

Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH

Title: Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program

[USMA version]

Principal Investigator: Suzanne L. Hurtado, MPH

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to volunteer to participate in a research study titled, “Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program.” Your participation is completely voluntary. We are inviting you to take part in a focus group.

This research is being conducted by researchers at the Naval Health Research Center (NHRC) in San Diego, California, San Diego State University (SDSU), and Research Triangle Institute (RTI) with funding from Department of Defense Medical Technology Enterprise Consortium.

Purpose

The purpose of the study is to develop programs to prevent both sexual assault and alcohol misuse, to be delivered at military installations or Service Academies. As part of this study, we will talk with cadets. We are interested in your input about how best to adapt sexual assault and alcohol misuse prevention programs to be relevant and helpful to service members and cadets across all branches.

Duration

Your participation in the research involves spending approximately 90 minutes on one occasion.

Activities

We will be asking you to take part in an in-person focus group discussion or remote phone interview, and to complete a brief questionnaire.

Benefits

The information from this research study may help researchers learn more about how to best tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your



branch of the military, which could help other service members in the future.

Risks

The primary risk to you in taking part in this study is minimal and includes psychological discomfort. There is also a potential risk of loss of privacy and/or confidential information about you.

Compensation

You will receive a 2 Post Morning Inspection (PMI) incentive for your participation in this study.

If you decide to take part in this research study, you will be asked to check a box at the end of this document indicating your agreement to participate. Before you mark this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are a cadet at the USMA West Point. The purpose of this research study is to learn your opinion about current training on alcohol misuse and sexual assault prevention, and about the content in two programs that we want to improve for cadets. Specifically, we want to learn from you how we can improve the content of the program so that it is maximally relevant to cadets, and also what you think is the best way to implement the program. The duration of participation is 90 minutes on one occasion.

There will be about 60 cadets and service members taking part in this part of the study, over a period of one year.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, the researchers will confirm with you if you are eligible for the study. Eligible participants will be in the age range of 18 to 24 years old, and be currently enrolled at USMA.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to spend 90 minutes to take part in an in-person focus group discussion or remote phone interview, and complete a brief questionnaire. In this focus group, you will be in a room with 3-8 other cadets and 2-3 study staff members. At this time, you will be asked some questions about current training on the topic of alcohol and sexual assault prevention and specific aspects of life at USMA that may impact the training needed in these areas. Then we will show you some materials in the training that is used in this study, including video clips, and ask you to



provide feedback about these materials both verbally and on a written questionnaire. We will audio record the focus group session to make sure that we don't miss any of the feedback.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of psychological discomfort and accidental disclosure of your information. We will remind you not to disclose personal information during the sessions and you will be provided a study ID number to use in place of your name. You do not have to answer any questions that make you feel uncomfortable. You will be reminded not to disclose any of your personal experiences with sexual assault or alcohol misuse; we are only seeking your feedback, opinions, and recommendations on these topics. It would also put you at risk if you made statements admitting wrong-doing in the focus group or interview setting. This information could potentially be used against you by those who have a responsibility to report illegal activity or health hazard information. The researchers administering this study will keep all of your comments confidential except as required by law.

If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or the following resources:

- Center for Personal Development (CPD) - 845-938-2360/3022
- SHARP 24/7 Hotline - 845-659-7467
- Army Substance Abuse Program (ASAP) - 845-938-5847

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information or other information researchers have stored about you. There are several safeguards in place to minimize the risk of accidental disclosure of your information and protect your privacy. During this study, we will not use your name or any other identifying information, only your study ID. However, we will collect your email address and phone number to schedule the focus group or interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the focus group or interview, and have received the incentive. To protect your confidentiality during the focus group or interview, we will ask you not to use your name or any other identifying information, including your rank or title and to use only the study ID provided to you. To further protect your privacy, you and the other participants will also be asked not to discuss anything you learned or heard during the discussion with anyone.

While your responses will not be linked to you, a list of participants will be provided to USMA for the distribution of PMI points. This means that someone at USMA will know that you participated, even though they will not know of your responses. If you do not want your name included in this list and do not want to receive the PMI incentive you can tell the research staff to exclude your name from that list. While participants will be asked to keep each other's confidentiality, it is possible that other members of the focus group could still disclose that you participated.

There may also be other risks of taking part in this study that we do not yet know about.



6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others include helping researchers learn more about how to best tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members and cadets in the future.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes. You will receive a 2 Post Morning Inspection (PMI) incentive for your participation in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Suzanne L. Hurtado, MPH, at (619) 607-1910, suzanne.l.hurtado.civ@health.mil.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The Naval Health Research Center is conducting this study in collaboration with the following investigators from RTI:

Marni Kan, PhD, (919) 485-2756, mkan@rti.org
Katie Grimes, MPH, (360) 719-0558, kgrimes@rti.org

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

12. SOURCE OF FUNDING:

Medical Technology Enterprise Consortium, through the Military Operational Medicine Research Program, Department of Defense.

13. LOCATION OF THE RESEARCH:



This study is being conducted by researchers at the Naval Health Research Center in San Diego, CA, RTI in Durham, NC, and SDSU in San Diego, CA.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

The research team will keep your research records. These records may be looked at by staff from the Naval Health Research Center and their collaborators RTI and SDSU, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: No names or identifying information are required as part of the activities in study. Your contact information (personal email address and/or phone number) are the only potentially identifying information that will be requested and will be used only to schedule the focus groups (or individual interview, if needed) and to ensure receipt of the incentive. This contact information will be securely stored separately from study data and will be destroyed once you have completed the focus group or interview, and have received the incentive.

If you choose to participate, you will be asked to attend a focus group discussion or interview, during which you may be asked to discuss sexual assault prevention and alcohol misuse prevention training. To protect your confidentiality during the discussion, we will ask you not to use your name or any other identifying information, including your rank or title. For remote participation, we recommend that you find a private room where you will be comfortable participating without being overheard by others. When the audio recordings of the discussions are transcribed, any potentially identifying information, such as names and locations, will be redacted from the written transcripts. Once transcription has been completed and verified, all audio files will be permanently destroyed.

We will also ask that each of you respect the privacy of everyone in the focus group and not share or repeat what is said here in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we



recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

You will also be asked to complete a questionnaire that will contain questions such as rank, gender, and length of time in the military. The questionnaire will be completely anonymous and all of the data we collect from you will be kept private and confidential so that none of your responses can be linked back to you as an individual.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Access to all data will be limited to staff involved in this study at NHRC, RTI, and SDSU. Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. LONG TERM USE OF DATA

The researchers will not store your data for future use.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must write to the person in charge of the study, Suzanne Hurtado, at suzanne.l.hurtado.civ@health.mil, and the RTI point of contact in charge of collecting data at USMA, Katie Grimes, at kgrimes@rti.org or Marni Kan, PhD, mkan@rti.org. If you do not follow these procedures, you will still be considered an active participant in the study. When you revoke your permission, no new health information about you will be gathered after that date and you may no longer be allowed to participate in the study. Information that has already been gathered may still be used, and because all of your data will be collected



anonymously, there is no way to guarantee that it can be removed from the electronic database for this study.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

19. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator and other members of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Suzanne L. Hurtado

Phone: (619) 607-1910

Mailing Address: Naval Health Research Center, 140 Sylvester Rd., San Diego, CA 92106

RTI Associate Investigators:

Marni Kan, PhD, (919) 485-2756, mkan@rti.org

Katie Grimes, MPH, (360) 719-0558, kgrimes@rti.org

Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director/HRPP POC:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE MARKING THIS CONSENT FORM. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A copy of this document will be given to you.



SIGNATURE OF PARTICIPANT

By marking this consent form below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By marking this form, I have not given up any of my legal rights as a research participant.

☐ I provide my consent to participate in this study.

☐ I understand that the focus group discussion or interview will be audio recorded and I provide my consent to be recorded.

Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual

Date



Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH

Title: Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program

[Marine Corps version]

Principal Investigator: Suzanne L. Hurtado, MPH

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to volunteer to participate in a research study titled, “Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program.” Your participation is completely voluntary. We are inviting you to take part in a focus group.

This research is being conducted by researchers at the Naval Health Research Center (NHRC) in San Diego, California, San Diego State University (SDSU), and Research Triangle Institute (RTI) with funding from Department of Defense Medical Technology Enterprise Consortium.

Purpose

The purpose of the study is to develop programs to prevent both sexual assault and alcohol misuse, to be delivered at military installations or Service Academies. As part of this study, we will talk with groups of men and women Marines. We are interested in your input about how best to adapt sexual assault and alcohol misuse prevention programs to be relevant and helpful to service members across all branches.

Duration

Your participation in the research involves spending approximately 90 minutes during your off-duty or liberty time on one occasion.

Activities

We will be asking you to take part in an in-person focus group discussion or remote phone interview, and to complete a brief questionnaire.

Benefits

The information from this research study may help researchers learn more about how to best



tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

Risks

The primary risk to you in taking part in this study is minimal and includes psychological discomfort. There is also a potential risk of loss of privacy and/or confidential information about you.

If you decide to take part in this research study, you will be asked to check a box at the end of this document indicating your agreement to participate. Before you mark this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are an active duty Marine. The purpose of this research study is to learn your opinion about current training on alcohol misuse and sexual assault prevention, and about the content in two programs that we want to improve for service members. Specifically, we want to learn from you how we can improve the content of the program so that it is maximally relevant to Marines, and also what you think is the best way to implement the program. The duration of participation is 90 minutes during your off-duty or liberty time on one occasion.

There will be about 60 people taking part in this part of the study, over a period of one year.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, the researchers will confirm with you if you are eligible for the study. Eligible participants will be in the age range of 18 to 24 years old, and be enlisted, active duty members.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to spend 90 minutes during your off-duty or liberty time to take part in an in-person focus group discussion or remote phone interview, and complete a brief questionnaire. In this focus group, you will be in a room with 3-8 other service members and 2-3 study staff members. At this time, you will be asked some questions about current training on the topic of alcohol and sexual assault prevention and specific aspects of life in your branch of service that may impact the training needed in these areas. Then we will show you some materials in the training that is used in this study, including video clips, and ask you to provide feedback about these materials both verbally and on a written questionnaire. We will audio record the focus group session to make sure that we don't miss any of the feedback.



5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of psychological discomfort and accidental disclosure of your information. We will remind you not to disclose personal information during the sessions, and you will be provided a study ID number to use in place of your name. You do not have to answer any questions that make you feel uncomfortable. You will be reminded not to disclose any of your personal experiences with sexual assault or alcohol misuse; we are only seeking your feedback, opinions, and recommendations on these topics. It would also put you at risk if you made statements admitting wrong-doing in the focus group or interview setting. This information could potentially be used against you by those who have a responsibility to report illegal activity or health hazard information. The researchers administering this study will keep all of your comments confidential except as required by law.

If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or the Veterans Crisis Line (800-273-8255).

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information or other information researchers have stored about you. There are several safeguards in place to minimize the risk of accidental disclosure of your information and protect your privacy. During this study, we will not use your name or any other identifying information, only your study ID. However, we will collect your email address and phone number to schedule the focus group or interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the discussion. To protect your confidentiality during the focus group or interview, we will ask you not to use your name or any other identifying information, including your rank or title and to use only the study ID provided to you. To further protect your privacy, you and the other participants will also be asked not to discuss anything you learned or heard during the discussion with anyone.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others include helping researchers learn more about how to best tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?



No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Suzanne L. Hurtado, MPH, at (619) 607-1910, suzanne.l.hurtado.civ@health.mil.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The Naval Health Research Center is conducting this study. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

12. SOURCE OF FUNDING:

Medical Technology Enterprise Consortium, through the Military Operational Medicine Research Program, Department of Defense.

13. LOCATION OF THE RESEARCH:

This study is being conducted by researchers at the Naval Health Research Center in San Diego, CA, RTI in Durham, NC, and SDSU in San Diego, CA.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

The research team will keep your research records. These records may be looked at by staff from the Naval Health Research Center and their collaborators RTI, and SDSU, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties



include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: No names or identifying information are required as part of the activities in study. Your personal email address and/or phone number are the only potentially identifying information that will be requested and will be used only to schedule the focus groups (or individual interview, if needed). This contact information will be securely stored separately from study data and will be destroyed once you have completed the focus group or interview.

If you choose to participate, you will be asked to attend a focus group discussion or interview, during which you may be asked to discuss sexual assault prevention and alcohol misuse prevention training. To protect your confidentiality during the discussion, we will ask you not to use your name or any other identifying information, including your rank or title. For remote participation, we recommend that you find a private room where you will be comfortable participating without being overheard by others. When the audio recordings of the discussions are transcribed, any potentially identifying information, such as names and locations, will be redacted from the written transcripts. Once transcription has been completed and verified, all audio files will be permanently destroyed.

We will also ask that each of you respect the privacy of everyone in the focus group and not share or repeat what is said here in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

You will also be asked to complete a questionnaire that will contain questions such as rank, gender, and length of time in the military. The questionnaire will be completely anonymous and all of the data we collect from you will be kept private and confidential so that none of your responses can be linked back to you as an individual.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Access to all data will be limited to staff involved in this study at NHRC, RTI and SDSU. Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will be de-identified.



16. LONG TERM USE OF DATA

The researchers will not store your data for future use.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must write to the person in charge of the study, Suzanne Hurtado, at suzanne.l.hurtado.civ@health.mil. If you do not follow these procedures, you will still be considered an active participant in the study. When you revoke your permission, no new health information about you will be gathered after that date and you may no longer be allowed to participate in the study. Information that has already been gathered may still be used, and because all of your data will be collected anonymously, there is no way to guarantee that it can be removed from the electronic database for this study.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

19. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Suzanne L. Hurtado

Phone: (619) 607-1910

Mailing Address: Naval Health Research Center, 140 Sylvester Rd., San Diego, CA 92106

Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director/HRPP POC:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil



Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE MARKING THIS CONSENT FORM. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

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By marking this form, I have not given up any of my legal rights as a research participant.

☐ I provide my consent to participate in this study.

☐ I understand that the focus group discussion or interview will be audio recorded and I provide my consent to be recorded.

Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
--

(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual

Date



Meets 2018 Common Rule Requirements

Naval Health Research Center
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[Navy version]

Principal Investigator: Suzanne L. Hurtado, MPH

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tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

Risks

The primary risk to you in taking part in this study is minimal and includes psychological discomfort. There is also a potential risk of loss of privacy and/or confidential information about you.

Compensation

If you complete your participation during your off-duty time, you will receive a gift card valued at \$40 for your participation in this study.

If you decide to take part in this research study, you will be asked to check a box at the end of this document indicating your agreement to participate. Before you mark this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are an active duty Sailor. The purpose of this research study is to learn your opinion about current training on alcohol misuse and sexual assault prevention, and about the content in two programs that we want to improve for service members. Specifically, we want to learn from you how we can improve the content of the program so that it is maximally relevant to Sailors, and also what you think is the best way to implement the program. The duration of participation is 90 minutes during your off-duty or liberty time on one occasion.

There will be about 60 people taking part in this part of the study, over a period of one year.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, the researchers will confirm with you if you are eligible for the study. Eligible participants will be in the age range of 18 to 24 years old, and be enlisted, active duty members.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to spend 90 minutes during your off-duty or liberty time to take part in an in-person focus group discussion or remote phone interview, and complete a brief questionnaire. In this focus group, you will be in a room with 3-8 other service members and 2-3 study staff members. At this time, you will be asked some questions about current training on the topic of alcohol and sexual assault prevention and specific aspects of life in your branch of service that



may impact the training needed in these areas. Then we will show you some materials in the training that is used in this study, including video clips, and ask you to provide feedback about these materials both verbally and on a written questionnaire. We will audio record the focus group session to make sure that we don't miss any of the feedback.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of psychological discomfort and accidental disclosure of your information. We will remind you not to disclose personal information during the sessions and you will be provided a study ID number to use in place of your name. You do not have to answer any questions that make you feel uncomfortable. You will be reminded not to disclose any of your personal experiences with sexual assault or alcohol misuse; we are only seeking your feedback, opinions, and recommendations on these topics. It would also put you at risk if you made statements admitting wrong-doing in the focus group or interview setting. This information could potentially be used against you by those who have a responsibility to report illegal activity or health hazard information. The researchers administering this study will keep all of your comments confidential except as required by law.

If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or the Veterans Crisis Line (800-273-8255).

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information or other information researchers have stored about you. There are several safeguards in place to minimize the risk of accidental disclosure of your information and protect your privacy. During this study, we will not use your name or any other identifying information, only your study ID. However, we will collect your email address and phone number to schedule the focus group or interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the discussion. To protect your confidentiality during the focus group or interview, we will ask you not to use your name or any other identifying information, including your rank or title and to use only the study ID provided to you. To further protect your privacy, you and the other participants will also be asked not to discuss anything you learned or heard during the discussion with anyone.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others include helping researchers learn more about how to best tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?



Your alternative is not to participate in this research.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes. If you complete your participation during your off-duty time, you will receive a gift card valued at \$40 for your participation in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Suzanne L. Hurtado, MPH, at (619) 607-1910, suzanne.l.hurtado.civ@health.mil.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The Naval Health Research Center is conducting this study. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

12. SOURCE OF FUNDING:

Medical Technology Enterprise Consortium, through the Military Operational Medicine Research Program, Department of Defense.

13. LOCATION OF THE RESEARCH:

This study is being conducted by researchers at the Naval Health Research Center in San Diego, CA, RTI in Durham, NC, and SDSU in San Diego, CA.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon



request, or you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

The research team will keep your research records. These records may be looked at by staff from the Naval Health Research Center and their collaborators RTI and SDSU, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: No names or identifying information are required as part of the activities in study. Your personal email address and/or phone number are the only potentially identifying information that will be requested and will be used only to schedule the focus groups (or individual interview, if needed) and to ensure receipt of incentives. This contact information will be securely stored separately from study data and will be destroyed once you have completed the focus group or interview and we have ensured that your incentive was received.

If you choose to participate, you will be asked to attend a focus group discussion or interview, during which you may be asked to discuss sexual assault prevention and alcohol misuse prevention training. To protect your confidentiality during the discussion, we will ask you not to use your name or any other identifying information, including your rank or title. For remote participation, we recommend that you find a private room where you will be comfortable participating without being overheard by others. When the audio recordings of the discussions are transcribed, any potentially identifying information, such as names and locations, will be redacted from the written transcripts. Once transcription has been completed and verified, all audio files will be permanently destroyed.

We will also ask that each of you respect the privacy of everyone in the focus group and not share or repeat what is said here in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

You will also be asked to complete a questionnaire that will contain questions such as rank, gender, and length of time in the military. The questionnaire will be completely anonymous and all of the data we collect from you will be kept private and confidential so that none of your responses can be linked back to you as an individual.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Access to all data will be limited to staff involved in this study at NHRC, RTI, and SDSU. Those listed above will have access to your records and agree to safeguard your protected health



information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. LONG TERM USE OF DATA

The researchers will not store your data for future use.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must write to the person in charge of the study, Suzanne Hurtado, at suzanne.l.hurtado.civ@health.mil. If you do not follow these procedures, you will still be considered an active participant in the study. When you revoke your permission, no new health information about you will be gathered after that date and you may no longer be allowed to participate in the study. Information that has already been gathered may still be used, and because all of your data will be collected anonymously, there is no way to guarantee that it can be removed from the electronic database for this study.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

19. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Suzanne L. Hurtado

Phone: (619) 607-1910

Mailing Address: Naval Health Research Center, 140 Sylvester Rd., San Diego, CA 92106



Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director/HRPP POC:
Phone: (619) 553-8424
Email: USN.NHRC.IRB@health.mil

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Phone: (619) 553-8424
Email: USN.NHRC.IRB@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE MARKING THIS CONSENT FORM. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A copy of this document will be given to you.



SIGNATURE OF PARTICIPANT

By marking this consent form below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By marking this form, I have not given up any of my legal rights as a research participant.

- ☐ I provide my consent to participate in this study.
- ☐ I understand that the focus group discussion or interview will be audio recorded and I provide my consent to be recorded.
- ☐ I attest that I am participating in this study while in off-duty, liberty or leave status.

Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual

Date



Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH

Title: Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program

[Leader/Practitioner version]

Principal Investigator: Suzanne L. Hurtado, MPH

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your peers) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to volunteer to participate in a research study titled, “Formative Research for the Adaptation of a Risky Drinking and Sexual Assault Prevention Program.” Your participation is completely voluntary. We are inviting you to take part in an in-depth interview.

This research is being conducted by researchers at the Naval Health Research Center (NHRC) in San Diego, California, San Diego State University (SDSU), and Research Triangle Institute (RTI) with funding from Department of Defense Medical Technology Enterprise Consortium.

Purpose

The purpose of the study is to develop programs to prevent both sexual assault and alcohol misuse, to be delivered at military installations or Service Academies. As part of this study, we will talk with Sailors, Marines, and service members from the United States Military Academy (USMA), as well as civilian practitioners serving these communities. We are interested in your input, as a leader or practitioner, about how best to adapt sexual assault and alcohol misuse prevention programs to be relevant and helpful to service members across all branches.

Duration

Your participation in the research involves spending approximately 60 minutes during your time on one occasion.

Activities

We will be asking you to take part in an in-person or remote in-depth interview.

Benefits

The information from this research study may help researchers learn more about how to best



tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

Risks

The primary risk to you in taking part in this study is minimal and includes psychological discomfort. There is also a potential risk of loss of privacy and/or confidential information about you.

If you decide to take part in this research study, you will be asked to check a box at the end of this document indicating your agreement to participate. Before you mark this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are the experts in leading Sailors, Marines, or USMA cadets and preventing and/or dealing with sexual assault or alcohol misuse prevention. The purpose of the study is to develop programs to prevent both sexual assault and alcohol misuse, to be delivered at military installations or Service Academies. Specifically, we want to learn from you how we can improve the content of the program so that it is maximally relevant to service members, and also what you think is the best way to implement the program. The duration of participation is 60 minutes on one occasion.

About 84 people will take part in this study over a period of one year, and this will include a subset of leaders and practitioners like yourself.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to spend 60 minutes to take part in an in-person or remote in-depth interview. We will ask you questions about current training on the topic of alcohol and sexual assault and specific aspects of life in your branch of service that may impact the training needed in these areas. We will ask about recommendations for improvement of training, factors relevant to adapting and implementing training, and leadership's role in the process. We will audio record the interview to make sure that we don't miss any of the feedback.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of psychological discomfort and accidental disclosure of your information. We will remind you not to disclose personal information during the sessions and you will be provided a study ID number to use in place of your name. You do not have to answer any questions that make you feel uncomfortable. You will be reminded not to



disclose any of your personal experiences with sexual assault or alcohol misuse; we are only seeking your feedback, opinions, and recommendations on these topics. It would also put you at risk if you made statements admitting wrong-doing in the interview setting. This information could potentially be used against you by those who have a responsibility to report illegal activity or health hazard information. The researchers administering this study will keep all of your comments confidential except as required by law.

If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or the Veterans Crisis Line (800-273-8255). If you are not a veteran, you may call or text 988 or chat 988lifeline.org

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information or other information researchers have stored about you. There are several safeguards in place to minimize the risk of accidental disclosure of your information and protect your privacy. During this study, we will not use your name or any other identifying information, only your study ID. However, we will collect your email address and phone number to schedule the interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the discussion. To protect your confidentiality during the interview, we will ask you not to use your name or any other identifying information, including your rank or title and to use only the study ID provided to you.

There may also be other risks of taking part in this study that we do not yet know about.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others include helping researchers learn more about how to best tailor a combined sexual assault prevention and alcohol misuse prevention intervention to your branch of the military, which could help other service members in the future.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):



Suzanne L. Hurtado, MPH, at (619) 607-1910, suzanne.l.hurtado.civ@health.mil.

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The Naval Health Research Center is conducting this study in collaboration with the following investigators from RTI:

Marni Kan, PhD, (919) 485-2756, mkan@rti.org
Katie Grimes, MPH, (360) 719-0558, kgrimes@rti.org

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

11. SOURCE OF FUNDING:

Medical Technology Enterprise Consortium, through the Military Operational Medicine Research Program, Department of Defense.

12. LOCATION OF THE RESEARCH:

This study is being conducted by researchers at the Naval Health Research Center in San Diego, CA, RTI in Durham, NC, and SDSU in San Diego, CA.

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

The research team will keep your research records. These records may be looked at by staff from the Naval Health Research Center and their collaborators RTI, and SDSU, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.



Procedures to protect the confidentiality of the data in this study include but are not limited to: No names or identifying information are required as part of the activities in study. Your personal email address and/or phone number are the only potentially identifying information that will be requested and will be used only to schedule the interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the interview.

If you choose to participate, you will be asked to take part in an in-depth interview, during which you may be asked to discuss sexual assault prevention and alcohol misuse prevention training. To protect your confidentiality during the discussion, we will ask you not to use your name or any other identifying information, including your rank or title. For remote participation, we recommend that you find a private room where you will be comfortable participating without being overheard by others. When the audio recordings of the interviews are transcribed, any potentially identifying information, such as names and locations, will be redacted from the written transcripts. Once transcription has been completed and verified, all audio files will be permanently destroyed.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Access to all data will be limited to staff involved in this study at NHRC, RTI, and SDSU. Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

15. LONG TERM USE OF DATA

The researchers will not store your data for future use.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part, which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?



Should you choose to withdraw, you must write to the person in charge of the study, Suzanne Hurtado, at suzanne.l.hurtado.civ@health.mil. If you do not follow these procedures, you will still be considered an active participant in the study. When you revoke your permission, no new health information about you will be gathered after that date and you may no longer be allowed to participate in the study. Information that has already been gathered may still be used, and because all of your data will be collected anonymously, there is no way to guarantee that it can be removed from the electronic database for this study.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Suzanne L. Hurtado

Phone: (619) 607-1910

Mailing Address: Naval Health Research Center, 140 Sylvester Rd., San Diego, CA 92106

Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director/HRPP POC:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Phone: (619) 553-8424

Email: USN.NHRC.IRB@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE MARKING THIS CONSENT FORM. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A copy of this document will be given to you.



SIGNATURE OF PARTICIPANT

By marking this consent form below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By marking this form, I have not given up any of my legal rights as a research participant.

☐ I provide my consent to participate in this study.

☐ I understand that the interview will be audio recorded and I provide my consent to be recorded.

Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual

Date

