

PI: [REDACTED]	Title: [REDACTED]	
Received: 02/11/2014	FOA: PA14-046	Council: 10/2014
Competition ID: FORMS-C	FOA Title: MENTORED CLINICAL SCIENTIST RESEARCH CAREER DEVELOPMENT AWARD (PARENT K08)	
[REDACTED]	Dual:	Accession Number: 3666979
IPF: [REDACTED]	Organization: [REDACTED]	
Former Number:	Department: Health Sciences	
IRG/SRG: CHHD-B	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A)	Animals: N Humans: Y Clinical Trial: N Current HS Code: E4 HESC: N	New Investigator: N Early Stage Investigator: N
Year 1: 122,500		
Year 2: 122,500		
Year 3: 122,500		
Year 4: 122,500		
Senior/Key Personnel:		
	Organization:	Role Category:
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]

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

1. TYPE OF SUBMISSION*		3. DATE RECEIVED BY STATE	State Application Identifier
<input type="radio"/> Pre-application <input type="radio"/> Application <input checked="" type="radio"/> Changed/Corrected Application		4.a. Federal Identifier	b. Agency Routing Number
2. DATE SUBMITTED	Application Identifier	c. Previous Grants.gov Tracking Number	
5. APPLICANT INFORMATION		Organizational DUNS*:	
Legal Name*:	[REDACTED]		
Department:	[REDACTED]		
Division:	[REDACTED]		
Street1*:	[REDACTED]		
Street2:	[REDACTED]		
City*:	[REDACTED]		
County:	[REDACTED]		
State*:	[REDACTED]		
Province:	[REDACTED]		
Country*:	[REDACTED]		
ZIP / Postal Code*:	[REDACTED]		
Person to be contacted on matters involving this application			
Prefix:	First Name*:	Middle Name:	Last Name*:
	[REDACTED]	[REDACTED]	[REDACTED]
			Suffix:
			[REDACTED]
Position/Title:	[REDACTED]		
Street1*:	[REDACTED]		
Street2:	[REDACTED]		
City*:	[REDACTED]		
County:	[REDACTED]		
State*:	[REDACTED]		
Province:	[REDACTED]		
Country*:	[REDACTED]		
Phone Number*:	Fax Number:	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	
6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)*			
[REDACTED]			
7. TYPE OF APPLICANT*			
Other (Specify): [REDACTED]			
<input type="radio"/> Women Owned <input type="radio"/> Socially and Economically Disadvantaged			
8. TYPE OF APPLICATION*		If Revision, mark appropriate box(es).	
<input checked="" type="radio"/> New <input type="radio"/> Resubmission <input type="radio"/> Renewal <input type="radio"/> Continuation <input type="radio"/> Revision		<input type="radio"/> A. Increase Award <input type="radio"/> B. Decrease Award <input type="radio"/> C. Increase Duration <input type="radio"/> D. Decrease Duration <input type="radio"/> E. Other (specify) :	
Is this application being submitted to other agencies?*			
<input type="radio"/> Yes <input checked="" type="radio"/> No What other Agencies?			
9. NAME OF FEDERAL AGENCY*		10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER TITLE:	
[REDACTED]		[REDACTED]	
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*			
[REDACTED]			
12. PROPOSED PROJECT		13. CONGRESSIONAL DISTRICTS OF APPLICANT	
Start Date*	Ending Date*	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: [redacted] First Name*: [redacted] Middle Name: [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title: [redacted]

Organization Name*: [redacted]

Department: [redacted]

Division: [redacted]

Street1*: [redacted]

Street2: [redacted]

City*: [redacted]

County: [redacted]

State*: [redacted]

Province: [redacted]

Country*: [redacted]

ZIP / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested* \$529,200.00

b. Total Non-Federal Funds* \$0.00

c. Total Federal & Non-Federal Funds* \$529,200.00

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: [redacted]

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: [redacted]

19. AUTHORIZED REPRESENTATIVE

Prefix: [redacted] First Name*: [redacted] Middle Name: [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]

Organization Name*: [redacted]

Department: [redacted]

Division: [redacted]

Street1*: [redacted]

Street2: [redacted]

City*: [redacted]

County: [redacted]

State*: [redacted]

Province: [redacted]

Country*: [redacted]

ZIP / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] Email*: [redacted]

Signature of Authorized Representative* [redacted] Date Signed* [redacted]

20. PRE-APPLICATION File Name: [redacted]

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 -----	5
Project Summary/Abstract(Description) -----	6
Project Narrative -----	7
Bibliography & References Cited -----	8
Facilities & Other Resources -----	12
Other Attachments -----	14
1240-FINALreferees -----	14
Research & Related Senior/Key Person -----	15
Research & Related Budget Year - 1 -----	29
Research & Related Budget Year - 2 -----	32
Research & Related Budget Year - 3 -----	35
Research & Related Budget Year - 4 -----	38
Budget Justification -----	41
Research & Related Cumulative Budget -----	42
PHS398 Cover Page Supplement -----	43
PHS 398 Career Development Award -----	45
Candidate Background -----	46
Career Goals and Objectives -----	47
Career Development and Training Activities -----	48
Responsible Conduct Of Research -----	53
Statements of Support -----	54
Letters of Support -----	60
Institutional Environment -----	63
Institutional Commitment -----	64
Specific Aims -----	65
Research Strategy -----	66
Protection of Human Subjects -----	72
Inclusion of Women and Minorities -----	73
Inclusion of Children -----	74

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]

File Name

Additional Location(s)

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* <input checked="" type="radio"/> Yes <input type="radio"/> No 1.a. If YES to Human Subjects Is the Project Exempt from Federal regulations? <input checked="" type="radio"/> Yes <input type="radio"/> No If YES, check appropriate exemption number: - 1 - 2 - 3 <input checked="" type="checkbox"/> 4 - 5 - 6 If NO, is the IRB review Pending? <input type="radio"/> Yes <input type="radio"/> No IRB Approval Date: Human Subject Assurance Number 00002636	
2. Are Vertebrate Animals Used?* <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	
3. Is proprietary/privileged information included in the application?* <input type="radio"/> Yes <input checked="" type="radio"/> No	
4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* <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:	
5. Is the research performance site designated, or eligible to be designated, as a historic place?* <input type="radio"/> Yes <input checked="" type="radio"/> No 5.a. If yes, please explain:	
6. Does this project involve activities outside the United States or partnership with international collaborators?* <input type="radio"/> Yes <input checked="" type="radio"/> No 6.a. If yes, identify countries: 6.b. Optional Explanation:	
7. Project Summary/Abstract*	Filename 1236-Abstract.pdf
8. Project Narrative*	1237-Projectnarrative.pdf
9. Bibliography & References Cited	1238-FINALReferences.pdf
10. Facilities & Other Resources	1239-FINALResources.pdf
11. Equipment	
12. Other Attachments	1240-FINALreferees.pdf

Project Abstract

The purpose of this application for a Mentored Clinical Scientist Research Career Development Award (K08) is to provide [REDACTED]

[REDACTED] sufficient protected time to 1) develop the statistical and methodological skills necessary to perform high quality health services research in obstetrics, 2) develop additional skills in study design and implementation for both population-based and clinical research, and 3) further develop leadership and management skills to lead a productive clinical and health-services research team. In the long term, [REDACTED] hopes to: 1) identify areas of sub-optimal care and health care variation using administrative datasets and data from large clinical trials, 2) identify optimal care improvement strategies within the context of comparative effectiveness research, and 3) perform clinical research to assess the validity and benefit of quality improvement initiatives.

Through formal biostatistical training including obtaining a Master of Science in Biostatistics through the [REDACTED] active participation in analysis of complex datasets, close mentorship by [REDACTED] attending lectures, journal clubs, conferences, and symposia, and performing the research analysis outlined in the application, [REDACTED] will enhance his capabilities as a researcher. [REDACTED] has identified [REDACTED] because of their expertise in epidemiology, biostatistics, and health outcomes research as well as their long track record of successfully mentoring junior faculty. [REDACTED] is an internationally renowned perinatal epidemiologist who has published more than 250 manuscripts, has a long history of achieving grant funding, and has extensive experience mentoring junior faculty. [REDACTED] is a gynecologic oncologist, experienced clinical trialist, translational researcher, and epidemiologist who has collaborated extensively with other non-surgical researchers including [REDACTED] [REDACTED] has identified a senior advisory panel to oversee his progress that will meet quarterly. The research strategy for this application is a novel population-based study evaluating candidate measures for intrapartum care quality. To summarize the study, [REDACTED] notes little is known about baseline adherence to obstetric practices that may be representative of care quality during labor and childbirth and how physician, provider, and patient factors influence adherence. Compared to many other specialties obstetrics lags behind in the implementation of systems to improve quality. Measuring obstetric quality will provide important knowledge for patients, payers, and providers, and assist in developing actionable, pragmatic interventions to improve obstetric care quality. Given that there is no agreement on how to best measure the quality of obstetric care, valid measures of intrapartum care quality are urgently needed. With his excellent mentorship team, [REDACTED] research plan may result in clinically useful findings that improve maternal care.

Project Narrative

This project will allow [REDACTED] a highly productive [REDACTED] the opportunity to develop skills necessary to independently perform clinical and population-based research via a Master of Biostatistics degree, intensive mentoring, and a research project evaluating potential intrapartum care quality metrics.

References

1. Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: structure, process, or outcomes? *J Am Coll Surg* 2004;198:626-32.
2. Lilford R, Mohammed MA, Spiegelhalter D, Thomson R. Use and misuse of process and outcome data in managing performance of acute medical care: avoiding institutional stigma. *Lancet* 2004;363:1147-54.
3. Bradley EH, Herrin J, Elbel B, et al. Hospital quality for acute myocardial infarction: correlation among process measures and relationship with short-term mortality. *JAMA : the journal of the American Medical Association* 2006;296:72-8.
4. Raval MV, Bilimoria KY, Stewart AK, Bentrem DJ, Ko CY. Using the NCDB for cancer care improvement: an introduction to available quality assessment tools. *J Surg Oncol* 2009;99:488-90.
5. Werner RM, Bradlow ET. Relationship between Medicare's hospital compare performance measures and mortality rates. *JAMA : the journal of the American Medical Association* 2006;296:2694-702.
6. Ferguson TB, Jr., Peterson ED, Coombs LP, et al. Use of continuous quality improvement to increase use of process measures in patients undergoing coronary artery bypass graft surgery: a randomized controlled trial. *JAMA : the journal of the American Medical Association* 2003;290:49-56.
7. Shahian DM, Edwards FH, Ferraris VA, et al. Quality measurement in adult cardiac surgery: part 1-- Conceptual framework and measure selection. *Ann Thorac Surg* 2007;83:S3-12.
8. O'Brien SM, Shahian DM, DeLong ER, et al. Quality measurement in adult cardiac surgery: part 2-- Statistical considerations in composite measure scoring and provider rating. *Ann Thorac Surg* 2007;83:S13-26.
9. Main EK. New perinatal quality measures from the National Quality Forum, the Joint Commission and the Leapfrog Group. *Current opinion in obstetrics & gynecology* 2009;21:532-40.
10. National Voluntary Consensus Standards for Perinatal Care 2008: A Consensus Report. (Accessed December 23, 2013, at www.qualityforum.org.)
11. Janakiraman V, Ecker J. Quality in obstetric care: measuring what matters. *Obstetrics and gynecology* 2010;116:728-32.
12. Callaghan WM. Overview of maternal mortality in the United States. *Seminars in perinatology* 2012;36:2-6.
13. Hamilton BE, Martin JA, Ventura SJ. Births: preliminary data for 2012. *National vital statistics reports : from the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System* 2013;62:1-20.
14. Clark SL. Strategies for reducing maternal mortality. *Seminars in perinatology* 2012;36:42-7.
15. Bailit JL. Measuring the quality of inpatient obstetrical care. *Obstetrical & gynecological survey* 2007;62:207-13.
16. Bailit JL, Grobman WA, Rice MM, et al. Risk-adjusted models for adverse obstetric outcomes and variation in risk-adjusted outcomes across hospitals. *American journal of obstetrics and gynecology* 2013;209:446 e1- e30.
17. Frankman EA, Wang L, Bunker CH, Lowder JL. Episiotomy in the United States: has anything changed? *American journal of obstetrics and gynecology* 2009;200:573 e1-7.
18. ACOG Practice Bulletin. Episiotomy. *Clinical Management Guidelines for Obstetrician-Gynecologists*. Number 71, April 2006. *Obstetrics and gynecology* 2006;107:957-62.
19. Carroli G, Mignini L. Episiotomy for vaginal birth. *The Cochrane database of systematic reviews* 2009:CD000081.
20. Hartmann K, Viswanathan M, Palmieri R, Gartlehner G, Thorp J, Jr., Lohr KN. Outcomes of routine episiotomy: a systematic review. *JAMA : the journal of the American Medical Association* 2005;293:2141-8.
21. American College of O-G. ACOG Practice Bulletin. Episiotomy. *Clinical Management Guidelines for Obstetrician-Gynecologists*. Number 71, April 2006. *Obstetrics and gynecology* 2006;107:957-62.
22. Sleep J, Grant A. West Berkshire perineal management trial: three year follow up. *British medical journal* 1987;295:749-51.
23. Sleep J, Grant A, Garcia J, Elbourne D, Spencer J, Chalmers I. West Berkshire perineal management trial. *British medical journal* 1984;289:587-90.
24. Eason E, Labrecque M, Wells G, Feldman P. Preventing perineal trauma during childbirth: a systematic review. *Obstetrics and gynecology* 2000;95:464-71.
25. Ohlsson A, Shah VS. Intrapartum antibiotics for known maternal Group B streptococcal colonization. *The Cochrane database of systematic reviews* 2013;1:CD007467.
26. American College of O, Gynecologists Committee on Obstetric P. ACOG Committee Opinion No. 485: Prevention of early-onset group B streptococcal disease in newborns. *Obstetrics and gynecology* 2011;117:1019-27.

27. Endorsement Summary: Perinatal and Reproductive Health Measures. 2011. (Accessed February 1, 2014, 2014, at www.qualityforum.org.)
28. Wing DA, Lovett K, Paul RH. Disruption of prior uterine incision following misoprostol for labor induction in women with previous cesarean delivery. *Obstetrics and gynecology* 1998;91:828-30.
29. Lin C, Raynor BD. Risk of uterine rupture in labor induction of patients with prior cesarean section: an inner city hospital experience. *American journal of obstetrics and gynecology* 2004;190:1476-8.
30. Plaut MM, Schwartz ML, Lubarsky SL. Uterine rupture associated with the use of misoprostol in the gravid patient with a previous cesarean section. *American journal of obstetrics and gynecology* 1999;180:1535-42.
31. Society of O, Gynaecologists of C. SOGC clinical practice guidelines. Guidelines for vaginal birth after previous caesarean birth. Number 155 (Replaces guideline Number 147), February 2005. *Int J Gynaecol Obstet* 2005;89:319-31.
32. American College of O, Gynecologists. ACOG Practice bulletin no. 115: Vaginal birth after previous cesarean delivery. *Obstetrics and gynecology* 2010;116:450-63.
33. Chauhan SP, Ananth CV. Induction of labor in the United States: a critical appraisal of appropriateness and reducibility. *Seminars in perinatology* 2012;36:336-43.
34. Caughey AB, Sundaram V, Kaimal AJ, et al. Maternal and neonatal outcomes of elective induction of labor. *Evidence report/technology assessment* 2009:1-257.
35. Grobman WA. Elective induction: When? Ever? *Clinical obstetrics and gynecology* 2007;50:537-46.
36. James BC, Savitz LA. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Aff (Millwood)* 2011;30:1185-91.
37. Allison JJ, Kiefe CI, Weissman NW, et al. Relationship of hospital teaching status with quality of care and mortality for Medicare patients with acute MI. *JAMA : the journal of the American Medical Association* 2000;284:1256-62.
38. Joynt KE, Harris Y, Orav EJ, Jha AK. Quality of care and patient outcomes in critical access rural hospitals. *JAMA : the journal of the American Medical Association* 2011;306:45-52.
39. Werner RM, Goldman LE, Dudley RA. Comparison of change in quality of care between safety-net and non-safety-net hospitals. *JAMA : the journal of the American Medical Association* 2008;299:2180-7.
40. Lindenauer PK, Behal R, Murray CK, Nsa W, Houck PM, Bratzler DW. Volume, quality of care, and outcome in pneumonia. *Annals of internal medicine* 2006;144:262-9.
41. Lindenauer PK, Pekow P, Gao S, Crawford AS, Gutierrez B, Benjamin EM. Quality of care for patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. *Annals of internal medicine* 2006;144:894-903.
42. Lindenauer PK, Pekow P, Wang K, Mamidi DK, Gutierrez B, Benjamin EM. Perioperative beta-blocker therapy and mortality after major noncardiac surgery. *The New England journal of medicine* 2005;353:349-61.
43. Lindenauer PK, Pekow PS, Lahti MC, Lee Y, Benjamin EM, Rothberg MB. Association of corticosteroid dose and route of administration with risk of treatment failure in acute exacerbation of chronic obstructive pulmonary disease. *JAMA : the journal of the American Medical Association* 2010;303:2359-67.
44. Lindenauer PK, Rothberg MB, Pekow PS, Kenwood C, Benjamin EM, Auerbach AD. Outcomes of care by hospitalists, general internists, and family physicians. *The New England journal of medicine* 2007;357:2589-600.
45. Rothberg MB, Pekow PS, Lahti M, Brody O, Skiest DJ, Lindenauer PK. Antibiotic therapy and treatment failure in patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. *JAMA : the journal of the American Medical Association* 2010;303:2035-42.
46. Auerbach AD, Hilton JF, Maselli J, Pekow PS, Rothberg MB, Lindenauer PK. Shop for quality or volume? Volume, quality, and outcomes of coronary artery bypass surgery. *Annals of internal medicine* 2009;150:696-704.
47. Friedman AM, Ananth CV, Lu YS, D'Alton ME, Wright JD. Underuse of postcesarean thromboembolism prophylaxis. *Obstetrics and gynecology* 2013;122:1197-204.
48. Sundararajan V, Grann VR, Jacobson JS, Ahsan H, Neugut AI. Variations in the use of adjuvant chemotherapy for node-positive colon cancer in the elderly: a population-based study. *Cancer J* 2001;7:213-8.
49. Sundararajan V, Mitra N, Jacobson JS, Grann VR, Heitjan DF, Neugut AI. Survival associated with 5-fluorouracil-based adjuvant chemotherapy among elderly patients with node-positive colon cancer. *Annals of internal medicine* 2002;136:349-57.
50. Grann VR, Hershman D, Jacobson JS, et al. Outcomes and diffusion of doxorubicin-based chemotherapy among elderly patients with aggressive non-Hodgkin lymphoma. *Cancer* 2006;107:1530-41.
51. Sundararajan V, Hershman D, Grann VR, Jacobson JS, Neugut AI. Variations in the use of chemotherapy for elderly patients with advanced ovarian cancer: a population-based study. *J Clin Oncol* 2002;20:173-8.

52. Hershman D, Jacobson JS, McBride R, et al. Effectiveness of platinum-based chemotherapy among elderly patients with advanced ovarian cancer. *Gynecol Oncol* 2004;94:540-9.
53. Hershman D, Fleischauer AT, Jacobson JS, Grann VR, Sundararajan V, Neugut AI. Patterns and outcomes of chemotherapy for elderly patients with stage II ovarian cancer: a population-based study. *Gynecol Oncol* 2004;92:293-9.
54. Wright J, Doan T, McBride R, Jacobson J, Hershman D. Variability in chemotherapy delivery for elderly women with advanced stage ovarian cancer and its impact on survival. *Br J Cancer* 2008;98:1197-203.
55. Hershman DL, Wang X, McBride R, Jacobson JS, Grann VR, Neugut AI. Delay of adjuvant chemotherapy initiation following breast cancer surgery among elderly women. *Breast Cancer Res Treat* 2006;99:313-21.
56. Hershman D, Hall MJ, Wang X, et al. Timing of adjuvant chemotherapy initiation after surgery for stage III colon cancer. *Cancer* 2006;107:2581-8.
57. Neugut AI, Matasar M, Wang X, et al. Duration of adjuvant chemotherapy for colon cancer and survival among the elderly. *J Clin Oncol* 2006;24:2368-75.
58. Hershman D, McBride R, Jacobson JS, et al. Racial disparities in treatment and survival among women with early-stage breast cancer. *J Clin Oncol* 2005;23:6639-46.
59. Wright JD, Shah, M., Mathew, L., Burke, W.M., Culhane, J., Schiff, P.B., Herzog, T.J. Patterns of care and access to fertility-conserving surgery for patients with ovarian sex cord stromal and germ cell tumors. 40th Annual Meeting of the Society of Gynecologic Oncologists; 2009; San Antonio, Texas.
60. Wright JD, Buck AM, Shah M, Burke WM, Schiff PB, Herzog TJ. Safety of ovarian preservation in premenopausal women with endometrial cancer. *J Clin Oncol* 2009;27:1214-9.
61. Wright JD, Grigsby PW, Brooks R, et al. Utility of parametrectomy for early stage cervical cancer treated with radical hysterectomy. *Cancer* 2007;110:1281-6.
62. Wright JD, Grigsby PW, Rader JS, et al. Effect of a T0 radical hysterectomy specimen on survival for early stage cervical cancer. *Gynecol Oncol* 2007;107:280-4.
63. Wright JD, NathavithArana R, Lewin SN, et al. Fertility-conserving surgery for young women with stage IA1 cervical cancer: safety and access. *Obstetrics and gynecology* 2010;115:585-90.
64. Wright JD, Shah M, Mathew L, et al. Fertility preservation in young women with epithelial ovarian cancer. *Cancer* 2009;115:4118-26.
65. Hershman DL, Buono D, McBride RB, et al. Surgeon characteristics and receipt of adjuvant radiotherapy in women with breast cancer. *J Natl Cancer Inst* 2008;100:199-206.
66. Hershman DL, Buono D, Jacobson JS, et al. Surgeon characteristics and use of breast conservation surgery in women with early stage breast cancer. *Ann Surg* 2009;249:828-33.
67. Wright JD, Burke WM, Wilde ET, et al. Comparative effectiveness of robotic versus laparoscopic hysterectomy for endometrial cancer. *J Clin Oncol* 2012;30:783-91.
68. Wright JD, Neugut AI, Wilde ET, et al. Physician characteristics and variability of erythropoiesis-stimulating agent use among Medicare patients with cancer. *J Clin Oncol* 2011;29:3408-18.
69. Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, Koroukian SM. Adherence to surgical care improvement project measures and the association with postoperative infections. *JAMA : the journal of the American Medical Association* 2010;303:2479-85.
70. Kuklina EV, Whiteman MK, Hillis SD, et al. An enhanced method for identifying obstetric deliveries: implications for estimating maternal morbidity. *Maternal and child health journal* 2008;12:469-77.
71. Yeast JD, Jones A, Poskin M. Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions. *American journal of obstetrics and gynecology* 1999;180:628-33.
72. Obstetrics ACoPB--. ACOG Practice Bulletin No. 107: Induction of labor. *Obstetrics and gynecology* 2009;114:386-97.
73. Dublin S, Lydon-Rochelle M, Kaplan RC, Watts DH, Critchlow CW. Maternal and neonatal outcomes after induction of labor without an identified indication. *American journal of obstetrics and gynecology* 2000;183:986-94.
74. Gregory KD, Korst LM, Cane P, Platt LD, Kahn K. Vaginal birth after cesarean and uterine rupture rates in California. *Obstetrics and gynecology* 1999;94:985-9.
75. Henry OA, Gregory KD, Hobel CJ, Platt LD. Using ICD-9 codes to identify indications for primary and repeat cesarean sections: agreement with clinical records. *American journal of public health* 1995;85:1143-6.
76. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373-83.
77. Bailit JL, Garrett JM, Miller WC, McMahon MJ, Cefalo RC. Hospital primary cesarean delivery rates and the risk of poor neonatal outcomes. *American journal of obstetrics and gynecology* 2002;187:721-7.

78. Srinivas SK, Fager C, Lorch SA. Evaluating risk-adjusted cesarean delivery rate as a measure of obstetric quality. *Obstetrics and gynecology* 2010;115:1007-13.
79. Grobman WA, Feinglass J, Murthy S. Are the Agency for Healthcare Research and Quality obstetric trauma indicators valid measures of hospital safety? *American journal of obstetrics and gynecology* 2006;195:868-74.
80. Goodney PP, Lucas FL, Stukel TA, Birkmeyer JD. Surgeon specialty and operative mortality with lung resection. *Ann Surg* 2005;241:179-84.
81. Wright JD, Herzog TJ, Shah M, et al. Regionalization of care for obstetric hemorrhage and its effect on maternal mortality. *Obstetrics and gynecology* 2010;115:1194-200.
82. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *The New England journal of medicine* 2003;349:2117-27.
83. Weber WP, Guller U, Jain NB, Pietrobon R, Oertli D. Impact of surgeon and hospital caseload on the likelihood of performing laparoscopic vs open sigmoid resection for diverticular disease: a study based on 55,949 patients. *Arch Surg* 2007;142:253-9; discussion 9.
84. Friese CR, Earle CC, Silber JH, Aiken LH. Hospital characteristics, clinical severity, and outcomes for surgical oncology patients. *Surgery* 2010;147:602-9.
85. Bailit JL, Love TE, Dawson NV. Quality of obstetric care and risk-adjusted primary cesarean delivery rates. *American journal of obstetrics and gynecology* 2006;194:402-7.
86. Tita AT, Rouse DJ, Blackwell S, Saade GR, Spong CY, Andrews WW. Emerging concepts in antibiotic prophylaxis for cesarean delivery: a systematic review. *Obstetrics and gynecology* 2009;113:675-82.

Facilities and Resources

██████████ the grant's principal investigator, has all of the required institutional support necessary to complete the proposed work. The ██████████ provides a rich environment to undertake the proposed research. The ██████████ houses a number of schools and programs that will be integral to undertaking the proposed research including ██████████. All logistical and administrative support for the grant will be coordinated within the ██████████. ██████████ will receive salary support and all the required resources to complete the grant.

██████████ provides an ideal environment to undertake this grant. The ██████████ faculty has demonstrated repeated success in performing multicenter clinical trials, basic science work, and health outcomes and epidemiologic research. The academic and research culture and infrastructure allow for ready implementation of major research initiatives. The ██████████ has a strong track record of every stage of research, ranging from design, implementation, data analysis and dissemination of findings. This infrastructure will be available to ██████████. Aspects of ██████████ research and academic culture that will be of particular importance to ██████████ are:

- The presence of a critical mass of academic full time faculty with sufficient time and skill to perform leading clinical, epidemiological, and basic science research.
- An established research environment in which experienced, independently funded researchers facilitate and promote research by junior faculty.
- A proven track record of advancing junior faculty to independent funding.

██████████ and their co-investigators conduct their epidemiologic studies on the ██████ floor of the ██████████. Their group is set within a larger ██████████ facility that houses a research staff dedicated entirely to OBGYN research projects. ██████████ research space consists of a large office suite that currently houses ██████ full time research biostatisticians and data analysts. These biostatisticians form a core devoted to comparative effectiveness and outcomes research in obstetrics and gynecology. The group has weekly meetings in which the team reviews data and plans future analyses. Each research analyst has their own desk, file cabinet space, harddrive and monitors and access to dedicated server space for data storage and back-up. The research suite has all necessary computer hardware and software with connections to the server required to undertake the proposed work.

The ██████████ is a leading school of public health in the United States with a world-class faculty, a diverse student body, and numerous interdisciplinary programs. The school has ██████ core departments, each with a strong academic presence and robust research programs. In addition to research programs within the local community and throughout the U.S., the school has forged a number of international alliances to improve the health of populations in underserved regions of the world. ██████████ both have joint appointments within the ██████████ within the ██████████ and, as such, will have access to the core resources within the school. Additionally, ██████████ will have access to core resources within the school by virtue of ██████ enrollment in a master's degree program. Importantly, the ██████████ has a robust infrastructure devoted to biostatistics, comparative effective research, outcomes research, and health economics. Importantly, the resources of the ██████████ cannot only be leveraged to undertake the proposed research, but also to disseminate the findings and broaden applications to other venues.

██████████ and the ██████████ provide an ideal environment to undertake this grant. The proposed grant will be performed by a multidisciplinary group of clinicians, biostatisticians and epidemiologists supporting ██████████. The group has weekly meetings to review data and the progress of the investigations. ██████████ has regular seminars and conferences devoted to outcomes, care quality, and health services research. ██████████ will attend these meetings and our data will be presented at several of these meetings. In addition to publication, ██████████ will present results from the grant at national meetings.

Computer: All research staff has a desktop PC in the main research office that is networked to the hospital mainframe, and therefore, each staff member has access to the multiple information systems available on campus. This access facilitates ongoing data collection and research processes. These computers are equipped with internet service and e-mail capabilities for effective communication. The research office also has a color laser jet printer that is on a local area network for use of all personnel, a dedicated fax machine, and a full service copier.

Data System in the OB/GYN Department: At [REDACTED] integrated data on the continuum of care is maintained within a customized Microsoft Access™ database. Eighty obstetrical and demographic variables are collected and entered on each patient. Presently, the system contains data on over 65,000 patients. The system has its own query and reporting facilities and more complex statistical analyses can be performed by exporting data to a spreadsheet or other format, or importing it into any of several programs specifically designed for statistical analysis. A full-time data-base manager employed by the department extracts data daily from the electronic medical records used by the institution. Eclipsys™ is the electronic medical record used for physician L&D and antepartum in-patient documentation. Eclipsys is used in the Neonatal Intensive Care Unit (NICU) as the medical record.

Library Facilities: There are [REDACTED] libraries at [REDACTED] and its affiliated institutions to access the rich array of both traditional and electronic information services with an outstanding staff that builds and manages the collections and technologies and provides strong and innovative services across the [REDACTED] [REDACTED] with over 10 million volumes, over 100,000 current journals and serials, and an extensive collection of electronic resources, manuscripts, rare books, microforms, and other non-print formats, rank as one of the top five academic library systems in the nation. Services are available to students and faculty that advance each user's learning, teaching, and research experience at [REDACTED]

GRANT REFEREES

The following referees have been chosen to write recommendation letters for this grant because of they are highly qualified to comment on the applicants research commitment and abilities:

- [REDACTED]
- [REDACTED]
- [REDACTED]

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator				
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:			
Credential, e.g., agency login				
Project Role*:		Other Project Role Category: Mentor		
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*: [REDACTED]

Organization Name*: [REDACTED]

Department: [REDACTED]

Division:

Street1*: [REDACTED]

Street2:

City*: [REDACTED]

County:

State*: [REDACTED]

Province:

Country*: [REDACTED]

Zip / Postal Code*: [REDACTED]

Phone Number*: [REDACTED] Fax Number: [REDACTED]

Credential, e.g., agency login: [REDACTED]

Project Role*: Other (Specify) Other Project Role Category: Mentor

Degree Type: [REDACTED] [REDACTED]

File Name

Attach Biographical Sketch*: [REDACTED]

Attach Current & Pending Support: [REDACTED]

[Redacted text block]

[Redacted text block]

3.

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[REDACTED]

[REDACTED]

[REDACTED]

OTHER SUPPORT

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted text block]

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]	181,500.00	9.00			75,000.00
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
Total Number Other Personnel						Total O
Total Salary, Wages and Fringe						

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

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. Foreign Travel Costs	
Total Travel Cost	

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 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	25,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	25,000.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	122,500.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. MTDC	8.00	122,500.00	9,800.00
Total Indirect Costs			9,800.00
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number) [REDACTED]			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	132,300.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: 1234-FINALBudgetjustification.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*: [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]	181,500.00	9.00			75,000.00

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
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 2

ORGANIZATIONAL DUNS*: [REDACTED]

Budget Type*: Project Subaward/Consortium

Organization: [REDACTED]

Start Date*: [REDACTED]

End Date*: [REDACTED]

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)	
2. Foreign Travel Costs	
Total Travel Cost	

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*: [REDACTED]

End Date*: [REDACTED]

Budget Period: 2

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	25,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	25,000.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	122,500.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. MTDC	8.00	122,500.00	9,800.00
Total Indirect Costs			9,800.00
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number) [REDACTED]			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	132,300.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: 1234-FINALBudgetjustification.pdf (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*: [REDACTED] End Date*: [REDACTED] 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]	181,500.00	9.00			75,000.00
Total Funds Requested for all Senior Key Persons in the attached file										
Additional Senior Key Persons: File Name:										Total Seni

B. Other Personnel						
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fr
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 3

ORGANIZATIONAL DUNS*: [REDACTED]

Budget Type*: Project Subaward/Consortium

Organization: [REDACTED]

Start Date*: [REDACTED]

End Date*: [REDACTED]

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)

2. Foreign Travel Costs

Total Travel Cost

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*: [REDACTED] End Date*: [REDACTED] Budget Period: 3

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	25,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	25,000.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	122,500.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. MTDC	8.00	122,500.00	9,800.00
Total Indirect Costs			9,800.00
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number) [REDACTED]			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	132,300.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: 1234-FINALBudgetjustification.pdf (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*: [REDACTED] End Date*: [REDACTED] 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]	181,500.00	9.00			75,000.00

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
----------------------	---------------	-----------------	-----------------	---------------	------------------------	----

Total Number Other Personnel Total O

Total Salary, Wages and Fringe

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*: [REDACTED]

End Date*: [REDACTED]

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)

2. Foreign Travel Costs

Total Travel Cost

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 4

ORGANIZATIONAL DUNS*: [REDACTED]

Budget Type*: Project Subaward/Consortium

Organization: [REDACTED]

Start Date*: [REDACTED]

End Date*: [REDACTED]

Budget Period: 4

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	25,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	25,000.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	122,500.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1. MTDC	8.00	122,500.00	9,800.00
Total Indirect Costs			9,800.00
Cognizant Federal Agency [REDACTED]			
(Agency Name, POC Name, and POC Phone Number) [REDACTED]			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	132,300.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*
File Name: 1234-FINAL.Budgetjustification.pdf (Only attach one file.)

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

Budget Justification

The budget will remain constant for each year 01-04 of the award

Principal Investigator: [REDACTED] is applying for this Mentored Clinical Scientist Research Career Development Award (K08). [REDACTED] will have 75% (9 calendar months) of his time protected during this 4-year award and will use this time to pursue population-based research and to develop statistical and methodological skills. [REDACTED] salary exceeds the NIH Executive Level salary cap of \$181,500; therefore, the cap was used to project salary support.

Statistician: A statistician is in the process of being recruited to [REDACTED] and will be available to assist in statistical analysis for this award. This person will be available with 50% of their time dedicated to [REDACTED] research. The award will provide a portion of the dedicated salary with the [REDACTED] and [REDACTED] covering the remainder.

Software and Education: Funds are requested to support [REDACTED] education activities including fees, books, and software related to coursework at the [REDACTED]. The credits for the [REDACTED] degree will be covered by a tuition benefit at [REDACTED]. [REDACTED] requests funds for software related to his research including relevant statistical programs.

Travel: [REDACTED] will attend several conferences each year necessary for his academic development. Funds are requested that will approximate airfare and conference fees. The balance of expenses related to travel will be covered by an annual professional development stipend from the [REDACTED].

Professional development: [REDACTED] requests funds for membership in professional organizations such as the [REDACTED] and the Society for Maternal-Fetal Medicine. These organizations are critical to his continuing education, training, and professional development.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals (\$)
Section A, Senior/Key Person	390,000.00
Section B, Other Personnel	
Total Number Other Personnel	
Total Salary, Wages and Fringe Benefits (A+B)	390,000.00
Section C, Equipment	
Section D, Travel	
1. Domestic	
2. Foreign	
Section E, Participant/Trainee Support Costs	
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
6. Number of Participants/Trainees	
Section F, Other Direct Costs	100,000.00
1. Materials and Supplies	100,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other 1	
9. Other 2	
10. Other 3	
Section G, Direct Costs (A thru F)	490,000.00
Section H, Indirect Costs	39,200.00
Section I, Total Direct and Indirect Costs (G + H)	529,200.00
Section J, Fee	

PHS 398 Cover Page Supplement

OMB Number [redacted]

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

Prefix:
First Name*: [redacted]
Middle Name:
Last Name*: [redacted]
Suffix:

2. Human Subjects

Clinical Trial? [checked] No [] Yes
Agency-Defined Phase III Clinical Trial?* [] No [] Yes

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)?

[] Yes [checked] No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? [] Yes [checked] No

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 is currently empty.

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. 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 Career Development Award Supplemental Form

Introduction (if applicable)

1. Introduction to Application
(for RESUBMISSION applications only)

Candidate Information

- 2. Candidate's Background 1241 [REDACTED]
- 3. Career Goals and Objectives 1242-C [REDACTED]
- 4. Career Development/Training Activities During Award Period 1243 [REDACTED]
- 5. Training in the Responsible Conduct of Research 1244 [REDACTED]
- 6. Candidate's Plan to Provide Mentoring (as applicable)

Statements of Support

- 7. Plans and Statements of Mentor and Co-Mentor(s) 1245 [REDACTED]
- 8. Letters of Support from Collaborators, Contributors, and Consultants 1246-I [REDACTED]

Environment and Institutional Commitment to Candidate

- 9. Description of Institutional Environment 1247 [REDACTED]
- 10. Institutional Commitment to Candidate's Research Career Development 1248 [REDACTED]

Research Plan

- 11. Specific Aims 1249 [REDACTED]
- 12. Research Strategy* 1250 [REDACTED]
- 13. Progress Report Publication List (for RENEWAL applications only)

Human Subject Sections

- 14. Protection of Human Subjects 1251 [REDACTED]
- 15. Inclusion of Women and Minorities 1252 [REDACTED]
- 16. Inclusion of Children 1253- [REDACTED]

Other Research Plan Sections

- 17. Vertebrate Animals
- 18. Select Agent Research
- 19. Consortium/Contractual Arrangements
- 20. Resource Sharing Plan(s)

Appendix (if applicable)

21. Appendix

Citizenship*:

- U.S. Citizen or noncitizen national
- Non-U.S. Citizen with temporary U.S. visa
- Permanent Resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award)
- Permanent Resident of U.S. Pending

Candidate Information

My goal is to develop a career as an independent researcher focusing on quality of obstetric care and comparative effectiveness research designing clinical, health services, and population-based research studies. I have an interest in assessing clinical uptake of evidence-based guidelines, obstetric safety, and translating findings related to clinical variation into actionable, pragmatic clinical interventions. I have published 25 publications as a medical student, resident, fellow, and a junior attending along with dozens of research abstracts. The majority of these publications have focused on care quality, maternal outcomes, and screening strategies to optimize maternal care. I have also collaborated on a number of grant applications in the past year that are pending (with one intramural grant having just been funded). I have completed my training at highly regarded research institutions within my field for both residency and fellowship and accepted an academic position at a leading research center in maternal-fetal medicine and obstetrics after graduation. Additionally, I have a background in biostatistics and epidemiology having earned a Master of Public Health Degree. I currently have several clinical and population based research projects that have been recently published or are in the process of being published. I have served as a research mentor to several residents and fellows in obstetrics and gynecology and maternal fetal medicine. I am also involved in clinically improving maternal care via my participation as a committee member or director of care quality initiatives on the institutional, local, and state level. This academic and clinical training and experience has confirmed my commitment to research and provides a sound starting point on which to start training for an independently funded research career.

[REDACTED]

[Redacted text block]

[Redacted text block]

[Redacted text block]

- 2. Research methodology focusing on regression analysis, statistical modeling of hospital variation, and comparative effectiveness metrics
- 3. Editing, collaboration, and support for grant applications and manuscript submissions

[REDACTED] is committed to advising and working closely with me. [REDACTED] will continue to meet for one hour each week to discuss my research progress. In addition to discussing difficulties that arise with administrative, scientific, and statistical modeling issues, these meetings focus on grant and manuscript submissions, leadership mentoring, and future study development. [REDACTED] have already mentored my successful grant application as principal investigator for pilot funding for a major clinical research project at [REDACTED]. In addition to these weekly meetings, I will attend the following meetings that relate to care quality and/or outcomes research: twice monthly maternal-fetal medicine divisional research meetings, weekly meetings for the departmental morbidity and mortality conference, twice monthly divisional obstetrical-critical care meetings, twice monthly divisional journal club meetings, monthly meetings of the [REDACTED] on which I serve, monthly meetings of the [REDACTED], relevant epidemiologic meetings at the [REDACTED] and meeting four times a year meetings for the statewide [REDACTED].

Combining [REDACTED] expertise in clinical outcomes and comparative effectiveness research and [REDACTED] expertise in perinatal epidemiology and biostatistics methodology this co-mentorship will enhance my career development and strengthen my research pursuits. Together, we have developed the following comprehensive career development and mentoring plan (Table 1). In addition, I have selected key faculty members from the [REDACTED] to serve as advisors.

[REDACTED]

[REDACTED]

[REDACTED]

Table 1: Career Development: Meeting Schedule and Training Plan

	Year 1-2	Year 3-4
Grant Applications	Y1: Intramural pilot grant (Irving Institute) Y2: R03: Maternal Early Warning System	Y3-4: R01: Comparative effectiveness of interventions to reduce maternal mortality and severe morbidity
Presentations	Y1,2: Society for Maternal-Fetal Medicine	Y3,4: Society for Maternal-Fetal Medicine
National Meetings	Y1,2: Society for Maternal-Fetal Medicine Y1,2: Society for Epidemiologic Research Y1,2: American Congress of Obstetricians and Gynecologists	Y3,4: Society for Maternal-Fetal Medicine Y3,4: Society for Epidemiologic Research Y3,4: American Congress of Obstetricians and Gynecologists
Publications	Y1: Manuscript for specific aim 1 Y2: Manuscript for specific aim 2	Y3: Manuscript for specific aim 3 Y4: Manuscript for specific aim 4
Conferences and seminars	<ul style="list-style-type: none"> - Grand rounds - Quality Assurance conferences - Maternal critical care conferences - Journal club - Divisional research meetings - ACOG II Safe Motherhood Initiative - Perinatal Practice Committee meetings - Selected seminars - CUMC Faculty Development Series 	<ul style="list-style-type: none"> - Grand rounds - Quality Assurance conferences - Maternal critical care conferences - Journal club - Divisional research meetings - ACOG II Safe Motherhood Initiative - Perinatal Practice Committee meetings - Selected seminars - CUMC Faculty Development Series
Mentoring	<ul style="list-style-type: none"> -Weekly meeting with mentor -Review of grants and manuscripts -Quarterly review of progress 	<ul style="list-style-type: none"> -Weekly meeting with mentor -Review of grants and manuscripts -Quarterly review of progress

C. Training Activities

During the career development grant I will pursue three concurrent training modules:

- 1) Development of comprehensive statistical analysis, data modeling, and study methodology knowledge
- 2) Application of research tools to design research studies that foster actionable, pragmatic strategies to improve patient care
- 3) Manuscript publication and grant applications

Research module #1: Training in statistical analysis, data modeling, and study methodology. Objective: To develop a comprehensive methodological skill set that will allow me to perform high-quality population-based outcomes research. *Classes:* I plan to take Statistical Computing with SAS (P6110), Applied Regression Analysis I (P8100), Applied Regression Analysis II (P8110), Nonparametric Statistics (P8117), and Analysis of Categorical Data (P8120) (Table 2). This grouping of courses will provide formal training in areas of statistical analysis highly important to my research interests. *Training:* The Department of Obstetrics and Gynecology is committed to supporting my research and grant progress with a data analyst funded at 50% full-time equivalent for my work. This analyst will have expertise in population-based research and I will work closely with her to develop the practical skills and knowledge to query and extract data from complex administrative datasets including the Perspective Premier, which incorporates data on hospital, provider, and patient characteristics, as well as billed services such as medications, procedures and devices, in addition to ICD-9 diagnosis coding. Other datasets with which I will develop expertise will include the Nationwide Inpatient Sample, the American Hospital Association Annual Survey, US natality data, and data sets from large clinical trials. I will also work with the data analyst to develop expertise in formatting and importing data into SAS for analysis. *Meetings:* I will meet with the data analyst, [REDACTED] regularly to make progress towards these goals. By the end of the training grant I will be able to independently model data from administrative data sets and perform analyses in SAS.

Research Module #2: Application of research tools to design research studies that foster actionable, pragmatic strategies to improve patient care. *Classes:* I plan to take the following classes on research study design: Cost benefit analysis and health economics (P8541), Outcomes research: Methods & public health implications (P8482), Epidemiology II: Design and conduct of observational epidemiology (P8438), and the Randomized Clinical Trial (P8140) (Table 2). While I have a prior basic biostatistics and epidemiologic training, more advanced coursework will be critical to becoming an independent investigator. *Training/Meetings/Advisors:* [REDACTED] and my data analyst to apply appropriate research methodologies and study designs to care quality research questions in obstetrics. In addition to master's degree coursework, I will review relevant research literature from other specialties with [REDACTED] to identify and utilize novel study methodologies and techniques to expand my research skill set. During meetings with [REDACTED] and [REDACTED] we will focus on designing population-based research that can be translated into clinical research ideas that will meaningfully improve maternal outcomes. *Meetings/Workshops:* I will attend relevant grand rounds, seminars, and colloquiums at the [REDACTED]. Each year I will attend the annual meeting of the Society for Epidemiologic Research. I will attend education sessions for relevant clinical and population-based at annual meetings for the [REDACTED] and the [REDACTED]. [REDACTED] By the end of this training grant I will be able to identify and utilize appropriate study methodologies to answer obstetric care quality questions and lead a research team that includes data analysts and junior faculty.

Research Module #3: Training in research dissemination and professional development. Objective: To further my skills in manuscript and grant writing to facilitate my development as an independent researcher. *Mentors:* [REDACTED] will continue to focus on career development, manuscript submission, and promotion. We will continue to meet weekly. I already have an extensive track record of preparing manuscripts with [REDACTED] and have assisted them with grant writing as a co-investigator. They have supported my successful grant application for a pilot intramural grant for a major clinical research project at [REDACTED] (see below). *Seminars:* I will attend the 8-part monthly [REDACTED] [REDACTED] providing junior faculty with important skills, such as manuscript preparation and approaches to receiving independent research support.

Advisory Committee for evaluation of progress during the training period: My progress toward fulfilling these training and research goals will be assessed during regular meetings with [REDACTED]. In addition, they will convene an advisory meeting consisting of my entire mentorship team including [REDACTED] [REDACTED] on a quarterly basis to review my progress in achieving the training and research objectives of the award. This will provide a forum to consider modifications to the training and research plans to enhance my skill development. I will attend these quarterly meetings and receive direct feedback.

D. Classes/Workshops

I will begin coursework in the [REDACTED] in [REDACTED] semester [REDACTED]. My planned schedule is detailed in Table 2. While I have selected coursework that primarily focuses on statistical modeling, the degree program will include a broad exposure to study design including outcomes research and health economics. In addition to these classes, I will attend selected workshops and tutorials, which focus on developing investigator-initiated concepts, with the goal of achieving career independence, as well as relevant grand rounds and seminars through the [REDACTED] [REDACTED]. This coursework will be supported by the tuition benefit at [REDACTED].

Table 2: [REDACTED]

Year 1	Year 2
Principles of epidemiology (P6400) Introduction to biostatistical methods (P6104) Statistical computing with SAS (P6110)	Applied regression analysis I (P8100) Nonparametric statistics (P8117) Analysis of categorical data (P8120)
Year 3	Year 4

Cost benefit analysis and health economics (P8541) Outcomes research: Methods & public health implications (P8482) Applied regression analysis II (P8110)	Epidemiology II: Design and conduct of observational epidemiology (P8438) The randomized clinical trial (P8140) Master's essay in biostatistics (P9160)
--	--

I selected the classes above specifically to develop my ability to independently perform high-quality epidemiologic research in my field. While I had an excellent exposure to the fundamentals of statistical principles and epidemiology through my prior Master of Public Health degree, I need additional, higher level classes in statistics and study design to appropriately perform research work that identifies opportunities for care improvement. I believe strongly that these formal didactics, in conjunction with my mentorship plan, will allow me to develop a skill set that is urgently needed but relatively rare in my field.

E. Other Anticipated Activities: Mentorship, Clinical Research, and Grant and Manuscript Submissions

During the last 2 years, I have mentored several obstetrics and gynecology residents and maternal-fetal medicine fellows on research projects, and am actively involved in current research projects for several current trainees. I have mentored the following residents and fellows on clinical research projects that have been published in peer-reviewed journals: [REDACTED]

[REDACTED]

[REDACTED] Mentees with research projects that are currently active include: [REDACTED] [REDACTED] [REDACTED] maternal-fetal medicine fellow, [REDACTED]

[REDACTED] I plan during the career development grant to mentor several other residents and fellows on substantive research projects.

I plan to continue work on a major clinical research project: evaluating a maternal early warning system (MEWS) that seeks to identify obstetric patients prior to the development of major morbidity and critical illness by prompt, protocol-guided evaluation of abnormal vital sign and physical exam parameters. This prospective study involving thousands of obstetric patients hospitalized at [REDACTED] will evaluate time to diagnosis and treatment of leading causes of severe maternal morbidity. This research serves as an example of the type of clinical research focused on improving patient care quality that I hope to design based on findings from population-based outcomes research. It is pragmatic and actionable, and if positive results are demonstrated, implementation may translate into meaningfully improved patient outcomes. This project is currently supported by an intramural grant from the [REDACTED] at [REDACTED] for which I am [REDACTED]. It will serve as the basis for an additional intramural grant during Year 1 of the training grant, and serve as the basis for an R03 application during Year 2 of the training grant.

Training in the Responsible Conduct of Research

As a frequent research collaborator, [REDACTED] is well-versed and up-to-date on the required training for the responsible conduct of research at [REDACTED]. He will pursue further formal coursework offered from [REDACTED] as part of their conduct of research didactics when enrolled in a [REDACTED] program as well as taking several courses on research study design and implementation which all include formal components on the responsible conduct of research. This coursework will include individual courses on outcomes research, the randomized clinical trial, and design and conduct of observational epidemiology. The importance of training in the responsible conduct of research is central to a successful research career, so continuing education and training is paramount.

To further satisfy the NIH RCR training requirement for in person training [REDACTED] will fulfill the requirement for RCR instruction by participating as a lecturer and discussion leader in the one-semester course on responsible conduct of research required for students in the [REDACTED] to attend through the [REDACTED].

Format

[REDACTED] has attended, and will continue to attend, formal didactic training via both on-line courses and classroom instruction by the [REDACTED]. The classroom instruction occurs with members of the IRB presenting on the responsible conduct of research during specific sessions of the twice monthly research seminars offered by the [REDACTED]. Further classroom instruction occurs during an annual "research bootcamp" during which a full day of research didactics includes dedicated time for presentations from the IRB. Further didactics related to the responsible conduct of research will occur via research seminars at [REDACTED] relevant to [REDACTED] research focus.

Subject matter

All researchers must complete HIPAA training and Good Clinical Practice before they can initiate a project. Other topics covered by mandatory IRB training include: conflict of interest, policies regarding human subject research, data acquisition, manuscript publication, and peer review.

Duration and frequency of instruction

Training available from the IRB is conducted on a year-round basis. This curriculum provides 8-10 hours of training in the responsible conduct of research at [REDACTED]. The annual "research bootcamp" provides an additional full 8 hours of training. Additional training will take place upon enrollment in the [REDACTED] program. As noted by the Table, [REDACTED] is up-to-date on all required formal research training.

Table. Completed formal research training by [REDACTED] and dates of expiration

Course Title	Date Passed	Expires On
TC0019 - HIPAA	[REDACTED]	N/A
TC0087 - HSP (CITI)	[REDACTED]	[REDACTED]
TC0088 - Research with Minors (CITI)	[REDACTED]	[REDACTED]
TC1451 - COI for PHS Researchers	[REDACTED]	[REDACTED]

Letters of Recommendation

Removed

[Redacted text block]

[Redacted text block]

- [Redacted list item]
- [Redacted list item]
- [Redacted list item]

[Redacted text block]

[Redacted text block]

[Redacted text block]

Specific Aims

The measurement of quality is a critically important goal in obstetrical care. Over the last decade quality improvement initiatives have focused on common medical conditions (i.e., myocardial infarction, pneumonia) and the performance of high-risk surgical procedures (i.e., coronary artery bypass grafting). Obstetric care has not received the same focus and research on quality in obstetrics is limited. This lack of evidence is particularly troubling given that 1) childbirth is extremely common with over 4 million births in the United States annually, and 2) obstetric severe morbidity and mortality have been rising over the past three decades, a significant portion of which may be preventable.

In this proposal we will evaluate multiple quality measures focusing on intrapartum care in relation to major adverse maternal outcomes. While some of these measures have been utilized in prior obstetric care quality research, others are entirely novel. To our knowledge no set of measures specifically focusing on intrapartum care quality has been rigorously assessed as a group. Poor intrapartum care quality may be a significant source of major obstetric morbidity and/or mortality. In this proposal we will determine the validity of the proposed obstetric quality measures, examine compliance with these metrics, and comprehensively analyze the patient, physician, and hospital factors associated with adherence as well as explore between-hospital variation. The specific aims of our proposal are to:

1. Evaluate the rate of inappropriate use of prostaglandins during trial of labor after cesarean (TOLAC).
 - a. Determining the rate of inappropriate use of prostaglandins during TOLAC.
 - b. Analyzing the patient, physician, and hospital characteristics associated with inappropriate use of prostaglandins during TOLAC.
 - c. Determining the between hospital variability of inappropriate use of prostaglandins during TOLAC.
2. Evaluate the rate of appropriate antibiotics use in women undergoing vaginal delivery who are group B streptococcus (GBS) positive.
 - a. Determining the rate of appropriate antibiotics use in women undergoing vaginal delivery who are GBS positive.
 - b. Analyzing the patient, physician, and hospital characteristics associated with appropriate antibiotics use in women undergoing vaginal delivery who are GBS positive.
 - c. Determining the between hospital variability of appropriate antibiotics use in women undergoing vaginal delivery who are GBS positive.
3. Evaluate the rate of use of episiotomy in women undergoing vaginal delivery.
 - a. Determining the rate of use of episiotomy in women undergoing vaginal delivery.
 - b. Analyzing the patient, physician, and hospital characteristics associated use of episiotomy in women undergoing vaginal delivery.
 - c. Determining the between hospital variability of use of episiotomy in women undergoing vaginal delivery.
4. Evaluate the rate of labor induction without indication by
 - a. Determining the rate of labor induction without indication.
 - b. Analyzing the patient, physician, and hospital characteristics associated with labor induction without indication.
 - c. Determining the between hospital variability of induction without indication.

HYPOTHESIS: We hypothesize that a) the care of a significant number of parturients does not meet the quality-based recommendations under study, b) hospital and provider factors may be important determinants of intrapartum care quality, and c) individual care quality metrics may be particularly sensitive in predicting good quality care (i.e. account for the other outcomes under review). Our work will determine the validity of proposed intrapartum obstetric quality measures. We will examine adherence to four process measures and comprehensively analyze the patient, physician, and hospital characteristics and between-hospital variability associated with use of these measures. This proposal will provide important data on how best to measure intrapartum obstetric quality in the U.S. This data will lay the groundwork for developing readily implementable, pragmatic quality improvement initiatives. This work will also provide important background for the development of national systems to measure and report the quality of obstetric care.

RESEARCH PLAN

A. Significance

A.1 Quality in Obstetrics

Valid measurement of health care quality is an important research goal given its vital importance for care quality improvement.^{1,2} Prior quality measurement research has focused on common medical conditions and surgical procedures¹⁻⁵ with substantial resources dedicated to improving adherence to evidence based guidelines for conditions such as myocardial infarction, pneumonia, and congestive heart failure^{3,5,6} and improving the quality of care for patients undergoing high-risk surgical procedures such as cardiovascular interventions.^{7,8} To date, obstetric care in the U.S. has received inadequate attention despite the fact that severe maternal morbidity is common, preventable and increasing in incidence.⁹⁻¹² Approximately 4.0 million births occur in the United States each year,¹³ and more than 50,000 women will suffer severe obstetric morbidity and/or mortality.¹² Measuring obstetric quality will provide important knowledge for patients, payers, and providers, and assist in developing actionable, pragmatic interventions to improve obstetric care quality. Given that a) there is no agreement on how to best measure the quality of obstetric care,^{9,11} and b) compared to many other specialties obstetrics lags behind in the implementation of systems to improve quality,^{4,7,8,14} there is strong interest in developing validated, reproducible perinatal quality metrics.^{9,10,14-16} In this proposal we will examine proposed measures of intrapartum care quality in the U.S. and analyze the factors that influence adherence to these measures. Little is known about baseline adherence to obstetric practices that may be representative of care quality during labor and childbirth⁹ and how physician, provider, and patient factors influence adherence. We will provide estimates of the adherence to these measures and examine the influence of patient, physician, and hospital characteristics as well as between-hospital variation on adherence.

A.2 Proposed Intrapartum Quality Measures

The rationale for each proposed quality measure is discussed below.

Rate of episiotomy: Episiotomy, an incision through the perineum to facilitate delivery, is a commonly performed obstetric procedure.¹⁷ While the goal of the procedure is to facilitate the second stage of labor, indications for episiotomy are largely based on clinical opinion.¹⁸ Research trials and meta-analyses have favored restricted use of episiotomy,¹⁹⁻²¹ and based on the available, evidence one systematic review concluded that there were “no benefits from episiotomy.”²⁰ With restrictive episiotomy women are more likely to have an intact perineum,^{22,23} and episiotomy has been found to protect against anal sphincter trauma or tears.²⁴ ACOG now recommends against the routine use of episiotomy.¹⁸ The National Quality Forum has recognized limiting routine episiotomy as an important measure of quality and patient safety.^{9,10}

Rate of antibiotic treatment for group B streptococcus (GBS) carrier status: Administration of intrapartum antibiotics for known maternal Group B streptococcal colonization reduces the risk of neonatal GBS infections.²⁵ Intrapartum treatment for carrier status is recommended by the Centers for Disease Control and Prevention and supported by the American Congress of Obstetricians and Gynecologists (ACOG).²⁶ Intrapartum antibiotic prophylaxis for GBS has been endorsed as a health measure by the National Quality Forum.²⁷

Rate of inappropriate use of misoprostol for induction in women undergoing TOLAC: The association between misoprostol induction and increased risk for uterine rupture in women undergoing TOLAC is well established.²⁸⁻³⁰ Multiple professional societies make clear recommendations against the use of misoprostol in women undergoing TOLAC.^{31,32}

Rate of induction without listed indication: Induction of labor occurs in 1 in 4 women in the United States, despite the fact that indications for induction occur in only 14% of women.³³ While data is currently insufficient to determine if elective induction beyond 39 and 41 weeks gestational age is associated with adverse maternal and neonatal outcomes,³⁴ induction without indication provides no defined benefit³⁵ and reducing elective induction is associated with cost savings.³⁶ While no society guidelines preclude induction without indication, given the costs, high frequency, and lack of medical benefit of this procedure, variation in this practice may be representative of care quality and more data on clinical practice patterns are needed.

A.3 Between-Hospital Variation

Hospital factors impose a strong influence on the care an individual patient receives.³⁷⁻³⁹ Identification of significant institutional variation may represent a critical means of identifying high or poor quality patient care. While identifiable hospital characteristics such as teaching status, size, and location play an important role in the allocation of care,^{37,38} even after accounting for these traits, substantial variation exists in how a given hospital delivers care. While racial composition and payor mix of facilities have also been shown to influence care for

some medical conditions,³⁹ the factors that further underlie variability have been difficult to elucidate. Data on institutional variation may be important for patients and providers to obtain high quality care, and may allow individual institutions to target care improvement initiatives. We will analyze the between-hospital variation in obstetric quality and explore the hospital factors that contribute to this variation.

A.4 Summary

In this proposal we will comprehensively determine baseline adherence to four proposed intrapartum quality metrics and examine the influence of patient, physician, and hospital characteristics and between-hospital variation on compliance with these process measures. The purpose of any obstetric quality measure is to improve the safety of women and neonates during pregnancy and delivery. Obstetric process measures are quantifiable, applicable to all providers, and translatable into pragmatic, actionable initiatives that improve patient care.^{1,2} In order to gain widespread acceptance of new patient safety goals, population-based comparative outcomes data is needed to demonstrate validity. Findings from outcomes and comparative effectiveness research may offer important evidence to justify large-scale clinical trials assessing care quality initiatives. Furthermore, in community hospitals and in underserved areas, significant prospective research initiatives may not be feasible. This grant will lay the groundwork for initiatives designed to measure and compare the quality of intrapartum obstetric care in the U.S. and ultimately to design pragmatic initiatives to improve the quality of care during childbirth in the community.

B. Innovation

The goal of this proposal is to evaluate the quality of intrapartum care in the United States. We will examine four common intrapartum management scenarios, all of which may be associated with adverse outcomes, and determine adherence to evidence-based quality guidelines (when applicable) and examine predictors of adherence. This work has a number of innovative conceptual approaches including:

- 1. This proposal represents one of the first studies to focus on intrapartum care quality.** While there is a growing literature on obstetric care quality and safety, relatively little is known specifically about the quality of intrapartum management and how intrapartum care quality may relate to overall obstetric care quality.
- 2. This proposal will include novel and innovative statistical approaches.** Our analysis of hospital variability will include random effects/hierarchical regression models to address within and between-hospital variation.
- 3. This proposal will utilize a unique, validated dataset.** The database chosen for this study has been validated for health outcomes in high-quality journals.⁴⁰⁻⁴⁶ With the data set we are using we are uniquely posed to examine labor induction, misoprostol use, and administration of antibiotics. Birth certificate data, which is commonly used in obstetric studies, does not capture drug administration and as such does not provide adequate data to examine the measures we will be evaluating.
- 4. This proposal will address questions that could not be answered through clinical trials.** Prospective observational trials are the gold standard for quality research. However, prospective research is limited by cost, sample size restrictions that may be not be adequate for evaluating rare outcomes, and generalizability to non-teaching institutions that are less likely to participate in research. This work will include millions of women from a mixture of centers throughout the U.S. and represent high-quality evidence to complement ongoing prospective research.
- 5. This proposal will provide data to guide the development of pragmatic and ready implementable interventions to improve the quality of obstetric care.** We will comprehensively determine factors that predict non-adherence to quality measures. These findings will allow for the development of interventions targeted specially at patients, physicians, and hospitals that fall below current quality standards.

C. Approach

C.1 Preliminary Studies

Our group has worked extensively in evaluating health outcomes, care quality, and disparities in access to care. Our team has expertise in the tools and methods for working with large administrative datasets, and conducts regular meetings to review data and study design and methodology. Given our prior experience and our pilot data, we believe our plan is eminently feasible.

Obstetric care quality studies

Our study team has performed a number of studies evaluating obstetrical care quality. In an analysis of 1,263,205 patients who underwent cesarean section, we found that only 24.3% received prophylaxis although rates did increase over the study period. We identified a strong correlation between geographic region and prophylaxis administration with only modest increases in prophylaxis use in the presence of medical and surgical risk factors.⁴⁷ Using the Perspective database we have recently completed an analysis of perioperative antibiotic

use in more than one million women undergoing cesarean delivery. This analysis demonstrated that 59.6% of women received perioperative antibiotics, with usage increasing over time. (Manuscript currently submitted for publication.) Regional variation was again noted, and whether a patient received antibiotics was highly dependent on hospital variation.

Oncology care quality studies

The study group has performed a number of studies examining the quality of care for patients with cancer. We have examined under-use of indicated chemotherapy and explored the quality (prompt initiation and appropriate duration) of chemotherapy delivery for breast, ovarian, and colon cancer.⁴⁸⁻⁵⁸ We have analyzed the safety of conservative surgery for gynecologic cancers and explored disparities in access to fertility-conserving surgery.⁵⁹⁻⁶⁴ Our group has examined the influence of physician and hospital characteristics in the utilization of breast conserving surgery and adjuvant radiotherapy for breast cancer.^{65,66} Finally, we have performed a number of studies examining use of new drugs and technologies.^{67,68}

C.2 Overview and Conceptual Framework

The overall objective of our study is to determine the validity of proposed intrapartum obstetric quality measures. We will examine the rates of four process measures: induction without a listed indication, appropriate use of intrapartum antibiotics during labor in GBS positive patients, inappropriate use of misoprostol for induction for patients with a prior cesarean section, and episiotomy. For each of these measures we will examine the influence of patient, physician, and hospital characteristics and between-hospital variation on adherence to the quality indicator.

C.3. Data Source

Perspective: The Perspective database is a nationwide, voluntary, fee-supported database maintained by Premier Inc (Charlotte, North Carolina) that was developed to measure resource utilization and quality. Perspective collects inpatient data from more than 500 acute-care hospitals (representing approximately 1 of every 5 discharges for the entire United States on an annual basis). The sample captures hospitals from throughout the U.S. and includes both urban and rural facilities as well as a mixture of teaching and non-teaching hospitals. Each participating institution submits electronic data updates quarterly. The data undergoes 95 separate quality assurance measures and validations prior to release for research.⁶⁹ Perspective comprehensively captures patient demographic data, all primary and secondary diagnoses, and procedures (ICD-9 codes) performed during a hospitalization. In addition, the database collects information on all billed services. As such, Perspective records all drugs, medications, and devices received by a patient as well as all radiologic and laboratory tests and any therapeutic service rendered during a patient's hospital stay. The Perspective database has been validated and utilized in a number of studies published in high-quality journals.^{40-44,48}

Patient File: The patient file includes detailed sociodemographic data on each patient. The patient file contains data on the length of stay, disposition, and the attending physician of record (including their unique identification number and specialty).

ICD-9 File: The ICD-9 file contains all ICD-9 coded diagnoses and procedures linked to individual patients. Each ICD-9 diagnostic code is categorized as an admitting code (A), primary diagnosis code (P), or secondary diagnosis code (S). The ICD-9 codes are listed in the order in which they were submitted to Premier. Each ICD-9 procedure code is linked to the procedure date and to the procedure physician (including their unique identification number and specialty).

Billing File: The billing file includes all billed services during a hospital admission. The billed services are linked to individual patients through their patient identification number. The billing file includes laboratory and radiologic tests, devices, therapeutic services and interventions and consultation codes. Each drug or service is linked to the date on which the service/drug was provided. For drugs and medications data on the dose of the drug is also provided.

C.4 Sample Selection (Eligibility Criteria)

Delivery hospitalizations will be identified utilizing an enhanced methodology.⁷⁰ The patient cohort for each specific aim will be identified according to the parameters in *Table 1*.

Appropriate use of antibiotics for GBS carrier status during labor (specific aim 1): Patients identified as GBS carriers will be identified. Administration of antibiotics will be queried from the Perspective dataset. Patients with other indications for antibiotics, such as infection, will be excluded

Induction without indication (specific aim 2): All patients undergoing labor followed by a vaginal delivery or cesarean section will be identified. Patients with ICD-9 coding indicating induction and patients receiving prostaglandin induction agents will be included as having an induction. Indications for induction have been

Specific Aim	Parameter	Corresponding ICD-9 and/or DRG codes and/or other criteria
GBS positive	<i>GBS positive</i>	V02.51
	<i>Exclusion criteria</i>	Diagnoses of infection including chorioamnionitis; cesarean delivery; preterm premature rupture of membranes (PPROM)
Induction without indication	<i>Indications</i> ⁷¹⁻⁷³	Postdates, hypertension, PROM, PPROM, diabetes (gestational or established), abnormal fetal testing, growth restriction, multiple gestation, fetal demise, chorioamnionitis, Rh sensitization, maternal medical complications, intrauterine growth restriction, polyhydramnios, oligohydramnios, preterm delivery, abruption
	<i>Induction</i>	659.0x, 659.1x, 73.0, 73.1, 73.4
Episiotomy	<i>Procedure</i>	73.6
Misoprostol use with TOLAC	<i>Prior cesarean delivery</i>	654.20, 654.21, 654.23
	<i>Presence of labor</i> ^{74,75}	653 (disproportion), 660 (obstructed labor), 661 (abnormal uterine forces), 662 (long labor), 652.1 (successful version), 659 (failed induction), 656.3 (fetal distress), 662 (long labor), 663 (cord complications), 72 (forceps and vacuum), 73 (induction)
	<i>Exclusion criteria</i>	Fetal death

determined by an iterative process after review of the literature.⁷¹⁻⁷³

Episiotomy (specific aim 3): All patients who underwent a vaginal delivery with the exception of women with shoulder dystocia will be included in this analysis.

Inappropriate use of misoprostol for induction after a prior cesarean section (specific aim 4): Patients undergoing trial of labor after cesarean will be identified by validated methodology.^{74,75} Women with prior cesarean section undergoing elective repeat cesarean section will be excluded. The Premier database will be queried for misoprostol administration. Patients with postpartum hemorrhage will be excluded given that this may be a confounding indication for prostaglandin administration.

C.5 Covariates/Explanatory Variables

Patient characteristics

Key patient level, provider level, and hospital level covariates are listed in *Table 2*.

Baseline demographic characteristics: Age and race are important factors in assessing variation of care and will be included in the analysis. To account for temporal trends patients will be stratified based on their year of delivery. Each woman's area of residence and insurance status (commercial, Medicaid, Medicare, none) will be analyzed.

Maternal medical and obstetric complications: Comorbid medical conditions may impact the allocation of treatment.⁷⁶ As the obstetric population is relatively young and healthy, the validity of commonly used comorbidity indices in this population is unknown.⁷⁶ We will utilize a modification of previously published risk adjustment strategies to account for underlying maternal medical conditions and obstetric complications.⁷⁷⁻⁷⁹

Physician characteristics

Specialty: For other diseases and procedures physician specialty has been shown to influence adherence to evidence-based guidelines and affect outcome.⁸⁰ We will examine the influence of provider specialty (general ob/gyn, maternal-fetal medicine specialist, family practice) on adherence to the four process measures described.

Obstetric volume: Volume influences the quality of care for a number of medical, surgical, and obstetric conditions.^{81,82} To assess the effect of overall obstetric volume, physicians will be stratified into volume-based tertiles: low, intermediate, and high as previously described.^{81,83} The classification will be based on the number of deliveries (vaginal, instrumented, and cesarean) performed per year. Only years in which the physician recorded at least one delivery will be included in the calculation of mean annual delivery volume.

Hospital characteristics

Baseline hospital characteristics: Hospital size (number of beds), teaching status (teaching or non-teaching) and metropolitan location (urban or rural) will be examined. All of these characteristics have been shown to influence access to care and outcomes.⁸⁴

Obstetric volume: Overall obstetric volume (annual number of vaginal, instrumented, and cesarean deliveries) will be calculated as described above. Hospitals will be stratified into volume-based tertiles.⁸¹⁻⁸³

Adjusted cesarean delivery rate: The adjusted cesarean delivery rate is an important predictor of hospital obstetric quality.^{77,78,85} Adverse outcomes are more frequent at hospitals with above or below average risk-adjusted cesarean rates.^{77,85} Adjusted cesarean delivery rates will be calculated for each hospital as previously described.⁷⁷ Hospitals will be categorized into 3 groups: above, below, or within the expected cesarean delivery rate.^{77,85}

Table 2. Key variables in the analysis.⁷⁷⁻⁷⁹

Patient characteristics	Physician characteristics	Hospital characteristics
Age	Obstetric volume	Teaching status
Race/ethnicity	Specialty (family practice vs. general ob/gyn vs. maternal fetal medicine)	Number of beds
Year of treatment		Metropolitan location
Area of residence		Obstetric volume
Insurance status		Adjusted cesarean delivery rate

C.6 Outcome Variables

For each specific aim, sub-aim A will examine the overall use of a process measure. Sub-aim B of each specific aim examines predictors (patient, physician, and hospital characteristics) of adherence to the quality measure. Sub-aim C examines between-hospital variation.

C.6.1 Appropriate use of antibiotics for GBS carrier status during labor (specific aim 1)

Process measure: Patients identified as GBS carriers during a vaginal delivery hospitalization will be identified. Administration of antibiotics will be queried from the Premier data set. Patients with other indications for antibiotics such as an infection or chorioamnionitis will be excluded. Patients with fetal death will be excluded.

C.6.2 Induction without listed indication (specific aim 2)

Process measure: Patients undergoing induction of labor will be identified. Through an iterative process and literature review leading indications for labor were identified. Patients with an indication for induction will be excluded.

C.6.3 Episiotomy (specific aim 3)

Performance of episiotomy (process measure): We will determine the overall use of episiotomy and predictors of episiotomy use. Patients with a delivery shoulder dystocia will be excluded, given that this is a recognized indication for performing an episiotomy.

C.6.4 Use of misoprostol for induction in women undergoing TOLAC (specific aim 4): We will identify women who have had a prior cesarean delivery and who either had a successful vaginal delivery or had a repeat cesarean section after labor. Patients who had received misoprostol will be identified. Women who had a fetal death will be excluded.

C.7 Pilot Data for the Current Sample Size Estimates and Feasibility

We have queried Premier to create a preliminary cohort of patients who may be included for each of the specific aims. Patients were identified as having a) been hospitalized with a vaginal or cesarean delivery utilizing an enhanced methodology⁷⁰ and b) meeting specific inclusion criteria specified in our analysis (Table 1). In this preliminary analysis, 151,623 women were identified as having a TOLAC (of whom 84,978 succeeded and had a vaginal delivery), 901,636 women underwent an induction of labor, 733,084 women had vaginal delivery in the setting of being GBS positive, and 613,079 women underwent episiotomy. The large preliminary sample indicates that our study will be uniquely poised to detect outcomes of interest in our specified analyses.

C.8 Analytic Plan

For each of the Specific Aims the analytic approach for the sub-aims is similar.

SUB-AIM A. To determine the rate of each obstetric quality measure. For each quality metric we will determine the rates of use with 95% confidence intervals. We will perform descriptive analyses for the various treatments across the explanatory variables described above. We will develop frequency tables to evaluate distributions and use contingency tables and chi-square tests to assess the association of treatments with predictor variables.

SUB-AIM B and C. To determine the influence of patient, physician, and hospital characteristics and between-hospital variation on adherence to each quality measure. The primary analysis will be based on fitting hierarchical generalized linear models to meet two goals: (i) to account for clustering of obstetric patients within hospitals; and (ii) to estimate the total variability in the proportion of patients that receive that given quality metric that are accounted for by variations within institutions and between providers. Accordingly, our proposed approach to use hierarchical models will be based on fitting a two-stage random effects log-linear regression model. These models will account for patient (age, race, year of diagnosis, marital status, insurance status, area

of residence, comorbidity), physician (specialty, volume), and hospital (teaching status, size, location, volume, adjusted cesarean delivery rate) characteristics.

Let Y_i denote the quality metric (operationalized definition of quality care, defined as quality metric met=1 and quality metric not met=0) for the i^{th} subject, and let x_{ij} denote the primary risk factor (exposure) of interest. Given the cohort nature of the dataset, we will apply log-linear regression models to evaluate the influence of patient, physician, and hospital characteristics on adherence to the quality metric. Subjects will be classified based on whether or not our quality metric was achieved. The model will be of the following general form:

$$\log[\text{Pr}(\text{Quality metric}=1|x_{ij})] = \beta_0 + \beta_1(\text{Patient char}) + \beta_2(\text{Phys char}) + \beta_3(\text{Hosp char})$$

where patient, physician, and hospital characteristics are sets of predictor variables. From these models, we will estimate, directly, the risk ratio (95% confidence interval) of quality care in relation to patient, physician, and hospital characteristics. We will also estimate the proportion of patients that receive the quality metric that are accounted for by patient-level characteristics and what proportion of patients that receive the quality metric that are accounted for by between-hospital variation. To accomplish this goal, we will fit a two-stage random-effects log-linear regression model of the form:

$$\log[\text{Pr}(\text{Quality metric}=1|x_{ij})] = (\beta_{00} + \beta_{0j}) + \gamma(\text{Patient char}) + \beta_2(\text{Phys char}) + \beta_3(\text{Hosp char})$$

where β_{00} is the overall probability (risk on a logarithmic scale) of receipt of the quality metric, β_{0j} is the random-effect for the overall probability of receipt of quality metric in the j^{th} hospital ($1 \leq j \leq k$) with $\beta_{0j} = N(0, \sigma_k^2)$ assumed to follow, approximately, a multivariate Normal distribution with mean 0 and variance estimated as σ_k^2 for the j^{th} hospital. From these models, we will determine the total variation (in the rate of use of the quality metric) in relation to individual patient-level characteristics and between-hospital variation. In this two-stage random-effects regression model, the parameter β_{00} is the overall proportion of patients that receive the quality metric averaged across the random-effect (hospital) parameter, and β_{0j} is an estimate of the proportion of patients that receive the quality metric in the j^{th} hospital.

C.9 Timeline

We will obtain data and create datasets immediately. We anticipate completion of Aim 1 in the first 12 months with manuscript preparation to follow. Analysis of Aim 2 will begin in 12 months, Aim 3 in 24 months and Aim 4 in the final year of the grant. Abstracts and papers will be generated throughout.

C.10 Strengths and Weaknesses

1. The quality of Premier data has been tested and validated in a number of ways. A number of sentinel studies that have been published in high-quality journals have utilized Perspective data.⁴²⁻⁴⁵
2. While we will be able to capture the use and duration of use of antibiotics for GBS, we are unable to determine the precise timing of administration. Therefore it is possible that patients may receive delayed and/or substandard care that this dataset will not be able to ascertain.⁸⁶
3. While it is often difficult to rely on ICD9 coding the covariates of interest in our study represent major obstetrical conditions. Prior studies have confirmed the sensitivity and validity of several of these factors.
4. Our very large sample size will allow detection of even small differences in outcomes that would likely not be detected using any other study design.

C.11 Future Directions

Our work will determine the validity of proposed intrapartum obstetric quality measures. We will examine adherence to four process measures and comprehensively analyze the patient, physician, and hospital characteristics and between-hospital variability associated with use of these measures. This proposal will provide important data on how best to measure intrapartum obstetric quality in the U.S. This data will lay the groundwork for developing readily implementable, pragmatic quality improvement initiatives. This work will also provide important background for the development of national systems to measure and report the quality of obstetric care.

PROTECTION OF SUBJECTS

This research project utilizes fully de-identified data from an administrative database and is exempt, per Exemption #4.

Inclusion of Women and Minorities

Women: The proposed research includes no gender-based inclusion or exclusion criteria. The subjects will all be women by virtue of the fact that pregnancy cannot be studied in men.

Minorities: The proposed trial does not discriminate by race/ethnicity. All patients meeting criteria irrespective of race will be included. The Perspective database which will be used to conduct the database includes approximately 1 in 5 discharges from acute care hospitals nationally. From a recent analysis we performed evaluating post-cesarean thromboembolism prophylaxis 52% of women were Caucasian, 16% were African-American, 12% were Hispanic, and the remaining 20% were either other or unknown. Given the large sample size, the race and ethnicity of patients in this analysis will reflect the racial and ethnic diversity of obstetric populations within the United States as a whole.

INCLUSION OF CHILDREN

Children will not be included in this study.