1. Contacts and Title

1. Principal Investigator:

Timothy Simmons

Email	Training	CoI Date
Timothy.Simmons@hsc.utah.edu	4/8/2012 M	9/25/2012

a. Position of Principal Investigator:

- ○ Faculty
- ◉ **Student**
- ○ Staff
- ○ Resident/Fellow
- ○ Other

If Other, describe:

b. Will the Principal Investigator consent participants? ◉ **Yes** ○ No

2. Contact Person(s) (if different from the PI):

Name	Email	Training
There are no items to display		

3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):

Name	Email	Training	Obtaining Consent	CoI Date
There are no items to display				

4. External Sub-Investigator(s) (Investigators outside the University of Utah):

Last Name	First Name	Affiliation
Barton	Jessica	Santa Barbara Lactation
Frey	Frances	University of Texas San Antonio

5. Faculty Sponsor (if needed):

Theron Casper

6. Guests:

Last Name	First Name	E-Mail
There are no items to display		

7. What type of application is being submitted?

New Study Application (or Amendment/Continuing Review)

8. Title Of Study:
Factors affecting mothers' milk volume and mothers' perceptions of their milk supplies

9. Study Purposes and Objectives:

To our knowledge, no research has examined mothers' perceptions of their milk volume after beginning any of the various methods of contraception. Mothers' perceptions of low milk supply, substantiated or not, is the most commonly reported reason for giving up breastfeeding [1], [8], [10]. Given the health risks to both infant [6], [12] and mother [4], [7] of not breastfeeding, both mothers' actual and perceived milk supplies are important public health concerns.

The aim of this study is to explore the association between the use of contraceptives and perceptions of changes in milk supply within a convenience sample of breastfeeding mothers in order to spur further interest in this topic and provide effect sizes that will be useful in the design of future studies. [Run this by Frankie/Jessica]

10. Background and Introduction:

Interest in hormonal contraceptive use during breastfeeding has a long history. The research on the effects of contraceptives during lactation has included studies comparing combined hormonal contraceptives with progestin-only or non-hormonal methods on breastfeeding duration, milk volume, and infant growth

studies comparing combined hormonal contraceptives with progestin-only or non-hormonal methods on breastfeeding duration, milk volume, and infant growth [9], [13]. Other studies have compared the amount of contraceptive medication found in mothers' plasma and infants' urine [5], [11], the amount of medication found in the breast milk [9], and breastfeeding rates at intervals postpartum [3]. However, a meta-analysis of studies comparing combined hormonal contraceptives with progestin-only methods found that "evidence from randomized controlled trials on the effect of hormonal contraceptives during lactation is limited and of poor quality" [14], and concluded that "the existing randomized controlled trials are insufficient to establish an effect of hormonal contraception, if any, on milk quality and quantity" [14].

To our knowledge, no research has examined mothers' perceptions of their milk volume after beginning any of the various methods of contraception. Mothers' perceptions of low milk supply, substantiated or not, is the most commonly reported reason for giving up breastfeeding [18], [10]. Given the health risks to both infant [6], [12] and mother [4], [7] of not breastfeeding, both mothers' actual and perceived milk supplies are important public health concerns.

Anecdotal reports of detrimental effects of progestin-only contraceptive methods (particularly progestin-only IUDs) on milk volume during lactation are common, but to-date have not been substantiated. One small study comparing combined birth control pills with progestin-only pills found declines in milk volume of 41.9% and 12% respectively, as compared with 6% in the control group [13]. Many factors, including breastfeeding management, mothers' anatomy and physiology, infants' anatomy and physiology, and use of certain medications and herbs, are all known to influence mothers' milk supplies [1], so when a mother experiences a reduction in supply, there may often be several factors contributing to the decrease.

We propose a study designed to examine how mothers' milk volumes and mothers' perceptions of their milk supplies may be influenced by many factors including breastfeeding management practices, mothers' anatomy and physiology, infants' anatomy and physiology, events during and after the birth, and the use of medications, in particular progestin-only contraceptives.

2. Study Location and Sponsors

1. **Department:**
   FAMILY AND PREVENTIVE MEDICINE
2. **Location of Study:**

   University of Utah - Main Campus (Outside the Covered Entity)

   Other Intermountain Healthcare Sites:
3. **Is this a Multicenter Study (i.e., the study involves other sites with other PIs):**

   ○ Yes ◉ **No**

   a. **If yes, are you the lead investigator of this study, or is this the central location for the study?**

      ○ Yes ○ No
4. **Indicate other locations that are participating in the study for which you, as the PI, are responsible:**

Site Name	Site Investigator	Investigator/Main Contact
There are no items to display		

   a. **How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?**
5. **Indicate the source(s) of funding obtained or applied for to support this study.**

Sponsor	Sponsor Type	Sponsor Contact Information
There are no items to display		
6. **Does this study have functions assigned to a Contract Research Organization (CRO)?**

   ○ Yes ◉ **No**

   If yes, CRO Contact Information:
7. **Does this study involve use of the Utah Population Database (UPDB)?**

   ○ Yes ◉ **No**

3. Participants

1. **Ages of Participants:**
   18 and older (Consent form needed)
2. **Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**
   18+

3. **Indicate any vulnerable participant groups (other than children) included:**

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

○ Yes ◉ **No**

4. **Number of participants to be enrolled during the entire study:**

At Utah: 2000

All Centers:

5. **Characteristics of Participants/Inclusion Criteria:**

Participants will be:

Female
Currently have a baby 18 months or under
Be fully or partially breastfeeding, or have breastfed within the last year.

6. **Participant Exclusion Criteria:**

None.

7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**

○ Yes ◉ **No**

4. Study Information

1. **Design of Study (select all that apply):**
Survey/Questionnaire Research
If Other, describe:

2. **Does your study involve the use of any placebo?**
○ Yes ◉ **No**

3. **Length of entire study, from initiation through closeout:** 1-2 years

4. **How will participants be recruited or identified for inclusion in the study?**

a. **Select all methods that will be used:**
Other

Participants will be recruited through online social networking (Facebook, email, etc.).

b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

Recruitment emails and Facebook requests will be sent initially to individuals and mothers' groups online such as La Leche League, breastfeeding Facebook groups, etc., and the online survey logic in SurveyMonkey will exclude ineligible respondents.

5. **How will consent be obtained?**
Informed Consent Process (with or without a document)

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

Participants will be recruited via a link to the survey which will be posted on social networking websites (such as Facebook) and emailed to likely participants and/or persons likely to pass along the link to breastfeeding mothers. To maintain confidentiality, responses to the survey will be submitted through SSL encryption. Since participation in the survey is voluntary and all but the initial screening questions are optional, participation will be understood to imply consent. The data gathered in administering the survey will be accessible only to investigators via the survey provider, and any data downloaded from the provider by the investigators will be stored on password protected computers.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
◉ **Yes** ○ No

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**

○ Yes ◉ **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   The primary goal of this study is to measure the association between the use of progestin-only contraceptives and mothers' perceptions of changes in their milk supply. Association will be quantified through a generalized linear model, adjusting for potential confounders captured in the survey, and will assume that participants are representative of all nursing mothers. Secondary analyses will include a time-to-event analysis, again adjusting for potential confounders, to determine if mothers using progestin-only contraceptives stop breastfeeding earlier than mothers who use no contraceptives or other types of contraceptives. Since this is an exploratory study, we have not completed any power calculations. We are hoping to obtain a large sample of participants (1,000-2,000).

Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Contacts and Title Page):**

   Timothy Simmons

   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).
   None.

2. **Describe the location(s) where consent will be obtained.**
   This is an online anonymous survey.

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
   The introductory page to the survey will describe the process of participation and will give a broad description of the purpose of the study. The decision to continue with the survey will be understood to imply consent. Participants will be informed that they may discontinue their involvement in the survey at any time without penalty.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
   The survey will be online; participation will be voluntary and participants will be informed before beginning the survey that they may discontinue their involvement in the study at any time without penalty.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
   Participants will be given the email address of one of the sub-investigators at the beginning and at the end of the survey. This will allow them to ask questions before beginning the survey and after completing it.

6. **Will a legally authorized representative (LAR) be used?**

   ○ Yes ◉ **No**

   If yes, describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period.

7. **Will a language other than English be used to obtain consent?**
   ○ Yes ◉ **No**

   If yes, complete the following:

   a. **Please indicate which form will be used:**

      If using the short form, please provide justification for why a full, translated consent document will not be used:

   b. **Describe whether translation services will be used for the consent process and how the consent process will be conducted?**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
   ◉ **Yes** ○ No

   If yes, complete the following:

   a. **Explain why the waiver of consent documentation is being requested.**
      This is an online anonymous survey.

   b. **Justification for the waiver is one of the following:**
      The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

   Allowing for anonymous submission of surveys and questionnaires

   Other or additional details (specify):

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   Storing research data on password protected computers or in locked cabinets or offices

   Complete de-identification of study data

   All data that will be transferred or transported outside of the institution will be encrypted

   Other or additional details (specify):

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ◉ **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

   Other or additional details (specify):

   Other additional details (specify):
   Because this is an online survey, response options are limited. We will be able check that all responses are within the specified range from each question; survey logic will prevent inconsistent answers; participants enter their own responses directly.

5. **Who will be the primary monitor of the study data and documentation?**

   Select all that apply:

   Principal Investigator

   Other or additional details (specify):

   Other or additional details (specify):
   Principal investigator and external sub-investigators.

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
   At study close out, just prior to analysis.

6. Risks and Benefits

1. **Describe the reasonable foreseeable risks or discomforts to the participants:**

   The only risk to participation we anticipate is discomfort in answering personal questions related to breastfeeding, perceptions of milk supply, family planning and contraception, and some health conditions. The discomfort will, however, be minimal as this is an online, anonymous survey and participants will be free to omit any question they would prefer not to answer. Participants will be informed that they may discontinue their involvement at any time without penalty.

2. **Describe the potential benefits to society AND to participants (do not include compensation):**

   Our study will explore the associations between the use of contraception and mothers' perceptions of milk supply. We hope the study will spur further interest in these associations and provide estimates for designing future experimental studies. Ultimately, the study may contribute to a better understanding of factors that affect milk supply, enabling better counselling and support of breast feeding mothers. Participants will gain the satisfaction of helping to promote breastfeeding through their participation.

3. **Are there any costs to the participants from participation in research?**

   ○ Yes ◉ **No**

   If yes, specify:

4. **Is there any compensation to the participants?**

   ○ Yes ◉ **No**

a. **If yes, answer the following:**
Specify overall amount:

b. **Specify when participants will be paid (e.g. at each visit, at end of study, etc.):**

c. **If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):**

d. **If applicable, explain plan for prorating payments if participant does not complete the study:**

8. Resources and Responsibilities

1. **State and justify the qualifications of the study staff:**

   The principal investigator is currently earning a master's degree in statistics with an emphasis in biostatistics. He has provided statistical support to the Intermountain Injury Control Research Center's Data Coordinating Center for the last one and a half years, and will be able to bring to this study the knowledge he has gained from that experience as well as the knowledge gained in his course work. He will also be able to consult with the faculty statisticians on his graduate advisory committee.

   The two external subinvestigators also have statistical expertise and are knowledgeable about breastfeeding. One holds a master's degree in psychology and has been employed as a psychometrician for the last decade, and the other is an International Board Certified Lactation Consultant (IBCLC).

2. **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   Since this is an online survey, responses will be collected automatically and no training will be necessary. The external subinvestigators will be largely responsible for analyzing the data and reporting the results. The subinvestigators will consult with the PI as needed in the course of the analysis to ensure that the statistical assumptions/approach are warranted after the data are available.

3. **Describe the facilities to be used for the research activities (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.):**
   Survey responses will be submitted through SurveyMonkey using SSL encryption. No identifying information will be collected, and the data gathered in administering the survey will be accessible only to investigators via the survey provider, and any data downloaded from the provider by the investigators will be stored on password protected computers.

4. **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   Not applicable. This is an online survey and participants can discontinue their involvement at any time without penalty.

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2

Assent Document (Highlighted Changes)

Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified
There are no items to display			

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Parental Permission Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

Assent Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

VA Consent Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified
There are no items to display			

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified
There are no items to display			

Grant Application:

Name	Version	Date Created	Date Modified
There are no items to display			

Literature Cited/References:

Name	Version	Date Created	Date Modified
Literature Cited 02_06_2013.pdf	0.01	2/6/2013 5:59 PM	2/6/2013 5:59 PM

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified
Simmons CV	0.01	9/22/2012 4:58 PM	9/22/2012 4:58 PM

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified
Casper CV	0.01	3/1/2011 10:01 AM	3/1/2011 10:01 AM

Other Stamped Documents:

Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.

Name	Version	Date Created	Date Modified
There are no items to display			

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Other Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

Finish Instructions

Finish Instructions

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**