Study Name:	WOMEN SHARE	
NCT Number:	NCT03323086	
Grant Title:	REDUCING ALCOHOL-RELATED HIV/STI RISK FOR WOMEN IN REPRODUCTIVE HEALTH CLINICS	
Grant #:	R34AA023158	
Dates of Document:	September 28, 2017	(IRB approval)
	October 4, 2017	(revised for IRB; see footer)
	October 9, 2017	(IRB accepted)
	May 24, 2018:	(IRB expiration)
Principal Investigator:	Michael P. Carey, PhD The Miriam Hospital Providence, RI 02906	
Content:	Consent Form	

Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

☐ Rhode Island Hospital
☐ Bradley Hospital
☒ The Miriam Hospital
☐ Newport Hospital
☐ Gateway Healthcare

Agreement to Participate in a Research Study
And Authorization for Use and Disclosure of Information

208515
Committee #

Name of Study Volunteer

WOMEN SHARE STUDY
STUDY # 3

You are being asked to take part in a research study being conducted by researchers at The Miriam Hospital (a Lifespan hospital), Brown University, and Planned Parenthood. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government, and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. Please ask any questions that you have. The purpose of this discussion is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

The purpose of this research is to study two approaches to providing health-related information and guidance to young women with respect to alcohol use and sexual health. We want to learn if women find these approaches acceptable and if they are helpful. The study is sponsored by National Institutes of Health. We expect 50 women to participate.

2. Explanation of Procedures

If you choose to take part in this study, you will provide consent by signing this form. After that, there are three phases: (a) baseline phase, (b) educational phase, and (c) follow-up phase. All 50 study participants will be asked to take part in these three phases.

For the baseline phase, you will first complete a survey on a laptop computer in a private room. The survey asks about your medical history, as well as your attitudes and plans regarding several health behaviors (including substance use and sexual behavior), feelings (such as anxiety and depression), and your relationship history. You can choose not to answer any of these questions. The survey should take about 45 minutes to complete. We will link the answers that you provided while screening to your baseline survey as to not have to repeat questions.

For the educational phase, you will be assigned at random to one of two conditions, either (i) brochures or (ii) health coaching. Neither you nor the research staff can choose which condition you will be in. You will have an equal chance of being placed in either condition.

i. If you are in the brochure condition: You will be given, and asked to review, two pamphlets prepared by the Centers for Disease Control and Prevention. These pamphlets provide detailed information about sexual health (including HIV and other sexually transmitted diseases) and alcohol use. Reviewing these pamphlets is expected to take you about 30 minutes.

If you are in the health coaching condition: You will meet with a health coach who will discuss your survey responses with you. The coach may ask you additional questions about your health behaviors, and you will be encouraged to ask any questions that you have. This session should also take about 1 hour. The discussion will be audiotaped so that the coach can receive supervision and the research team can learn from the session. The audiotape may be typed into a transcript. The audiotape will be erased once we are certain the transcript is accurate. All identifying information will be removed from the transcript. After meeting with the health coach, you will be given access to a website developed with feedback from other women. You will also receive daily text messages with health facts and website updates for 3 months. These text messages are one-way, that is you will not be able to reply to the text messages.

For the follow-up phase, we are asking your permission to review your medical chart at The Providence Health Center to note use of health services such as visit frequency, reason for visit(s), and test results over the past 3 months. You will be also asked to return three months after the baseline appointment to complete a second survey on a laptop computer in a private room. The survey is expected to take about 45 minutes. Following the survey we will ask you about your experiences in the program to get suggestions and feedback from you. The discussion will be audiotaped so that the research team can learn from it. The audiotape may be typed into a transcript. The audiotape will be erased once we are certain the transcript is accurate. All identifying information will be removed from the transcript.

Compensation. You will receive $30 for completing the baseline survey, and $40 for completing the follow-up survey. Thus, you may earn $70 for participating in the study.

Contact Information: If you have any questions or concerns about this study, please feel free to call Dr. Michael Carey, PhD, who is the senior researcher in charge of this study, at (401) 793-8218.

3. Discomforts and Risks

There are two risks associated with taking part in this research.

First, answering questions about or discussing sensitive topics (such as sexual behavior and substance use) may cause minor distress. If you should be distressed by the survey or discussion, please let the research assistant (RA) or health coach know. The RA and health coach are experienced and trained on how to help in such circumstances. You can choose not to answer any question that makes you uncomfortable, and you can discontinue the survey or coaching at any time.

Second, a breach of confidentiality is possible. This is highly unlikely though because our staff are well-trained in how to protect private information and are ethically required to do so. In addition, there are a number of steps we take to protect the information you share with us. All information collected for the study will be identified by a Research Identification Number (RIN) and not your name. Information that you provide will be stored separately from forms that include your name or other identifying information. The phone number used for daily texts will be stored in an encrypted file on a password protected Lifespan computer. When your participation in the study ends, all locator information such as your name, telephone number, and address will be destroyed. All electronic data will be stored on a secure hospital server in a location that only the research team can access. If the results of the research are presented at professional meetings or in a scientific publication, the results will be averaged across all participants. Your name will never be used.

Overall, the risks associated with taking part in this research are considered low.

4. Benefits

You may or may not benefit from participation. Although not guaranteed, it is expected that receiving brochures or coaching may provide information that can help you live a healthier life.

5. Alternative Therapies

Instead of being in this study, you could request information from your health provider in the Center. You could obtain health information from respected books and websites such as CDC.gov. There may be other research studies in the community that you might participate in. Whether or not you choose to participate in this study will not, in any way, change your relationship with your health care providers at The Providence Health Center (Planned Parenthood) or at other places where you receive services.

6. Refusal and Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. It is also possible that the sponsor may end the study at any time, for reasons unrelated to health care. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you are doing during the next 3 months. We would appreciate if you would permit us to get follow-up information about any new sexually transmitted infections from your medical record.

_____ If I withdraw from the study, you have my permission to collect information about my health from my medical record at The Providence Health Center.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____
Signature of Study Volunteer Date signed

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to end your participation in the study, please contact the senior researcher, Dr. Michael Carey at (401) 793-8218.

7. Medical Treatment / Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research., providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The National Institutes of Health, the section of the U. S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Additionally, a description of this clinical trial will be available on http://www.ClinicalTrials.gov*,* as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

To further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent us from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances.

1. If officials of the Department of Health and Human Services were concerned that the research team was acting inappropriately, these officials might audit our research records to (a) protect your rights as a research participant, and (b) to make sure that this research is being conducted ethically and as promised. If such an audit were conducted, Dr. Carey might be required to share the research records with the auditors. However, the auditors are required to protect your privacy.

2. If you told us that you intend to harm yourself or to harm another person, or if you report child abuse or neglect, we would act to protect you, the other person, or the child.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document expires on 5/24/2018.

DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

_____	_____	_____
Signature of Study Volunteer	Date when signed	Time when signed
_____	_____	_____
Signature of Researcher or Designate	Date when signed	Time when signed

Permission to Contact for Future Research:

Signing below provides you the opportunity to be contacted for future research opportunities with the Centers for Preventive and Behavioral Medicine at The Miriam Hospital. You **do not** need to give permission to be contacted for future research if you do not want to. You **do not** need to give permission to be contacted for future research to be included in the current study. If you are contacted in the future you will make the decision at that time if you would like to be involved with a future project. Signing this form **does not** obligate you to participate in any future studies.

I agree to be contacted for future research:

_____	_____	_____
Signature of Study Volunteer	Date when signed	Time when signed