Official Title: Interventions to Improve the HIV PrEP Cascade Among Methamphetamine Users

NCT Number: NCT03584282

Consent Form

Document date: 9/29/2020

UNIVERSITY OF WASHINGTON
CONSENT FORM

Interventions to Improve the HIV PrEP Cascade among Methamphetamine Users

Joanne Stekler, MD MPH	Associate Professor, Medicine	206/744-8312
Dana Atkins, MPH	Research Coordinator	206/595-9747
Noah Frank	Peer Navigator	206/849-4951
Emergency 24-hour number	**Dr. Joanne Stekler**	**206/744-3000**

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will keep a copy of this consent form at your PrEP clinic and the University of Washington and give you a copy for your records.

PURPOSE OF THE STUDY

You are being asked to volunteer for this research study because you are a cisgender man or on the transgender variant spectrum; have sex with cis men, trans women or trans men; have used methamphetamine in the past 3 months; are seeking pre-exposure prophylaxis (PrEP) for HIV prevention; and have a cell phone. PrEP only works when it is taken *consistently* during periods when a person is exposed to HIV. Taking PrEP consistently and continuing to take it to cover periods of HIV risk can be difficult. Therefore, we are trying to study ways to support people taking PrEP consistently and for as long as they need it. The purpose of this research is to assess if peer support is an acceptable and feasible strategy to help people take PrEP daily.

Approximately 40 people who seek PrEP at a clinic in King County will participate in this project. The study is being conducted by the University of Washington. The information below is to help you decide if you would like to participate in this study.

STUDY PROCEDURES

This study will add procedures for the next 6 months to the procedures you will already have as part of your regular PrEP care. Your regular PrEP visits will include blood draws for laboratory tests, a check on how you are doing taking your PrEP pills, and refills of your pills. If you choose to take part in this study, you will have additional procedures associated with your first PrEP visit, and then 1, 3, and 6 months later, as described below.

Release of Information: We will ask that you complete a release of information form today. This form will allow the clinic where you are receiving PrEP to share information about your PrEP follow-up with the research team at the University of Washington during your study participation. Examples of shared information are when you have a PrEP follow-up appointment and PrEP prescription refills are ordered. This information is important for the researchers to assess if and how the text messaging and peer support interventions are helping participants take their PrEP consistently.

UNIVERSITY OF WASHINGTON
CONSENT FORM

Interventions to Improve the HIV PrEP Cascade among Methamphetamine Users

Joanne Stekler, MD MPH	Associate Professor, Medicine	206/744-8312
Dana Atkins, MPH	Research Coordinator	206/595-9747
Noah Frank	Peer Navigator	206/849-4951
Emergency 24-hour number	**Dr. Joanne Stekler**	**206/744-3000**

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will keep a copy of this consent form at your PrEP clinic and the University of Washington and give you a copy for your records.

PURPOSE OF THE STUDY

You are being asked to volunteer for this research study because you are a cisgender man or on the transgender variant spectrum; have sex with cis men, trans women or trans men; have used methamphetamine in the past 3 months; are seeking pre-exposure prophylaxis (PrEP) for HIV prevention; and have a cell phone. PrEP only works when it is taken *consistently* during periods when a person is exposed to HIV. Taking PrEP consistently and continuing to take it to cover periods of HIV risk can be difficult. Therefore, we are trying to study ways to support people taking PrEP consistently and for as long as they need it. The purpose of this research is to assess if peer support is an acceptable and feasible strategy to help people take PrEP daily.

Approximately 40 people who seek PrEP at a clinic in King County will participate in this project. The study is being conducted by the University of Washington. The information below is to help you decide if you would like to participate in this study.

STUDY PROCEDURES

This study will add procedures for the next 6 months to the procedures you will already have as part of your regular PrEP care. Your regular PrEP visits will include blood draws for laboratory tests, a check on how you are doing taking your PrEP pills, and refills of your pills. If you choose to take part in this study, you will have additional procedures associated with your first PrEP visit, and then 1, 3, and 6 months later, as described below.

Release of Information: We will ask that you complete a release of information form today. This form will allow the clinic where you are receiving PrEP to share information about your PrEP follow-up with the research team at the University of Washington during your study participation. Examples of shared information are when you have a PrEP follow-up appointment and PrEP prescription refills are ordered. This information is important for the researchers to assess if and how the text messaging and peer support interventions are helping participants take their PrEP consistently.

Surveys: We will ask you to complete an online survey within 7 days of your first PrEP appointment, and then 3 and 6 months later. The surveys will ask questions about you (for example your age, race, and gender), your sexual practices, and your drug use. You may refuse to answer almost any question in the survey that you do not wish to answer. We will require that you answer questions about your gender, the gender of your sex partners, your drug use, and PrEP adherence. We will also require answers to questions about the study interventions, including how acceptable you find the intervention. We require answers to these questions because this information is needed to meet the study aims.

If you do not respond to the survey within 7 days from your first PrEP appointment, we will ask you to not continue in the study.

Fingerstick for dried blood spots (DBS): At your 1, 3, and 6 month visits the clinic staff will collect drops of blood from a fingerstick, and put those drops on a blood collection card. These drops of blood will be tested for the two medications that are in PrEP. We will clean your finger with an alcohol wipe and then make a prick with a small needle called a lancet to collect the drops of blood.

Enrollment	Month 1	Month 3	Month 6
Consent & randomization			
Survey		Survey	Survey
	DBS	DBS	DBS

Randomization: Randomization means that you will be assigned to one of two groups by chance. This assignment will be done using a computer program. You will be "randomized" to one of the twor groups we describe ahead. Neither you nor your provider can choose which group you will be in. You will have the same chance of being assigned to either one of the two groups. Up to 20 people will be assigned to each group. You will be randomized into one of the two groups after you complete your first survey (within the 7 days of your first PrEP appointment).

- **Standard of care:** Up to 20 participants will only receive all of the services at the clinic where they receive PrEP, which include reminder calls for visits (this is called "standard of care"). It is important to have a group that does not receive additional research activities in order to describe if the research interventions were successful or not.
- **Peer support:** Up to 20 participants will (be randomly selected to) receive peer support to help them take their PrEP. For those participants who are in the peer support group, the support will be tailored to their needs, so it may look different for each participant. If you are in the peer support group, the peer will request that you meet with the them during the first week of the study to introduce themselves and to talk about what kinds of support you may want for taking PrEP. During that meeting the peer will work with you to complete an "individualized plan" to identify what types of support would be helpful for you. The types of support that will be available to participants in the peer support group will include, but will not be limited to, help with transport to and from appointments or picking up prescriptions; assistance calling the pharmacy and requesting PrEP refills; attending PrEP appointments; helping with referrals to other resources; and texting, emailing, or talking throughout the study.

Standard of Care	20
Peer Navigation	20

Time: We expect that the research procedures for today's visit, including consenting for the study, will take approximately 60 minutes. The only research procedure done in the clinic during your visits 1, 3, and 6 months from today will be the fingerstick and blood spot collection, which we expect to take 5 minutes.

The online surveys should each take approximately 20 minutes. The text message intervention should take approximately 5 minutes a day to read the texts received. The amount of time that the peer support intervention will take will depend on the requests and needs of the participants who are in this group.

RISKS, STRESS, OR DISCOMFORT

Surveys: The questions we ask on the surveys about your sexual behavior or drug use may make you uncomfortable. However, you do not have to answer most of the survey questions if you do not want to, and you can stop answering questions at any time. In addition, it is possible that someone else may see your replies to the survey if you take the survey in a place where other people are present. To protect your confidentiality, we recommend to take the surveys in a private location, where nobody else can see your replies. We will not ask you to enter any identifying information into the study surveys.

Fingerstick for DBS: The fingerstick for blood collection may cause a small amount of pain or bruising, and the site may bleed slightly after collection.

.

Peer support: If you are in the peer support group, you will correspond with the peer how you choose. This could include email, text messages, and phone calls. Because unencrypted email, text messaging, and phone conversations are unsecured types of communication, information that is sent using these methods can be intercepted by a third party *and you should think carefully before sending information about illegal behavior or other sensitive topics*. Since the peer may help you remember your appointments, provide transport assistance, and help you with refills, you and the peer may send private information such as your name, date of birth, or address. If you or the peer send this information by email, text, or phone, there is a potential risk that someone else could capture the information while it is being sent. We will always communicate with the least identifiable information as possible and will talk with you about ways to reduce these risks, like deleting messages after you send or receive them. Furthermore, it is possible that somebody could see the messages on your computer, phone, or other communication device. Please initial below if you have read and understand these risks, and would still like to participate in the study.

_____ I have read the statement about risks of unsecured text messaging and communication and have had time to ask questions.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Your alternative to participating in this study would be to not participate. If you choose not to participate in this study, you can still receive PrEP as part of your regular care at the clinic where you choose to receive PrEP. You will not lose any benefits in the clinic because you do not want to be in the study.

BENEFITS OF THE STUDY

If you are assigned to the standard of care group, we do not expect that being a part of this study will result in any direct benefit for you. However, your participation will help us better understand ways to support PrEP use among people who use methamphetamine. If you are in the peer support group, we expect that you may benefit from receiving peer support to take your PrEP and having assistance with other needs you may ask for help with.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the National Institute on Drug Abuse (NIDA) to conduct this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will record your name, contact information, and other personal identifying information while you are in this study. This information will be used to send the study surveys and reimbursements to all participants. We will also use this information to send texts to those participants tocommunicate with those in the peer support group.

We will also use your names to collect data related to your PrEP use from your clinical chart at the clinic where you receive PrEP. We will ask you to sign two separate documents today in addition to this informed consent form: a HIPAA Authorization and Release of Information. These forms allow us to communicate with your PrEP clinic and pharmacy about your clinical records related to PrEP. The dried blood spots that we collect from you will be stored at the University of Washington and will be sent for testing after the study is completed. These stored specimens will be labeled with only a study ID and will not have your name on them.

If you are in the peer support group, we will record your individualized plans and we will count and categorize the peer's communications with you. For example, the frequency of texts or what kind of contact you and the peer have (e.g., phone call to refill prescription). This information is important for us to be able to describe the peer support activities.

Your surveys, individualized plans, and stored dried blood spots will only be labeled with a unique ID, and will not have identifying information on them. Text messages, phone calls, and emails for participants in the peer support group will have identifying information on them. They will be kept as securely as possible. If you are in the peer support group, we will remove as much identifying information from your correspondence with the peer as possible when you finish the study. However, some correspondence (e.g., email, text messages) may be stored with identifiers if we cannot remove them.

All of the study data we collect will be kept in a locked cabinet, encrypted phone, or password-protected computer files. Results that are published from this study will not include any personal information about you. We will keep a link between the study ID and your name in a secure office at the University of Washington. The link for this data will be destroyed after the records retention period required by state and/or federal law.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- government authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others. Also, if we learn of child or elderly abuse or the intent to hurt someone else, we will call the police. If we learn of an intent to hurt yourself we will provide appropriate referrals for you, including the King County Crisis Line.

OTHER INFORMATION

We will discuss the study with you. You may refuse to participate and you are free to withdraw from this study at any time without any penalty or loss of benefits to which you are otherwise entitled. In the unlikely event we think that your participation in the study is harmful to yourself or study staff, we may end your participation in the study early.

If you leave our PrEP program and start taking PrEP at a different clinic during the study we will ask that you still complete the online surveys in this study. We will also ask that you allow us to receive information about your PrEP use from the new clinic until the end of your study participation (6 months after your first PrEP visit). If you are assigned to receive peer support, we will also ask that you continue to receive texts and/or peer support while you are taking PrEP at your new clinic until the end of your study participation.

There are no others cost for participating in this study. You will receive a $20 Amazon gift card for each of the surveys you complete in this study. If you complete all 3 surveys, you will receive $60 in Amazon gift cards for your participation. If you are in the peer support group and run out of text messages on your cell phone plan, the study will cover the costs of additional text messages related to your participation.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. If you think you have been harmed from being in this

research, you can contact Dr. Joanne Stekler by paging her (206-744-3000) right away. This number is monitored 24 hours a day. She will treat you or refer you for treatment if appropriate.

If you have questions later on about this research study, you can ask one of the researchers listed above. If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at (206) 543-0098.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent	Signature	Date

Printed name of HIV tester (telemedicine visit only)	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Surveys: We will ask you to complete an online survey within 7 days of your first PrEP appointment, and then 3 and 6 months later. The surveys will ask questions about you (for example your age, race, and gender), your sexual practices, and your drug use. You may refuse to answer almost any question in the survey that you do not wish to answer. We will require that you answer questions about your gender, the gender of your sex partners, your drug use, and PrEP adherence. We will also require answers to questions about the study interventions, including how acceptable you find the intervention. We require answers to these questions because this information is needed to meet the study aims.

If you do not respond to the survey within 7 days from your first PrEP appointment, we will ask you to not continue in the study.

Fingerstick for dried blood spots (DBS): At your 1, 3, and 6 month visits the clinic staff will collect drops of blood from a fingerstick, and put those drops on a blood collection card. These drops of blood will be tested for the two medications that are in PrEP. We will clean your finger with an alcohol wipe and then make a prick with a small needle called a lancet to collect the drops of blood.

Enrollment	Month 1	Month 3	Month 6
Consent & randomization			
Survey		Survey	Survey
	DBS	DBS	DBS

Randomization: Randomization means that you will be assigned to one of two groups by chance. This assignment will be done using a computer program. You will be "randomized" to one of the twor groups we describe ahead. Neither you nor your provider can choose which group you will be in. You will have the same chance of being assigned to either one of the two groups. Up to 20 people will be assigned to each group. You will be randomized into one of the two groups after you complete your first survey (within the 7 days of your first PrEP appointment).

- **Standard of care:** Up to 20 participants will only receive all of the services at the clinic where they receive PrEP, which include reminder calls for visits (this is called "standard of care"). It is important to have a group that does not receive additional research activities in order to describe if the research interventions were successful or not.
- **Peer support:** Up to 20 participants will (be randomly selected to) receive peer support to help them take their PrEP. For those participants who are in the peer support group, the support will be tailored to their needs, so it may look different for each participant. If you are in the peer support group, the peer will request that you meet with the them during the first week of the study to introduce themselves and to talk about what kinds of support you may want for taking PrEP. During that meeting the peer will work with you to complete an "individualized plan" to identify what types of support would be helpful for you. The types of support that will be available to participants in the peer support group will include, but will not be limited to, help with transport to and from appointments or picking up prescriptions; assistance calling the pharmacy and requesting PrEP refills; attending PrEP appointments; helping with referrals to other resources; and texting, emailing, or talking throughout the study.

Standard of Care	20
Peer Navigation	20

Time: We expect that the research procedures for today's visit, including consenting for the study, will take approximately 60 minutes. The only research procedure done in the clinic during your visits 1, 3, and 6 months from today will be the fingerstick and blood spot collection, which we expect to take 5 minutes.

The online surveys should each take approximately 20 minutes. The text message intervention should take approximately 5 minutes a day to read the texts received. The amount of time that the peer support intervention will take will depend on the requests and needs of the participants who are in this group.

RISKS, STRESS, OR DISCOMFORT

Surveys: The questions we ask on the surveys about your sexual behavior or drug use may make you uncomfortable. However, you do not have to answer most of the survey questions if you do not want to, and you can stop answering questions at any time. In addition, it is possible that someone else may see your replies to the survey if you take the survey in a place where other people are present. To protect your confidentiality, we recommend to take the surveys in a private location, where nobody else can see your replies. We will not ask you to enter any identifying information into the study surveys.

Fingerstick for DBS: The fingerstick for blood collection may cause a small amount of pain or bruising, and the site may bleed slightly after collection.

.

Peer support: If you are in the peer support group, you will correspond with the peer how you choose. This could include email, text messages, and phone calls. Because unencrypted email, text messaging, and phone conversations are unsecured types of communication, information that is sent using these methods can be intercepted by a third party *and you should think carefully before sending information about illegal behavior or other sensitive topics*. Since the peer may help you remember your appointments, provide transport assistance, and help you with refills, you and the peer may send private information such as your name, date of birth, or address. If you or the peer send this information by email, text, or phone, there is a potential risk that someone else could capture the information while it is being sent. We will always communicate with the least identifiable information as possible and will talk with you about ways to reduce these risks, like deleting messages after you send or receive them. Furthermore, it is possible that somebody could see the messages on your computer, phone, or other communication device. Please initial below if you have read and understand these risks, and would still like to participate in the study.

_____ I have read the statement about risks of unsecured text messaging and communication and have had time to ask questions.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Your alternative to participating in this study would be to not participate. If you choose not to participate in this study, you can still receive PrEP as part of your regular care at the clinic where you choose to receive PrEP. You will not lose any benefits in the clinic because you do not want to be in the study.

BENEFITS OF THE STUDY

If you are assigned to the standard of care group, we do not expect that being a part of this study will result in any direct benefit for you. However, your participation will help us better understand ways to support PrEP use among people who use methamphetamine. If you are in the peer support group, we expect that you may benefit from receiving peer support to take your PrEP and having assistance with other needs you may ask for help with.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the National Institute on Drug Abuse (NIDA) to conduct this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will record your name, contact information, and other personal identifying information while you are in this study. This information will be used to send the study surveys and reimbursements to all participants. We will also use this information to send texts to those participants tocommunicate with those in the peer support group.

We will also use your names to collect data related to your PrEP use from your clinical chart at the clinic where you receive PrEP. We will ask you to sign two separate documents today in addition to this informed consent form: a HIPAA Authorization and Release of Information. These forms allow us to communicate with your PrEP clinic and pharmacy about your clinical records related to PrEP. The dried blood spots that we collect from you will be stored at the University of Washington and will be sent for testing after the study is completed. These stored specimens will be labeled with only a study ID and will not have your name on them.

If you are in the peer support group, we will record your individualized plans and we will count and categorize the peer's communications with you. For example, the frequency of texts or what kind of contact you and the peer have (e.g., phone call to refill prescription). This information is important for us to be able to describe the peer support activities.

Your surveys, individualized plans, and stored dried blood spots will only be labeled with a unique ID, and will not have identifying information on them. Text messages, phone calls, and emails for participants in the peer support group will have identifying information on them. They will be kept as securely as possible. If you are in the peer support group, we will remove as much identifying information from your correspondence with the peer as possible when you finish the study. However, some correspondence (e.g., email, text messages) may be stored with identifiers if we cannot remove them.

All of the study data we collect will be kept in a locked cabinet, encrypted phone, or password-protected computer files. Results that are published from this study will not include any personal information about you. We will keep a link between the study ID and your name in a secure office at the University of Washington. The link for this data will be destroyed after the records retention period required by state and/or federal law.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- government authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others. Also, if we learn of child or elderly abuse or the intent to hurt someone else, we will call the police. If we learn of an intent to hurt yourself we will provide appropriate referrals for you, including the King County Crisis Line.

OTHER INFORMATION

We will discuss the study with you. You may refuse to participate and you are free to withdraw from this study at any time without any penalty or loss of benefits to which you are otherwise entitled. In the unlikely event we think that your participation in the study is harmful to yourself or study staff, we may end your participation in the study early.

If you leave our PrEP program and start taking PrEP at a different clinic during the study we will ask that you still complete the online surveys in this study. We will also ask that you allow us to receive information about your PrEP use from the new clinic until the end of your study participation (6 months after your first PrEP visit). If you are assigned to receive peer support, we will also ask that you continue to receive texts and/or peer support while you are taking PrEP at your new clinic until the end of your study participation.

There are no others cost for participating in this study. You will receive a $20 Amazon gift card for each of the surveys you complete in this study. If you complete all 3 surveys, you will receive $60 in Amazon gift cards for your participation. If you are in the peer support group and run out of text messages on your cell phone plan, the study will cover the costs of additional text messages related to your participation.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. If you think you have been harmed from being in this

research, you can contact Dr. Joanne Stekler by paging her (206-744-3000) right away. This number is monitored 24 hours a day. She will treat you or refer you for treatment if appropriate.

If you have questions later on about this research study, you can ask one of the researchers listed above. If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at (206) 543-0098.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent	Signature	Date

Printed name of HIV tester (telemedicine visit only)	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date