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KURT SCHAEFER
19TH DISTRICT

COMMITTEES
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JOINT COMMITTEE ON LEGISLATIVE RESEARCH--OVERSIGHT SUBCOMMITTEE, CHAIRMAN

October 30, 2015

Chancellor R. Bowen Loftin
Office of Chancellor
University of Missouri
105 Jesse Hall
Columbia, Missouri 65211

Dear Chancellor Loftin:

It has come to my attention that there is a research study currently taking place at Planned Parenthood's St. Louis facility which the University of Missouri Campus Institutional Review Board approved on April 29, 2015, with the express benefit of helping "Planned Parenthood of the St. Louis Region and Southwest Missouri improve its services to better meet the needs of women seeking abortions." *See* attached.

This study purports to "gain a better understanding of the abortion decision-making process," as well as the effects of Missouri's 72-hour waiting period on the decision to have an abortion. The principal investigator is a student at the University of Missouri School of Social Work, and Dr. Marjorie Sable, the Director of the School of Social Work and a board member and Secretary of Planned Parenthood of Kansas and Mid-Missouri, serves as the adviser for the study. However, Planned Parenthood research staff will collect data from over 200 women at the St. Louis facility, and all information produced by the study is to be stored at the St. Louis facility. Additionally, all communications from participants concerning the study are directed to the principal investigator at the St. Louis facility's address.

This is a concerning revelation considering the University's recent troubling connections to Planned Parenthood. According to Section 188.205, RSMo, "[i]t shall be unlawful for any public funds to be expended for the purpose of performing or assisting an abortion, not necessary to save the life of the mother, or for the purpose of encouraging or counseling a woman to have an abortion not necessary to save her life." Identical language also prohibits such activity by public employees and public facilities. *See* Sections 188.210 and 188.215, RSMo. It is difficult to understand how a research study approved by the University, conducted by a University student, and overseen by the Director of the School of Social Work at the University can be perceived as anything but an expenditure of public funds to aid Planned Parenthood in improving "its services to better meet the needs of women seeking abortions" in clear violation of Missouri law.

This study does not appear to be designed as an objective, unbiased research project, but rather as a marketing aid for Planned Parenthood—one that is funded, in part or in whole, by taxpayer dollars.

In order for the Committee to determine the extent to which the University of Missouri's public funds, employees, or facilities were or are currently being used in this study, please provide me with copies of:

- the complete research study protocol for IRB project number 200068;
- any communication in the possession of the Institutional Review Board or any other entity, employee, or agent of the University regarding this study; and
- any documents, correspondence, or communications in the possession of the University or its agents or employees regarding any funds used or to be used for this study.

Please provide any documents responsive to this letter no later than 4 p.m. Friday, November 6, 2015, to the Senate Administrator's Office, Room 324 – State Capitol.

Sincerely,

Kurt Schaefer – Chairman
Senate Interim Committee on Sanctity of Life

KS:lmb

C: Senate Interim Committee on the Sanctity of Life Members
Senator Ron Richard
House Committee on Ways and Means Chair
House Committee on Children and Family Chair

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

TITLE:	Abortion Decision-Making and the Impact of the 72-Hour Waiting Period
INVESTIGATOR:	Lindsay R. Ruhr, MSW, MPPA Planned Parenthood of the St. Louis Region and Southwest Missouri 4251 Forest Park Ave St Louis, Missouri 63108 United States
SITE:	Reproductive Health Services of the Planned Parenthood St. Louis Region and Southwest Missouri 4251 Forest Park Ave St Louis, Missouri 63108 United States
STUDY-RELATED PHONE NUMBER:	Lindsay Ruhr, MSW, MPPA 314-531-7526 ext 338
MEDICAL DIRECTOR:	David Eisenberg, MD, MPH 314-531-7526

INTRODUCTION:

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

You are being asked to participate in a research study. This research is being conducted to gain a better understanding of the abortion decision-making process and the impact of the new, mandatory 72-hour abortion waiting period in Missouri. When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to better understand why a significant number of women sign the 72-hour consent form to have an abortion, but then never return to the clinic to have the abortion procedure. Additionally, this study aims to understand how the new 72-hour waiting period law in Missouri is impacting women and their decision whether or not to have an abortion.

HOW MANY PEOPLE WILL BE IN THE STUDY?

Approximately 200 women will take part in the baseline survey and we will attempt to conduct a follow-up interview via telephone or email with all women who completed the baseline survey.

WHAT AM I BEING ASKED TO DO?

If you agree to participate in this study, the following three events will occur:

- Today, you will be asked to complete a confidential, paper-based baseline survey about your decision to have an abortion.
- In 3 weeks, Planned Parenthood research staff will contact you via telephone or email to conduct a confidential, follow-up survey.
- The research team intends to access your medical records to obtain the following information: (1) Gestational age as confirmed by a routine ultrasound obtained at Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri; (2) Date of abortion procedure, if applicable; (3) Type (medication or surgical) of abortion procedure, if applicable.

HOW LONG WILL I BE IN THE STUDY?

If you agree to participate in this study, your involvement will only last 3 weeks. The baseline survey that you will take today should not take longer than 20 minutes to complete and the telephone or email follow-up survey which will occur 3 weeks from now should not take longer than 25 minutes to complete. In total, we will only need about 45 minutes of your time. You can stop participating at any time without penalty.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There will be no direct benefit to you for participating in this study. The information that you provide may help Planned Parenthood of the St. Louis Region and Southwest Missouri improve its services to better meet the needs of women seeking abortions.

WHAT ARE THE RISKS OF BEING IN THE STUDY?

There are no serious physical side effects from participating in this study. Some survey questions may cause you to feel uncomfortable; however, you are free to skip any questions you prefer not to answer. There are questions in both the baseline and follow-up surveys that ask about sensitive topics such as pregnancies and birth, abortion, abuse, and mental health history. If any of questions make you

uncomfortable, then you are free to skip them. In the follow-up survey, there is one question that ask about illegal drug usage so be aware of this if a breach of privacy or confidentiality occurs. However, you may choose to leave them question blank if it makes you uncomfortable. While there is always a risk of a breach of privacy or confidentiality, the research team takes every possible measure to prevent such risks.

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also provides, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you.

WHAT OTHER OPTIONS ARE THERE?

You have the option of not participating in this study, and will not be penalized for your decision.

CONFIDENTIALITY

Information produced by this study will be stored securely at Planned Parenthood and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will not be guaranteed compensated for participating in the study. However, if you complete the baseline survey, then you will be entered into a drawing to receive one of two $20 Visa gift cards. If you also complete the follow-up survey, then you will be entered into another drawing where you could be randomly selected to receive one of two $50 Visa gift cards. All drawings will be conducted after the final participant has enrolled in the study which is projected to be in November 2015. All gift card winners will be notified by the method of contact (phone or email) that was given at enrollment.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study.

You will also be informed of any new information discovered during the course of this study that might influence your health, welfare, or willingness to be in this study.

WHO DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

Please contact Lindsay R. Ruhr (Principal Investigator) at 314-531-7526 ext 338 or Dr. Marjorie Sable (Adviser) at the School of Social Work at the University of Missouri at 573-882-0914, if you have questions about the research. Additionally, you may ask questions, voice concerns or complaints to any member of the research team at Planned Parenthood.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Campus Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-9585 or umcresearchcirb@missouri.edu.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Lindsay R. Ruhr at 314-531-7526 ext 338. Additionally, you may contact Dr. Marjorie Sable in the School of Social Work at the University of Missouri at 573-882-0914.

A copy of this Informed Consent form will be given to you before you participate in the research.

SIGNATURES

I have read this consent form and my questions have been answered. My signature below means that I do want to be in the study. I know that I can remove myself from the study at any time without any problems.

By signing this consent form I have not given up any of my legal rights.

_____
Subject's Name (Printed)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Campus IRB Use Only
Approval Date: 04/29/2015
Expiration Date: 04/29/2016
IRB Project Number: 200068

UNIVERSITY OF MISSOURI-COLUMBIA
Institutional Review Board

HIPAA AUTHORIZATION FORM

Authorization for the Use and Disclosure of Personal Health Information Resulting from Participation in a Research Study

Principal Investigator's Name: Lindsay R. Ruhr
Project #: IRB #200068 C
Project Title: Abortion Decision-Making and the Impact of the 72-hour Abortion Waiting Period in Missouri

You have agreed to participate in the study mentioned above. This authorization form gives more detailed information about how your health information will be protected.

1. Description of the information
My authorization applies to the information described below. Only this information may be used and/or disclosed in accordance with this authorization: (1) Gestational age as confirmed by a routine ultrasound obtained at Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri; (2) Date of abortion procedure, if applicable; (3) Type (medication or surgical) of abortion procedure, if applicable.

2. Who may use and/or disclose the information
I authorize the following persons (or class of persons) to make the authorized use and disclosure of my PHI: Lindsay R. Ruhr (Principle Investigator) and the research team at Planned Parenthood of the St. Louis Region and Southwest Missouri.

3. Who may receive the information
I authorize the following persons (or class of persons) to receive my personal health information: Dr. David L. Eisenberg (Medical Director of Planned Parenthood of the St. Louis Region and Southwest Missouri) and the University of Missouri Campus Institutional Review Board (IRB).

4. Purpose of the use or disclosure
My PHI will be used and/or disclosed upon request for the following purposes:
Publications and presentation that will not identify me, auditing, administrative and billing reviews, study outcomes including safety and efficacy

5. Expiration date or event
This authorization expires upon:
☐ The following date: _____
■ End of research study
☐ No expiration date
☐ Other: _____

6. Right to revoke authorization
I understand that I have a right to revoke this authorization at any time. My revocation must be in writing in a letter sent to the Principal Investigator at 4251 Forest Park Avenue, St. Louis, MO 63108. I am aware that my revocation is not effective to the extent that the persons I have authorized to use and/or disclose my PHI have already acted in reliance upon this authorization.

7. Statement that re-disclosures are no longer protected by the HIPAA Privacy Rule

IRB USE ONLY
Acknowledged Date: 04/29/2015

I understand that my personal health information will only be used as described in this authorization in relation to the research study. I am also aware that if I choose to share the information defined in this authorization to anyone not directly related to this research project, the law would no longer protect this information. In addition, I understand that if my personal health information is disclosed to someone who is not required to comply with privacy protections under the law, then such information may be re-disclosed and would no longer be protected.

8. Right to refuse to sign authorization and ability to condition treatment, payment, enrollment or eligibility for benefits for research related treatment

I understand that I have a right not to authorize the use and/or disclosure of my personal health information. In such a case I would choose not to sign this authorization document I understand I will not be able to participate in a research study if I do not do so. I also understand that treatment that is part of the research project will be conditioned upon my authorization for the use and/or disclosure of my personal health information to and for use by the research team.

9. Suspension of right to access personal health information

I agree that I will not have a right to access my personal health information obtained or created in the course of the research project until the end of the study.

10. If I have not already received a copy of the University of Missouri Healthcare Privacy Notice, I may request one. If I have any questions or concerns about my privacy rights I should contact, the HS Privacy Officer at 573-882-9054 or the Campus Privacy Officer at 573-882-9500.

11. Individuals' signature and date

I certify that I have received a copy of the authorization.

_____

Research Participant's Name (Printed)

_____ _____

Signature of Research Participant Date

IRB USE ONLY
Acknowledged Date: 04/29/2015