESTIMATED PROJECT FUNDING**

a. Total Federal Funds Requested*	\$3,036,518.00
b. Total Non-Federal Funds*	\$0.00
c. Total Federal & Non-Federal Funds*	\$3,036,518.00
d. Estimated Program Income*	\$0.00

**16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?\***

a. YES     THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:  
 DATE:  
 b. NO     PROGRAM IS NOT COVERED BY E.O. 12372; OR  
            PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

**17. By signing this application, I certify (1) to the statements contained in the list of certifications\* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances \* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)**

I agree\*

\* The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

**18. SFLLL or OTHER EXPLANATORY DOCUMENTATION**

File Name:

**19. AUTHORIZED REPRESENTATIVE**

Prefix:            First Name\*: [REDACTED]            Middle Name:            Last Name\*: [REDACTED]            Suffix:  
 Position/Title\*: [REDACTED]  
 Organization Name\*: [REDACTED]  
 Department: [REDACTED]  
 Division:  
 Street1\*: [REDACTED]  
 Street2:  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province:  
 Country\*: [REDACTED]  
 ZIP / Postal Code\*: [REDACTED]  
 Phone Number\*: [REDACTED]            Fax Number:            Email\* [REDACTED]

Signature of Authorized Representative\*  
 [REDACTED]

Date Signed\*  
 [REDACTED]

**20. PRE-APPLICATION** File Name:

**21. COVER LETTER ATTACHMENT** [REDACTED]

## 424 R&R and PHS-398 Specific Table Of Contents

Page Numbers

SF 424 R&R Cover Page-----	1
Table of Contents-----	3
Performance Sites-----	4
Research & Related Other Project Information-----	6
Project Summary/Abstract(Description)-----	7
Project Narrative-----	8
Facilities & Other Resources-----	9
Research & Related Senior/Key Person-----	11
Research & Related Budget Year - 1-----	42
Research & Related Budget Year - 2-----	45
Research & Related Budget Year - 3-----	48
Research & Related Budget Year - 4-----	51
Research & Related Budget Year - 5-----	54
Budget Justification-----	57
Research & Related Cumulative Budget-----	63
Research & Related Budget Consortium Budget (Subaward 1)-----	64
PHS398 Cover Page Supplement-----	83
PHS 398 Research Plan-----	85
Specific Aims-----	86
Research Strategy-----	87
Human Subjects Section-----	99
Protection of Human Subjects-----	99
Women & Minorities-----	103
Planned Enrollment Report-----	104
Children-----	106
Multiple PI Leadership Plan-----	107
Bibliography & References Cited-----	108
Letters Of Support-----	113

### Project/Performance Site Location(s)

#### Project/Performance Site Primary Location

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [REDACTED]  
 Duns Number: [REDACTED]  
 Street1\*: [REDACTED]  
 Street2: [REDACTED]  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province: [REDACTED]  
 Country\*: [REDACTED]  
 Zip / Postal Code\*: [REDACTED]  
 Project/Performance Site Congressional District\*: [REDACTED]

#### Project/Performance Site Location 1

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [REDACTED]  
 DUNS Number: [REDACTED]  
 Street1\*: [REDACTED]  
 Street2: [REDACTED]  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province: [REDACTED]  
 Country\*: [REDACTED]  
 Zip / Postal Code\*: [REDACTED]  
 Project/Performance Site Congressional District\*: [REDACTED]

#### Project/Performance Site Location 2

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [REDACTED]  
 DUNS Number: [REDACTED]  
 Street1\*: [REDACTED]  
 Street2: [REDACTED]  
 City\*: [REDACTED]  
 County: [REDACTED]  
 State\*: [REDACTED]  
 Province: [REDACTED]  
 Country\*: [REDACTED]  
 Zip / Postal Code\*: [REDACTED]  
 Project/Performance Site Congressional District\*: [REDACTED]

---

File Name

Additional Location(s)

## RESEARCH & RELATED Other Project Information

<b>1. Are Human Subjects Involved?*</b> <input checked="" type="radio"/> Yes <input type="radio"/> No 1.a. If YES to Human Subjects Is the Project Exempt from Federal regulations? <input type="radio"/> Yes <input checked="" type="radio"/> No If YES, check appropriate exemption number:        _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 If NO, is the IRB review Pending? <input checked="" type="radio"/> Yes <input type="radio"/> No IRB Approval Date: Human Subject Assurance Number            00004009	
<b>2. Are Vertebrate Animals Used?*</b> <input type="radio"/> Yes <input checked="" type="radio"/> No 2.a. If YES to Vertebrate Animals Is the IACUC review Pending? <input type="radio"/> Yes <input type="radio"/> No IACUC Approval Date: Animal Welfare Assurance Number	
<b>3. Is proprietary/privileged information included in the application?*</b> <input type="radio"/> Yes <input checked="" type="radio"/> No	
<b>4.a. Does this project have an actual or potential impact - positive or negative - on the environment?*</b> <input type="radio"/> Yes <input checked="" type="radio"/> No 4.b. If yes, please explain: 4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? <input type="radio"/> Yes <input type="radio"/> No 4.d. If yes, please explain:	
<b>5. Is the research performance site designated, or eligible to be designated, as a historic place?*</b> <input type="radio"/> Yes <input checked="" type="radio"/> No 5.a. If yes, please explain:	
<b>6. Does this project involve activities outside the United States or partnership with international collaborators?*</b> <input type="radio"/> Yes <input checked="" type="radio"/> No 6.a. If yes, identify countries: 6.b. Optional Explanation:	
<b>7. Project Summary/Abstract*</b>	Filename Abstract_final1017118450.pdf
<b>8. Project Narrative*</b>	Narrative_Public_health_relevance_final_017118908.pdf
<b>9. Bibliography &amp; References Cited</b>	bibliography1017118909.pdf
<b>10. Facilities &amp; Other Resources</b>	Facilities_final1017118531.pdf
<b>11. Equipment</b>	

## **Project Summary/Abstract**

Prior studies suggest that women with intellectual and developmental disabilities and their infants are at elevated risk of having adverse obstetric health outcomes. Yet, there is no research on pregnancy or infant health outcomes with a population-based sample of US women with intellectual and developmental disabilities or their infants. As a result, many questions remain unanswered about the unmet perinatal health care needs and health outcomes of women with intellectual and developmental disabilities. In the proposed study, we plan to address this gap in the literature and use our findings to develop perinatal care recommendations to improve care for women with intellectual and developmental disabilities. The specific aims of this study are to (1) Investigate pregnancy and childbirth complications, outcomes, and inpatient costs among women with intellectual and developmental disabilities and women in the general US obstetric population, (2) Examine longitudinal health outcomes and health care utilization and costs of women with intellectual and developmental disabilities around the time of their pregnancy and for their infants (up to 1 year of age) compared to other women, and (3) Identify unmet needs and barriers to perinatal care for women with intellectual and developmental disabilities through in-person interviews with pregnant women and new mothers with IDD and telephone interviews with the health care professionals who provide their health care. The study will be conducted using nationally-representative population-based data from the Healthcare Cost and Utilization Project (HCUP) and the [REDACTED] Pregnancy to Early Life Longitudinal-All Payer Claims Database (PELL-APCD) linked data system to determine differences in perinatal health care utilization, outcomes, and costs between women with and without intellectual and developmental disabilities and their infants. Finally, the study will develop perinatal care recommendations, providing clinicians with practical tools to address the unique needs of this highly vulnerable population of women with IDD.

## **Project Narrative (Public Health Significance)**

The U.S. Department of Health and Human Services has declared eliminating disparities, and improving the health of all groups as one of the overarching goals of *Healthy People 2020*. The proposed study will determine whether there are disparities in maternal and infant outcomes, complications, health care utilization and costs among women with and without intellectual and developmental disabilities using existing population-based data. Through individual interviews with women with intellectual and developmental disabilities and their health care providers, it will seek to explain any such disparities and improve care by creating a set of practice recommendations for perinatal care for women with intellectual and developmental disabilities.

## Facilities & Other Resources

The office and computing resources of the [REDACTED] [REDACTED] available to perform the effort proposed are described below. Laboratory, animal, and clinical resources are not applicable to this proposal.

[REDACTED] [REDACTED] is one of five campuses in the [REDACTED] [REDACTED] system. Established in [REDACTED] mission is to advance the health and well-being of the people of the Commonwealth and the world through pioneering education, research, and health care delivery. [REDACTED] accomplishes its mission in conjunction with its clinical partner [REDACTED] [REDACTED] the largest health care provider [REDACTED]

[REDACTED] is one of the fastest-growing research institutions in the country, possessing extensive resources to support the success of this proposal. Federal and private research grants and contracts at [REDACTED] exceeded \$250 million in fiscal year 2010. [REDACTED] was recently awarded a prestigious 5-year, \$20-million [REDACTED] [REDACTED] by the National Institutes of Health and now joins [REDACTED] of the top medical institutions in the country in a network of research centers focused on clinical and translational science.

The [REDACTED] main campus, with state of the art education and research facilities, is located at [REDACTED] [REDACTED].

### Center for Health Care Policy and Research (CHPR)

Founded in [REDACTED] the [REDACTED] is one of many units that comprise [REDACTED] a division of [REDACTED] that seeks to improve health outcomes for those served by public health and human service programs. To achieve that mission, [REDACTED] works with public sector agencies and other non-profit health care and research organizations to conduct applied research, evaluation, and education aimed at informing policy decisions that improve people's health and well-being.

[REDACTED] maintains a staff of more than [REDACTED] including a core of biostatisticians and analysts with extensive experience in the programming and analysis of large datasets created from Medicaid claims and other public databases. [REDACTED] faculty investigators contribute expertise in areas such as health services research, health services design, health and disability, qualitative and quantitative methods, program evaluation, survey and implementation research, quality measurement, economic evaluation, physician workforce development, and dissemination of knowledge related to evidence-based best practices. The ability of our team to be successful is broadened by its capacity to consult or collaborate with other faculty members within the [REDACTED] system. Faculty at [REDACTED] hold dual appointments in [REDACTED] Departments, including Medicine, Psychiatry, Pediatrics, Family Medicine & Community Health, Maternal and Fetal Medicine, and Quantitative Health Sciences. [REDACTED] is located in [REDACTED] and is less than [REDACTED] minutes away from the [REDACTED] main campus and its clinical partner, the [REDACTED] [REDACTED] is housed in a first-class research and development complex comprised of [REDACTED] square feet with [REDACTED] rooms equipped with state-of-the-art video conferencing equipment and other amenities. [REDACTED] researchers have full access to a wide array of technological and research assets available through [REDACTED] including the considerable resources of the [REDACTED]. The [REDACTED] serves the research and clinical community of [REDACTED] and has an extensive collection of over [REDACTED] print volumes, including subscriptions to [REDACTED] print and electronic journals and access to [REDACTED] bibliographic databases. Under contract with the [REDACTED] the [REDACTED] serves as the [REDACTED] for the [REDACTED] serving health providers and the public with timely access to health information.

### Computing Resources

[REDACTED] maintains a research computing environment that employs state-of-the-art data, voice and video network capabilities (wired and secure wireless) providing all employees with data connectivity, computer, telephones, voice mail, facsimile and video conferencing. [REDACTED] has over [REDACTED] and laptops with the latest machines running Windows 7 at 2.50 GHz or greater with 2+ gigabytes of memory.

For the storage and analysis of PHI/PII-sensitive data, [REDACTED] has established a "regulated environment" Tier 1 data center, in which [REDACTED] has acquired 16 Tbytes of storage hosted on an EMC CLARiiON disk array. The statistical facilities within the regulated environment include rSTATS: a Dell R905 server with four six-core 2.8 gigahertz 64 bit Opteron processors for a total of 24 processors and 256 GB of fast RAM memory. rSTATS runs Redcap Linux version of UNIX operating system and is accessible only by secure VPN and terminal server links. The facilities also include a new EMC CLARiiON CX4-240 high speed disk array with a potential usable capacity of 180 terabytes of 7200 rpm high capacity storage or a lesser amount if high performance 15000 rpm drives are used. As mentioned, [REDACTED] has acquired 16 Tbytes of storage within this facility for use by [REDACTED] investigators. Drives are configured into RAID5 or RAID10 disk arrays (depending upon desire for performance versus capacity). These arrays allow for redundancy which enables protection from disk failures. In most disk failures, crashed disks can be replaced "on the fly" without loss of data or down time. There are also standard backups: incremental daily backups, full backups weekly and monthly full backups retained for a minimum of 7 years at the vendor [REDACTED] site.

For the storage and analysis of non-PHI/PII-sensitive data, [REDACTED] Research Computing provides a Sun Sunfire X4600 Server running the Sun Solaris x86 (Unix) operating system, with 8 Opteron 2.8 Ghz Dual Core Processors (16 processors total), 128 Gb DDR2 memory, and 2 Tbytes of 10k RPM disk drives. This server was configured in consultation with SAS, Inc. to maximize its capability for analyses of very large datasets using SAS such as those encountered often in health services research. In addition to the full complement of SAS modules, this server also has the latest version of the STATA statistical software, STATA MP, which is optimized to use the server's multiple processors.

[REDACTED] researchers have access to a variety of standard software packages for word processing, spreadsheets, and graphics including the Microsoft Office Suite, Microsoft Project, Microsoft Visio, Apple OSX5.X and related Apple applications. Staff and faculty employ a variety of data analysis and statistical software such as SAS, STATA, SPSS, and Arc-GIS. In addition, a number of audio visual, multi-media, and webcast hosting services are available to [REDACTED] including Adobe Connect, Horizon Wimba, and WebRoom, as well as a host of business process management systems and tools used throughout the [REDACTED]

[REDACTED] employs extensive security measures to protect all sensitive data and communications. Additional security mechanisms include desktop and laptop whole disk encryption software (Checkpoint PointSec) and laptop tracking software (Computrace). All email accessed through the [REDACTED] email servers is encrypted and secure data transfer is available on all workstations and servers. In addition, secure remote connectivity to the email and network systems is available to staff and faculty through [REDACTED] Virtual Private Network (VPN) structure. These resources ensure that sensitive data are protected and help to secure intellectual property and maintain human subject protections.

The [REDACTED] computing infrastructure of hardware and networks is maintained by a help center and a host of IT and infrastructure personnel that provide hardware and software applications and telephone and desk side support, including a 24-hour help desk line, to all faculty and staff.

## RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator				
Prefix:	First Name* [REDACTED]	Middle Name	Last Name*: [REDACTED]	Suffix: [REDACTED]
Position/Title*:	[REDACTED]			
Organization Name*:	[REDACTED]			
Department:	[REDACTED]			
Division:				
Street1*:	[REDACTED]			
Street2:				
City*:	[REDACTED]			
County:	[REDACTED]			
State*:	[REDACTED]			
Province:				
Country*:	[REDACTED]			
Zip / Postal Code*:	[REDACTED]			
Phone Number*:	[REDACTED]	Fax Number:	[REDACTED]	E-Mail*:
[REDACTED]				
Credential, e.g., agency login: [REDACTED]				
Project Role*: PD/PI			Other Project Role Category:	
Degree Type: [REDACTED]			Degree Year: [REDACTED]	
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:			[REDACTED]	

PROFILE - Senior/Key Person				
Prefix:	First Name*: [REDACTED]	Middle Name	Last Name*: [REDACTED]	Suffix: [REDACTED]
Position/Title*:				
Organization Name*:	[REDACTED]			
Department:				
Division:				
Street1*:	[REDACTED]			
Street2:				
City*:	[REDACTED]			
County:				
State*:	[REDACTED]			
Province:				
Country*:	[REDACTED]			
Zip / Postal Code*:	[REDACTED]			
Phone Number*:	[REDACTED]	Fax Number:	[REDACTED]	E-Mail*:
[REDACTED]				
Credential, e.g., agency [REDACTED]				
Project Role*: PD/PI			Other Project Role Category:	
Degree Type: [REDACTED]			Degree Year:	
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:			[REDACTED]	

PROFILE - Senior/Key Person

Prefix:	First Name*:	Middle Name	Last Name*:	Suffix:
Position/Title*:				
Organization Name*:				
Department:				
Division:				
Street1*:				
Street2:				
City*:				
County:				
State*:				
Province:				
Country*:				
Zip / Postal Code*:				
Phone Number*:	Fax Number:	E-Mail*:		
Credential, e.g., agency login:				
Project Role*:	Other Project Role Category:			
Degree Type:	Degree Year:			
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:				

PROFILE - Senior/Key Person

Prefix:	First Name*:	Middle Name	Last Name*:	Suffix:
Position/Title*:				
Organization Name*:				
Department:				
Division:				
Street1*:				
Street2:				
City*:				
County:				
State*:				
Province:				
Country*:				
Zip / Postal Code*:				
Phone Number*:	Fax Number:	E-Mail*:		
Credential, e.g., agency login:				
Project Role*:	Other Project Role Category:			
Degree Type:	Degree Year:			
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:				

**PROFILE - Senior/Key Person**

Prefix:	First Name*:	Middle Name	Last Name*:	Suffix:
Position/Title*:				
Organization Name*:				
Department:				
Division:				
Street1*:				
Street2:				
City*:				
County:				
State*:				
Province:				
Country*:				
Zip / Postal Code*:				
Phone Number*:		Fax Number:		E-Mail*:
Credential, e.g., agency login:				
Project Role*:			Other Project Role Category:	
Degree Type:			Degree Year:	
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:				

**PROFILE - Senior/Key Person**

Prefix: Dr.	First Name*:	Middle Name	Last Name*:	Suffix:
Position/Title*:				
Organization Name*:				
Department:				
Division:				
Street1*:				
Street2:				
City*:				
County:				
State*:				
Province:				
Country*:				
Zip / Postal Code*:				
Phone Number*:		Fax Number		E-Mail*:
Credential, e.g., agency login:				
Project Role*:			Other Project Role Category:	
Degree Type:			Degree Year:	
Attach Biographical Sketch*:			File Name	
Attach Current & Pending Support:				

PROFILE - Senior/Key Person

Prefix: First Name\*: [REDACTED] Middle Name Last Name\*: [REDACTED] Suffix: [REDACTED]

Position/Title\*:

Organization Name\*: [REDACTED]

Department:

Division:

Street1\*: [REDACTED]

Street2:

City\*: [REDACTED]

County:

State\*: [REDACTED]

Province:

Country\*: [REDACTED]

Zip / Postal Code\*: [REDACTED]

Phone Number\*: [REDACTED] Fax Number: E-Mail\* [REDACTED]

Credential, e.g., agency login:

Project Role\*: [REDACTED] Other Project Role Category:

Degree Type: [REDACTED] Degree Year: [REDACTED]

File Name

Attach Biographical Sketch\*: [REDACTED]

Attach Current & Pending Support:





[Redacted text block]

[Redacted text block]

**D. Research Support**

[Redacted text block]

[Redacted text block]

[Redacted text block]









[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 09

[REDACTED]

[REDACTED]

[REDACTED]

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME [REDACTED]		POSITION TITLE [REDACTED]	
eRA COMMONS USER NAME (credential, e.g., agency login) [REDACTED]			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

### A. Personal Statement

[REDACTED]

### B. Positions and Honors

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**D. Research Support**

[Redacted text block containing multiple paragraphs of obscured content]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME [REDACTED]	POSITION TITLE [REDACTED]
eRA COMMONS USER NAME (credential, e.g., agency login) [REDACTED]	[REDACTED]

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**A. Personal Statement**

[REDACTED]

**B. Positions and Honors**

[REDACTED]

- [Redacted]

- [Redacted]

- [Redacted]

- [Redacted]

[Redacted text block]

**D. Research Support**

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME [REDACTED]	POSITION TITLE [REDACTED]
eRA COMMONS USER NAME	

**EDUCATION/TRAINING**

INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**A. Personal Statement**

[REDACTED]

**B. Positions and Employment**

[REDACTED]

[Redacted text block]

[Redacted text block]

[Redacted text block]

**C. Selected Peer-reviewed Publications**

- [Redacted list item 1]
- [Redacted list item 2]
- [Redacted list item 3]
- [Redacted list item 4]
- [Redacted list item 5]
- [Redacted list item 6]
- [Redacted list item 7]

[Redacted]

[Redacted text block]

**D. Research Support**

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

# BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME [REDACTED]		POSITION TITLE [REDACTED]	
eRA COMMONS USER NAME (credential, e.g., agency login) [REDACTED]		[REDACTED]	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

## A. Personal Statement:

[REDACTED]

## B. Positions and Honors

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME [REDACTED]		POSITION TITLE [REDACTED]	
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

### A. Personal Statement

[REDACTED]

### B. Positions and Honors

[REDACTED]

**D. Research Support**

[REDACTED]

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: [REDACTED]

End Date\*: [REDACTED]

Budget Period: 1

A. Senior/Key Person											
	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	101,906.00	4.8			40,762.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	108,171.00	2.4			21,634.00
3.		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	173,206.00	0.6			8,660.00
4.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	90,212.00	0.6			4,511.00
5.	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	181,500.00	0.84			12,705.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Sen

B. Other Personnel						
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fr
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
	Secretarial/Clerical					
1	Nurse Practitioner	0.36			3,400.00	
1	Research Associate	4.8			21,016.00	
1	Biostatistician	4.8			37,841.00	
3	<b>Total Number Other Personnel</b>					<b>Total O</b>

Total Salary, Wages and Fringe

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: [REDACTED]

End Date\*: [REDACTED]

Budget Period: 1

**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

**D. Travel**

Funds Requested (\$)\*

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	2,461.00
--	----------

2. Foreign Travel Costs	
-------------------------	--

<b>Total Travel Cost</b>	<b>2,461.00</b>
--------------------------	-----------------

**E. Participant/Trainee Support Costs**

Funds Requested (\$)\*

1. Tuition/Fees/Health Insurance	
----------------------------------	--

2. Stipends	
-------------	--

3. Travel	
-----------	--

4. Subsistence	
----------------	--

5. Other:	
-----------	--

Number of Participants/Trainees	
---------------------------------	--

<b>Total Participant Trainee Support Costs</b>	<b>0.00</b>
--	-------------

RESEARCH & RELATED Budget (C-E) (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: [REDACTED]      End Date\*: [REDACTED]      Budget Period: 1

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	5,500.00
2. Publication Costs	
3. Consultant Services	8,550.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	206,768.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Expert Advisory Committee Stipends	2,250.00
9. Transcription	320.00
10. PELL-APCD data	12,000.00
<b>Total Other Direct Costs</b>	<b>235,388.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>432,271.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. On_Campus	67.5	250,503.00	169,090.00
<b>Total Indirect Costs</b>			<b>169,090.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>601,361.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: [REDACTED]

End Date\*: [REDACTED]

Budget Period: 2

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	103,945.00	4.8			41,578.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	110,335.00	2.4			22,067.00
3.		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	176,670.00	0.6			8,834.00
4.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	92,016.00	0.6			4,601.00
5.	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	181,500.00	0.84			12,705.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Sen

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	F
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
	Secretarial/Clerical					
1	Nurse Practitioner	0.36			3,468.00	
1	Research Associate	4.2			18,757.00	
1	Biostatistician	6			48,248.00	
3	<b>Total Number Other Personnel</b>					<b>Total O</b>

**Total Salary, Wages and Fringe**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2016

End Date\*: 12-31-2016

Budget Period: 2

### C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

### D. Travel

	Funds Requested (\$)*
1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	3,862.00
2. Foreign Travel Costs	
<b>Total Travel Cost</b>	<b>3,862.00</b>

### E. Participant/Trainee Support Costs

	Funds Requested (\$)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
<b>Number of Participants/Trainees</b>	
<b>Total Participant Trainee Support Costs</b>	<b>0.00</b>

RESEARCH & RELATED Budget (C-E) (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2016

End Date\*: 12-31-2016

Budget Period: 2

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	5,500.00
2. Publication Costs	
3. Consultant Services	12,797.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	220,758.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Expert Advisory Committee Stipends	2,250.00
9. Transcription	1,600.00
<b>Total Other Direct Costs</b>	<b>242,905.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>453,757.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. On_Campus	67.5	232,999.00	157,274.00
<b>Total Indirect Costs</b>			<b>157,274.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>611,031.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]		[REDACTED]	106,023.00	4.8			42,409.00
2.		[REDACTED]		[REDACTED]		[REDACTED]	112,541.00	2.4			22,508.00
3.		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	180,204.00	0.6			9,010.00
4.		[REDACTED]		[REDACTED]		[REDACTED]	93,856.00	0.6			4,693.00
5.	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	181,500.00	1.2			18,150.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Sen

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fr
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
	Secretarial/Clerical					
1	Nurse Practitioner	0.36			3,537.00	
1	Research Associate	3.6			16,399.00	
1	Biostatistician	6			49,213.00	
3	<b>Total Number Other Personnel</b>					<b>Total O</b>
						<b>Total Salary, Wages and Fringe</b>

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

### C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

### D. Travel

Funds Requested (\$)\*

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	3,922.00
--	----------

2. Foreign Travel Costs	
-------------------------	--

<b>Total Travel Cost</b>	<b>3,922.00</b>
--------------------------	-----------------

### E. Participant/Trainee Support Costs

Funds Requested (\$)\*

1. Tuition/Fees/Health Insurance	
----------------------------------	--

2. Stipends	
-------------	--

3. Travel	
-----------	--

4. Subsistence	
----------------	--

5. Other:	
-----------	--

Number of Participants/Trainees	
---------------------------------	--

<b>Total Participant Trainee Support Costs</b>	<b>0.00</b>
--	-------------

RESEARCH & RELATED Budget (C-E) (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	13,888.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	211,747.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Transcription	4,000.00
9. Expert Advisory Committee Stipends	2,250.00
10. Provider Inter. stipends	2,250.00
<b>Total Other Direct Costs</b>	<b>234,635.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>452,856.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. On_Campus	67.5	241,109.00	162,749.00
<b>Total Indirect Costs</b>			<b>162,749.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>615,605.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget (F-K) (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4**

ORGANIZATIONAL DUNS\*: 603847393

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2018

End Date\*: 12-31-2018

Budget Period: 4

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]		[REDACTED]	108,144.00	4.8			43,258.00
2.		[REDACTED]		[REDACTED]		[REDACTED]	114,792.00	2.4			22,958.00
3.		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	181,500.00	0.6			9,075.00
4.		[REDACTED]		[REDACTED]		[REDACTED]	95,733.00	0.6			4,787.00
5.	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	181,500.00	1.2			18,150.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Ser

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	F
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
	Secretarial/Clerical					
1	Nurse Practitioner	0.36			3,608.00	
1	Research Associate	4.2			19,514.00	
1	Biostatistician	6			50,197.00	
3	<b>Total Number Other Personnel</b>					<b>Total O</b>
						<b>Total Salary, Wages and Fringe</b>

RESEARCH & RELATED Budget (A-B) (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2018

End Date\*: 12-31-2018

Budget Period: 4

### C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

### D. Travel

Funds Requested (\$)\*

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)

3,986.00

2. Foreign Travel Costs

**Total Travel Cost**

**3,986.00**

### E. Participant/Trainee Support Costs

Funds Requested (\$)\*

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

**Number of Participants/Trainees**

**Total Participant Trainee Support Costs**

**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2018

End Date\*: 12-31-2018

Budget Period: 4

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	13,888.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	205,871.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Expert Advisory Committee Stipends	2,250.00
9. Transcription	4,000.00
10. Provider Interv. stipends	2,250.00
<b>Total Other Direct Costs</b>	<b>228,759.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>454,315.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. On_Campus	67.5	248,444.00	167,700.00
<b>Total Indirect Costs</b>			<b>167,700.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>622,015.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2019

End Date\*: 12-31-2019

Budget Period: 5

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	110,307.00	4.8			44,123.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	117,088.00	1.8			17,563.00
3.		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	181,500.00	0.6			9,075.00
4.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	97,648.00	0.6			4,882.00
5.	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	181,500.00	0.84			12,705.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Sen

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fi
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
	Secretarial/Clerical					
1	Research Associate	4.8			22,749.00	
1	Biostatistician	4.8			40,961.00	
2	<b>Total Number Other Personnel</b>					<b>Total O</b>

**Total Salary, Wages and Fringe**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project     Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2019

End Date\*: 12-31-2019

Budget Period: 5

### C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment:    File Name:

### D. Travel

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)

9,448.00

2. Foreign Travel Costs

**Total Travel Cost**

**9,448.00**

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

**Number of Participants/Trainees**

**Total Participant Trainee Support Costs**

**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2019

End Date\*: 12-31-2019

Budget Period: 5

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	3,500.00
2. Publication Costs	
3. Consultant Services	8,550.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	208,961.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Meeting expenses	1,500.00
9. Expert Advisory Committee Stipends	4,725.00
10. Transcription	1,280.00
<b>Total Other Direct Costs</b>	<b>228,516.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>434,361.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. On_Campus	67.5	225,400.00	152,145.00
<b>Total Indirect Costs</b>			<b>152,145.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>586,506.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

[Redacted]

[REDACTED] as a personnel fringe rate of 29.16%

Year 1 Total Requested Salary: \$ 150,530, Fringe: \$43,892  
Year 2 Total Requested Salary: \$ 160,258, Fringe: \$46,732  
Year 3 Total Requested Salary: \$ 165,919, Fringe: \$48,380  
Year 4 Total Requested Salary: \$ 171,547, Fringe: \$50,023  
Year 5 Total Requested Salary: \$ 152,057, Fringe: \$44,340

**Travel:**

Year 1: Travel costs are included to permit [REDACTED] to present research findings at one scholarly conference in year 1. The cost is \$1,495 (\$450 for airfare + 3 nights at \$209 per night + \$71/day for meals and incidentals for 2.5 days + \$60 x 4 trips to and from the airport by taxi or shuttle). Also included in year 1 is mileage for [REDACTED] and one [REDACTED] to travel to [REDACTED] monthly for project meetings. The total for this is \$812 (\$.565/mile x 54.9 miles round trip [REDACTED] to [REDACTED] + \$2.80 in tolls once a month for 12 months). In year 1, [REDACTED] will travel to [REDACTED] in [REDACTED] twice for meetings for a cost of \$154 (\$.565/mile x 72.6 miles round trip [REDACTED] to [REDACTED] + \$30 for parking + \$6.20 for tolls). **The total amount for travel in year 1 is \$2,461.**

Year 2: Travel costs are included to permit [REDACTED] and one of the [REDACTED] each to present research findings at one scholarly conference in year 2. The cost is \$1,525 (\$462 for airfare + 3 nights at \$213 per night + \$72/day for meals and incidentals for 2.5 days + \$61 x 4 trips to and from the airport by taxi or shuttle) times 2 (\$3,050 for both investigators). Also included in year 2 is mileage for [REDACTED] and [REDACTED] to travel to [REDACTED] monthly for project meetings. The total for this is \$812 (\$.565/mile x 54.9 miles round trip [REDACTED] + \$2.80 in tolls once a month for 12 months). **The total amount for travel in year 2 is \$3,862.**

Year 3: Travel costs are included to permit [REDACTED] and one of the [REDACTED] each to present research findings at one scholarly conference in year 3. The cost is \$1,555 (\$474 for airfare + 3 nights at \$217 per night + \$73/day for meals and incidentals for 2.5 days + \$62 x 4 trips to and from the airport by taxi or shuttle) times 2 (\$3,110 for both investigators). Also included in year 3 is mileage for [REDACTED] and one [REDACTED] to travel to [REDACTED] monthly for project meetings. The total for this is \$812 (\$.565/mile x 54.9 miles round trip [REDACTED] to [REDACTED] + \$2.80 in tolls once a month for 12 months). **The total amount for travel in year 3 is \$3,922.**

Year 4: Travel costs are included to permit [REDACTED] and one of the [REDACTED] each to present research findings at one scholarly conference in year 4. The cost is \$1,587 (\$487 for airfare + 3 nights at \$221 per night + \$74/day for meals and incidentals for 2.5 days + \$63 x 4 trips to and from the airport by taxi or shuttle) times 2 (\$3,174 for both investigators). Also included in year 4 is mileage for [REDACTED] and one [REDACTED] to travel to [REDACTED] monthly for project meetings. The total for this is \$812 (\$.565/mile x 54.9 miles round trip [REDACTED] + \$2.80 in tolls once a month for 12 months). **The total amount for travel in year 4 is \$3,986.**

Year 5: Travel costs are included to permit [REDACTED] and one of the [REDACTED] each to present research findings at one scholarly conference in year 5. The cost is \$1,618 (\$500 for airfare + 3 nights at \$225 per night + \$75/day for meals and incidentals for 2.5 days + \$64 x 4 trips to and from the airport by taxi or shuttle) times 2 (\$3,236 for both investigators). Also included in year 5 is mileage for [REDACTED] and one [REDACTED] to travel [REDACTED] monthly for project meetings. The total for this is \$812 (\$.565/mile x 54.9 miles round trip [REDACTED] + \$2.80 in tolls once a month for 12 months).

In year 5 a one-day meeting of the expert advisory committee will take place. Advisory Committee members including [REDACTED] and [REDACTED] along with the [REDACTED] and the [REDACTED] will attend the meeting. We are requesting \$900 for travel expenses and accommodations for each of [REDACTED] non-local attendees, \$5,400 total (\$225 for one night hotel + \$256 for transportation to and from airport + 419 for airfare per person for [REDACTED] people).

**The total amount for travel in year 5 is \$9,448.**

**Other Direct Costs:**

**Supply Costs:**

In years 1-5 we are requesting \$500 for each of the five years for general office supplies, including paper, notepads, notebooks, binders, manila and hanging folders, etc. In each of years 1 and 2 we are requesting an additional \$5,000 for server and data storage costs of MA APCD data. In year 5 \$3,000 is being allocated to print the practice recommendations for dissemination.

[REDACTED]

We will apply for access to the [REDACTED] linked data. The [REDACTED] is comprised of linked data from medical claims as well as member information, benefit design, and providers for all payers covering [REDACTED] residents and maternal and infant birth records. There are a number of fees to access the data. We are requesting funds for the application fee and access to several of the data files. The total cost requested for [REDACTED] access is \$12,000 in year 1.

**Provider Interview Stipends**

We will conduct interviews with 30 health care providers who provide services to women with intellectual and developmental disabilities. Each provider will be paid a \$150 stipend for his or her time. We will conduct 15 interviews in year 3 and 15 in year 4 for a total amount of \$4,500.

**Transcription**

We will have all interview recordings transcribed by a professional transcription vendor. A total of \$11,200 is budgeted for this spread across the 5 years of the project based on the expected completion of interviews. This includes 30 provider interviews and 40 interviews with women with intellectual and developmental disabilities. Each interview will be one hour and an estimated 5 hours of transcription is required per hour of interview. The transcription rate is \$32 per hour. (70 x 5 x \$32 = \$11,200)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Year 2:  
63.5 hours of [REDACTED] time (at her rate of \$50/hour)=\$3,175  
7 participant stipends (\$50 each)= \$350  
300 miles of travel to interviews at 0.56/mile=\$168  
Office supplies and other administrative costs=\$554  
**The cost for [REDACTED] services in year 2 is \$4,247.**

Year 3:  
75 hours [REDACTED] time (at her rate of \$50/hour)=\$3,750  
10 participant stipends (\$50 each)= \$500  
700 miles of travel to interviews at 0.56/mile=\$392  
Office supplies and other administrative costs=\$696  
**The cost for [REDACTED] services in year 3 is \$5,338.**

Year 4:  
75 hours of [REDACTED] time (at her rate of \$50/hour)=\$3,750  
10 participant stipends (\$50 each)= \$500  
700 miles of travel to interviews at 0.56/mile=\$392  
Office supplies and other administrative costs=\$696  
**The cost for [REDACTED] services in year 4 is \$5,338.**

These costs include [REDACTED] time to assist with interview development and conduct the interviews, stipends for participants, and travel costs to the interviews for 20 interviews (plus 7 pilot) with women with intellectual and developmental disabilities in [REDACTED]

**The total cost for [REDACTED] services is \$14,923 over years 2, 3, and 4 of the grant.**



## RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals (\$)	
<b>Section A, Senior/Key Person</b>		<b>595,947.00</b>
<b>Section B, Other Personnel</b>		<b>437,731.00</b>
Total Number Other Personnel	14	
<b>Total Salary, Wages and Fringe Benefits (A+B)</b>		<b>1,033,678.00</b>
<b>Section C, Equipment</b>		
<b>Section D, Travel</b>		<b>23,679.00</b>
1. Domestic	23,679.00	
2. Foreign		
<b>Section E, Participant/Trainee Support Costs</b>		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
<b>Section F, Other Direct Costs</b>		<b>1,170,203.00</b>
1. Materials and Supplies	15,500.00	
2. Publication Costs		
3. Consultant Services	57,673.00	
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	1,054,105.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	12,250.00	
9. Other 2	12,895.00	
10. Other 3	17,780.00	
<b>Section G, Direct Costs (A thru F)</b>		<b>2,227,560.00</b>
<b>Section H, Indirect Costs</b>		<b>808,958.00</b>
<b>Section I, Total Direct and Indirect Costs (G + H)</b>		<b>3,036,518.00</b>
<b>Section J, Fee</b>		

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of [REDACTED]

Start Date\*: 01-01-2015

End Date\*: 12-31-2015

Budget Period: 1

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	181,500.00	3.6			54,450.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	72,188.00	4.2			25,266.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Sen

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fi
	Post Doctoral Associates					
1	Graduate Students	3			7,123.00	
	Undergraduate Students					
	Secretarial/Clerical					

1 Total Number Other Personnel Total O

Total Salary, Wages and Fringe

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2015

End Date\*: 12-31-2015

Budget Period: 1

**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

**D. Travel**

**Funds Requested (\$)\***

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	1,897.00
2. Foreign Travel Costs	0.00
<b>Total Travel Cost</b>	<b>1,897.00</b>

**E. Participant/Trainee Support Costs**

**Funds Requested (\$)\***

1. Tuition/Fees/Health Insurance	0.00
2. Stipends	0.00
3. Travel	0.00
4. Subsistence	0.00
5. Other:	0.00
<b>Number of Participants/Trainees</b>	<b>Total Participant Trainee Support Costs</b>
	<b>0.00</b>

RESEARCH & RELATED Budget {C-E} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2015

End Date\*: 12-31-2015

Budget Period: 1

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	2,400.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	11,081.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Participant Incentives	450.00
<b>Total Other Direct Costs</b>	<b>13,931.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>127,438.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. Predetermined MTDC	62	63,719.00	39,506.00
2. Predetermined MTDC	62.5	63,719.00	39,824.00
<b>Total Indirect Costs</b>			<b>79,330.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>206,768.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: SubParishBudgetjustPD_PI1017118833.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2016

End Date\*: 12-31-2016

Budget Period: 2

### A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	185,130.00	3.6			55,539.00
2.	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	73,631.00	4.2			25,771.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Ser

### B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	F
1	Post Doctoral Associates					
1	Graduate Students	6			14,531.00	
	Undergraduate Students					
	Secretarial/Clerical					
1	<b>Total Number Other Personnel</b>					<b>Total C</b>

**Total Salary, Wages and Fringe**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: [REDACTED]

[REDACTED]

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2016

End Date\*: 12-31-2016

Budget Period: 2

**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

**D. Travel**

**Funds Requested (\$)\***

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	3,272.00
2. Foreign Travel Costs	
<b>Total Travel Cost</b>	<b>3,272.00</b>

**E. Participant/Trainee Support Costs**

**Funds Requested (\$)\***

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

**Number of Participants/Trainees**

**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2016

End Date\*: 12-31-2016

Budget Period: 2

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	11,081.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Participant Incentives	250.00
<b>Total Other Direct Costs</b>	<b>11,331.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>135,851.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. Predetermined MTDC	62.5	67,926.00	42,454.00
2. Provisional MTDC	62.5	67,925.00	42,453.00
<b>Total Indirect Costs</b>			<b>84,907.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>220,758.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget (F-K) (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

**A. Senior/Key Person**

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	188,833.00	3.6			56,650.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	75,104.00	3.6			22,531.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Ser

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	F
	Post Doctoral Associates					
1	Graduate Students	6			14,822.00	
	Undergraduate Students					
	Secretarial/Clerical					
1	<b>Total Number Other Personnel</b>					<b>Total O</b>

**Total Salary, Wages and Fringe**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

### C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)*
----------------	-----------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

### D. Travel

Funds Requested (\$)\*

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	3,331.00
--	----------

2. Foreign Travel Costs	
-------------------------	--

<b>Total Travel Cost</b>	<b>3,331.00</b>
--------------------------	-----------------

### E. Participant/Trainee Support Costs

Funds Requested (\$)\*

1. Tuition/Fees/Health Insurance	
----------------------------------	--

2. Stipends	
-------------	--

3. Travel	
-----------	--

4. Subsistence	
----------------	--

5. Other:	
-----------	--

Number of Participants/Trainees

**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2017

End Date\*: 12-31-2017

Budget Period: 3

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	11,081.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Participant Incentives	250.00
<b>Total Other Direct Costs</b>	<b>11,331.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>133,476.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. Provisional MTDC	62.5	125,233.00	78,271.00
<b>Total Indirect Costs</b>			<b>78,271.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>211,747.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name:
	[REDACTED]
(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4**

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2018

End Date\*: 12-31-2018

Budget Period: 4

A. Senior/Key Person											
	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
1.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	192,610.00	3.6			57,783.00
2.		[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	76,606.00	3			19,152.00
<b>Total Funds Requested for all Senior Key Persons in the attached file</b>											
Additional Senior Key Persons:										File Name:	Total Sen

B. Other Personnel						
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fi
	Post Doctoral Associates					
1	Graduate Students	6			15,118.00	
	Undergraduate Students					
	Secretarial/Clerical					
1	<b>Total Number Other Personnel</b>					<b>Total O</b>
						<b>Total Salary, Wages and Fringe</b>

RESEARCH & RELATED Budget (A-B) (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2018

End Date\*: 12-31-2018

Budget Period: 4

**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

<b>Equipment Item</b>	<b>Funds Requested (\$)*</b>
-----------------------	------------------------------

Total funds requested for all equipment listed in the attached file

**Total Equipment**

Additional Equipment: File Name:

**D. Travel**

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	3,391.00
--	----------

2. Foreign Travel Costs

<b>Total Travel Cost</b>	<b>3,391.00</b>
--------------------------	-----------------

**E. Participant/Trainee Support Costs**

1. Tuition/Fees/Health Insurance	
----------------------------------	--

2. Stipends

3. Travel

4. Subsistence

5. Other:

**Number of Participants/Trainees**

**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS\*: [REDACTED]  
 Budget Type\*:  Project  Subaward/Consortium  
 Organization [REDACTED]

Start Date\*: 01-01-2018      End Date\*: 12-31-2018      Budget Period: 4

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	11,081.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Participant Incentives	250.00
<b>Total Other Direct Costs</b>	<b>11,331.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>130,952.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. Provisional MTDC	62.5	119,871.00	74,919.00
<b>Total Indirect Costs</b>			<b>74,919.00</b>
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>205,871.00</b>

J. Fee	Funds Requested (\$)*

**K. Budget Justification\***      File Name: [REDACTED]  
 [REDACTED]  
 (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period

ORGANIZATIONAL DUNS\*: [REDACTED]  
 Budget Type\*:  Project  Subaward/Consortium  
 Enter name of Organization: [REDACTED]

Start Date\*: 01-01-2019      End Date\*: 12-31-2019      Budget Period: 5

**A. Senior/Key Person**

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Request Salary (\$)
1.	[REDACTED]		[REDACTED]		[REDACTED]	196,462.00	3.6			58,939.
2.	[REDACTED]		[REDACTED]		[REDACTED]	78,138.00	3			19,535.
<b>Total Funds Requested for all Senior Key Persons in the attached file</b>										

Additional Senior Key Persons: File Name:

Total St

**B. Other Personnel**

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*
	Post Doctoral Associates				
1	Graduate Students		6		15,421.00
	Undergraduate Students				
	Secretarial/Clerical				
1	<b>Total Number Other Personnel</b>				

Total O

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Total Salary, Wages and Fringe

Tracking Number: [REDACTED]

## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2019

End Date\*: 12-31-2019

Budget Period: 5

C. Equipment Description		Funds Requested (\$)*
List items and dollar amount for each item exceeding \$5,000		
Equipment Item		Funds Requested (\$)*
Total funds requested for all equipment listed in the attached file		
Total Equipment		
Additional Equipment: File Name:		

D. Travel		Funds Requested (\$)*
1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)		3,211.00
2. Foreign Travel Costs		
Total Travel Cost		3,211.00

E. Participant/Trainee Support Costs		Funds Requested (\$)*
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	Total Participant Trainee Support Costs	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS\*: [REDACTED]

Budget Type\*:  Project  Subaward/Consortium

Organization: [REDACTED]

Start Date\*: 01-01-2019

End Date\*: 12-31-2019

Budget Period: 5

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	11,081.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Participant Incentives	0.00
<b>Total Other Direct Costs</b>	<b>11,081.00</b>

G. Direct Costs	Funds Requested (\$)*
<b>Total Direct Costs (A thru F)</b>	<b>132,853.00</b>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. Provisional MTDC	62.5	121,772.00	76,108.00
<b>Total Indirect Costs</b>			<b>76,108.00</b>
Cognizant Federal Agency		DHHS, Jeffrey Warren, (212) 264-2069	
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>208,961.00</b>

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: SubParishBudgetjustPD_P11017118833.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**OTHER DIRECT COSTS**

**Participant Incentives**

Women with intellectual and developmental disabilities who participate in the interviews will be paid \$50 to compensate them for their time, transportation and child care costs. For 20 women with intellectual and developmental disabilities, the total cost will be \$1,000. The interviews with

the women will be conducted in Years 1-4. We will also conduct cognitive testing to develop the interview guide. Two women with intellectual and developmental disabilities will be paid \$50 for participating in the cognitive interviews in Year 1 for this. Two other women with intellectual and developmental disabilities will be recruited to pilot test the interview guide in Year 1. These women will also be paid \$50 for their time, transportation costs and child care. Cognitive testing and pilot testing will occur in Year 1, for a total of \$200.

**Materials**

The budget includes \$450 to purchase three high-quality digital audio recorders for use at interviews. Data purchase costs of \$1,950 are also included to permit us to acquire the [redacted] for 2006-2012. These data are being purchase to address Aim 1 of the project.

**Travel**

Travel costs are included to permit [redacted] to present research findings at one scholarly conference in Year 1 and at two scholarly conferences in Years 2 through Year 5 in the US. Conference costs include airfare, hotel for 3 nights, per diem at the federal rate, transportation to and from the airport, and ground transportation to the conference venue, totaling \$1,495 in Year 1 and \$3,044 in Year 2, with a 2% escalation in Years 3 through Year 5. Local transportation at standard mileage rates is also included in Years 1 through Year 4 for [redacted] to conduct in-person interviews with women with intellectual and developmental disabilities.

Purpose	Departing City	Destination	# Trips	# of Staff	Driving Transportation			Air Transportation		Lodging			Meals & Incidentals			Local Transportation			Total
					Est. Mileage Rate	Miles to and from	Total Cost To Drive	Airfare	Total Airfare	Federal Lodging Rate	# Nights	Total Lodging Cost	Federal Per Diem Rate	# of Days	Total M&IE	Taxi, Car Rental, Shuttle	# of Trips*	Total Local Travel Cost	
Conference	[redacted]	[redacted]	1	1	0.565	0	0	450	450	209	3	627	71	3	178	60	4	240	1,495
Participant Interview	[redacted]	[redacted]	9	1	0.565	79	402	0	450	0	0	627	0	0	0	0	0	0	402
PERIOD 1			10	2															
Conference	[redacted]	[redacted]	2	1	0.576	0	0	459	918	213	3	627	72	3	178	61	4	240	1,897
Participant Interview	[redacted]	[redacted]	5	1	0.576	79	228	0	918	0	0	1,278	0	0	360	0	0	488	3,044
PERIOD 2			7	2															
Conference	[redacted]	[redacted]	2	1	0.588	0	0	468	936	217	3	1,302	73	3	360	62	4	496	3,098
Participant Interview	[redacted]	[redacted]	5	1	0.588	79	232	0	936	0	0	1,278	0	0	365	0	0	0	228
PERIOD 3			7	2															
Conference	[redacted]	[redacted]	2	1	0.600	0	0	477	954	221	3	1,326	74	3	370	63	4	504	3,331
Participant Interview	[redacted]	[redacted]	5	1	0.600	79	237	0	954	0	0	1,302	0	0	370	0	0	0	237
PERIOD 4			7	2															
Conference	[redacted]	[redacted]	2	1	0.612	0	0	487	974	225	3	1,326	75	3	375	64	4	512	3,381
Participant Interview	[redacted]	[redacted]	5	1	0.612	79	0	0	974	0	0	1,350	0	0	375	0	0	0	237
PERIOD 5			2	1															
Total Domestic Travel			33	9			1,099	4,232	15	5,883	15	1,648			20	2,240		15,102	
escalation rate:	1.02																		

\*Includes travel to and from the airport in Departing and Destination cities

[Redacted text block]

months) in Year 1, 10.53% (1.3 calendar months) in Year 2, 10.19% (1.2 calendar months) in Year 3, 9.97% (1.2 calendar months) in Year 4 and 9.64% (1.2 calendar months) in Year 5.

The cost of the subaward is \$11,081 in each year of the project.

**FACILITIES AND ADMINISTRATIVE (INDIRECT) COST (F&A)**

██ are 62% for fiscal year 2015 (07/01/2014-06/30/2015) and 62.5% for fiscal year 2016 (07/01/2015-06/30/2016). 62.5% is also the provisional rate beginning 07/01/2016 until amended. The F&A base is modified total direct costs (MTDC).

## RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals (\$)	
<b>Section A, Senior/Key Person</b>		518,160.00
<b>Section B, Other Personnel</b>		68,303.00
Total Number Other Personnel	5	
<b>Total Salary, Wages and Fringe Benefits (A+B)</b>		<b>586,463.00</b>
<b>Section C, Equipment</b>		
<b>Section D, Travel</b>		<b>15,102.00</b>
1. Domestic	15,102.00	
2. Foreign		
<b>Section E, Participant/Trainee Support Costs</b>		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
<b>Section F, Other Direct Costs</b>		<b>59,005.00</b>
1. Materials and Supplies	2,400.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	55,405.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	1,200.00	
9. Other 2		
10. Other 3		
<b>Section G, Direct Costs (A thru F)</b>		<b>660,570.00</b>
<b>Section H, Indirect Costs</b>		<b>393,535.00</b>
<b>Section I, Total Direct and Indirect Costs (G + H)</b>		<b>1,054,105.00</b>
<b>Section J, Fee</b>		

PHS 398 Cover Page Supplement

1. Project Director / Principal Investigator (PD/PI)

Prefix:
First Name\*:
Middle Name:
Last Name\*:
Suffix:

2. Human Subjects

Clinical Trial?
Agency-Defined Phase III Clinical Trial?\*

3. Permission Statement\*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

4. Program Income\*

Is program income anticipated during the periods for which the grant support is requested?
If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Table with 3 columns: Budget Period\*, Anticipated Amount (\$)\*, Source(s)\*. The table contains several rows of dotted lines for data entry.

## PHS 398 Cover Page Supplement

### 5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?\*       No       Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm). Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s):                       Specific stem cell line cannot be referenced at this time. One from the registry will be used.

### 6. Inventions and Patents (For renewal applications only)

Inventions and Patents\*:       Yes       No

If the answer is "Yes" then please answer the following:

Previously Reported\*:       Yes       No

### 7. Change of Investigator / Change of Institution Questions

Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name\*:

Middle Name:

Last Name\*:

Suffix:

Change of Grantee Institution

Name of former institution\*:

# PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

[REDACTED]

**1. Introduction to Application**

(for RESUBMISSION or REVISION only)

**2. Specific Aims**

[REDACTED]

**3. Research Strategy\***

[REDACTED]

**4. Progress Report Publication List**

**Human Subjects Sections**

**5. Protection of Human Subjects**

[REDACTED]

**6. Inclusion of Women and Minorities**

[REDACTED]

**7. Inclusion of Children**

[REDACTED]

**Other Research Plan Sections**

**8. Vertebrate Animals**

**9. Select Agent Research**

**10. Multiple PD/PI Leadership Plan**

[REDACTED]

**11. Consortium/Contractual Arrangements**

**12. Letters of Support**

[REDACTED]

**13. Resource Sharing Plan(s)**

**Appendix (if applicable)**

**14. Appendix**

## 1. SPECIFIC AIMS

During the eugenics movement in the early 20<sup>th</sup> century, 31 American states passed laws prohibiting women with intellectual and developmental disabilities (IDD) from marrying or procreating. Because these laws were repealed by the early 1970s, recent generations of such women have had the same reproductive rights as their non-disabled peers. However, there is negligible information on the incidence of pregnancy and childbirth, health outcomes, health care barriers, unmet needs and pregnancy-related health care costs among US women with IDD. A few small-scale studies from other countries suggest mothers with IDD suffer greater economic hardship, endure stigmatization and are more socially isolated than other mothers. Even less is known about the health outcomes of infants born to women with IDD.

Our pilot studies suggest US women with IDD and their infants are at an elevated risk for adverse pregnancy and childbirth outcomes. Although their numbers may be proportionally small (fewer than 1% of US pregnancies in our pilot sample), associated health care costs among these women may be exceptionally high. Efforts to improve the care they receive during pregnancy and reduce costs would benefit substantially from a more definitive assessment of the potential pregnancy risks and outcomes. However, the methodological difficulties of including women with IDD in population-based surveys make this challenging. Using national health services administrative data, and unique linked longitudinal data available in [REDACTED] as well as interviews with women with IDD and their health care providers, we **propose a mixed-method study to understand pregnancy experiences, health outcomes, related health care costs and unmet perinatal health care needs of women with IDD and their infants.**

We will examine three fundamental questions about the health of women with IDD during their pregnancy and their infants: 1) Are there differences in pregnancy complications, outcomes, health service utilization and costs among women with and without IDD?; 2) What needs of pregnant women with IDD currently go unmet?; and 3) Can we make specific recommendations assist providers in providing and improving perinatal care for pregnant women with IDD? **Our study will lead to a systematic understanding of pregnancy and infant health outcomes and pregnancy care costs for US women with IDD, thus establishing a foundation for development and testing of future interventions to improve outcomes.** We have three **Specific Aims:**

1. Compare pregnancy and childbirth complications, outcomes, and inpatient costs among women with IDD and women in the general US obstetric population using data from the nationally-representative 2007-12 Healthcare Cost and Utilization Database (HCUP), Nationwide Inpatient Sample (NIS).

### **Hypotheses:**

- a. Women with IDD are more likely to experience pregnancy-related complications and adverse pregnancy outcomes, including longer delivery hospitalization length of stay, early labor, preterm birth, stillbirth, and preeclampsia, in comparison to women without IDD.
  - b. The direct health care costs of pregnancy and childbirth are substantially elevated for women with IDD compared to women without IDD.
2. Examine longitudinal health outcomes and health care utilization and costs of women with IDD around the time of their pregnancy and for their infants (up to 1 year of age) compared to other women using linked data from the [REDACTED] Pregnancy to Early Life Longitudinal – All Payer Claims Database (PELL-APCD).

### **Hypotheses:**

- a. Women with IDD are less likely to have adequate outpatient prenatal care and are more likely to have pre- and post-delivery hospital use (emergency, inpatient, and observational) in contrast to women in the general obstetric population.
  - b. Infants born to mothers with IDD are more likely to have adverse health outcomes, including preterm and low birth weight, and consequently increased health care costs, compared to other infants.
3. Identify unmet needs and barriers to perinatal care for women with IDD through (a) in-person interviews with pregnant women and new mothers with IDD, and (b) telephone interviews with the health care professionals who provide their health care. This information will be used to generate practice recommendations to improve the perinatal health of women with IDD and their infants.

This proposal is submitted in response to *PAR-11-258*, which seeks projects investigating the incidence, course, and outcomes of pregnancy among women with disabilities. Our project is well-aligned with the *PAR* objectives because it (a) investigates pregnancy and health outcomes and costs among women with IDD and their infants, and (b) develops recommendations for perinatal care for women with IDD.

## 2a. RESEARCH STRATEGY: SIGNIFICANCE

This study focuses on the perinatal experiences of women with intellectual and developmental disabilities (IDD), defined as conditions with onset during childhood and characterized by significant limitations in both intellectual functioning and in adaptive behavior.<sup>1</sup> For the study purposes, perinatal care is defined as health care delivered during pregnancy and twelve months post-partum. As noted in the *PAR-11-258*, “studies of pregnant women with intellectual disabilities have been limited in number,” and thus understanding these women’s pregnancy outcomes is a key priority of the *PAR*. The objectives of this *PAR* are consistent with several public health statements. The Surgeon General’s *Closing the Gap* report (2002) called for research to address the dearth of existing evidence about the health and health care access of adults with IDD.<sup>2</sup> It was concluded that researchers should develop interventions to reduce disparities in health and health care. The report found, “Especially as adolescents and adults, people with [IDD] ... face ever-growing challenges in finding and financing primary and specialty health care that responds both to the characteristics of [IDD] and to the distinctive health care needs of each stage of life.”<sup>2</sup> *Healthy People 2020* outlines various priorities related to improving the well-being of expectant mothers and their children and reducing health disparities of vulnerable populations, including people with disabilities. Salient *HP2020* aims include reducing low birth weight and preterm births, and increasing receipt of adequate prenatal care.<sup>3</sup>

In the first half of the 20<sup>th</sup> century, involuntary sterilization and institutionalization were commonly used in the US to prevent women with IDD from becoming pregnant.<sup>4,5</sup> Deinstitutionalization and repeal of these laws led to unprecedented numbers of women with IDD living in community settings.<sup>6,7</sup> Using US Census Bureau data and CDC prevalence estimates that 1.3% of women have IDD, we estimate nearly 820,000 US women of childbearing age have IDD.<sup>8,9</sup> Many women with IDD are bearing children.<sup>10-15</sup> However, little is known about their pregnancy outcomes, associated health care costs, or their infants’ health outcomes.

**To date, there is no research on pregnancy or infant health outcomes with a population-based sample of US women with IDD.** Research on non-US populations has been limited to four clinical investigations of pregnancy outcomes, and three subjective, typically phenomenological studies of women’s perceptions of their pregnancy experiences. A study in one Sydney, Australia hospital found women with IDD (n=57) were more likely than other women to develop preeclampsia, and their newborns were more likely to have low birth weight. Further, both mothers with IDD and their newborns were more likely require care in the ICU.<sup>16</sup> Two Swedish national registry studies (n=326 women and 326 infants) found significantly elevated rates of Caesarean section and preterm birth and a higher prevalence of risk factors associated with adverse pregnancy outcomes, including young maternal age, obesity, and current smoking. Infants of women with IDD were more likely to be stillborn or die within the first week of life, be preterm, and be small for gestational age.<sup>17</sup> In a UK survey, women with IDD (n=120) were less likely than other women to receive prenatal care during the first trimester.<sup>18</sup> These four studies suggest women with IDD and their infants are at elevated risk of having adverse obstetric health outcomes, and the associated public health costs are likely to be high.

Three small-scale studies have investigated women’s perceptions of pregnancy and childbirth. Irish women with IDD (n=6) reported welcoming pregnancy, but their health care providers viewed them as high-risk ‘liabilities.’ These women also reported needing, but not receiving, disability accommodations to make choices about childbirth experiences.<sup>19</sup> Australian women with IDD (n=3) reported anxiety about becoming parents and not receiving support from family or from their health care providers.<sup>20</sup> Swedish women with IDD (n=10) reported not understanding the labor and delivery process and being unable to cope with hospital events.<sup>21</sup> Together, these studies suggest women with IDD need but may not receive sufficient support through pregnancy and childbirth. **Further research concerning perceptions and experiences of pregnancy and childbirth among US women with IDD are clearly warranted, particularly with larger samples.**

There are virtually no epidemiological or clinical outcomes data to guide perinatal care for women with IDD. The American Congress of Obstetricians and Gynecologists (ACOG) has taken steps to address this problem by developing web-based resources and Committee Opinions and by distributing information to providers generally. However, no perinatal care recommendations exist to address the specific needs of women with IDD during pregnancy. **Our study will build on these efforts by creating practice recommendations that our partners at ACOG and the American College of Nurse Midwives** and other members of our expert advisory committee will disseminate (see letters of support). Notably, co-investigator [REDACTED] has just been appointed to the ACOG Practice Bulletin Committee on Obstetrics, and is well-positioned to support these dissemination efforts.

The overall study goal is to systematically examine the health care experiences, outcomes and costs of

women with IDD during and after pregnancy. **We hypothesize women with IDD and their infants have worse prenatal and postpartum health than other women and children. We further hypothesize women with IDD experience substantial unmet needs and barriers to receiving appropriate perinatal care.**

In Specific Aim 1, we will determine national inpatient pregnancy-related hospitalization use and outcomes for women with IDD using the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS). We will expand on these findings, in Specific Aim 2, by examining longitudinal inpatient and outpatient healthcare utilization, health outcomes and health care costs of women with IDD and their infants (up to 1 year of age) using linked data from the [REDACTED] Preg [REDACTED].

[REDACTED]. In Specific Aim 3, we will develop perinatal care recommendations derived from in-depth qualitative interviews with obstetric health care providers and women with IDD from two states with highly disparate health care and intellectual disability service systems, [REDACTED] and [REDACTED]. All three aims will enable us to determine unmet perinatal health care needs of these women.

This study addresses conspicuous research gaps about women with IDD and their pregnancy outcomes, experiences, perinatal health service utilization, and pregnancy- and childbirth-related costs as well as the health outcomes of their infants. The findings will generate population-level information about IDD-associated pregnancy-related risks, complications, outcomes, and costs. This study will employ the concept of unmet need, frequently used in health services research to “indicate barriers to care... and other problems necessitating health policy interventions.”<sup>22</sup> By identifying unmet perinatal care needs, this study will define shortcomings in health care and other support systems. These findings will inform development of evidence-based policies and practices to improve perinatal care for these women and ultimately improve their outcomes and those of their infants. Finally, the study will develop perinatal care recommendations, providing clinicians with practical tools to address the unique needs of this highly vulnerable population of women with IDD.

## **2b. RESEARCH STRATEGY: INNOVATION**

Our study **will be the first systematic, mixed-method investigation of pregnancy and health costs, and health service utilization and outcomes for US women with IDD and their infants.** We will document demographic characteristics of the population, and determine their health care experiences, pregnancy-related complications and outcomes, and health care utilization and costs. The sample provided by the 2007-12 HCUP will include ~ 2040 deliveries among women with IDD. The linked 2009-2017 PELL-APCD will include ~700 deliveries among women with IDD. As noted above, few studies have investigated these issues, and none with the US population or with such large samples. HCUP and the [REDACTED] PELL-APCD analyses will enable this project to generate population-based findings of maternal and infant outcomes. In addition, the proposed qualitative interviews will complement the population-based findings and provide the first investigation of pregnancy experiences from the perspective of both US women with IDD and obstetric care providers.

This study will thus provide a **first-ever picture of pregnancy-related outcomes and health service utilization among US women with IDD.** Investigating these issues from complementary vantage points is an important strength (i.e., nationally-representative inpatient population data; inpatient and ambulatory population data from [REDACTED] and in-depth information from obstetric providers and women with IDD). The HCUP Nationwide Inpatient Sample will offer nationally-representative insights about pregnancy-related inpatient hospitalizations, costs, complications and outcomes. The PELL-APCD is a unique, longitudinal dataset that links all [REDACTED] birth certificates, fetal death records, birth-related hospital records, inpatient and outpatient health care utilization and costs for mothers and their infants. This dataset will offer uniquely detailed information beyond any available elsewhere. [REDACTED] is the only state for which these linked data are available. **US researchers have not leveraged the opportunity posed by these datasets to study perinatal care, pregnancy outcomes and costs for US women with IDD and their infants.**

Another study innovation is the **use of the construct of unmet need as it relates to perinatal care for women with IDD.** Unmet need is a widely used concept in health services research with other vulnerable populations (e.g., children with special health care needs, adults with disabilities).<sup>22-29</sup> As *PAR-11-258* noted, there is a critical need for studies of the barriers specific to perinatal care of women with IDD. There are no systematic studies on perinatal care barriers for US women with IDD. Thus, **we will break new ground by investigating barriers to perinatal health care for women with IDD.**

**An additional innovation will be the development of obstetric care practice recommendations for women with IDD.** These recommendations will be informed by both clinicians and women with IDD, as well as findings from the HCUP and PELL-APCD analyses. These recommendations will be widely

disseminated to clinicians through our collaborators at ACOG and ACNM (see letters of support).

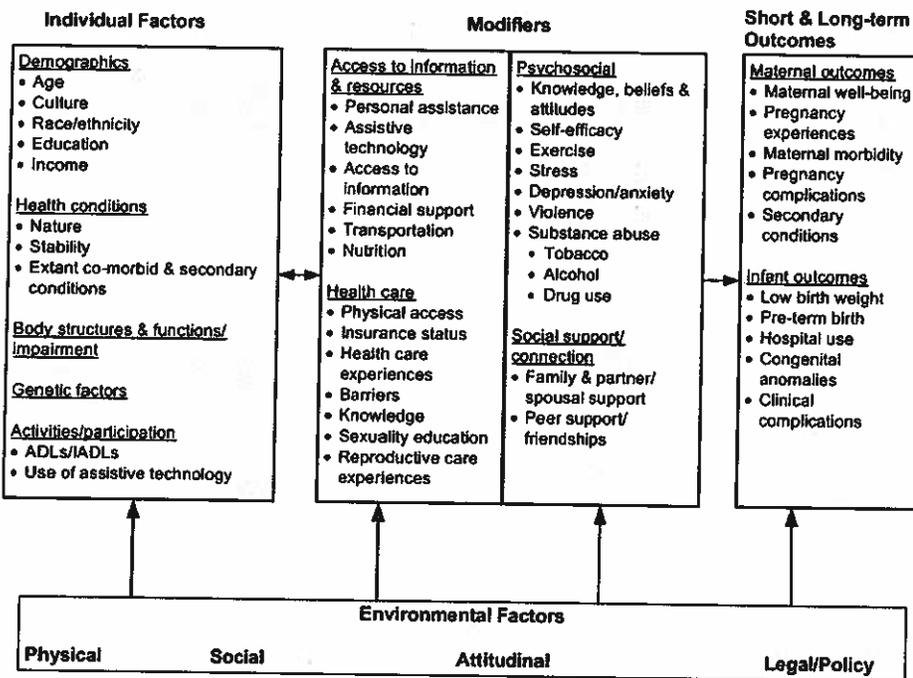
## 2c. RESEARCH STRATEGY: APPROACH

### 2.c.1 Perinatal Health Framework for Women with Disabilities<sup>30</sup>

This theoretical model guides our study. It delineates the risk and mediating factors for HCUP and PELL-APCD analyses (Aims 1 & 2) and informs interview guide development (Aim 3). The framework is based on the International Classification of Functioning, Disability and Health (ICF)<sup>31</sup> and the reproductive health maintenance model of Nosek and her colleagues.<sup>32</sup> The ICF defines disability as an “umbrella term for impairments, activity limitations or participation restrictions,” conceiving a “person’s functioning and disability... as a dynamic interaction between health conditions (diseases, disorders, injuries, traumas) and contextual factors.”<sup>31</sup> The Framework (Fig. 1) reflects that short- and long-term pregnancy outcomes for women with IDD result from the interaction of numerous factors, including those present across a woman’s lifespan and around the time of pregnancy. *Environmental factors* are (1) physical (e.g., transportation, accessibility of the clinician’s office); (2) social (e.g., social supports); (3) attitudinal (e.g., those of clinicians and family about pregnancy of women with IDD); and (4) legal/policy (e.g., Medicaid, Supplemental Security Income, and related regulations). Environmental factors (physical, social, attitudinal, and policy) will be explored in Specific Aim 3 through interviews with women with IDD and obstetric care providers.

*Individual factors* include: (1) demographics (e.g., age, race, income); (2) body structures; (3) functions (e.g., body system operations); (4) impairments, which refer to deviation from population standards for body structures and functions; (5) genetic factors which may affect any woman and are condition-specific; (6) activities (e.g., individuals’ execution of actions); (7) participation is “involvement in a life situation”;<sup>31</sup> and (8) health conditions (e.g., nature of the primary impairment, comorbid or secondary conditions). *Comorbidities* are unrelated to the disability, such as complications of pregnancy that could occur in anyone (e.g., premature rupture of membranes).<sup>31</sup> *Secondary conditions* are unrelated to the impairment, but those for which women with IDD are at higher risk generally, such as obesity, hypertension, and diabetes.<sup>33-35</sup> Complications and secondary conditions can overlap as pregnancy may increase an already elevated risk of developing certain medical conditions due to the nature of the underlying impairment.

**Figure 1: Perinatal Health Framework for Women with Disabilities**



The framework also illustrates modifiers of the relationship between *environmental and individual factors* and outcomes. These include four categories with potential to affect perinatal health for women with IDD: (1) **access to information and resources** (e.g., preconception counseling, knowledge of pregnancy, transportation to prenatal care visits); (2) **health care** factors including attitudinal barriers interfering in relationships with health care providers; (3) **psychosocial** factors ranging from the woman’s beliefs about childbearing and motherhood to increased risk for abuse during pregnancy, and (4) **social support** factors (e.g., family support, relationships with partners). These factors will be explored in Aim 3.

Outcomes occur in two categories: (1) **maternal outcomes**, including overall maternal well-being, experiences of pregnancy, maternal morbidity, complications and secondary conditions; and (2) **infant outcomes**, such as low birth weight, preterm birth, hospital use, and clinical complications (See Table 1).

Many *individual* and *environmental factors* in the Framework suggest women with IDD are at elevated risk for adverse outcomes.<sup>30</sup> With regard to *environmental factors*, women with IDD are more likely than others

to live in poverty, lack social supports, and experience abuse.<sup>36</sup> They also face pregnancy-related stigma from clinicians.<sup>19</sup> *Individual factors* include increased genetic risk, elevated stress, depression and anxiety,<sup>37</sup> increased tobacco use,<sup>38</sup> poor nutrition,<sup>39</sup> and relatively low self-efficacy.<sup>40</sup> *Chronic conditions are also individual risk factors*, and they are elevated among women with IDD (obesity, hypertension, diabetes, and cardiovascular disease).<sup>33,39</sup> These women often have communication difficulties that impede effective communication with care providers; their cognitive impairments may make it challenging to follow care recommendations.<sup>41</sup> High rates of medication use<sup>42</sup> pose unclear risks to their infants' well-being.<sup>43</sup>

**Table 1: Definitions and Source of Outcome Variables for HCUP and PELL-APCD Analyses**

	Definition	HCUP (Aim 1)	PELL-APCD (Aim 2)
<b>Maternal Outcomes</b>			
Prenatal hospital utilization	Number of emergency or inpatient visits (i.e., admissions and observational stays) during pregnancy		X
Postpartum hospital utilization	Receipt of any emergency or inpatient (i.e., admissions and observational stays) services occurring through 1 <sup>st</sup> year post delivery		X
Type of delivery	Caesarean section or vaginal delivery	X	X
Length of stay for delivery	Length of stay in hospital during delivery (days)	X	X
Maternal complications	Preeclampsia or other hypertensive condition, hemorrhage, placenta previa, placenta abrupto, gestational diabetes, trauma to perineum/vulva, prolonged labor, threatened labor	X	X
Adequacy of prenatal care	As measured by the Kotelchuck Index <sup>44</sup>		X
Maternal postpartum visit	Health care visit within 4-6 weeks postpartum		X
Delivery related costs	Total costs related to delivery	X	X
Inpatient health care costs	Total inpatient costs from pregnancy through 1 year postpartum		X
Outpatient healthcare costs	Total outpatient costs from pregnancy through 1 year postpartum		X
<b>Fetal/Perinatal Outcomes</b>			
Multiple births	>1 live born or stillborn infants of at least 350g or 20 wks gestation		X
Preterm birth	Live born <37 weeks gestation		X
Small-for-gestational age	Birth weight <10th percentile for gestational age		X
Low birth weight	Birth weight less than 2500g	X	X
Fetal death/Stillbirth	Stillbirth of at least 20 weeks' gestation and/or >350g	X	X
Neonatal mortality	Death of a live born infant before 28 days of life		X
Apgar Score	< 5 at 5 minutes		X
Abnormalities	As noted in the Massachusetts birth certificate		X
NICU	Admission to NICU		X
Cost of delivery	Total costs associated with childbirth	X	X
<b>Infant (up to 1 year) Outcomes</b>			
Hospital services	Number of emergency or inpatient (i.e., admissions and observational stays) services occurring up to 1 year after birth		X
Specific clinical morbidities	Specific morbidity diagnoses reported on hospital discharge, emergency department, or observational stay		X
Postneonatal and infant mortality	Death occurring ≥28 days after birth but before 1 year of age identified through the PELL linkage to Massachusetts death certificates or linkage to the National Death Index		X
Health maintenance visits	Timeline of well-child visits to pediatrician		X
Inpatient healthcare costs	Total inpatient costs incurred from childbirth to 1 year of age		X
Outpatient healthcare costs	Total outpatient costs incurred from childbirth to 1 year of age		X

### 2.c.2. Preliminary Studies

We have conducted preliminary studies on the maternal complications and delivery outcomes of women with IDD utilizing both the 2010 HCUP Nationwide Inpatient Sample and the [REDACTED] Pregnancy to Early Life Longitudinal (PELL) data. In both studies, women with IDD and their infants were at elevated risk for adverse outcomes, including preterm birth, low birth weight, and pre- and post-delivery hospital use in comparison to the general population.<sup>45,46</sup> For both studies (summarized in Tables

2 and 3), we used ICD-9 diagnostic codes to identify women with IDD.<sup>47-50</sup> Our 2010 HCUP analyses found women with IDD comprise fewer than 1% of US deliveries (n=340, representing a weighted 1,705 of the 3.9 million US births), but are at elevated risk of adverse outcomes. This is the **first population-based study of the percentage of all US deliveries to women with IDD**. Compared to other women, those with IDD were younger, more likely to be Black, less likely to be Latina and more likely to have Medicaid or Medicare. **They were more likely to experience Cesarean delivery, preeclampsia, preterm birth, and deliver infants with poor fetal growth compared to the general obstetric population, and they had longer hospital stays.** After adjusting for race, Hispanic ethnicity, age, and payer, US women with IDD were still more likely than other women to have Cesarean sections, preeclampsia, and preterm birth (data not shown).<sup>45</sup>

**Table 2: Preliminary findings: analysis of 2010 HCUP<sup>45</sup>**

	Deliveries among women with IDD (n=340) % (n)	Deliveries among without IDD (n=768,891) % (n)
Race: Non-Hispanic White***	52 (162)	44 (2,861)
Race: Non-Hispanic Black***	28 (82)	20 (1,289)
Race: Hispanic***	12 (35)	25 (1,639)
Race: Non-Hispanic other***	8 (24)	10 (672)
Insurance Payer: Medicaid***	55 (184)	46 (347,871)
Insurance Payer: Medicare***	19 (64)	1 (4,350)
Cesarean delivery***	49 (167)	33 (250,882)
Preeclampsia***	21 (71)	10 (72,588)
Preterm birth***	13 (45)	7 (56,800)
Poor fetal growth***	4 (14)	2 (18,123)
	<b>Mean (SD)</b>	<b>Mean (SD)</b>
Days in hospital***	4 (<1)	3 (<1)
Age***	26 (<1)	31(<1)

Our PELL analyses found that among the 616,286 women in [redacted] who gave birth between 1998-2009, fewer than 1% (n=494) were women with IDD.<sup>46</sup> In contrast with other women, those with IDD were younger (11% were <20 years), more likely to be Black or Latina, less educated, more likely to have Medicaid, more likely to receive inadequate prenatal care (as measured by the Kotelchuck or Adequacy of Prenatal Care Utilization Index),<sup>44</sup> have Cesarean delivery, and have longer hospital stays (data not shown). Seventy percent of

Note: Percentages are weighted \*\*\* p<.001

women with IDD received prenatal care in the first trimester, compared to 84% of women in the general population. After adjusting for a host of demographic characteristics, parity, plurality,

health insurance, prenatal care adequacy, and tobacco use during pregnancy, **women with IDD were more likely than other women to have Cesarean sections, low birth weight infants, and higher hospitalization rates during pregnancy and one-year post-delivery** (data not shown).<sup>46</sup>

Our findings of elevated complications and adverse outcomes for women with IDD **highlight the need for a systematic investigation of the pregnancy risks, complications, care, costs and outcomes** of these women. These results

demonstrate our ability to execute the research plan and while they shed new light on the pregnancy outcomes of US women with IDD, the proposed study will extend this work in important ways. First, it will use 6 years of US data (~2040 women with IDD) and 10 years of [redacted]'s linked inpatient and outpatient health care utilization data (~700 deliveries) to investigate differences in and risk factors for complications and outcomes for women with IDD and their infants. We will also determine the outpatient costs associated with pregnancy and childbirth among US women with IDD and inpatient and outpatient costs associated with pregnancy

**Table 3: Preliminary findings: analysis of [redacted] PELL**

	Deliveries among Women with IDD (n=722) % (n)	Deliveries among Women without IDD (n=879,301) % (n)
Prenatal care was inadequate ***	18 (132)	9 (75,458)
Prenatal care in first trimester ***	70 (213)	84 (143,338)
Cesarean delivery ***	37 (191)	28 (205,975)
Low birth weight ***	16 (116)	8 (66,437)
Pre-term delivery ***	14 (99)	8 (73,066)
<b>Pre-delivery hospital utilization ***</b>	56 (404)	27 (235,537)
Hospital discharge ***	19 (139)	4 (37,343)
Observational stay ***	30 (213)	14 (122,876)
Emergency department ***	35 (249)	14 (119,048)
<b>Post-delivery hospital utilization</b>	13 (91)	9 (77,216)
Hospital discharge ***	6 (44)	2 (21,063)
Observational stay ***	4 (20)	1 (10,624)
Emergency department	6 (40)	6 (51,089)

Note: Percentages are weighted; \* p <.05; \*\* p <.01; \*\*\* p <.001.

among [REDACTED] women with IDD and their infants. Finally, we will investigate inpatient and outpatient perinatal health service utilization.

### **2.c.3. Specific Aim 1 Approach**

Specific Aim 1 is to *investigate pregnancy and childbirth complications, outcomes, hospital utilization, and delivery-related inpatient costs among women with IDD in comparison with the general obstetric population*. Major research questions for Specific Aim 1 include: **(1) What are the disparities in hospital utilization, pregnancy complications and outcomes among women with IDD compared to other women?; (2) What are the differences in hospital costs related to pregnancy and childbirth between women with and without IDD?; and (3) What is the impact of pregnancy complications and other maternal characteristics on maternal outcomes and inpatient costs of women with IDD in comparison to other women?** We hypothesize women with IDD will experience disparities in pregnancy complications, outcomes and health care costs in comparison to other women. We will analyze 2007-12 Healthcare Cost and Utilization Project Nationwide Inpatient Sample to address these questions.

#### **2.c.3.1. Nationwide Inpatient Sample, Healthcare Cost and Utilization Project (HCUP)**

We will use hospital discharge data from the Nationwide Inpatient Sample (NIS) of the HCUP, sponsored by the Agency for Healthcare Research Quality to provide nationwide estimates of inpatient care. The NIS is the largest all-payer, publicly-available US inpatient health care database. It contains data on ~8 million hospital stays each year from about 1,000 hospitals sampled to approximate a 20% stratified sample of US hospitals. The NIS contains more than 100 clinical and nonclinical data elements for each hospital stay, including primary and secondary diagnoses and procedures (up to 14 secondary diagnoses and procedures coded using ICD-9 CM), admission and discharge status, patient demographic characteristics (e.g., sex, age, race), hospital characteristics (e.g., size, teaching status), expected payer, total charges, length of stay, condition severity and comorbidity measures.<sup>51</sup> The NIS does not include unique patient identifiers and the unit of analysis is thus the hospital discharge (i.e., the hospital stay). However, each delivery is associated with only one pregnancy; any woman who delivered more than once in a single calendar year was counted twice. However, this situation is uncommon because short interpregnancy intervals that result in US women giving birth within a twelve-month period are relatively rare<sup>52</sup> and thus even fewer women give birth twice in one calendar year. Additional methodological details of the HCUP NIS are available.<sup>53</sup> Hospitalizations of women with IDD will be identified through ICD-9 CM diagnostic coding of IDD (and subsequently ICD-10 CM) in the discharge summary. Identification of the population with IDD using billing codes is a demonstrated, recommended strategy.<sup>47,49,54</sup> We will not assess infant outcomes except preterm birth and poor fetal growth, because maternal and infant record linkages are not possible with the HCUP NIS.

#### **2.c.3.2 Analysis of HCUP Nationwide Inpatient Sample data**

We will use HCUP NIS to create a case-control analysis in which each woman with IDD (case) is matched to two women without IDD (controls). This case-control approach is justified since the pregnancy outcomes of interest are age-related. To avoid an imbalance of age between the cases and the controls, we will match women based on age, number of previous pregnancies, and geography. For the first research question, the primary outcomes are fetal and other maternal outcomes (Table 1) compared between women with and without IDD. Health outcomes are binary (yes/no), permitting use of conditional logistic models (conditioned on the matching) to investigate the relationship between the outcome and predictors, including case-control status, sex of the infant, and other pregnancy and pre-pregnancy factors of interest. From these models, we will be able to assess the effect of case-control status on the outcome of interest; for example, are women with IDD more (or less) likely than other women to have a preterm birth. The parameter for case-control status and other predictors in the logistic or Poisson model will be tested using a standard Wald chi-square. For the conditional logistic models, we will examine the -2 log likelihood and its adjustments, the Akaike Information Criterion (AIC) and the Schwarz (Bayesian Information) Criterion, as the overall test of the global hypothesis of  $\beta=0$ . If that test is significant ( $p \leq 0.05$ ), then we will assess each factor for significance (i.e.,  $\beta_i \neq 0$ ). We will also investigate the model for overdispersion and use the Williams' method as needed. For all factors, we will use a p-value of 0.05 to indicate a significant difference of the regression parameter ( $\beta$ ) from zero. All analyses will use the latest version of SAS software (SAS Institute Inc., Cary NC, USA).

In addition to modeling pregnancy outcomes as described above, we will also investigate differences in total hospital costs. We will model the cost outcome using general linear models with case-control status as the main predictor along with other factors of interest. We will convert the charges reported in HCUP to costs using

HCUP Cost-to-Charge Ratios based on hospital accounting reports from the Centers for Medicaid and Medicare Services.<sup>55</sup> For each linear model, we will first assess the goodness of model fit with the global test of model fit (overall ANOVA test) followed by assessment of the significance of each factor. For factors with multiple degrees of freedom (e.g., gestational age in three groups: < 34 weeks, 34-37 weeks, and ≥ 37 weeks), we will first assess the overall Type III test for evidence of significant variability among the levels of the factor and, if significant, assess the significance of each level of the factor (compared to a reference level) in the regression. Finally, we will examine the residuals for evidence of heteroscedasticity, indicating the need for data transformation or recoding to achieve a normal distribution of the residuals.

For the second research question, we will model hospital costs related to pregnancy and childbirth as the outcome using general linear models with predictors case-control status, sex of the infant, and other factors of interest. For the third research question, impact of pregnancy complications and maternal characteristics on maternal outcomes and inpatient costs, we will use similar modeling approaches as described above. Specifically, we will model binary maternal outcomes (e.g., type of delivery) as well as continuous outcomes (e.g., inpatient costs) while including as predictors case-control status and the occurrence of pregnancy complications (such as preeclampsia or gestational diabetes). For each model used to address the research questions above, as exploratory analyses and to the extent possible given the sample size, we will investigate the interaction of case-control status with the other prediction factors of interest to determine if certain factor effect women with IDD significantly differently (either quantitatively or qualitatively) than women without IDD.

**Statistical power.** With a sample of ~ 2040 women with IDD (340 in each of six years) and a matching sample of 4080 women without IDD (controls), we can calculate minimum detectable differences for binary health outcomes and continuous cost outcomes. For binary outcomes (e.g., preeclampsia), for a two-sided chi-square (Mantel-Haenszel) test of differences in the outcome between women with and without IDD, in the most conservative case for  $p=0.50$  for one of the groups of women, we will have over 90% power to detect a difference of 0.05 between the two groups (a small Cohen's effect size). Since we lack information on the rate of preeclampsia for women with IDD,  $p=0.50$  is used as it will have the largest standard deviation of any proportion, yielding the most conservative estimate. If the proportions are less than or greater than 0.50, the detectable difference will be smaller. With a logistic model, we would expect even greater power. For continuous outcomes (e.g., hospital costs), again, because we lack estimates of the mean or standard deviation for those outcomes, we assume a standard deviation of 1.0. For a two-sided t-test of differences between women with and without IDD, we will have over 90% power to detect a difference of 0.10 standard deviations between the two groups of women (a small Cohen's effect size). Even if the variables are not normally distributed and we use a non-parametric test (Mann-Whitney U test), we will still have 90% power to detect differences in the 0.10 range. These approaches to power (minimum detectable differences) estimates are for unadjusted analyses, due to uncertainty about the factors in the models and the correlations among them. However, they represent a conservative estimate of the minimum detectable differences since analyses using models will have more power due to subsetting the variance among the model components. We will also not try to estimate the power for interaction effects given the complexity of specifying the nature of the interaction and that analysis of interactions is an exploratory outcome for which very little information exists in the literature. We realize that a non-significant interaction may not mean that there is no interaction effect, but that we may not have had the sample size to demonstrate that effect.

#### 2.c.4. Specific Aim 2 Approach

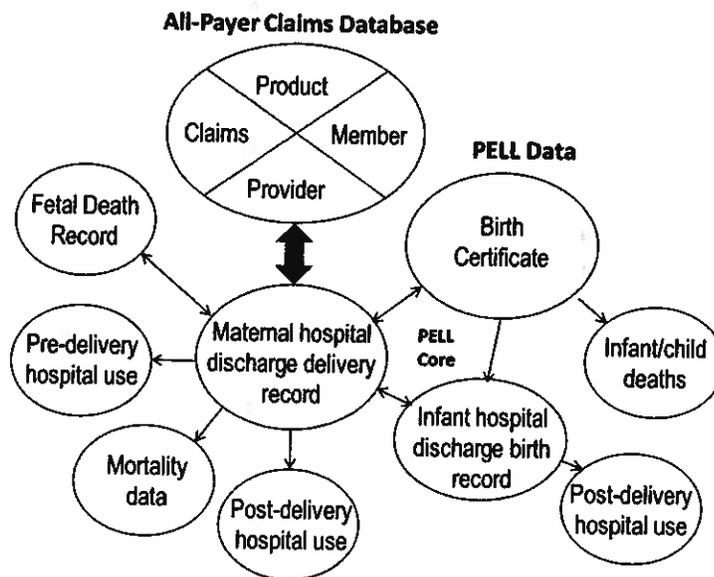
Specific Aim 2 is to *examine the longitudinal pregnancy complications, health outcomes and inpatient and ambulatory health care utilization and costs of women with IDD and their infants (up to 1 year of age) and compare them to other women using [REDACTED] Pregnancy to Early Life Longitudinal data linked to 2009-2017 All Payer Claims Database (PELL-APCD).* Major research questions include: **(1) Are there differences in the adequacy of prenatal care, pregnancy complications, maternal and infant outcomes, and health care utilization and costs between women with IDD and other women?; (2) Are there differences in the health outcomes, healthcare utilization and costs among infants born to mothers with IDD compared to other infants; and (3) What is the impact of prenatal care, pregnancy complications, and other maternal characteristics on maternal and infant outcomes, health care utilization and costs of women with and without IDD?** We hypothesize women with IDD are less likely to receive timely prenatal care, more likely to have poor maternal and infant outcomes, and incur higher perinatal costs. We further hypothesize infants born to women with IDD are more likely to have adverse health outcomes, including low birth weight, and incur higher health care costs in comparison to other infants (see

Table 1). Specific Aim 2 builds upon Aim 1 by examining prenatal care adequacy, pre- and post-natal inpatient and outpatient health care utilization and costs, infant outcomes, and infant healthcare utilization and costs. Women with IDD will be identified through ICD-9 (and subsequently ICD-10) diagnostic coding.

2.c.4.1. [REDACTED] PELL-APCD Linked Database

PELL is a longitudinal linked data system created to comprehensively utilize a broad range of existing public health data to examine the impact of pregnancy-related experiences on subsequent maternal and child health.<sup>50</sup> PELL enables researchers to study risk and protective factors and health outcomes longitudinally. It is one of the most comprehensive maternal-child health population databases in the US.<sup>56-58</sup> PELL annually links all [REDACTED] deliveries with hospital discharge records, maternal and infant death certificates, maternal and child observational stays, emergency department visits and program participation including the Birth Defects Registry, and Early Intervention data. Over 99% of birth certificates have been linked to their corresponding maternal or infant hospital discharge record, and over 95% of linked records have a robust linkage weight.<sup>56-58</sup> APCD is comprised of all medical, pharmacy, and dental claims, in addition to information about member eligibility, benefit design, and insurance providers, for all payers covering residents who are insured (notably, most [REDACTED]

Figure 2: [REDACTED] PELL-APCD Data Linkage



residents, particularly those disabilities with are insured).<sup>59</sup> The [REDACTED] includes four files: product (includes characteristics of the health insurance plan and individual and family deductibles), member (demographic characteristics, benefit coverage), claims (utilization) and provider (primary and specialty).

This project will develop the linked PELL-APCD database (see Figure 2) of all [REDACTED] live births and fetal deaths, hospital discharge records, and medical, pharmacy, and dental claims for all payers in the state between 2009-2017. We will use this linked database to assess the effect of having IDD on short- and long-term maternal and child health outcomes. The process of establishing the linkage between PELL and APCD is currently underway between [REDACTED] and the Center for Health Information and Analysis, custodian of APCD (see letter of support from [REDACTED] and [REDACTED]). During Year 1, this linkage will be performed for 2009-2013, and in each subsequent study year, the database will be updated to include the most recent data available through 2017 (available in 2019). The PELL will also be updated annually at the Department of Public Health. Linkage of PELL and APCD data will be carried out at the [REDACTED] on secure, restricted servers by [REDACTED] and [REDACTED] as described below (see letter of support).

**Linkage of APCD to PELL and advantages for the proposed project.** The algorithm used to match APCD and PELL will require an iterative process, similar to those that link PELL with other public health datasets. LinkPro, a SAS software application system for probabilistic and deterministic record linkage will be used. Primary linkage variables will include date of birth, name, encrypted Social Security number, and zip code. To improve matching, two functions in the software will be used (SOUNDEX and SPEDIS). Each linked delivery record will be assigned a randomly-generated unique Delivery ID that will be placed on both the linked APCD and PELL records. Unique babies, unique deliveries and unique women will have identification numbers in the linked PELL-APCD records. Identifying keys will be maintained at the [REDACTED] a restricted access folder on the secure PELL server. Data quality assessment efforts will be extensive. Discordant matches will be scrutinized and records unlinked as needed. Data linkages will be performed using SAS software on the secure PELL drive at the Department of Public Health following strict confidentiality guidelines. Once women and infants are linked, their protected health information will be deleted.

**The PELL-APCD linkage will create a wholly unique database** of detailed inpatient and outpatient health care utilization and costs, insurance coverage, and data from birth certificates and fetal death certificates. It will also contain Medicaid data, including an indicator of whether women are receiving services from the state's Department of Developmental Services, which is the state agency responsible for IDD services. To our knowledge, [REDACTED] is the first state for which linked APCD-birth certificate linked data will be available to execute these planned analyses. As noted above, we have already conducted a PELL study of pregnancy outcomes.<sup>46</sup> Team members [REDACTED] and [REDACTED] are currently analyzing the APCD, and [REDACTED] and [REDACTED] are analyzing PELL data to examine pregnancy outcomes among women with mobility disabilities so we have the requisite expertise on the team to execute the study as planned.

#### **2.c.4.2. Analysis of [REDACTED] PELL-APCD Linked Data**

Similar to the analysis for Specific Aim 1, we will use a matched case-control analysis for Specific Aim 2. As in Specific Aim 1, each woman with IDD will be a case, matched for age and number of previous live births to two women without IDD (controls). For Specific Aim 2, we will conduct analysis of the linked hospital discharge data with the medical and pharmacy claims data from the linked PELL-APCD for 2009-17. While the data are collected and recorded longitudinally for each woman and her infant, we are not analyzing any repeated measures, so our approach will be to use outcomes from longitudinal data, such as any occurrence of hospitalization in the first year of life (to be analyzed using a conditional logistic model) or the number of hospitalizations in the first year of life (to be analyzed using a conditional Poisson regression model). Adjustment for any correlation between measures on the same woman or infant may not be necessary in these analyses as would be needed for repeated measures of, say, weight of the infant. However, some women will have multiple pregnancies reported in the eight years of PELL-APCD data. For certain outcomes, such as infant's birth weight, we will use mixed effects models to take into account the inherent correlation of birth weight for infants with the same mother.

As our first step in identifying all possible women with IDD, prior to establishing the case-control matching, we will use both the PELL (IDD as a listed diagnosis in hospital discharge records) as well as a search of diagnoses in the APCD (IDD as a listed diagnosis in medical or dental claims data). A single listing of an ICD-9 diagnostic code for IDD in the APCD will not be taken as firm evidence of IDD, but we will require a pattern of IDD codes listed on multiple claims as well as relevant procedure codes to classify women as IDD.

For the first research question, we will compare women with and without IDD in terms of the adequacy of prenatal care, frequency of pregnancy complications, and occurrence of maternal and infant outcomes (as defined in Table 1) using Mantel-Haenszel chi-square tests (to account for the matching) for unadjusted comparisons as well as health care utilization (e.g., frequency of use of emergency department) and total costs using non-parametric tests of distributions. For adjusted comparisons between the two groups of women, we will use conditional logistic models for the categorical outcomes (conditioning on the matching) and general linear models for the continuous outcomes. Depending on the distribution of the health care utilization indicators, we may use conditional Poisson regression models to analyze frequency of usage. The modeling approach will be similar to that described for Specific Aim 1 above.

For the second research question, we will compare infants of women with and without IDD in terms of binary health outcomes (Table 1, e.g., preterm birth, Apgar score < 5 at 5 minutes, abnormalities), health care utilization as counts or binary events (Table 1, e.g., hospital/pediatrician visits in first year of life, clinical morbidities), and costs as continuous outcomes (Table 1, e.g., inpatient costs and outpatient costs) using approaches similar to the first research question.

For the third research question, we will model the relationship between prenatal care, pregnancy complications, and maternal characteristics (such as age and number of live births) on maternal and infant outcomes (all as defined in Table 1) using conditional logistic models, health care utilization using conditional logistic or Poisson models (depending on the distribution of utilization), and costs using general linear models. In each model, we will include IDD status as a binary predictor as above. For this analysis, we will have a sample large enough to investigate interactions of IDD status with prenatal care (for example) on infant outcomes (such as APGAR score at 5 minutes post-delivery recorded in the PELL data). As with Specific Aim 1, as exploratory analyses, we will investigate interaction effects of predictive factors on the association between case-control status and the outcomes to the extent possible given the sample size.

The major advantage of linking the PELL and APCD data is that the PELL dataset contains outcome data from medical records, and vital statistics from birth and fetal death certificates, but limited data related to cost and utilization whereas the APCD has complete information on medical care utilization and cost over time.

The use of both data sets will enhance the ability to provide an accurate answer to the question and, in addition, provide the opportunity to pursue additional research questions. Without the APCD data, the analysis of the infants' experience over the first year of life would not be attainable. All claims data programming will be performed using the latest version of SAS software.

**Statistical Power for Aim 2.** Given our preliminary study of the PELL (Table 3, above) we expect to have an average of 80 deliveries annually to women with IDD over the nine years of the PELL-APCD data that will be available by the end of the project (2009-2017), for a total of 720 women with IDD, who will serve as the cases. Using a 2:1 matching as described for Specific Aim 1, we expect to have n=1,440 women without IDD serve as matched controls. For categorical outcomes (e.g., preeclampsia), assuming a two-sided Mantel-Haenszel chi-square test conducted at  $\alpha=0.05$  and further assuming the most conservative proportion (0.50) with the largest standard deviation, we will have 90% power to detect a difference of 0.075 between two proportions with one proportion being 0.50 (a small Cohen's effect size). For continuous outcomes (e.g., inpatient costs), because we lack good estimates of the mean or standard deviation for those outcomes in the IDD population, we assume a standard deviation of 1.0. For a two-sided t-test of differences between women with and without IDD, we will have over 90% power to detect a difference of 0.15 standard deviations between the two groups of women (a Cohen's small effect size). Even if the variables are not normally distributed and we use a non-parametric test (Mann-Whitney U Test), we will still have 90% power to detect differences in the 0.15 range.

For both Specific Aims 1 and 2, we will have the power to detect small differences between women with and without IDD. Some of these statistically significant differences may not be meaningful, however. Thus, we will meet as a research team prior to any analysis to determine a meaningful difference for each outcome and use those determinations to guide our interpretation of the results. This is also true of the modeling approaches, in which any correlation (the main statistic on which regression coefficients are based) greater than 0.10 is significant. We will determine a meaningful correlation or standardized regression coefficient as a guide in interpreting the importance of the association.

## **2.c.5 Specific Aim 3 Approach**

### **2.c.5.1 In-person interviews with women with IDD**

We will conduct 40 in-person interviews with a racially diverse sample of new mothers with IDD from two states [REDACTED] and [REDACTED] purposively chosen for the marked differences in their intellectual disabilities service systems,<sup>7</sup> their distinct health insurance systems, notable differences in their maternal and child health programs<sup>60,61</sup> and their disparate demographic and sociopolitical characteristics.<sup>62,63</sup> Sampling women from such different states will provide insights about pregnancy experiences of women with IDD who live in highly dissimilar contexts. The sample will include twenty women from each state, and will be drawn from geographically-dispersed areas across each state. We will use purposive sampling to recruit women in partnership with hospitals, obstetricians, disability service organizations, and state agencies. Recruitment partners include the Positive Parenting Resource Center, which serves mothers with IDD, [REDACTED] [REDACTED] and the Department of Obstetrics and Gynecology of the [REDACTED] (co-investigator [REDACTED] is the Director of the Research Division of the Department) (see letters of support). We will apply for a Certificate of Confidentiality to protect participants against disclosure of sensitive information. We will also obtain informed consent from the women's guardians, as appropriate. Disability accommodations will be provided as needed, and in-person interviews will be conducted by [REDACTED] and [REDACTED]. Both have extensive experience interviewing women with IDD about health and reproductive health care.<sup>48</sup> Participants will receive \$50 for their time, childcare and transportation costs. The interview guide will be open-ended and developed after review of the research literature and in consultation with our expert advisory committee. The broad guiding questions for the interviews will be derived from the Perinatal Health Framework for Women with Disabilities,<sup>30</sup> described above. We will also follow established standards for cognitive testing<sup>64</sup> and pilot testing of the instrument to derive the final interview guide. The goal of the interviews is to understand women's perspectives and preferences and identify unmet needs and barriers for health care and other supports, as well as recommendations for improving perinatal care for women with IDD.

### **2.c.5.2 Telephone interviews with obstetric health care providers**

We will conduct 30 clinician interviews with a sample of obstetric health care providers from across the US. The interviews will be semi-structured and open-ended, and developed based on the Perinatal Health

Framework for Women with Disabilities,<sup>30</sup> a review of the research literature, and in consultation with our expert advisory committee. The obstetric health care providers will be recruited with the help of [REDACTED] from the American Congress of Obstetrics and Gynecology, [REDACTED] and [REDACTED] from the American College of Nurse Midwives, [REDACTED] and our advisory committee (see letters of support). OB/GYNs and certified nurse midwives from across the US will be identified, contacted, and invited to participate in telephone interviews. We will also use snowball sampling techniques in which interviewees nominate other potential participants. [REDACTED] will interview the clinicians. As an obstetrician, [REDACTED] possesses the credibility and requisite medical expertise to effectively interview other clinicians, who may speak more frankly to a peer, ensuring high quality data are obtained. At the conclusion of each interview, [REDACTED] will record field notes of her impressions of the interview. During the interviews, she will share the findings from Aims 1 and 2 with participants, and inquire about their perspectives on the determinants of these patterns of perinatal care and outcomes. [REDACTED] will also ask participants about unmet needs and barriers to care that have not previously been identified. She will seek their recommendations for improving perinatal care and outcomes of women with IDD, as well as their advice about ways to effectively disseminate findings to other US clinicians. Participants will receive \$150 for their time.

#### **2.c.5.3 Analysis of interviews with clinicians and women with IDD**

All interviews will be audio-taped with the participants' permission, transcribed verbatim by a confidential, professional transcription service, and verified for accuracy by the research team. We will use the web-based qualitative analysis tool Dedoose to analyze the interview transcripts. We will use a grounded theory approach to data analysis, which combines inductive and deductive approaches and constantly compares indicators, concepts and categories as theories emerge from the data that are collected.<sup>65,66</sup> Team members [REDACTED] and [REDACTED] will conduct debriefing sessions immediately after the interviews to generate reflexive memos and identify emerging themes discussed by participants. These memos and themes will then inform development of the initial coding framework. They will independently conduct line-by-line open coding of 2-3 transcripts to establish coding decision rules and a coding manual. [REDACTED] will then train the graduate research assistant to apply the coding scheme. [REDACTED] and the graduate research assistant will then independently conduct line-by-line open coding of all transcripts and memos. New codes will be developed as needed, using the constant comparative method<sup>67</sup> and codes may be expanded or collapsed over time, consistent with standard practices in qualitative data analysis<sup>68</sup>. We will use a function in Dedoose to examine inter-coder reliability (i.e., kappa statistic, which adjusts for the likelihood of chance agreement).<sup>69</sup>

We will use several established approaches to ensure the rigor of the qualitative phase of the study, including using highly trained and skillful data collectors; continuing data collection until saturation is achieved; clarifying, elaborating on, and evaluating interview data immediately after it is collected; and meeting regularly as a research team during the data collection process to share observations and discuss ideas and interpretations.<sup>68</sup> Techniques pertinent to data analysis are important in ensuring rigor in qualitative research, and we will use the following standard practices: generating and assessing rival conclusions; seeking disconfirming cases that do not fit within the prevailing data patterns; triangulating observers and/or theories; and considering how design constraints affect the data.<sup>68</sup>

#### **2.c.5.4 Developing and disseminating practice recommendations for women with IDD**

In Year 5, we will hold a one-day, face-to-face meeting in [REDACTED] with the research team and expert advisory committee to review findings from both the qualitative and quantitative phases of the study. The purpose of the meeting will be to (a) begin developing a set of perinatal care recommendations tailored to the unique needs of women with IDD; (b) develop a specific plan and strategies to disseminate the results of the study and the recommendations to clinicians who provide perinatal care for women with IDD; and (c) identify strategies to promote translation and integration of the recommendations into practice. Materials will be prepared and distributed to participants in advance of the meeting, to ensure the day will be highly productive. The research team will subsequently develop, refine and disseminate the practice recommendations. The practice recommendations will be widely disseminated through our partners at the American Congress of Obstetricians and Gynecologists and the American College of Nurse Midwives. We anticipate writing numerous scientific manuscripts, hosting webinars and developing practice recommendations.

#### **2.c.6. Possible Limitations**

The use of ICD-9 codes in identifying women with IDD may result in an underestimation of the number of pregnancies among women in this population. Additionally, the data used in the two datasets are not

validated by chart review. The ██████████'s PELL-APCD linked data are not nationally representative. However it is the *only* dataset, to our knowledge, that links birth and fetal death certificate, hospital discharge, and all-payer claims data to provide a comprehensive set of health data for this study. The interviews with the women with IDD are subject to the limitations of recall bias and social desirability bias. However, in our prior research, women with IDD had relatively good specificity and sensitivity in reporting reproductive health care procedures.<sup>70</sup> Further, we will attempt to obtain a broad range of clinician input in order to be assured we identify the most salient issues. Despite these limitations, a significant strength of the proposed study is that **these multiple approaches each provide a different, complementary window into the perinatal health care and pregnancy outcomes of women with IDD.**

**2.c.7 Summary and Future Directions**

This study will generate high quality information to guide the development of perinatal health care recommendations for women with IDD. It will also break new ground by determining the unmet needs for perinatal health care for these vulnerable women. Finally, it will describe, for the first time with a population-based sample, pregnancy, childbirth, infant health outcomes, hospitalization use and costs for women with IDD. These findings will provide a fertile field for developing policy and practice interventions to address the perinatal care disparities suggested by our preliminary research. Appropriate interventions may include those targeted at obstetric health care providers as well as educational interventions for women with IDD themselves.

As a next step to this study, we will seek future funding to develop a continuing education program with CME credits for obstetric clinicians to become knowledgeable about perinatal care of women with IDD. Parallel to the development of the continuing education program, we will use findings from this study to develop standardized measures to assess the safety and quality of perinatal care for women with IDD. The National Quality Foundation (NQF) developed 17 consensus standards that address care received during the last trimester of pregnancy through hospital discharge for both mother and newborn.<sup>71</sup> The consensus standards address care provided by both individual clinicians (i.e., physicians and midwives) and facilities, including both hospitals and freestanding birthing centers. We plan to develop similar measures to develop a mechanism to measure the quality of perinatal care for women with IDD as well as improve standards of care.

**Table 4. Timeline: We propose a 5-year timeline for this study (January 2015 – December 2019)**

	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4																
Preliminary grant logistics																				
<b>Aim 1 HCUP data analysis</b>																				
IRB and data access logistics																				
Analysis of HCUP																				
Manuscripts for publication																				
<b>Aim 2 Massachusetts PELL-APCD</b>																				
PELL-APCD data use agreement/IRB																				
Link the PELL-APCD datasets																				
PELL-APCD analysis																				
Manuscripts for publication																				
<b>Aim 3.1 Interview women with IDD</b>																				
Interview methods/guide/IRB																				
Recruitment																				
Interviews																				
Transcription/analysis																				
Manuscripts for publication																				
<b>Aim 3.2 Interview health care providers</b>																				
Interview methods/guide/IRB																				
Recruitment																				
Interviews																				
Transcription/analysis																				
Manuscripts for publication																				
One day meeting																				
Development and dissemination of practice recommendations																				

## Protection of Human Subjects

### 1. Risks to Human Subjects: Specific Aim 1 – Healthcare Cost and Utilization Project (HCUP) Dataset

#### 1.1.a. Human Subjects Involvement, Characteristics, and Design

For **Specific Aim 1**, we plan to analyze the **Healthcare Cost and Utilization Project (HCUP)** database. No subjects will be recruited or consented. The HCUP data will be accessed from the national database, which is publicly available. The HCUP data files are de-identified and meet the definition of de-identified datasets under the HIPAA Privacy Regulations. The HCUP data are maintained by the Center for Delivery, Organization, and Markets (CDOM) within the Agency for Healthcare Research and Quality (AHRQ). HCUP data are subject to the data standards and protections established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (P.L. 104-191) and implementing regulations (“the Privacy Rule”). [REDACTED] will receive the de-identified analytic file only after further restrictions have been outlined in the Data Use Agreement for the Nationwide Databases for the Healthcare Cost and Utilization Project from AHRQ.

#### 1.1.b. Source of Materials

All data for analysis will be de-identified. Information obtained will include US national data on childbirth outcomes, complications, and health care costs.

**1.1.c. Potential Risks** Data are de-identified so breach of confidentiality risk is absent. The data will be extracted from existing databases, therefore no contact with human subjects is involved. Subjects will not be recruited and will not be consented.

### 1.2. Adequacy of Protection Against Risks

#### 1.2.a. Recruitment and Informed Consent

Data will be accessed from an existing database. No subjects will be recruited or required to consent. Data are de-identified.

#### 1.2.b. Protections Against Risk

Identifiers will not be used in the data analysis so breach of confidentiality risk is absent.

### 1.3. Potential Benefits of the Proposed Research to Human Subjects and Others

There are no direct benefits to individual subjects. In our estimation, the broader potential benefits of this study to pregnant women with intellectual and developmental disabilities outweigh the minimal risk involved in this study.

### 1.4. Importance of Knowledge to be Gained

Because the data will be extracted from an existing database without identifiers, there is little to no risk to subjects. The potential contribution of this research to the field of health disparities between women with and without intellectual and developmental disabilities is substantial. There is currently no literature looking specifically at health disparities in this population. Examining this data is imperative to improving care and pregnancy outcomes for mothers with intellectual and developmental disabilities and their infants.

### 2. Risks to Human Subjects: Specific Aim 2 – [REDACTED] PELL-APCD Analysis

#### 2.1.a. Human Subjects Involvement, Characteristics, and Design

For **Specific Aim 2**, we examine the longitudinal health outcomes and health care costs of women with intellectual and developmental disabilities and their infants (up to 1 year of age) compared to other women using linked data from the [REDACTED]. No subjects will be recruited or consented. The [REDACTED] PELL dataset is constructed from existing programmatic and administrative data owned and collected by the [REDACTED] and the [REDACTED] Division of Health Care Finance and Policy, both hybrid-covered entities under HIPAA regulations. The APCD is comprised of medical, pharmacy, and dental claims, in addition to information about member eligibility, benefit design, and insurance providers, for all payers covering [REDACTED] residents who are insured. Linkage of PELL and APCD datasets will be carried out at [REDACTED].

██████████ on secure, restricted servers by ██████████ and ██████████. Data linkages will be performed using SAS on the secure PELL drive at ██████████ Department of Public Health following strict confidentiality guidelines. Once women and infants are linked to PELL records, their protected health information will be deleted by ██████████ staff. ██████████ and ██████████ staff will not have access to the PHI in the PELL-APCD data.

All data involving confidential identifiers are linked on a secure server, and non-confidential data are extracted for analyses by approved ██████████ staff. The data files of the ██████████ PELL-APCD will be de-identified and will meet the definition of de-identified datasets under the HIPAA Privacy Regulations. There will be no contact with any mother or infant at this stage of the study. Extensive safety procedures to protect the identities of individuals have been instituted in the ██████████ PELL-APCD data system per stipulations from the ██████████ Research and Data Access Review Committee. The ██████████ will receive the de-identified analytic files only after further restrictions have been outlined in a Memorandum of Understanding (MOU) established between ██████████ and ██████████ and signed by participants in this project (for PELL data) and a Center for Health Information and Analysis Data Use Agreement (for hospital data and APCD data) and after IRB approval from ██████████ Department of Public Health and the Center for Health Information and Analysis.

#### **2.1.b. Sources of Materials**

All data for analysis will be de-identified. Materials collected will include health care outcomes and cost data on ██████████ mothers and their infants (up to 1 year of age).

**2.c. Potential Risks** Data are de-identified so breach of confidentiality risk is absent. The data will be extracted from existing databases; therefore no contact with human subjects is involved. There are no direct benefits to individual subjects. In our estimation, the broader potential benefits of this study to pregnant women with disabilities outweigh the minimal risk involved in this study.

#### **2.2. Adequacy of Protection Against Risks:**

**2.2.a. Recruitment and Informed Consent** Data will be accessed from an existing database. No subjects will be recruited or required to consent. Data are de-identified.

#### **2.2.b. Protections Against Risk**

Identifiers will not be used in the data analysis so breach of confidentiality risk is absent.

#### **2.3. Potential Benefits of the Proposed Research to Human Subjects and Others**

There are no direct benefits to individual subjects. In our estimation, the broader potential benefits of this study to pregnant women with intellectual and developmental disabilities outweigh the minimal risk involved in this study.

#### **2.4. Importance of Knowledge to be Gained**

Because the data will be extracted from an existing database without identifiers, there is little to no risk to subjects. The potential contribution of this research to the field of health disparities between women with and without intellectual and developmental disabilities is substantial. There is currently no literature looking specifically at health disparities in this population. Examining this data is imperative to improving care and pregnancy outcomes for mothers with intellectual and developmental disabilities and their infants.

### **3. Risks to Human Subjects: Specific Aim 3 – Interviews with women with IDD and providers**

For **Specific Aim 3**, we will gather and analyze information through interviews with approximately 30 obstetric health care providers and 40 women with intellectual and developmental disabilities. Telephone interviews will be conducted with the health care providers, including obstetricians/gynecologists and certified nurse midwives, who will be from any part of the United States. In-person interviews will be conducted with 20 women with intellectual and developmental disabilities from ██████████ and 20 women with intellectual and developmental disabilities from ██████████. All interview procedures, scripts, and written materials will be reviewed and approved by the Institutional Review Boards of ██████████ and the ██████████ before any contacts are made with potential interviewees. Health care providers will be provided an honorarium of \$150; women with intellectual and developmental disabilities will be provided with an honorarium of \$50 for their time, childcare and transportation costs. We will apply for a Certificate of Confidentiality to protect participants against disclosure of sensitive information.

### **3.1.a. Human Subjects Involvement, Characteristics and Design**

Participant clinicians from across the United States will be identified, contacted, and invited to participate in a telephone interview. The purpose of these interviews will be to obtain expert input on the findings from Specific Aims 1 and 2, and to understand their perspectives as clinicians about the unmet needs of women with intellectual and developmental disabilities. We will also solicit their input on recommendations for perinatal care for women with IDD. This approach is justified because their clinical expertise and experience is necessary for all these purposes. They will be recruited with the help of Jeanne Mahoney from American Congress of Obstetrics and Gynecology (ACOG) and the American College of Nurse Midwives [REDACTED], and [REDACTED] (see attached letters of support). We will recruit additional clinicians using snowball sampling techniques (i.e., clinicians will be invited to nominate others to participate in the study).

New mothers with intellectual and developmental disabilities from across [REDACTED] and [REDACTED] will be identified, contacted and invited to participate in in-person interviews. The purpose of these interviews is to understand their perspectives and preferences regarding perinatal health care they received, and their views of unmet needs for care. This approach is justified because understanding health care from the perspectives of the patient is critically important, and the only way to address this aspect of the Specific Aims. These women will be recruited from intellectual and developmental disability service organizations in both states (see attached letters of support). We will recruit additional women using snowball sampling techniques.

**3.1.b. Sources of Materials** All interviews will be audio-recorded, and a professional transcription service will transcribe audiotapes verbatim for analysis. For analysis of the interview data from the obstetric health care providers, [REDACTED] will protect confidentiality by assigning every participant a pseudonym [REDACTED] will keep information on respondents' identities in a locked file cabinet in [REDACTED] office, separate from interview transcripts and only [REDACTED] will have access to the data. For analysis of the interview data from the women with intellectual and developmental disabilities, [REDACTED] will protect confidentiality by assigning every participant a pseudonym; she will keep information on respondents' identities in a locked file cabinet in her office, separate from interview transcripts and only [REDACTED] will have access to the data.

**3.1.c. Potential Risks** The risks to participants, both obstetric health care providers and women with intellectual and developmental disabilities are minimal. These risks include breach of confidentiality and a possible risk of psychological discomfort on being asked to reflect on one's own experiences as either a health care provider for women with intellectual and developmental disabilities, or as a woman with intellectual and developmental disabilities who has received obstetric health care. If any of the women with intellectual and developmental disabilities become upset during the interviews, they will be provided with referral to psychological services. We note that the interviewers of the women [REDACTED] have many years of research and work experience with women with intellectual and developmental disabilities, including in studies of reproductive health care access. There are no direct benefits to individual subjects. In our estimation, the broader potential benefits of this study to pregnant women with disabilities far outweigh the minimal risks.

### **3.2. Adequacy of Protection Against Risks**

**3.2.a. Recruitment and Informed Consent** [REDACTED] will contact and interview the obstetric clinicians. These participants will be mailed or emailed a written informed consent form and information about the study. Interviews will only be conducted after we have received a signed copy of this form. The informed consent form will describe interview procedures, planned use of the data, and potential risks of psychological or emotional discomfort from the questions. The informed consent form will also indicate that the interviewee can refuse to answer any questions that he or she wishes to refuse and to terminate the interview at any time without any negative consequences. [REDACTED] and [REDACTED] will contact and interview the women with intellectual and developmental disabilities who are new mothers. The study procedures, benefits, risks, planned use of the data, and their right to decline to answer any individual question or to terminate their participation in the whole interview. Consistent with our past research, we will develop consent materials that are appropriate for individuals with limited literacy and cognitive ability (video, reading the materials to them, use of pictures). If a woman decides that she is interested in participating, we will also seek consent from her guardian, if she has one. Interviews will only be conducted after we have received signed consent forms from both women and their guardians, if applicable.

**3.2.b. Protections Against Risks** The risks to individual subjects are minimal and no greater than what is encountered in everyday living. Every effort will be taken prior to, during and after the interviews to minimize such risks. At the outset of all interviews, the ground rules will be restated, namely, that participants have the right to decline to answer any individual question or to terminate the interview completely, at any time. This approach should minimize the potential for any psychological or emotional discomfort on the part of the key

informant. In the interviews with women with IDD [REDACTED] and M [REDACTED] will use simple questions and easy-to-understand language that will ensure both that the women understand the questions, and that they are not intimidated by the interview process.

For the participants who are health care providers, there will be one master list linking clinician-participant pseudonyms and participants' identifying information; this list will be kept separately from study records in a password protected, secure electronic folder on the [REDACTED] server. Only [REDACTED] and staff members authorized to work on the study will have access to this file. Similarly, for the participants who are women with intellectual and developmental disabilities, there will be two master lists (one in [REDACTED] and one in [REDACTED] linking participant pseudonyms and participants' identifying information; these lists will be kept separately from study records in an access-restricted folder at [REDACTED] respectively. Only [REDACTED] and [REDACTED] and staff authorized to work on the study will have access to these files. Participant names will be known only to the researchers and will not be used in any reports or publications of this study. The audio recordings for participants in [REDACTED] will be uploaded to a secure file storage location at [REDACTED], and then transferred to [REDACTED] using a secure file transfer protocol. The digital audio recordings will be transferred from [REDACTED] to the transcriptionist using a secure file transfer protocol. The transcriptionist will be asked to delete all audio files after the transcripts are developed and checked for accuracy. Hard copies of other source materials (e.g. transcripts) will be kept in locked office cabinets of with access restricted to only [REDACTED]s, and staff authorized to work on the study. Digital source materials (including transcripts, intake forms) will be kept in a restricted access, secure electronic folder on the [REDACTED] and [REDACTED] servers. All study staff members will complete human subjects training.

### **3.3. Potential Benefits of the Proposed Research to Human Subjects and Others**

This study does not offer direct benefits to the participants, other than the knowledge that they are helping to advance our understanding of perinatal health care outcomes for women with intellectual and developmental disabilities and their infants. This study has significant potential to understand an important public health priority, the perinatal health care access and outcomes of a highly vulnerable underserved minority, women with intellectual and developmental disabilities. A second important benefit of this study is its aim to develop obstetric health care recommendations and guidelines, which do not currently exist for women with intellectual and developmental disabilities.

### **3.4. Importance of Knowledge to be Gained**

This study will be the first population-based study of perinatal health outcomes for women with intellectual and developmental disabilities in the United States. It will also be the first study of the perspectives and preferences of these women about their pregnancies. Finally, it will be the first project to articulate guidelines for prenatal and postpartum care for US women with intellectual and developmental disabilities. As such, it will make an important contribution to the existing public health and clinical efforts to improve these women's health outcomes.

## Inclusion of Women and Minorities

The entire sample is comprised of women, because the aim of the study is to investigate pregnancy outcomes of women with intellectual and developmental disabilities. For **Specific Aim 1**, data will be analyzed from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample. These data are nationally representative of the US population of women who have given birth in hospitals and are therefore racially and ethnically diverse. For example, in our preliminary analyses of the 2010 data, 48% of the women in the sample were from racial and ethnic minority groups. We expect that the data analyzed for this specific aim will therefore fully reflect the diversity of the larger US population of women.

For **Specific Aim 2**, the linked [REDACTED] (PELL-APCD) provides access to claims data for all payers covering [REDACTED] residents and to linked birth certificate and hospitalization records. This dataset will permit analysis of all women who gave birth in [REDACTED]. In our preliminary analysis of the PELL, we found that 35% of women with intellectual and developmental disabilities were from racial and ethnic minority groups, which is a higher proportion than the [REDACTED] general population. The data for Specific Aim 2 will therefore enable us to ensure that our sample of women are more racially and ethnically diverse and representative of the diversity of the larger [REDACTED] population of women.

For **Specific Aim 3**, we will strive to achieve adequate representation of women with intellectual and developmental disabilities from racial and ethnic minority groups by working specifically with community-based organizations. These organizations will reach out to women in the ethnic and racial minority communities they each serve. We are partnering with statewide intellectual and developmental disabilities service organizations in both [REDACTED] and [REDACTED] (e.g., [REDACTED] – see letters of support). These organizations serve a racially diverse constituency. We will also recruit women with intellectual and developmental disabilities in partnership with [REDACTED] co-investigator. She will assist with recruitment from the [REDACTED] which serves a diverse range of counties in western and central [REDACTED]. The other members of our Expert Advisory Committee may also provide assistance with recruiting women with intellectual and developmental disabilities. We note that in our previous study of reproductive health care research of women with intellectual and developmental disabilities in [REDACTED] approximately half of the sample was African American, and we are confident we can recruit a diverse sample for this project as well. Notably, we will not be able to include women who are monolingual non-English speakers. The scope of this project does not permit us to include instruments and team members who are not fluent in English.

## Planned Enrollment Report

**Study Title:** Pregnancy Outcomes of Women with Intellectual and Developmental Disabilities (Women with I

**Domestic/Foreign:** Domestic

**Comments:** Women with intellectual and developmental disabilities

Racial Categories	Ethnic Categories			
	Not Hispanic or Latino		Hispanic or Latino	
	Female	Male	Female	Ma
American Indian/Alaska Native	0	0	0	0
Asian	4	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	16	0	1	0
White	15	0	4	0
More than One Race	0	0	0	0
<b>Total</b>	<b>35</b>	<b>0</b>	<b>5</b>	<b>0</b>

Study 1 of 2

Tracking Number: XXXXXXXXXX

XXXXXXXXXX Receiv

## Planned Enrollment Report

**Study Title:** Pregnancy Outcomes of Women with Intellectual and Developmental Disabilities (Providers)

**Domestic/Foreign:** Domestic

**Comments:** Obstetric health care providers

Racial Categories	Ethnic Categories			
	Not Hispanic or Latino		Hispanic or Latino	
	Female	Male	Female	Ma
American Indian/Alaska Native	0	0	0	0
Asian	3	2	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	2	3	1	1
White	8	8	1	1
More than One Race	0	0	0	0
<b>Total</b>	<b>13</b>	<b>13</b>	<b>2</b>	<b>2</b>

Study 2 of 2

## Inclusion of Children

This project is about pregnancy among women with intellectual and developmental disabilities. The Healthcare Cost and Utilization (HCUP) database (**Specific Aim 1**) contains information on women who are under 21 years of age. We shall use the information on women and girls under age 21 from the HCUP database. These data are de-identified and publicly available; therefore privacy and confidentiality risks are absent.

**Specific Aim 2** involves analysis of the linked [REDACTED] (PELL-APCD). We shall use information on women and girls aged under 21 years, and their infants (up to 1 year of age) from these data sources. We will receive de-identified data from [REDACTED] Department of Public Health and Center for Health Information and Analysis; therefore privacy and confidentiality risks are absent.

**Specific Aim 3** involves conducting interviews with women with intellectual and developmental disabilities (ages 21 and older) and with obstetric health care providers whose patients include women with intellectual and developmental disabilities. All of the health care providers will be aged 21 years or older. All of the women with intellectual and developmental disabilities who are interviewed will be aged 21 years or older, because this is one of our inclusion criteria for participation in the study.

## **Rationale for Multi-Principal Investigator Approach**

The Principal Investigators, [REDACTED] and [REDACTED] will work together as the leaders of this study and will together provide oversight for the entire study. In these roles, [REDACTED] will be responsible for the implementation of the specific aims and ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including human subject research.

Both investigators will oversee the analyses for specific aim 1 (HCUP data). [REDACTED] will assume responsibility of the human subject approval for HCUP data and the data sharing agreement with AHRQ regarding access to HCUP data. [REDACTED] will have primary responsibility of overseeing the analysis of the PELL-APCD linked data system (specific aim 2) and facilitating the linkages between the [REDACTED] data and the APCD data. [REDACTED] will also assume primary responsibility of the human subject approvals from [REDACTED] and the [REDACTED] Department of Public Health and the Center for Health Information and Analysis for access to PELL-APCD linked data. [REDACTED] will take the leadership role regarding specific aim 3, the interviews with women with IDD and obstetric health care providers, including the human subject approvals. Both PIs will work with the other members of the research team and the expert advisory committee in the interpretation of the data and development of manuscripts and presentations. [REDACTED] will serve as contact PI and will assume fiscal and administrative management including maintaining communication among PIs and key personnel through monthly meetings. [REDACTED] will be responsible for communication with NIH and submission of annual reports to NIH. [REDACTED] will assist with the preparation of all reports to NIH.

Publication authorship will be based on the relative scientific contributions of the PIs and other members of the research team. Overall, this Multi-PI approach assures the representation, participation and highest level of scientific contribution deriving from the two contributing members from [REDACTED] and [REDACTED] in order to successfully implement the proposed study.

The guiding principles of the Multi-PI relationship include: 1) Each of the parties will be an equal participant in the collaboration; 2) Each PI will be given the opportunity to be a co-author on publications that result from that study; and 3) Each partner institution may participate in the preparation of applications for funding in support of analytic projects and dissemination activities.

### **Communication**

Bi-weekly meetings will be held among the PIs, with the Project Associate, in person or via telecommunications, to review the conduct and progress of the study; monitor data linkage efforts; review data and interpret results; administer the recommendations of the expert advisory committee and the research team; prepare results for dissemination; and supervise personnel and monitor the budget.

### **Conflict Resolution**

If a potential conflict develops, [REDACTED] shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of one impartial senior executive from each PI's institution and a third impartial senior executive mutually agreed upon by both PIs. No members of the arbitration committee will be directly involved in the research grant or disagreement. Notably, the PIs on this project have worked together for approximately 18 months conducting analyses of the HCUP and PELL data, and two publications from that collaboration are under review. The PIs have an excellent working relationship and anticipate they will easily resolve any difficulties that arise over the course of the project.

### **Change in PI Location**

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions

## Bibliography and References Cited

1. American Association of Intellectual and Developmental Disabilities. Definition of intellectual disability. [http://aaidd.org/intellectual-disability/definition#.UuK\\_V\\_so5ph](http://aaidd.org/intellectual-disability/definition#.UuK_V_so5ph). Updated 2013. Accessed January 24, 2014.
2. Office of the Surgeon General (US), National Institute of Child Health and Human Development (US), Centers for Disease Control and Prevention (US). *Closing the Gap: Report of the Surgeon General's Conference on Health Disparities and Mental Retardation*. 2002.
3. United States Department of Health and Human Services. Healthy People 2020 Topics & Objectives 2013 - Maternal, Infant, and Child Health. <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=26>. Updated 2013. Accessed January 24, 2014.
4. Cepko R. Involuntary sterilization of mentally disabled women. *Berkeley Womens Law J*. 1993;8:122-165.
5. Shaman JR. Persons who are mentally retarded: Their right to marry and have children. *Family Law Quarterly*. 1978;12(1):61-84.
6. Heller T, Stafford P, Davis LA, Sedlesky L. Feature issue on aging and people with intellectual and developmental disabilities. *Impact*. 2010;23(1).
7. Braddock D, Hemp R, Rizzolo MC. State of the states in developmental disabilities: 2004. *Ment Retard*. 2004;42(5):356-370.
8. Howden L, Meyer J. *Age and sex composition: 2010*. Washington, D.C.: United States Census Bureau; 2011.
9. Centers for Disease Control and Prevention (CDC). Prevalence and most common causes of disability among adults-United States, 2005. *MMWR Morb Mortal Wkly Rep*. 2009;58(16):421-426.
10. Morris J, Wates M. *Supporting disabled parents and parents with additional support needs*. Bristol, United Kingdom: Social Care Institute for Excellence; 2006.
11. Sheerin F. Parents with learning disabilities: A review of the literature. *J Adv Nurs*. 1998;28(1):126-133.
12. Feldman MA, Varghese J, Ramsay J, Rajska D. Relationships between social support, stress and mother-child interactions in mothers with intellectual disabilities. *Journal of Applied Research in Intellectual Disabilities*. 2002;15(4):314-323.
13. Hur J. Review of research on parent training for parents with intellectual disability: Methodological issues. *International Journal of Disability, Development and Education*. 1997;44(2):147-162.
14. Murphy G, Feldman MA. Parents with intellectual disabilities. *Journal of Applied Research in Intellectual Disabilities*. 2002;15(4):281-284.
15. Booth T, Booth W. Parents together: Action research and advocacy support for parents with learning difficulties. *Health Soc Care Community*. 1999;7(6):464-474.
16. McConnell D, Mayes R, Llewellyn G. Women with intellectual disability at risk of adverse pregnancy and birth outcomes. *J Intellect Disabil Res*. 2008;52(Pt 6):529-535.
17. Høglund B, Lindgren P, Larsson M. Pregnancy and birth outcomes of women with intellectual disability in Sweden: A national register study. *Acta Obstet Gynecol Scand*. 2012;91(12):1381-1387.

18. Redshaw M, Malouf R, Gao H, Gray R. Women with disability: The experience of maternity care during pregnancy, labour and birth and the postnatal period. *BMC Pregnancy Childbirth*. 2013;13(1):174.
19. Walsh-Gallagher D, Sinclair M, Mc Conkey R. The ambiguity of disabled women's experiences of pregnancy, childbirth and motherhood: A phenomenological understanding. *Midwifery*. 2012;28(2):156-162.
20. Mayes R, Llewellyn G, McConnell D. Misconception: The experience of pregnancy for women with intellectual disabilities. *Scandinavian Journal of Disability Research*. 2006;8(2-3):120-131.
21. Hoglund B, Larsson M. Struggling for motherhood with an intellectual disability--a qualitative study of women's experiences in Sweden. *Midwifery*. 2013;29(6):698-704.
22. Newacheck PW, Hughes DC, Hung YY, Wong S, Stoddard JJ. The unmet health needs of America's children. *Pediatrics*. 2000;105(Supplement 3):989.
23. Szilagyi PG. Care of children with special health care needs. *The Future of Children*. 2003:137-151.
24. Henry AD, Long-Bellil L, Zhang J, Himmelstein J. Unmet need for disability-related health care services and employment status among adults with disabilities in the Massachusetts Medicaid program. *Disability and Health Journal*. 2011.
25. [REDACTED]
26. LaPlante MP, Kaye HS, Kang T, Harrington C. Unmet need for personal assistance services: Estimating the shortfall in hours of help and adverse consequences. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*. 2004;59(2):S98.
27. Kennedy J. Unmet and undermet need for activities of daily living and instrumental activities of daily living assistance among adults with disabilities: Estimates from the 1994 and 1995 disability follow-back surveys. *Med Care*. 2001;39(12):1305.
28. Newcomer R, Kang T, LaPlante M, Kaye S. Living quarters and unmet need for personal care assistance among adults with disabilities. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*. 2005;60(4):S205.
29. Allen SM, Mor V. The prevalence and consequences of unmet need: Contrasts between older and younger adults with disability. *Med Care*. 1997;35(11):1132-1148.
30. [REDACTED]
31. International Classification of Functioning, Disability and Health (ICF). World Health Organization. <http://www.who.int/classifications/icf/en/>. Updated 2014. Accessed February 4, 2014.
32. Nosek MA, Young ME, Rintala DH, Howland CA, Foley CC, Bennett JL. Barriers to reproductive health maintenance among women with physical disabilities. *Journal of Women's Health*. 1995;4(5):505-518.
33. Emerson E, Parish S. Intellectual disability and poverty: Introduction to the special section. *J Intellect Dev Disabil*. 2010;35(4):221-223.
34. Emerson E. Health status and health risks of the "hidden majority" of adults with intellectual disability. *Intellect Dev Disabil*. 2011;49(3):155-165.

35. Krahn GL, Hammond L, Turner A. A cascade of disparities: Health and health care access for people with intellectual disabilities. *Ment Retard Dev Disabil Res Rev.* 2006;12(1):70-82.
36. Randall W, Sobsey D, Parrila R. Ethnicity, disability, and risk for abuse. *Developmental Disabilities Bulletin.* 2001;29(1):60-80.
37. McConnell D, Mayes R, Llewellyn G. Pre-partum distress in women with intellectual disabilities. *J Intellect Dev Disabil.* 2008;33(2):177-183.
38. Steinberg ML, Heimlich L, Williams JM. Tobacco use among individuals with intellectual or developmental disabilities: A brief review. *Intellect Dev Disabil.* 2009;47(3):197-207.
39. Rimmer JH, Yamaki K. Obesity and intellectual disability. *Ment Retard Dev Disabil Res Rev.* 2006;12(1):22-27.
40. Emerson E, Malam S, Davies I, Spencer K. Adults with learning difficulties in England 2003/4. 2005.
41. Alborz A, McNally R, Glendinning C. Access to health care for people with learning disabilities in the UK: Mapping the issues and reviewing the evidence. *J Health Serv Res Policy.* 2005;10(3):173-182.
42. van Schroyen Lantman-de Valk, H., Schupf N, Patjia K. Reproductive & physical health. In: Heller T, Noonan-Walsh P, eds. *Health of women with intellectual disabilities.* Hoboken, NJ: Wiley-Blackwell; 2002.
43. Signore C, Spong CY, Krotoski D, Shinowara NL, Blackwell SC. Pregnancy in women with physical disabilities. *Obstet Gynecol.* 2011;117(4):935-947.
44. Kotelchuck M. An evaluation of the Kessner Adequacy of Prenatal Care Index and a proposed Adequacy of Prenatal Care Utilization Index. *Am J Public Health.* 1994;84(9):1414.
45. Parish SL, Mitra M, Son E, Bonardi A, Swoboda P. Pregnancy outcomes for women with intellectual and developmental disabilities: National evidence of disparities. (Submitted).
46. [REDACTED]
47. Bonardi A, Lauer E, Mitra M, Bershady J, Taub S, Noblett C. *Expanding surveillance of adults with intellectual disability in the US.* Center for Developmental Disabilities Evaluation and Research (CDDER), E. K. Shriver Center University of Massachusetts Medical School; 2011.
48. Swaine J, Parish SL, Luken K, Atkins L. Recruitment and consent of women with intellectual disabilities in a randomized control trial of a health promotion intervention. *J Intellect Disabil Res.* 2011;55(5):474-483.
49. Slayter EM. Demographic and clinical characteristics of people with intellectual disabilities with and without substance abuse disorders in a Medicaid population. *Intellect Dev Disabil.* 2010;48(6):417-431.
50. [REDACTED]
51. Houchens RL, Elixhauser A. *Using the HCUP nationwide inpatient sample to estimate trends (Updated for 1988-2004): HCUP methods series.* Rockville, MD: Agency for Healthcare Research and Quality; 2006.

52. Adams MM, Delaney KM, Stupp PW, McCarthy BJ, Rawlings JS. The relationship of interpregnancy interval to infant birthweight and length of gestation among low-risk women, Georgia. *Paediatr Perinat Epidemiol.* 1997;11 Suppl 1:48-62.
53. Agency for Healthcare Research and Quality, Rockville, MD. HCUP NIS related reports. [www.hcup-us.ahrq.gov/db/nation/nis/nisrelatedreports.jsp](http://www.hcup-us.ahrq.gov/db/nation/nis/nisrelatedreports.jsp). Updated 2013. Accessed January 24, 2014.
54. Slayter E. Medicaid-covered alcohol and drug treatment use among people with intellectual disabilities: Evidence of disparities. *Intellect Dev Disabil.* 2010;48(5):361-374.
55. Agency for Healthcare Research and Quality, Rockville, MD. HCUP cost-to-charge ratio files (CCR). <http://www.hcup-us.ahrq.gov/db/state/costtocharge.jsp>. Updated 2013. Accessed January 31, 2014.
56. Barfield WD, Clements KM, Lee KG, Kotelchuck M, Wilber N, Wise PH. Using linked data to assess patterns of early intervention (EI) referral among very low birth weight infants. *Matern Child Health J.* 2008;12(1):24-33.
57. Manning SE, Davin CA, Barfield WD, et al. Early diagnoses of autism spectrum disorders in Massachusetts birth cohorts, 2001-2005. *Pediatrics.* 2011;127(6):1043-1051.
58. Barfield WD, Barradas DT, Manning SE, Kotelchuck M, Shapiro-Mendoza CK. Sickle cell disease and pregnancy outcomes: Women of African descent. *Am J Prev Med.* 2010;38(4 Suppl):S542-9.
59. Gettens J, Mitra M, Henry AD, Himmelstein J. Have working-age people with disabilities shared in the gains of Massachusetts health reform? *Inquiry.* 2011;48(3):183-196.
60. The Maternal and Child Health Federal-State Partnership. Massachusetts Maternal & Child Health (MCH) measures. <https://mchdata.hrsa.gov/tvisreports/Snapshot/snapshot.aspx?statecode=MA>. Updated 2012. Accessed January 30, 2014.
61. The Maternal and Child Health Federal-State Partnership. North Carolina Maternal & Child Health (MCH) measures. <https://mchdata.hrsa.gov/tvisreports/Snapshot/snapshot.aspx?statecode=NC>. Updated 2012. Accessed January 30, 2014.
62. United States Census Bureau. State & county QuickFacts, North Carolina. <http://quickfacts.census.gov/qfd/states/37000.html>. Updated 2014. Accessed January 30, 2014.
63. United States Census Bureau. State & country QuickFacts, Massachusetts. <http://quickfacts.census.gov/qfd/states/25000.html>. Updated 2014. Accessed January 30, 2014.
64. Willis G. *Cognitive interviewing: A tool for improving questionnaire design*. Thousand Oaks, CA: Sage Publications; 2005.
65. Charmaz K. *Constructing grounded theory: A practical guide through qualitative analysis*. Sage Publications Ltd; 2006.
66. Corbin JM, Strauss AL. *Basics of qualitative research: Techniques and procedures for developing grounded theory*. 2<sup>nd</sup> ed. Sage Publications, Inc; 2008.
67. Morgan DL. *Focus groups as qualitative research*. Vol 16. Sage Publications, Inc; 1997.
68. Patton MQ. *Qualitative evaluation and research methods*. 3rd ed. Thousand Oaks, CA: Sage Publications; 2002.

---

69. Gordis L. *Epidemiology*. First ed. Philadelphia: W.B. Saunders; 1996.

70. Son E, Parish SL, Swaine JG, Luken K. Accuracy of self-reported cervical and breast cancer screening by women with intellectual disability. *American Journal on Intellectual and Developmental Disabilities*. 2013;118(4):327-336.

71. National Quality Forum (NQF). *National voluntary consensus standards for perinatal care 2008: A consensus report*. Washington, D.C.: NQF; 2009.









AMERICAN COLLEGE  
of NURSE-MIDWIVES

With women, for a lifetime®

[Redacted text block]

*W. Blue Kaph*

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



AMERICAN COLLEGE  
of NURSE-MIDWIVES

With women, for a lifetime®

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]

*Eileen Chudin Beard*

[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

*[Handwritten Signature]*

[REDACTED]

[REDACTED]





College of Nursing  
VILLANOVA  
UNIVERSITY



[Redacted text block]

*Suzanne Smetka*

[Redacted text block]









[REDACTED]

[REDACTED]

DEVAL L. PATRICK  
GOVERNOR

JOHN W. POLANOWICZ  
SECRETARY

CHERYL BARTLETT, RN  
COMMISSIONER

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]







[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



5171 Glenwood Avenue  
Suite 400  
Raleigh, NC 27612-3266  
Phone: 919.783.8898/ 800.662.7119  
Fax: 919.782.5486

North Carolina & Virginia

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

*Jaqueline Casoli*

[Redacted]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]