PennState

HRP-591 - Protocol for
Human Subject Research

Protocol Title:
Effect of formal contraception handouts on postpartum birth control use and methods.

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NCT03956030

Important Instructions for Using This Protocol Template:
This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS:**
   - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:**
     - Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Penn State College of Medicine/Penn State Health researchers**: Delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (http://irb.psu.edu)**.**
     - **Penn State researchers at all other campuses**: Do NOT delete the instructional boxes from the final version of the protocol.
   - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.
2. **CATS IRB LIBRARY:**
   - Documents referenced in this protocol template (e.g. SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
   - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
   - Update the Version Date on page 1 each time revisions are made.

If you need help…	
University Park and other campuses: Office for Research Protections Human Research Protection Program The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: irb-orp@psu.edu	**College of Medicine and Penn State Health:** Human Subjects Protection Office 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Email: irb-hspo@psu.edu

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1.0 Objectives

1.1 Study Objectives

The purpose of this study is to determine if an educational handout on birth control given in the prenatal period increases postpartum contraception use. In this randomized controlled trial, low-risk obstetric patients at 24-28 weeks gestational age will receive either an educational handout on contraception or a nutritional handout. Participants will be assessed at 8 weeks and 6 months postpartum regarding their contraception use. We hypothesize that a prenatal educational handout on contraception options will increase postpartum contraception use.

1.2 Primary Study Endpoints

The primary study endpoint is contraception use at 8 weeks postpartum.

1.3 Secondary Study Endpoints

The secondary study endpoints are contraception use at 6 months postpartum and method of contraception. In addition, we will assess patient satisfaction with prenatal contraception counseling and patient self-reported knowledge about contraception options.

2.0 Background

2.1 Scientific Background and Gaps

Reducing unintended pregnancies and those that are conceived within 18 months of a previous livebirth is an important health concern in the United States. Both unintended and close-interval pregnancies constitute 40% and 35% of pregnancies in the United States respectively with some overlap between the two categories and are associated with adverse maternal and fetal outcomes.[1] A national survey found that 17.8% of women using 'less-effective' methods and 23% of women using no birth control became pregnant in ≤18 months.[2] Access to better contraception education could potentially decrease the proportion of unintended pregnancies and close-interval pregnancies. In addition to the health concerns, 58% of women in the US would like more information about contraceptive options, and organized handouts on birth control have been shown to contribute to the choice in birth control.[3,4]

However, there has been conflicting evidence about which educational methods increase postpartum contraception use.[5-8] Therefore, we propose a randomized controlled trial (RCT) that assesses whether a handout on contraception options increases postpartum birth control use. The control group would receive a nutrition handout, and the intervention group would receive a handout on birth control options in addition to each receiving the standard of care. We will also give pre- and post-natal questionnaires, covering patient satisfaction, intention to use birth control, and how often a provider discusses birth control options.

2.2 Previous Data

There are currently no data analyzing 8-week postpartum contraception use in women who receive a standardized educational handout on birth control methods versus women who receive a standardized nutritional handout.

2.3 Study Rationale

The studies that have examined distributing educational materials on contraception have largely focused on unintended pregnancy rates. Furthermore, most of these studies did not use a recently postpartum population, which is one group that close-interval pregnancy can have severe and profound health effects on both the mother and the neonate. The few studies that did examine this population showed conflicting data as to which educational method was superior.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

1) Women who are pregnant and are 24-28 weeks gestational age at the time of recruitment
2) Women >18 years of age
3) Women with low-risk pregnancies

3.2 Exclusion Criteria

1) Women who receive prenatal care solely at the Maternal Fetal Medicine department for high-risk pregnancies
2) Women who are members of an at-risk population including any women who is a prisoner, cannot provide consent, or is <18 years of age
3) Non-English speaking
4) No access to a valid email address.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Patients will be withdrawn from the study should they deliver prior to 34 0/7 weeks gestational age or have a fetal demise, postpartum course complicated by an ICU stay, or receive an emergency hysterectomy at delivery. Patients will also be withdrawn if they fail to complete key components of the intake survey (i.e. name, date of birth, email address, or obstetric history) or the 8-week postpartum survey. Patients will be contacted by email and/or telephone. Should a patient fail to respond to these attempts at contact, they will be presumed to have withdrawn from the study. Additionally, any patient can withdraw from the study at any point upon their request. As this is a low-risk trial, we do not anticipate any patients being withdrawn for safety reasons or adverse health outcomes.

3.3.2 Follow-up for withdrawn subjects

At any point upon subject request or upon failure to complete surveys, patients will be withdrawn from the study. No further data will be collected on withdrawn subjects, and there will be no additional follow-up beyond the postpartum standard of care. Following the withdrawal of a subject, that individual will not be replaced in this study.

4.0 Recruitment Methods

4.1 Identification of subjects

Patients seen for prenatal care between 24-28 weeks gestation in the Obstetrics and Gynecology clinics at 35 Hope Drive, 121 Nyes Road and 3025 Market Street Camp Hill will be approached regarding participation in this study as part of their appointment.

4.2 Recruitment process

4.2. 1 How potential subjects will be recruited.

Patients will be approached in-person about participation in this study during their clinical visit.

4.2. 2 Where potential subjects will be recruited.

35 Hope Drive, 121 Nyes Road and 3025 Market Street Camp Hill OB/Gyn offices.

4.2. 3 When potential subjects will be recruited.

During or after their 24-28-week pregnancy visit, which is a standard and pre-appointed visit during all pregnancies.

4.2. 4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB.

Patient schedules and medical records will be reviewed for eligibility prior to obtaining informed consent.

5.0 Consent Process and Documentation

5.1 Consent Process:

Check all applicable boxes below:

X Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]*

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ **Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination." Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in "HRP-590- Consent Guidance for Exempt Research"):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete): The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see "HRP-312- Worksheet- Exemption Determination") is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2. 1 Timing and Location of Consent

Informed consent will be obtained at the patient's prenatal appointment at 24-28 weeks gestation. These appointments will take place at 35 Hope Drive,121 Nyes Road and 3025 Market Street Camp Hill on the Penn State Health campuses where the Obstetrics and Gynecology service has clinic.

5.2. 2 Coercion or Undue Influence during Consent

Consent will be obtained at the prenatal appointment from 24-28 weeks gestation. Patients will be informed verbally and in writing that participating in this study is entirely voluntary and that medical care is not contingent on agreeing to participate in this study.

5.3 Waiver of Written Documentation of Consent

N/A

5.3. 1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

X The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

5.3. 2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

N/A

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

5.4. 1 Indicate the elements of informed consent to be omitted or altered

N/A

5.4. 2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

N/A

5.4. 3 Describe why the research involves no more than minimal risk to subjects.

N/A

5.4. 4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

N/A

5.4. 5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

N/A

5.4. 6 Debriefing

N/A

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

N/A

5.6 Consent – Other Considerations

5.6. 1 Non-English-Speaking Subjects

Non-English-speaking subjects will not be included.

5.6. 2 Cognitively Impaired Adults

5.6.2.1 Capability of Providing Consent

N/A

5.6.2.2 Adults Unable to Consent

N/A

5.6.2.3 Assent of Adults Unable to Consent

N/A

5.6. 3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

N/A

5.6.3.2 Assent of subjects who are not yet adults

N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

X **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

X **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2. 1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2 .1.1 Plan to protect PHI from improper use or disclosure

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2 .1.2 Plan to destroy identifiers or a justification for retaining identifiers

Data will be stored in a secure web application as outlined below. Data will be de-identified with removal of PHI when abstracted and stored on a secure server for statistical analysis.

6.2. 2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Without PHI, it would be impossible to identify patients who would be eligible for this study.

6.2. 3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Without the ability to access the medical records of patients, it would be impossible to perform the prospective nature of this study.

6.3 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research 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 permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

Prospective randomized controlled trial.

7.2 Study Procedures

7.2.1 Timepoint 1: At 24-28 weeks gestation

At patients' previously-scheduled prenatal appointment at 24-28 weeks gestational age, patients will receive a research-specific packet to include demographic questionnaire and proprietary questionnaire after determining the individual's eligibility and obtaining informed consent. A cover letter will be provided to the patients briefly describing the study and their requested

participation. After obtaining proper consent and signing the necessary forms, patients will complete the demographic information found on the intake questionnaire in paper form. After completion of the initial demographic information (i.e. name, date of birth, email address, and mailing address), the patient will be randomized (randomization will be stratified by recruitment location) to either group A or B via REDCap and receive a sealed envelope containing the respective handout. The envelopes will simply be labeled "A" or "B" so that the study personnel are blinded to the allocation. The envelopes will be assembled by an individual outside of the study team who will determine the handout designations for A and B. A master copy of one sealed 'A' envelope and one sealed 'B' envelope will be provided to the statisticians; these envelopes will be opened at the end of the study to unblind the groups. Following randomization, the patient will receive her intake questionnaire with her demographic information already filled in to be completed during this visit. The completed intake questionnaire will then be returned and stored in a locked and secured location. These survey results will be compiled, entered, and stored under the Redcap database.

7.2.2 Timepoint 2: At 8 weeks post-partum

8 weeks following delivery, patients' medical records will be reviewed to assess continued eligibility. Eligible participants will receive an automated electronic mail message with a link to the questionnaire to be completed on REDCap. There is not a required office visit for this timepoint. If the questionnaire is not completed within one week, another reminder message with a link to the REDCap questionnaire will be sent via electronic mail. These results will be stored under the REDCap database.

7.2.3 Timepoint 3: At 6 months post-partum

6 months following delivery, those participants who were eligible at 8 weeks postpartum will receive an automated electronic mail message with a link to the questionnaire to be completed on REDCap. There is not a required office visit for this timepoint. If the questionnaire is not completed within one week, another reminder message with a link to the REDCap questionnaire will be sent via electronic mail. These results will be stored under the REDCap database.

7.3 Duration of Participation

Patients will participate in this study for approximately 10 months. Routine prenatal care necessitates a visit between 24- and 28-weeks gestation, which is the recruitment visit. Most women will deliver between 37- and 42-weeks gestation, and there will be questionnaires sent at 8 weeks and 6 months after delivery. The 8-week questionnaire is the primary endpoint for patient participation in this study.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

A sample size of 100 participants per group (200 total) will provide us with a sufficient sample size. However, we anticipate 10% of the participants may drop-out prior to study completion; therefore, we will enroll of total of 224 participants.

8.2 Sample size determination

We used 80% power to detect a difference between the proportions of women using birth control at 8 weeks of 0.75 in the nutrition informational handout and 0.90 in the birth control information handout using a two-sided chi-square test having a significance level of 0.05.

8.3 Statistical methods

To determine the difference in postpartum contraception use at 8 weeks, a two-sided chi-square test will be used to compare the women between those who receive a contraception-specific handout and those that receive a nutrition-specific handout.

9.0 Data and Safety Monitoring Plan

9.1 Periodic evaluation of data
N/A

9.2 Data that are reviewed
N/A

9.3 Method of collection of safety information
N/A

9.4 Frequency of data collection
N/A

9.5 Individuals reviewing the data
N/A

9.6 Frequency of review of cumulative data
N/A

9.7 Statistical tests
N/A

9.8 Suspension of research
N/A

10.0 Risks
Loss of confidentiality is the most significant risk associated with this study. This is an unlikely occurrence as their personal information will be securely kept in a Redcap database and those administering the handouts and collecting data will be HIPAA compliant per Penn State Hershey Medical Center requirements. There are no medical risks or foreseeable risks of any other type.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects
Patients may receive more educational information that may help in achieving their family planning goals.

11.2 Potential Benefits to Others
Data establishing an improvement in patient satisfaction with their contraception counseling and use would result in improved prenatal counseling and less ambiguity about family planning needs postpartum.

12.0 Sharing Results with Subjects
N/A

13.0 Subject Payment and/or Travel Reimbursements
Subjects will receive a $10 Amazon gift card upon completion of the three surveys.

14.0 Economic Burden to Subjects

14.1 Costs

N/A

14.2 Compensation for research-related injury

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charge to subjects or their insurance carriers

15.0 Resources Available

15.1 Facilities and locations

Penn State Hershey Campus

15.2 Feasibility of recruiting the required number of subjects

During the 2017-2018 fiscal year, there were 979 total deliveries who received their prenatal care at the Hope Drive OB/Gyn office. We would need approximately 23% of these patients for our study. We will also include patients seen at the 121 Nyes Road and 3025 Market Street Camp Hill offices to increase the likelihood of capturing adequate participant numbers.

15.3 PI Time devoted to conducting the research

The primary investigator will engage in this project over the one year here at Penn State Milton S. Hershey Medical Center. As part of that training, the principle investigator has built in research/academic time which should facilitate completion of this study. Assistance from other project members, including Senior Investigator and professor of medicine, Dr. Cynthia Chuang, will also be available.

15.4 Availability of medical or psychological resources

Resources are available 24/7 at the Penn State Hershey Medical Center if needed

15.5 Process for informing Study Team

All members of the research team will have access to the IRB-approved protocol and supporting documents. There will be a training session for those involved with subject recruitment. Additionally, there will be periodic research meetings between the principal investigators and the researchers during which all aspects, including the progress and any barriers encountered will be discussed.

16.0 Other Approvals

16.1 Other Approvals from External Entities

N/A

16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of "HRP-901 - Human Body Fluids for Research Form" in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

X Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

17.0 Multi-Site Study

N/A

17.1 Other sites

N/A

17.2 Communication Plans

N/A

17.3 Data Submission and Security Plan

N/A

17.4 Subject Enrollment

N/A

17.5 Reporting of Adverse Events and New Information

N/A

17.6 Audit and Monitoring Plans

N/A

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

20.1 Data and/or specimens being stored

The following data will be collected: Name, age, medical history, pregnancy information, delivery information, surgical history, previous contraception use, desire for future children. Specimens will not be collected.

20.2 Location of storage

Secured in password-protected Redcap database

20.3 Duration of storage

Unless specifically requested by the patient, the dataset will be kept in electronic form indefinitely.

20.4 Access to data and/or specimens

Only the principal investigators and approved researchers will have access to the Redcap dataset.

20.5 Procedures to release data or specimens

Only those persons who contact either principal investigator, Dr. Christina DeAngelis, and request access to the dataset will be allowed to access the dataset

20.6 Process for returning results

Results will be returned to the principal investigator, Dr. Christina DeAngelis.

21.0 References

1. Ahrens KA, Thoma ME, Copen CE, Frederiksen BN, Decker EJ, Moskosky S. Unintended pregnancy and interpregnancy interval by maternal age, National Survey of Family Growth. Contraception. 2018;98(1):52–5.
2. White K, Teal SB, Potter JE. Contraception After Delivery and Short Interpregnancy Intervals Among Women in the United States. Obstetrics & Gynecology. 2015;125(6):1471–7.
3. Hooper DJ. Attitudes, Awareness, Compliance and Preferences among Hormonal Contraception Users. Clinical Drug Investigation. 2010;30(11):749–63.

4. Johnson LK, Edelman A, Jensen J. Patient satisfaction and the impact of written material about postpartum contraceptive decisions. American Journal of Obstetrics and Gynecology. 2003;188(5):1202–4.
5. Hersh A, Muñoz L, Rincon M, Alvarez C, Tolosa J, Moreno D, et al. Video vs. conversational contraceptive counseling during maternity hospitalization: the COMSE trial. Contraception. 2017;96(4):292.
6. Smith K, Spuy ZVD, Cheng L, Elton R, Glasier A. Is postpartum contraceptive advice given antenatally of value?. Contraception. 2002;65(3):237–43.
7. Goldstein S, Hubbard R. Standardized Contraceptive Handout Facilitates Contraceptive Counseling. Family Medicine. 2018;50(2):146–8.
8. Hebert LE, Hill BJ, Quinn M, Holl JL, Whitaker AK, Gilliam ML. Mobile contraceptive application use in a clinical setting in addition to standard contraceptive counseling: A randomized controlled trial. Contraception. 2018;98(4):281–7.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state

See the Research Data Plan Review Form.