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# Influence Of Previous Cesarean Section On Clinical Outcome Of Medication Abortion

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INFLUENCE OF PREVIOUS CESAREAN SECTION ON CLINICAL OUTCOME OF  
MEDICATION ABORTION

Master's Scholarly Thesis  
Submitted to the Faculty  
Yale University School of Nursing

In Partial Fulfillment  
of the Requirements for the Degree  
Master of Science in Nursing

Lauren Pellegrino

May 14<sup>th</sup>, 2012

This thesis is accepted in partial fulfillment of the requirements for the degree Master of Science  
in Nursing.

Ivy Alexander, PhD, APRN

Susan Richman, MD

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*Lauren Pellegrino*

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## ABSTRACT

### INFLUENCE OF PREVIOUS CESAREAN SECTION ON CLINICAL OUTCOME OF MEDICATION ABORTION

A retrospective chart review was conducted to assess for a relationship between previous Cesarean section delivery and failure of subsequent medication abortion. Several studies have shown a positive relationship between parity and failure of subsequent medication abortion; however, these studies did not isolate method of delivery (Cotte, Monniez, and Norel 2008; Ashok, Templeton, Wagaarachchi, & Flett, 2002; Niinimäki, Martikainen, and Talvensaari-Mattila, 2004; Bartley, Tong, Everington, & Baird, 2000). The sample was 196 women who underwent medication abortion and returned for a two week follow-up appointment at an urban women's health clinic during 2005-2010. The protocol for medication abortion was 200mg Mifepristone orally followed by 400mcg of misoprostol vaginally or buccally administered 12-24 hours later. Failure was defined as positive pregnancy test at follow-up. Demographic and outcome data was collected from patient self-report pre-procedure intake and follow-up questionnaire forms. Parity regardless of delivery type increased the risk of failure ( $p=0.0422$ ) but previous Cesarean section did not ( $p = 0.6141$ ). Duration of cramps experienced after Misoprostol insertion were negatively correlated with age ( $r = -0.25448$ ). A positive correlation was found between longer cramp duration and smoking status. A larger prospective study with a standardized formal clinician-guided measure is recommended. Future studies may benefit from a focus on other outcome measures—such as onset and duration of cramping or bleeding—rather than simply procedure failure or success.

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## I. Background

### Clinical Problem

The usage of mifepristone and misoprostol to terminate pregnancy is becoming an increasingly popular choice for first-trimester abortion for women in the United States. In the period between 2005 and 2008, the number of these procedures—known as “medication abortions”—rose 24%, while the total abortion rate only increased 1% (Jones & Kooistra, 2011). Concurrently, the rate of Cesarean delivery in the United States has risen 56% since 1996 to 32.3% of all 2008 births (Martin, Hamilton, et al. 2010). Several studies have shown a positive relationship between the number of previous full-term births and failure of subsequent medication abortion; however, these studies have not isolated method of delivery as a variable that may contribute to procedure failure (Cotte, Monniez, and Norel 2008; Ashok, Templeton, Wagaarachchi, & Flett, 2002; Niinimäki, Martikainen, and Talvensaari-Mattila, 2004; Bartley, Tong, Everington, & Baird, 2000). The combination of increasing use of medication abortion for termination and increasing rates of Cesarean section for delivery bring into focus a group of women who have had one or more previous Cesarean births who may choose medication abortion to terminate a pregnancy.

This study explored the relationship between the phenomena of medication abortion outcome in the context of women with prior deliveries by Cesarean section. It was performed in the interest of helping advanced practice nurses, midwives and other clinicians provide more purposive anticipatory guidance to their patients who have had a previous Cesarean delivery on the option of medication abortion for first-trimester termination. Additionally, as advanced practice nurses move into the role of primary providers of medication abortion, it is hoped that the findings will forward clinical-decision making for these advance practice nurse abortion

providers regarding which patients are the best candidates for a pregnancy termination by medication abortion.

### **Operational Definitions**

#### **Abortion**

“The...induced termination of pregnancy before the fetus reaches a viable age.” (*Taber’s Cyclopedic Medical Dictionary*, 2009)

#### **Cesarean Section**

“The operation used to deliver a baby through its mother's abdominal wall. It is performed when the risks to mother or child of vaginal delivery are thought to outweigh the problems associated with operative delivery...The operation is usually performed through a low, horizontal ‘bikini line’ incision.” (*Black’s Medical Dictionary*, 2010, p. 716)

#### **Coping Score**

A numerical value from 1-10 given by the patient as a response to the question, “On a scale of 1 to 10 (1 being the worst and 10 being the best) how well are you coping with your abortion?” on their follow-up visit questionnaire.

#### **Delivery Type**

Method of delivery of a newborn at the end of a full-term pregnancy: for this study, method is dichotomized to either vaginal delivery or Cesarean section.

#### **Medication Abortion**

Abortion is “the...induced termination of pregnancy before the fetus reaches a viable age.” (*Taber’s Cyclopedic Medical Dictionary*, 2009) Medication abortion is termination by usage of pharmacologic methods (Spitz, Bardin, Benton, & Robbins, 1998).

#### **Medication Abortion Failure**

Medication abortion failure is defined as a positive pregnancy test finding at a routine two week follow-up visit.

**Parity**

Number of previous live births.

**Smoking Status**

A nominal value of yes or no to given by the patient in response to the question, “Smoker?” on the initial, pre-procedure intake questionnaire. It determines whether the patient currently is smoking a substance, with tobacco smoking implied.

**Review of the Literature**

Abortion is “the...induced termination of pregnancy before the fetus reaches a viable age” (*Taber’s Cyclopedic Medical Dictionary*, 2009). Medication abortion is induced termination by pharmacological, instead of surgical, means. It is performed by administering 200mg of Mifepristone by mouth followed by a prostaglandin analogue, usually misoprostol, buccally or vaginally at a later time (Spitz, Bardin, Benton, & Robbins, 1998). The protocol for medication abortion used in the present study was 200mg of Mifepristone, a progesterone blocker, orally administered in the clinic setting followed by misoprostol, a prostaglandin analogue, administered vaginally or buccally by the patient in a 400mcg dose 12-24 hours after at home. This procedure is administered up to a gestational age of 63 days. Although reported success rates differ by the exact dosing of mifepristone and misoprostol and the interval between them, the success rate with this particular protocol was 97.5% in one large study (Kopp Kallner, Fiala, Stephansson, & Gemzell-Danielsson, 2010).

Clinical studies on predictive factors of successful outcome with medication abortion have mainly focused on gestational age (Gomez, et al. 2010). Multiple studies of medication

abortion outcome have a positive association between increasing parity and probability of medication abortion failure (Cotte, Monniez, & Norel, 2008; Hedley, Turner, & Coyaji, et al., 2004; Ashok, Templeton, Wagaarachchi, & Flett, 2002; Niinimäki, Martikainen, & Talvensaari-Mattila, 2004; Bartley, Tong, Everington, & Baird, 2000). In Niinimaki et al. (2004) multiparous women had a higher rate of failure as defined by necessity for aspiration. The failure rate for nulliparas was 6%, increasing to 7.3% with 1-2 live births and 27.5% with three or more. Conversely, a patient with three or more pregnancies regardless of pregnancy outcome had a failure rate of 14.4%, whereas a patient with two pregnancies or less had a failure rate of only 5.7%. LeFebvre et al. (2008) found that multiparas with four or more pregnancies had an 8% failure risk, almost 6 times the rate for nulliparas (1.4%), which persisted even after controlling for age.

### **Influence of Previous Cesareans**

All studies previously discussed did not differentiate between Cesarean and vaginal delivery in participants with prior full term births. Two studies, both small retrospective chart studies, identify this interaction: Odeh, Tendler, Sosnovsky, et al. (2010) and Wang, Li, Manconi et al. (2010). Odeh, Tenderl, Sosnovsky, et al. (2010) completed a retrospective chart analysis study that included data on gravidity as well as parity. The sample included 403 women who had undergone medication abortion at a department of obstetrics and gynecology over the course of two years, subdivided into those who were primigravidas and those with one or more previous pregnancies. Those who had prior pregnancies were separated by those with previous terminations and those with previous Cesarean sections. Failure was defined as the requirement of uterine curettage. The rate of failure in the primiparous group was 8.2% versus 18.9% in all multiparous women. Subset analysis on the multiparas who had no history of abortion showed a

22.4% medication abortion failure rate, supporting the connection between previous term birth and medication abortion failure. Women who had only previous term births and no Cesarean section or abortion had a 19.2% failure rate; those who had only had one previous Cesarean section had a 40% failure rate. However, the subgroups of women who had had Cesarean sections, term births, or abortions were not clearly defined in quantity for the individual woman and therefore a more direct comparison could not be analyzed from the data presented.

Wang, Li, Manconi, Dong, Zhang, & Sun (2010) also directly evaluated a connection between previous Cesarean delivery and subsequent medication abortion outcome. Charts were reviewed retrospectively from a larger sample of 668 women with previous uterine incision (Cesarean section or other procedure) without collecting other information on obstetrical history. The study established values for the variables at which curettage would be indicated in this population: "vaginal bleeding intervals  $\geq 21$  days and/or had a bilayer endometrial thickness  $\geq 15$  mm and/or serum  $\beta$ -hCG  $\geq 500$  IU/L after a [medication] abortion" (Wang et al., 2010, p. 65). Wang et al.'s sample was comprised entirely of women with previous uterine incision. There was no control group of women without previous uterine incision to provide a comparison failure rate. Therefore it cannot be determined from the results whether the presence or absence of a previous uterine incision would affect outcome of medication abortion.

In summary, research into the predictors of a successful medication abortion is limited, and the interaction between Cesarean delivery and outcome of subsequent medication abortion is no exception. Of the general studies that have been conducted, very few explore the relationship between parity and outcome; only two have directly studied Cesarean section specifically as a possible predictive risk factor in failure. Several studies have indicated that higher gravity or

parity was associated with an increased rate of incomplete abortion; however, there was no differentiation between methods of delivery.

## **II. Research Methods**

### **Research Question**

Does a previous Cesarean delivery increase the risk of medication abortion procedure failure?

### **Research Design**

This retrospective, de-identified triangulated or mixed methods chart review included quantitative research methods. The review was completed of patients who underwent medication abortion at a free-standing women's health clinic located in an urban area in the northeastern United States who met two basic inclusion criteria. First, they underwent medication abortion at the center during the years 2005-2010; second, they returned for a routine two week follow-up visit and filled out a patient questionnaire at that time. Demographic information, specifically age, pertinent past medical history, and obstetric history, was collected from the pre-procedure intake form. Obstetric history included gravity, parity, and outcomes of previous pregnancies: previous spontaneous or therapeutic abortion, and vaginal delivery or Cesarean section.

Data was also collected from written questionnaires completed by patients at the follow-up visit after the procedure. These questionnaires elicit self-reported written qualitative data from the patients about their experiences of first-trimester medication abortion, as well as more quantitative scaled data on physiological aspects of the experience such as pain. The study specifically examined the interval between misoprostol administration and the onset of bleeding, duration of bleeding, onset and duration of cramping, and a scaled coping score.

### **Sample & Setting**

The convenience sample included 196 women who underwent medication abortion at a single free-standing family planning clinic in a socioeconomically disadvantaged, urban area in the Northeast United States in the years 2005-2010 and then returned for their follow-up appointment scheduled for two weeks after procedure. These patients were identified by hand-reviewing their charts for inclusion elements of having completed both a medication abortion and follow-up appointment.

### **Data Collection Instruments**

The data collection tool was an adaptation of the intake and follow-up visit forms at use in the clinic (Appendix A). As the instrument was simply an adaptation of these forms to facilitate entry into Statistical Analysis Software (SAS) Analytics, validity was assessed by standardizing the data into discrete categories after data collection as well as in anticipation of possible errors that could be corrected or accounted for before analysis was begun.

### **Data Collection Procedures**

All data was collected from paper-based medical charts on-site during the fall of 2011 and recorded directly into the data collection tool on a secured laptop. The data collection tool was a front-end of the SAS database that was used for data analysis.

Human subjects were protected by several means. First, no identifying information was recorded from the paper charts. In the study clinic, each individual patient encounter is contained in a single folder together with all of the patients' previous visits. Therefore, no correlational list linking study numbers with identifiable patient information was needed to prevent subject redundancy and none was maintained. The patient's age at time of procedure was recorded but

not the date of birth. As there was a sole investigator, no health information collected in this study was disclosed to others.

### **Data Analysis**

SAS (version 9.2) and Statistical Package for Social Sciences (SPSS) (version 19) statistical software were used for the analyses. Fisher's exact test was performed to determine if there was a significant association between positive pregnancy test result and previous Cesarean section. Fisher's exact was used due to a small sample size. Pearson's correlation coefficient was used to measure any correlation between continuous variables including bleeding onset and duration, cramping onset and duration, and coping score versus age, obstetrical history, Cesarean section, and whether the woman was currently smoking at the time of her abortion (smoker status).

Linear regression was performed in SAS to predict a variety of outcomes including onset of bleeding, duration of bleeding, onset of cramping, duration of cramping, and coping score associated with abortion. Predictor variables included age, number of abortions, smoker status, and Cesarean section. Diagnostics were performed to assess normality through the normal probability plot. A log transformation was conducted on the outcome variable, cramp duration. Forward model selection was used to find the best fit model in SAS.

### **III. Results**

Demographic data revealed that 30% of the women were age 21-26 years at the time of their medication abortion (Table 1). The procedure failure rate, defined as positive pregnancy test, was 4% in this study sample. The patients were all scheduled for a routine two week follow-



up visit and returned for this an average of 18.4 days post misoprostol, with a range of 4 to 62 days.

Table 1  
*Demographics of Patient Age in Years at Time of Procedure*

Group	15-20	21-26	27-32	33-37	38-44	Total
Number	42	59	40	37	18	196
Percentage of Total	21%	30%	20%	18%	9%	99%

Note: Due to rounding, percentages do not add up to 100%.

Fisher's Exact Test found a  $p$  value of 0.6141, showing that previous Cesarean section did not increase the likelihood of a positive pregnancy test on follow-up. Of the eight patients who had a positive pregnancy test at follow-up, six had never had a Cesarean section, one had one previous Cesarean section, and one had two previous Cesareans (Table 2). Parity on its own, regardless of delivery type, was found to be a risk factor for failure ( $p=0.0422$ ) (Table 3).

Table 2  
*Patient Information by Previous Cesarean Section and Pregnancy Test Outcome at Follow-Up*

Outcome	Previous Cesarean Section				Total
	0	1	2	3	
Negative	150	23	11	2	186
Positive	6	1	1	0	8
Total	156	24	12	2	194

Note: Due to data error, 2 cases are not included from the negative pregnancy test group.

Table 3

*Demographic Data on Parity and Pregnancy Test Outcome at Follow-Up*

Outcome	Number of Previous Pregnancies						
	0	1	2	3	4	7	Total
Negative							
Frequency	121	41	15	5	5	1	188
Percent	61.73	20.92	7.65	2.55	2.55	0.51	95.92%
Positive							
Frequency	4	0	3	1	0	0	8
Percent	2.04	0.00	1.53	0.51	0	0	4.08%
Total	125	41	18	6	5	1	196
	63.78	20.92	9.18	3.06	2.55	0.51	100%

Coping score was not found to be correlated with previous Cesarean section, number of previous abortions, age or tobacco use. These demographic factors (previous Cesarean section, number of previous abortions, age, or tobacco use) were also not correlated with onset or duration of bleeding or onset of cramping after misoprostol. However, a Pearson correlational plot showed that the duration of cramps experienced after Misoprostol insertion were negatively correlated ( $y = -0.25448$ ) with age. Additionally, a forward selection model showed a positive correlation between longer cramp duration and current smoker status (Table 4).

Table 4

*Association Between Cramp Duration, Age, and Smoker Status*

Statistical Findings	Intercept	Variable	
		Age at Abortion	Currently Smoking
Parameter Estimate	79.60510	-1.72864	30.57794
Standard Error	14.79580	0.52198	9.52439
T Value	5.38	-3.31	3.21
Pr >  t	<.001	0.0011	0.0016

#### IV. Discussion

The purpose of this study was to see if there was a relationship between previous Cesarean section and the frequency of medication abortion failure. For those advance practice nurses who are primary providers of medication abortion, it is hoped that identification of the relationship between medication abortion success and prior history of Cesarean section will inform clinical decision-making when evaluating medication abortion as a possible option for a patient. The failure rate, as defined by a positive pregnancy test at follow-up, was 4% for all medication abortions, which is similar to previously published rates for the method (Kopp Kallner, Fiala, Stephansson, & Gemzell-Danielsson 2004). No significant relationship between Caesarean section and medication abortion failure was found with this study. Absolute number of previous pregnancies was found to be correlated with failure, which further confirms the positive correlation between parity and failure found by many previous studies (Cotte, Monniez, & Norel 2008; Hedley, Turner, & Coyaji et al., 2004; Ashok, Templeton, Wagaarachchi, & Flett, 2002; Niinimäki, Martikainen, & Talvensaari-Mattila, 2004; Bartley, Tong, Everington, & Baird, 2000).

Similarly to the lack of relationship found between prior Cesarean section and failure, many secondary variables—obstetrical history variables of parity and previous abortion, use of tobacco, and age—were not found to be correlated with failure. They were also not correlated with this study's measured aspects of the lived experience of a patient undergoing medication abortion. This includes post-abortion coping, as well as onset and duration of bleeding and cramping after misoprostol administration.

Incidental examination of other variables found two secondary dependent variables with significant connections to certain outcomes. Patient age was found to be negatively correlated

with length of cramp duration after misoprostol, although there was no controlling for differences in parity, which tends to increase with age. Although there is no evidence in the literature on relationships between age and cramp duration, this finding may add complexity to previous studies that show age as a negative factor in success rates (Hedley et al., 2004). Second, smoking status (current tobacco use) was found to be positively correlated with longer duration of cramping after misoprostol. This is a novel finding that has not been previously studied, and further inquiry into this connection, including factoring in quantity of cigarettes smoked and years of smoking history, may prove to be significant.

### **Limitations of the Study**

This study has several important limitations. The self-reported nature of patient questionnaires contributes negatively to the dependability of the study. Beyond the universal issue of recall bias, there was little standardization in the answers provided by the patients. The validity and reliability of the tool, despite being exactly the same as the original forms, still rely on the quality of the data entered into the form. Although no charts were discarded in order to preserve the randomness of the sample, many had data that had to be interpreted by the author post-hoc. Retrospective, chart-only data collection with no direct patient contact also puts limits on the thoroughness of the data and limits the data by not allowing for a control group.

Additionally, the sample was patients from a single clinical site with a homogenous patient demographic. Although sample size ( $n = 196$ ) was determined to be sufficient to find no relationship between the primary variables, few overall failures may have limited the ability to find a statistically significant result. Therefore, these results are given in hopes of inspiring future research and are not generalizable.

### **Conclusion & Recommendations**

The objective of this study was to identify whether previous Cesarean section is a predictive measure of increased risk of medication abortion failure. The many limitations of the present study guide recommendations for future research. First, a prospective study with a more formal clinician-guided measure instead of patient self-report is recommended. A larger sample size, or a design that focused on chart review of only medication abortion failures, may bring more fruitful data on the topic of Cesarean section. Future studies may benefit from a focus on other outcome measures—such as onset and duration of cramping or bleeding—rather than simply clinical failure or success. A focus on the events that all women undergoing medication abortion might experience may have more utility in light of the infrequency of medication abortion failure. Repeating these findings in a larger, more standardized study with a control group could lead to a clinician being able to provide better pre-abortion reassurance that these factors are not shown to have a negative impact.

If these preliminary and limited results are built upon by further studies, the lack of a connection between prior Cesarean section and increased frequency of medication abortion failure may lead providers to be able to more confidently recommend medication abortion as an option to women with previous Cesarean section deliveries. It is the hope that future inquiry will improve the anticipatory guidance given by advance practice nurses to their patients and the quality of reproductive healthcare in turn.

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## Appendix

### Demographic and Follow-Up Forms

Age: \_\_\_\_\_ Name and location of Gynecologist: \_\_\_\_\_

I agree to allow Summit to contact my physician for the purpose of continuity of care. yes / no

Date last period began: \_\_\_\_\_ Was last period: normal or lighter

# of: prior pregnancies: \_\_\_\_\_ Abortions: \_\_\_\_\_ Deliveries: \_\_\_\_\_ Miscarriages: \_\_\_\_\_

Ages of children: \_\_\_\_\_ Previous c-sections: yes / no what year(s)? \_\_\_\_\_

History of ectopic pregnancy: yes / no when? \_\_\_\_\_ Breastfeeding: yes / no

Allergies to medications, foods, or latex products: \_\_\_\_\_

Currently (in last 30 days) using any prescription medications or recreational drugs:

when/comments: \_\_\_\_\_

Any previous surgeries? \_\_\_\_\_ what/when: \_\_\_\_\_

Problems with anesthesia/pain medication: \_\_\_\_\_

Ever had:

- |                                                   |                                              |                                                             |                                 |
|---------------------------------------------------|----------------------------------------------|-------------------------------------------------------------|---------------------------------|
| <input type="checkbox"/> Asthma                   | <input type="checkbox"/> High Blood Pressure | <input type="checkbox"/> Phlebitis or blood clots           | <input type="checkbox"/> Cancer |
| <input type="checkbox"/> Diabetes                 | <input type="checkbox"/> Hypoglycemia        | <input type="checkbox"/> Hepatitis or Liver disease         | <input type="checkbox"/> Anemia |
| <input type="checkbox"/> HIV/AIDS                 | <input type="checkbox"/> Bleeding tendency   | <input type="checkbox"/> Seizures                           | <input type="checkbox"/> STIs   |
| <input type="checkbox"/> PID                      | <input type="checkbox"/> Breast lump/tumor   | <input type="checkbox"/> Heart murmur/Mitral Valve Prolapse |                                 |
| <input type="checkbox"/> Heart Disease            | <input type="checkbox"/> Rh negative         | <input type="checkbox"/> Thyroid condition                  |                                 |
| <input type="checkbox"/> Shellfish/Iodine allergy |                                              |                                                             |                                 |

None of the above

Additional diseases, conditions, or comments: \_\_\_\_\_

Smoker? \_\_\_\_\_ How much? \_\_\_\_\_ How long? \_\_\_\_\_

When was the last time you had anything by mouth? \_\_\_\_\_

**Medical Abortion Follow Up Information**

**Medical Information:**

1. Did you experience any bleeding or cramping after taking the Mifeprex in our office?  
 Yes No If yes, please explain: \_\_\_\_\_
2. How long after using the misoprostol (4 pills) did you begin bleeding? \_\_\_\_\_ hrs
3. Was your bleeding like: (circle) a normal period/ heavier than a normal period/ lighter than a normal period?
4. How long did any heavy bleeding last? \_\_\_\_\_ hrs
5. Did you have any cramping, nausea, headaches, diarrhea, dizziness or other side effects after using the misoprostol? Yes No If yes, please explain \_\_\_\_\_  
 \_\_\_\_\_
6. If you experienced cramping from the misoprostol, how long did it take for the cramping begin? \_\_\_\_\_ hrs.  
 How long did the cramps last? \_\_\_\_\_
7. Did you take anything for the cramping? \_\_\_\_\_ What? \_\_\_\_\_  
 Was it effective? \_\_\_\_\_
8. Would you recommend this process to other women? Yes No  
 Please explain \_\_\_\_\_

**Emotional Reactions**

1. On a scale of 1 to 10 (1 being the worst and 10 being the best) how well are you coping with your abortion? \_\_\_\_\_
2. Would you find it helpful to speak to a counselor concerning your abortion? Yes No

**Examination and Lab**

Pregnancy Test result: \_\_\_\_\_

Follow Up Ultrasound: (Attach print out to back of page)

ABORTION PROCEDURE PROBABLY: COMPLETE INCOMPLETE (circle one)

Additional medications given: \_\_\_\_\_

Suction abortion medically necessary and advised: YES NO (circle one)

Any Complications/Concerns: \_\_\_\_\_  
 \_\_\_\_\_

Cervical os closed? Yes No  
 Endometrial stripe seen? Yes No  
 Uterus Involuted? Yes No

Birth Control Method/Future Gyn Care: \_\_\_\_\_



**B. Letter of IRB Support****Yale University**

*Human Investigation Committee  
55 College Street  
New Haven CT, 06510*

*Telephone: 203-785-4688  
Fax: 203-785-2847  
<http://www.yale.edu/hrpp>*

**To:** Lauren Pellegrino  
**From:** The Human Investigation Committee  
**Date:** 08/15/2011  
**HIC Protocol #:** 1107008758  
**Study Title:** Influence of Previous Cesarean Section on Clinical Outcome Medication Abortion  
**Approval Date:** 08/15/2011  
**Submission Type:** Initial Application

The research that you describe in your application involving the above-named project is exempt from HIC review under the parts of the federal regulations as noted below. Please keep a copy of this letter for your records.

Based upon the description of your project, the HIC finds the criteria below to be met. Please note that any revisions to this project must be submitted to the HIC for further review. At that point, a determination will be made regarding the continued exempt status of the research. You may keep a copy of this letter for your records.

Investigators conducting research involving human participants are required to report within 48 hours of discovery any serious and unanticipated adverse events related to the research participation and unanticipated problems involving risks to subjects or others occurring in the course of the research.

You should keep a copy of this letter for your records.

**Review Comments:**

- A HIPAA waiver has been granted for access to Summit Women's Medical Center's medical records of women who underwent medication abortion between 2005-2010 without obtaining written approval ("authorization") from the subject for the use of the data. This waiver does not authorize subject contact. The IRB finds that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart; The IRB also finds that the research could not practicably be conducted without the waiver or alteration; and the research could not practicably be conducted without access to and use of the protected health information. HIPAA regulations require that accounting logs be

maintained when researchers access patient records under a waiver of authorization including those approved for recruitment purposes. You are thereby reminded of your obligation to create the log. A spreadsheet is available on the HIC web site to assist in the collection of accounting log information. These logs must be forwarded to Marie Follo, Deputy HIPAA Privacy Officer. For further information on the accounting of disclosures, please see <http://www.yale.edu/ppdev/policy/5032/5032.pdf>

- This research is exempt from IRB review under federal regulation 45 CFR 46.101(b)(4). This part of the federal regulations covers research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.