CT.gov Cover Page

Comprehensive Adaptive Multisite Prevention of University student Suicide (CAMPUS): A Feasibility Study
Adult/Duke version

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Consent to Participate in a Research Study
ADULT – Feasibility Study
Comprehensive Adaptive Multisite Prevention of University student Suicide (CAMPUS): A Feasibility Study

CONCISE SUMMARY

Suicidal thoughts affect many college students, and we still do not know the best ways to offer help. We are doing this study to learn more about different treatment strategies for college students with suicidal thoughts, and how to provide these treatments both online and in person.

If you join the study, you will initially receive one of three different psychotherapies to help manage your suicidal thoughts. These treatments vary in duration from 4-16 weeks. Treatment duration varies based upon your response and the treatment you receive. If you do not show enough improvement with the first treatment, you may be randomized (like flipping a coin) to an additional 8 weeks of treatment.

Therapy sessions may be online, in person, or both. There is evidence that the study's treatment strategies might be helpful, but we cannot guarantee that the study will help you. It is possible that talking about your feelings will upset you. We will help you manage any stress if this happens.

If you are interested in this study, please continue reading below.

We are asking you to join this research study because you are a student who has suicidal thoughts.

Please read this consent form carefully. Take your time to make a decision. Feel free to talk with your family and friends before you decide. Research studies are voluntary and include only people who choose to join. If you do not clearly understand any words or information in this form, please ask a study team member to explain them to you. What happens in this study, possible benefits and risks, and other important information are described on the following pages.

WHO IS THE PRINCIPAL INVESTIGATOR ON THIS STUDY?

Dr. Scott Compton is the Principal Investigator at Duke University. His contact information is included below if you have any questions or concerns about the study throughout your participation. If you decide to participate in this study, Dr. Compton will be in touch with your counselor while you are in the study and afterward, if needed.

This study is paid for by a grant from the National Institute of Mental Health (NIMH). This grant will help pay for part of Dr. Compton and his research team's salaries.

WHY IS THIS STUDY BEING DONE?

The main goal of this study is to learn how we can better help college students with suicidal thoughts. About 20% of college students will have suicidal thoughts, and there are many treatments that might help them. We hope this study will teach us how to better choose which

treatments will best fit individual students and how to adapt these treatments to work well online, when needed.

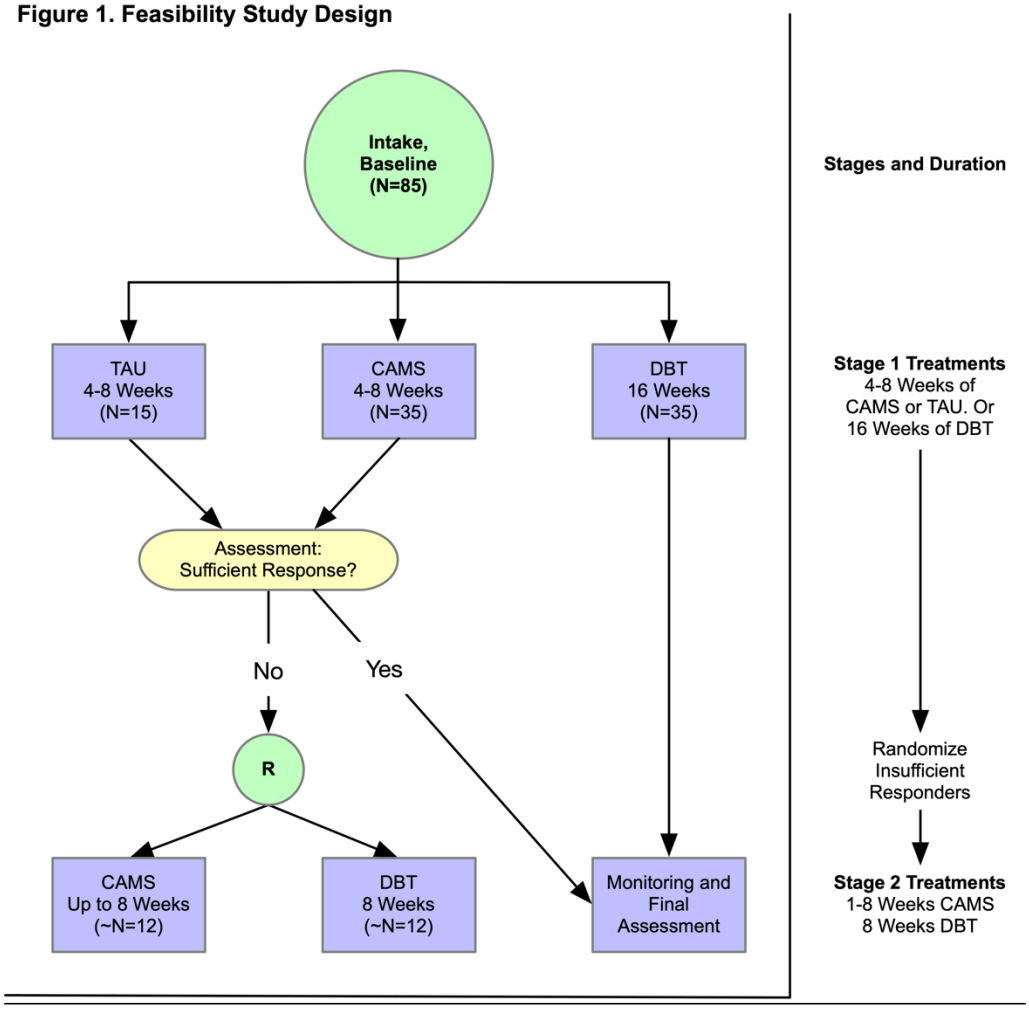
HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 85 students will be in this study at four different colleges. About 20 Duke University students will join this study.

WHAT IS INVOLVED IN THE STUDY?

Figure 1 provides a visual overview of the study design and its various stages.

Figure 1. Feasibility Study Design



Baseline Assessment

If you join the study, we will schedule you for a baseline (pre-treatment) assessment visit that will occur online via a HIPAA-compliant telehealth platform such as Zoom, or in person. We will interview you during this visit and ask you to complete some online questionnaires about your emotions, thoughts, behaviors, relationships, life experiences, school performance, and mental health history. You will also complete a brief online task about attitudes and beliefs.

Stage 1

After this first assessment visit and before your next treatment visit with your assigned counselor, you will be offered one of three different treatments. Your counselor will let you know which treatment you will be participating in during your next treatment visit. All treatments involve visits with a mental health counselor. Please note that if you join the study, you cannot choose which treatment you receive. Treatment visits may be conducted in person at Duke Counseling and Psychological Services (Duke CAPS), or online via a HIPAA-compliant telehealth platform such as Zoom. Decisions about whether treatment will occur in person or online will depend on the current policies at CAPS, your preferences, and your counselor's preferences. Study staff can answer any questions you have about this process.

One treatment is called "Treatment as Usual" or TAU. TAU will be provided by a Duke CAPS counselor. It is the standard care we currently offer to students with suicidal thoughts.

The second treatment is called "Collaborative Assessment and Management of Suicidality" or CAMS. This will also be provided by a Duke CAPS counselor. CAMS treatment will involve having you and your counselor complete a form together about the possible causes of your suicidal thoughts. This form will be used to organize the discussions you have during the treatment visits.

The third treatment is called "Dialectical Behavior Therapy" or DBT. DBT involves visits each week with a Duke CAPS counselor. Besides these visits, you will also have weekly skills training sessions. The skills training visits will focus on teaching you skills to help you manage your emotions and distress and may be provided individually or in a group format.

Each of the treatments described above have helped students feel less distressed. In addition to participating in treatment, you will be asked to complete several brief questionnaires at baseline, after the first treatment session of each treatment stage, and at the end of each treatment stage.

If you are assigned TAU or CAMS in Stage 1, your counselor will be assessing how you are doing at each treatment visit and treatment will proceed or end depending on sufficient progress/improvement.

If you experience sufficient improvement, your Stage 1 treatment could end after 4-8 sessions. If so, you will then move into the maintenance phase of the study which may include occasional meetings with your counselor and/or referrals to other treatments. If you do not experience sufficient improvement, you will move onto Stage 2 of the study (read below).

If you are initially assigned to DBT as your Stage 1 treatment you will complete 16 weeks of treatment. You will not be offered any Stage 2 care.

Stage 2

If you were offered TAU or CAMS in Stage 1 and do not show enough improvement, you will be randomly assigned (like flipping a coin) to either CAMS or DBT for Stage 2. If assigned to Stage 2 CAMS, you will receive an additional 1-8 weeks of treatment. If assigned to DBT, you will receive an additional 8 weeks of treatment.

CAMS: The CAMS treatment for Stage 2 will be similar to the CAMS treatment from Stage 1.

DBT: The DBT treatment for Stage 2 will be similar to the DBT treatment from Stage 1.

Assessment Visits

You will have 3 assessment visits during the study. You will be interviewed, fill out online questionnaires (via a secure internet website), and complete an activity online during these visits. You may be asked to do these visits either in person at Duke CAPS or you may do them online via HIPAA compliant telehealth platform, such as Zoom, with study staff. If you are completing assessment visits online, study staff will work with you to ensure that you have access to a private, confidential setting to complete the assessment.

In addition to the pre-treatment visit, you will have assessment visits 8 weeks later and 16 weeks later.

Please note that we will ask you to do these assessment visits even if you choose to leave treatment or if you stop treatment early because you show improvement.

Interview at End of Treatment

When you finish the study, we will ask you to schedule a final interview. This interview will last about one hour. We want to learn as much as we can about your experience in the study.

Access to Records

In order to gauge the impact of treatment, if any, on your campus life, we will ask your approval to obtain access to your Duke University school records (GPA, demographics, semester and cumulative grade point average or GPA, credits attempted, credits completed, and enrollment status) as well as your usage of health services on campus (Duke CAPS and Duke Student Health) for a period of 12 months after the consent signing date. This information will help us to assess how your treatment has impacted your educational and general functioning on campus, over a period of a year.

No specific information about the type of research you are participating in will be provided to the university personnel, except for the fact that you are a study participant who has given us permission to collect their institutional data. This may involve asking you to sign separate document(s), specifically requesting that the Campus Registrar's Office and Campus health

entities grant us access to only data and information noted above, and only over the 12 month timeframe. Once we receive the academic and health care use information, as part of maintaining your confidentiality, we will merge the information into a file with only a Global Universal Identifier (GUID) number and no names (GUID is further explained below, in the Confidentiality section).

{Please initial your selection below, then sign}

I agree to grant researchers access to my Duke University school records, as noted above, for the purposes of this study, for a period of 12 months from the date of signature below:

_____ Yes _____ No

_____ _____

Student Signature Date signed

Video and Audio-Recordings of Your Treatment and Assessment Sessions

To make sure that the treatment and assessments are being delivered as intended, all therapy sessions and focused interviews will be audio- or video-recorded. This is a requirement to participate in this study.

These recordings will be electronically stored on secure servers. Identifiers other than your image and voice (e.g., name, address, date of birth, social security number) will not be linked to these recordings. A separate ID number will be assigned to your recordings.

These recordings will remain confidential to members of Dr. Compton's clinical and research team (and clinical supervisors of your therapist(s), if applicable) with the following exceptions: (1) transcripts, suitably modified to protect your identity, may be used in writings by Dr. Compton as illustrations to enhance the understanding of persons with psychological difficulties similar to your own and their treatment and (2) edited sections of the recordings may be listened to or viewed by those providing training to the therapist(s) who provide these treatments. ***These exceptions are optional, please initial below if you are willing to allow use of your recordings for these professional purposes.***

Choose the options you prefer below and initial each one.	
Yes ☐ No ☐	I consent to use of sections of transcripts of my treatment sessions in writings for educational purposes. _____
Yes ☐ No ☐	I consent to use of edited sections of my video/audio recordings for professional training purposes. _____

HOW LONG WILL I BE IN THIS STUDY?

You can expect to be in this study for up to five months. You will be offered up to 16 weeks of treatment and asked to complete 3 assessments to assess your progress. You will have at least 4 treatment visits, and you may have as many as 16. The number of treatment visits will depend on the treatment you receive and/or on how well you are doing. If you are offered DBT during Stage 1 or randomized to DBT in Stage 2, you will also receive up to 10 weeks of DBT skills training.

There may be breaks in your treatment due to the nature of the academic calendar (e.g., winter break, summer break). Your study counselor will work with you to develop a plan for how to manage those breaks, which may include referrals to other treatments.

Table 1 provides an overview of the treatment and assessment schedule. Please note that the private treatment sessions will last about one hour each, skills training sessions will last about two hours each, and each assessment visit will take between one to two hours to complete.

Table 1. Study Visit and Assessment Schedule

		Stage 1								Stage 2							
Study Week	Baseline Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Private Treatment Visits* (1 hour)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Skills Training** (2 hours)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Assessment Visits (1-2 hours)	X								X								X

*Your progress will be monitored by your counselor weekly; you will continue to have weekly visits if you still need them. Your treatment participation could end as early as week 4. If you enter Stage 2 your progress will be monitored by your counselor weekly and you will continue to have weekly visits if you need them.

**You will participate in 10 skills training sessions if you are randomized to receive DBT. These sessions may occur individually or in a group format.

WHAT ARE THE RISKS OF THE STUDY?

It is possible that talking about your thoughts and feelings will be upsetting. Discussing painful details about yourself and your life can be difficult and stressful. Privacy and internet connection issues can also be problematic when receiving treatment online. We will help you manage your stress if this happens.

There might be unknown or unexpected risks to joining the study. That's why keeping in touch will be so important during and after the study.

It is possible that the study team might decide to end your participation. If this happens, we will

remain in contact with you and your care providers. The reasons why this might happen are described later in this form.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You will be treated for your suicidal thoughts during this study. There is evidence that the study's treatment strategies might help, but we cannot guarantee that being in this study will help you. In general, getting treatment is more helpful than trying to cope on your own.

We hope this study will help us create guidelines on how to best treat college students who have suicidal thoughts, including how to provide this treatment via telehealth or using a hybrid telehealth/in-person model.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

This study is for research purposes only and you do not have to join the study. If you do not join the study, you will receive the same care and treatment you would otherwise receive from Duke CAPS.

This treatment might include:

- Talk therapy and counseling
- Support groups
- Referrals to other local caregivers for medication and/or counseling

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Being in a research study involves some loss of privacy. This study will collect personal information like your name, date of birth, address, academic records, and health related information.

We understand that your information is personal, and we are committed to protecting your privacy. We will do our best keep your information confidential, but we cannot guarantee total confidentiality.

Personal information we collect may be seen by other people involved in this research and others, including those working with, funding, and regulating the study. This may include people who are not part of Duke University.

We will only share information needed for us to do research. Personal information may also have to be shared if required by law.

Your study information might be reported to NIMH and its partners. In addition, your records may be reviewed in order to meet federal or state regulations.

Reviewers might include people at NIMH, the Duke University Institutional Review Board, and others as appropriate. If any of these groups review your record, they may also need to review your medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this certificate, unless you have given your permission, the researchers may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. You have consented to the disclosure, including for your medical treatment; or
3. The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Confidentiality Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you must also actively protect your own privacy.

Finally, you should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The research team at Duke may share information gathered during your assessments with your study counselor at Duke CAPS to prevent harm to yourself or others and to help coordinate your care.

We will keep your study information in a research record for 7 years after the study is finished. When that time has passed, any information in the research record that identifies you will be removed. The study record might also be destroyed. Research information that is entered into your medical record will stay there forever.

Information we collect during this study might be shared at meetings, or it might be published in a report. If this happens, none of your personal information will be included.

Because email and texting are not completely secure and confidential, please call us if you want to guarantee privacy.

Risks Associated with Telehealth

Generally speaking, the risks and benefits of telehealth are similar to those of in-person sessions. There are additional risks, however. First, although we will use secure platforms (e.g., Zoom for Healthcare) with industry-standard encryption and security, there is no way to guarantee that this software is completely failure-proof. As with any technology, there is a chance of a security

breach that would affect the privacy of personal and/or medical information. Second, since you will be completing sessions in your own home, we cannot guarantee the same level of privacy that you have when you are in our clinic. This means that you are responsible for making sure that you are in a private area where disruptions (e.g., others coming into the room or hearing what you say in another room) are minimized as much as possible. Third, in the event of group sessions conducted via video, it is possible that your confidentiality could be breached if others in the group are not in a confidential setting.

In order to reduce risks to confidentiality, we suggest that all video or telephone sessions occur in a private room with no one else present and that you wear headphones to limit the possibility of other people overhearing confidential information.

Risks Associated with Audio-Recording or Video-Recording

Risks from audio- or video-recording therapy and assessment sessions include possible loss of privacy if the recordings are hacked or made available to non-study personnel. We will store and encrypt digital video recordings of your therapy sessions and assessments.

Encrypted video files will be shared with study staff at other institutions on HIPAA-compliant cloud servers. We label all recordings with your study ID number (not your name) and only study staff, both clinicians and researchers, will have access to them. We will not allow any further use of the recordings without your written permission.

We will keep video and audio data in your research record for seven (7) years after the study is completed. At that time, either the research information may be destroyed or information identifying you will be removed.

NIMH Data Sharing

Data from this study will be sent to the NIMH Database (NDA) at the National Institutes of Health (NIH). NDA is a large database of de-identified study data from many NIMH studies. De-identified study data means that all personal information about you (like name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your de-identified study data helps researchers learn new and important things about mental health and substance use more quickly.

During and after the study, the researchers will send de-identified study data to the NDA. Other researchers across the world can then request your de-identified study data for their research. Every researcher (and institutions to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity.

Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the NDA. The study data provided to the NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will never be contacted directly about the study data you contributed to the NDA.

How Will My Information be De-identified?

For our data sharing with the NDA, a unique identification number (Global Unique Identifier, or GUID) will be created for you. The GUID is in addition to your study ID and this number will be used to connect (link) your research information from this study to other research studies that you may participate in that also use the GUID system. To receive this number, study staff member will utilize a secure internet website on a computer at the research clinic (or alternate remote, secure means) and enter information about you: your first, middle and last names at birth, any suffixes (Jr., III, etc.), your date of birth, name of the city where you were born, and your country of birth. Once the GUID is created, your personal information will be deleted from the NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be sent to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today.

If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell the NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, visit http://nda.nih.gov.

Choose the option you prefer below and initial each one.

Yes ☐ No ☐ I consent to allow my study data to be sent to the NDA. _____

It is required by law to post this clinical trial on the website https://clinicaltrials.gov/. This post might include a summary of the study's results. There will be no information that can identify you. You can search this website at any time.

WHAT ARE THE COSTS TO YOU?

There is no additional cost to be in this study. The normal services you receive at Duke CAPS

are covered by the counseling fee you pay every semester and summer. As long as you are eligible to receive Duke CAPS services, you may participate in the study.

WHAT ABOUT COMPENSATION?

You will be paid for completing assessments at the following times:

- Baseline ($30)
- Week 8 (Stage 1) ($30)
- Week 16 (Stage 2) ($30)
- Therefore, the maximum total reimbursement for any student who completes the entire study (all assessments and self-reports) is $90.

In order to process your payment, we may need to collect your social security number. This information will be kept in a separate location from you research data and will be destroyed once your reimbursements have been processed.

WHAT ABOUT RESEARCH-RELATED INJURIES?

If you are injured because of being in this study, immediate necessary medical care is available at Duke University Health System. However, there is no commitment by Duke University and/or Duke University Health System, study researchers, or the study sponsor to provide financial compensation or free medical care in the event of a study-related injury.

If the researcher believes you need a higher level of care (like hospitalization or ambulance rides), the costs for that care will be the responsibility of you and/or your family as regular medical care.

For questions about the study or a research-related injury, contact Dr. Compton at (919) 668-0063 during regular business hours and at (919) 200-9885 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to join the study. If you do join the study, you may choose to leave the study at any time, for any reason. If you choose to leave the study, it will not affect your job status if you are a Duke University employee and/or your grades if you are a Duke University student.

If you do not sign this form, you will continue to receive care, but not as a part of this study. It is normal for a Duke CAPS to refer students to other providers if their problems are severe or complex. It is possible that Duke CAPS may refer you to other providers for this reason. If this

happens, it is not a penalty for choosing not to join the study.

If you choose to leave the study early, no new information about you will be collected unless there is an adverse event (a bad effect) related to the study. If an adverse event happens, we may need to review your medical record. Any information we collect about an adverse event related to the study will be sent to the study sponsor (NIMH).

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke University. If you withdraw, we ask that you contact Dr. Compton in writing and let him know that you are withdrawing from the study. His email address is: compt004@duke.edu.

We will tell you about new information we learn during the course of this study that might affect your health, welfare, or willingness to stay in this study.

Involuntary Termination from Treatment

If you miss 4 appointments in a row, you will be removed from the treatment component of the study. Dr. Compton or the study's review board may also remove you from the study if they find it necessary for your safety or well-being. Regular ups and downs are normal for people who have suicidal thoughts. However, if you appear to be getting much worse during the study, we must try a different treatment. If there are significant concerns about your ability to be treated remotely, different avenues for treatment (e.g., local treatment if you are not on campus) may be suggested by your counselor. If this happens, Dr. Compton and your counselor will explain your removal and discuss other treatment options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Compton at (919) 668-0063 during regular business hours and at (919) 200-9885 after hours and on weekends and holidays.

Please contact the Duke University Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have questions about your rights as a research participant.
- You want to discuss problems, concerns, or suggestions related to this study.
- You want to obtain information or offer input about this study.

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ADULT – Feasibility Study
Comprehensive Adaptive Multisite Prevention of University student Suicide (CAMPUS): A Feasibility Study

STATEMENT OF CONSENT

"The study team has explained the purpose of this study, the things that will happen, and the risks and benefits. I have been given the time to ask questions and the study team has answered them in full.

I know who to contact if I have any questions, comments, concerns, or suggestions or if I want to discuss any problems related to the study.

I have read this consent form and agree to be in this study, knowing that I can withdraw at any time. The study team will give me a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time