Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Reproductive Life Planning for Women Veterans with Mental Illness Pilot Trial

Principal Investigator: Amy Drapalski, Ph.D. 410-637-1855 VA Facility: Baltimore_512_

STUDY No: HP-00083206

SPONSOR: VA

- This is a research study. Your participation is voluntary. You can ask questions at any time.
- Our study is being carried out at the VA Maryland Health Care System (VAMHCS). Your participation in this study will occur at the VAMHCS or via remote visits (phone or telehealth) with VAMHCS researchers.

PURPOSE OF STUDY

- Women veterans with mental illness may benefit from the development of a reproductive life plan, a set of personal goals about whether or not to have children, when and how to have children, preventing pregnancy (e.g. contraception), and how those goals will be achieved. However, to date, many women veterans are not receiving these services or feel that the services they are receiving are not adequately addressing their reproductive life planning needs. The purpose of this project is to evaluate a new intervention to help women Veterans develop a reproductive life plan and reproductive life goals.
- You are being invited to volunteer for this study because a) you are a woman and b) you are currently receiving mental health treatment in the VA.
- You will be one of up to 45 women Veterans that will be asked to participate in this study.

PROCEDURES

- If you agree to participate in this study, you will be randomized to one of two groups: one where you complete a Reproductive Life Planning intervention (RLP-MH), or one where you are given written information/materials on reproductive life planning. The group you are assigned to will be chosen by chance, like flipping a coin. Neither you nor study staff will choose the study group you are assigned to. You will have an equal chance of being assigned to each group**.**

- If you are randomized to the RLP-MH intervention, you will meet with a reproductive life planning (RLP) coach for one session that lasts 45-60 minutes, during which you will complete the RLP-MH intervention with the RLP coach. This RLP session is conducted via telehealth. During the RLP session, you will be asked questions about your thoughts on having children, any physical or emotional health conditions and behaviors or life circumstances that may impact pregnancy, contraception, and action steps related to the reproductive life plan and life goals. Answers from these questions will be used to help you and the RLP coach develop a summary of your personal reproductive life plan, identify reproductive life goals, and develop action steps for addressing goals. All sessions will be audio recorded. Once the session is completed, you will receive a copy of your reproductive life plan and any action steps or questions identified while developing the plan. This plan will be entered into a note in your electronic medical record. After you complete the plan you will be asked to complete a few questionnaires about your thoughts on reproductive life planning and the RLP intervention (~ 15 min).

- One month after this appointment, the RLP-MH coach will conduct a follow-up session with you to discuss your reproductive life plans/goals and any obstacles or challenges you faced in taking steps to reach them. This is done by telephone and will last approximately 15 minutes.

- If you are randomized to the reproductive life planning information group, you will be provided with written information on how to develop your own reproductive life plan and goals, contraception methods, and VA resources. The RLP coach will briefly review these materials, their potential purpose and benefit, and how they might be used or shared with providers. This meeting will be done via phone or telehealth and will last approximately 10-15 minutes.

- Regardless of your group condition you are assigned to, you will be asked to complete two interviews. The first interview will be completed after you agree to participate and before you are assigned to one of the study groups. This interview will be done by phone, or via telehealth. The second interview will be two months after your first interview. This interview will be completed over the phone.
- During these interviews we will ask you to answer questions about your 1) age, employment, education, and living situation; 2) your relationships and sexual health

history; 3) your reproductive health service and contraception use; 4) your thoughts on reproductive life planning; 5) your current psychiatric symptoms; and 6) other aspects of your thoughts, feelings, and behaviors. Each interview will last about 1 hour.

- Your participation in this study will last approximately 3 months.

- If needed, we may want to contact you by phone following your interview/session in order to ask a few follow-up questions and/or clarify your answers given during the interview/session. Please initial below whether or not you agree for study staff to contact you about this interview:

  _____ Yes, I agree for study staff to contact me about my interview/session.

  _____ No, I do not want study staff to contact me about my interview/session.

- In the future, we may have additional studies related to services for women with mental illness. If another study about services for women with mental illness becomes available, we would like permission to contact you to tell you about it and see if you would like to participate. Please initial below whether or not you agree to be re-contacted for future studies about services for women:

  _____ Yes, I agree to be re-contacted for future studies about services for women with mental illness.

  _____ No, I do not want to be re-contacted for future studies about services for women with mental illness.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to:

- Participate in all study visits and/or phone visits/calls.
- Ask any questions you have about the study and your participation at any point during the study.
- Answer all study questions/questionnaires as honestly as possible.

- Let study staff know about any problems or concerns with the study or your participation.
- Let study staff know if you decide to drop out of the study.

POTENTIAL RISKS/DISCOMFORTS:

- There are no major risks to you from participating in this study. One minor risk is that you may find some questions boring, mildly stressful, or frustrating. It is also possible that you might become uncomfortable when discussing your health history, thoughts about pregnancy and contraception, or other questions that are part of this intervention and interview. You can refuse to answer any questions that cause discomfort. You can also ask to take a break at any time.

- There is always a slight risk that confidentiality may be breached. In order to prevent this from happening all records and recording will be identified only by code numbers and kept in locked cabinets in a locked office. Consent forms and any other forms with your name on them will be kept separately in a locked cabinet in a locked room. No participants will be personally identified in any publications or report of the study.

- Electronic data for this study will be labeled with a code, not your name. Electronic data files will only be accessible to those directly working on this study.

- There may be risks related to this study which are currently unforeseeable

POTENTIAL BENEFITS

- You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. However, your participation may help you to develop a personal reproductive life plan, and help you to take steps towards addressing your own reproduction life goals.

- Your participation in this study may also help us develop and/or improve reproductive life planning and contraceptive counseling services provided to women Veterans with mental illness.

ALTERNATIVES TO PARTICIPATION

- This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected.

COSTS TO PARTICIPANTS

- It will not cost you anything to take part in this study.

- You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT TO PARTICIPANTS

- You will be paid $25 for completing the first interview and $25 for completing the 2-month follow-up interview for a total of $50, if both interviews are completed.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

- Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

- If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. Amy Drapalski at 410-637-1855 during the day.

- The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

- All information collected during the study will be kept confidential to the fullest extent permitted by law. However, if the research staff hears about or sees that you intend to

harm yourself or someone else, s/he will need to tell your treatment provider or some other authority so that you can get help, even if that means telling them without your permission. In this situation, research staff would only disclose information that would prevent harm to you or other people that might be in danger. If we hear about or see something that would immediately endanger you or others, such as child abuse, we will seek help to protect the child. In addition, we must follow legal requirements concerning child abuse and neglect. If you tell us information about child abuse, we must disclose this information to the appropriate individuals and/or authorities.

- This study will involve confidential information. We have several procedures in place to help protect your confidentiality. Your name will not be included on the collected data. Instead, a code number will be placed on the data, and through an identification key, the researchers will be able to link your survey to your identity. Only the researchers will have access to the identification key. The information we collect from you will be stored at the VAMHCS. Electronic files with your information will be kept in secure computers in a locked room. The electronic data files with your information will be password protected. All audio recordings will be stored electronically, behind the VA firewall and labeled by code. Coded information will only be accessible to members of the research team and individuals involved in our data management process.

- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the University of Maryland Institutional Review Board (IRB), the VAMHCS Office of Research Compliance and other representatives of this organization. The study records can also be reviewed by federal agencies, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP). The monitors, auditors, and the IRB, will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access**.**

- 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.

- Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

- If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

- If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Amy Drapalski at 410-637-1855.

- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

- If you withdraw from this study, already collected data may not be removed from the study database.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.
- If you are an employee or student, your employment status or academic standing at the VAMHCS will not be affected by your participation or non-participation in this study

CAN I BE REMOVED FROM THE RESEARCH?

- The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: failure to follow instructions of the research staff or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study investigator will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, you may contact Amy Drapalski at 410-637-1855.

Please read the University's statement below.

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland Baltimore. The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO). The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56582
Room 3D-152

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____