STUDY INFORMATION:

Study Title: A SMART Approach to Treating Tobacco Use Disorder in Persons with HIV (SMARTTT)

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Yale New Haven Health System.

The purpose of this research study is to compare different strategies, involving medications (nicotine replacement therapy and varenicline) and contingency management to help people with HIV stop smoking. Contingency management is a behavioral treatment that uses rewards to help people engage in healthy behaviors. In this study, if you are assigned to receive contingency management, you will have the potential to receive rewards for not smoking cigarettes. If you are assigned to receive contingency management, you will have the potential to receive rewards if you do not smoke. Although nicotine replacement therapy and varenicline are medications that are approved by the U.S. Food and Drug Administration to help people to stop smoking, we do not know how well they work in combination with contingency management and this is part of what we are studying.

If you choose to participate, you will be asked to:

- Participate in three visits with the research assistant at baseline, 12 weeks and 24 weeks, each lasting about 60-90 minutes
- Participate in 11 visits with a clinical pharmacist, each lasting 20 minutes, over the course of 24 weeks who will prescribe medications for you to help you stop smoking.
- If you are randomized to receive contingency management, you will be invited to participate in five or ten sessions, over the course of 24 weeks. Contingency management means that you will earn extra rewards for positive behaviors, such as stopping smoking. All of your sessions

will take place at the clinic where you normally receive your HIV care. The contingency management sessions will be audio recorded if you consent to this.

- At 12 months, the research assistant will review your medical chart to follow up on your progress
- Undergo carbon monoxide breath tests and fill out study questionnaires at each visit with the research assistant if you report that you are not smoking. In addition, if you are in the contingency management group, you will undergo carbon monoxide breath tests at each contingency management visit to confirm you are not smoking.
- There are no costs to you for participation in the study.
- You will be provided compensation for your time and effort spent with the research assistant.

The main risks to you if you choose to participate are possible side effects to nicotine replacement therapy and/or varenicline.

You may also benefit from participation in this research if you are able to stop smoking, which may greatly improve your overall health.

Instead of participating in this research, you may 1) not participate or 2) ask your HIV doctor for help to stop smoking.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have been diagnosed with HIV and smoke cigarettes. For this project, we are including people who smoke cigarettes regularly.

In order to participate in this study, you must have a diagnosis of HIV, be at least 18 years old and be free of any major medical, surgical, or psychiatric condition based on review of your medical record. In addition, you will not be eligible to participate if you only use non-cigarette tobacco or nicotine products, are currently taking medications to help you stop smoking, are pregnant, nursing or trying to conceive (for women only), unable to provide at least one contact for a friend or family member, or live out of state.

Funds for conducting this research are provided by the National Cancer Institute.

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

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 24 weeks.
The number of people expected to take part in this research study at Yale New Haven Health Systems 172. The total number of people expected to take part in this research study across all sites is 632.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

The study will last 24 weeks.

All participants will be asked to meet with a research assistant at Yale New Haven Health System to complete questionnaires.

Then, you will be randomly assigned, by luck of the draw or chance, to one of two groups of participants. Depending on the group to which you are assigned, you will receive one of the following two types of treatments: Group A) Nicotine replacement therapy or Group B) Nicotine replacement therapy with Contingency Management.

The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what experimental study treatment you get. You will have a one to one chance of being given each experimental treatment.

Participants assigned to both groups will be invited to meet with a pharmacist six times within a 12-week period to start nicotine replacement therapy, check on progress with stopping smoking and to discuss any potential medication side effects. The pharmacist will initially prescribe 4 weeks of nicotine patches, with gum, lozenges, an inhaler or spray based on how much you smoke and your preferences. You will fill the prescription through your usual pharmacy of choice. Additional medication will be prescribed as you need it during the follow-up visits. If you are also receiving contingency management from the clinical pharmacist, you will also be eligible to earn rewards, if you do not smoke based on your report and carbon monoxide breath testing. For each single session, you may draw gift cards in the amount of $5 to $100.

Twelve weeks after starting the study, you will meet with the clinical pharmacist to determine whether you should continue your treatment or change treatments based on whether or not you are smoking:

- If you have stopped smoking based on what you tell us and carbon monoxide breath test, you will continue with the same treatment you started with (either nicotine replacement therapy or nicotine replacement therapy plus contingency management) for another 12 weeks. The Food and Drug Administration has made suggested changes to the labeling guidelines, and treatment with nicotine replacement therapy may be used for up to 24 weeks.
- If you continue smoking based on what you tell us and carbon monoxide breath test, you will be reassigned at week 12. You will be randomized to either switch medications from nicotine replacement therapy to varenicline (Chantix®), an FDA approved medication to help people stop smoking cigarettes, or to receive an increase in potential rewards with contingency management.
- All participants, regardless of which treatments they are receiving and their initial response to treatment during the first 12 weeks, will continue to meet with the clinical pharmacist as before to check on your progress with stopping smoking and monitor any side effects to the medications. We will continue to monitor your progress.
- The treatment phase of the study ends at after 24 weeks. At this point, we will discuss treatment options with you.

At 12 and 24 weeks, you will also meet with the research assistant to conduct questionnaires and complete the carbon monoxide breath test if you did not do this with the clinical pharmacist. You will be asked questions about your behaviors including your smoking and other substance use, symptoms, treatment services, adherence to tobacco treatment medication, and satisfaction with the study's activities. We will also collect a breath test to check your carbon monoxide level to give us information about how much you are smoking. We will also collect information on your blood test results through the electronic medical record. At the end of 24 weeks, your active participation is complete.

At 12 months, the research assistant will review and collect lab results from your medical chart, including CD4 count, HIV viral load and other measures of your health (hemoglobin, AST, ALT, albumin, white blood cell count, platelets, hepatitis C status, creatinine) and body mass index. You do not need to be present for this.

Because this project involves the use of medications, it is necessary that we make a note of your participation in the electronic medical record and when you complete study visits to address your smoking. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown. Also, prescriptions for nicotine replacement therapy and, if indicated, varenicline will also be noted in your electronic medical record as these will be prescribed for you to get from the pharmacy.

For Women:

Since you are participating in a research study that involves medications with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. If you are pregnant based on information you provide or a pregnancy test, you will not be eligible to participate. You should not participate if you are breastfeeding.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

For Men:
We are not aware of any particular risks specific to men.

Recording of Contingency Management Sessions:
We are also requesting your permission to digitally record all of your counseling sessions with the clinical pharmacist when you receive contingency management to be able to monitor your treatment and provide you with the best care possible. These recordings will be audio-taped only. These recordings may be used for any purpose relevant to research and medical education at the discretion of the Principal Investigators and will be erased 6 years after the completion of the study. We are recording the sessions so that we can ensure that the clinical pharmacists at each clinic are providing consistent treatment. 1.) You will not be identified by name in the recording; 2) only those persons involved in the research or teaching program will review these recordings and your confidentiality will otherwise be maintained; 3) none of the material on the recordings will be published in such a way that you can be identified; 4) you may withdraw this consent and at any time and if you withdraw consent, the use of the recording will be stopped immediately and all recordings authorized by this consent will be erased as soon as possible, but no later than four weeks after the withdrawal of consent is received; 5) any treatment provided as part of this study or by any of the providers involved in the study will not be affected by your refusal to consent to be recorded or by your withdrawal of consent at any time in the future; 6) in signing this consent form, you acknowledge that the taping procedure has been explained to you given your consent for audio recordings voluntarily.

USE OF YOUR DATA:

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your *name, gender, date of birth, medical number, telephone number*. This information will be coded at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The Principal Investigators will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research

team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. All collected study data or audiotapes will be coded within 6 years of study completion. The data will be kept in this anonymous form until it is destroyed.

Consistent with NIH policy, we are planning to make the results of this research study available to the public at large. Research data which do not contain any identifying personal health information may be made available to other researchers on request. We will make the data and associated documentation available to other researchers only under special agreements that they 1) can only use the data only for research purposes; 2) they cannot identify any individual participant; 3) they must protect the confidentiality of the data using appropriate computer technology; 4) they connect share the data with others; and 5) they must destroy or return the data after their analyses are completed. The researchers would like to ask your permission to keep the data collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

1) Will you allow the researchers to store your information to use in future research studies?

   Yes_____ No_____If no, please stop here. If yes, please continue to the next question.

2) The researchers will store your information anonymously (no one will know who the information is from). Please note that if you choose to have your information stored anonymously, you will not be able to change your mind to ask for your information to be destroyed at a future date.

   I would like my information to be stored anonymously:

   Yes_____No_____

3) Do you give permission to have portions of the information given to other researchers, including those at Yale University School of Medicine, other academic institutions, and for-profit companies, for use in research within the limits you have chosen above?

   Yes_____No_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: attending study visits and taking medications as prescribed.

If you are a woman, you need to use birth control while you are participating in the study.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to extra costs to you.

If you agree to take part in this research study, you will be compensated up to $150 for your time and effort, depending on how many visits you attend. For the first visit, 12 week visit, and 24 week visit you will earn $50 at the end of each session. If you are in the contingency management group, you have the potential to earn additional rewards for each session; these rewards will be in the form of a gift card to a local store.

Tax law may require the Yale University Finance Department to report the amount of payment you receive from participating in this study to the Internal Revenue Service (IRS) or other agencies, as applicable. For this study, this reporting would take place if you receive payments that equal $600 or more for this study from Yale University in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that you are able to stop smoking, which may greatly improve your overall health. In addition, this study will generate new information about clinical pharmacists might be able to best help other people with HIV stop smoking.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The main risks to you if you choose to participate are possible side effects to nicotine replacement therapy and/or varenicline.

Some possible side effects of nicotine replacement therapy are:

1) localized skin rash or allergic reaction from wearing the nicotine patch,
2) sleep disturbance or vivid dreams,
3) nausea or indigestion from the use of nicotine lozenges or nicotine gum.
4) dizziness
5) headache
6) myalgia
7) rapid heartbeat
8) mouth irritation
9) sore throat

10) jaw pain
11) bad taste
12) hiccups
13) dental problems

There is a very small risk of nicotine toxicity, if nicotine replacement products are used in higher quantities than prescribed or from smoking while using the products. Symptoms of nicotine toxicity include cold sweats, fainting, confusion, or pounding heart. The Food and Drug Administration has published new guidelines which suggest that these products are safe to use longer than 12 weeks.

Varenicline may cause nausea in some people, but this goes away over time. You may also experience sleep disturbance or vivid dreams. Less common side effects include indigestion, abdominal pain or gas, fatigue, headache or dry mouth.

There is a risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

If you are a woman and you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. You should not become pregnant while on this research study.

Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, your choices may include 1) not to participate or 2) asking your HIV doctor for help to stop smoking. Your doctor might provide counseling, medications or refer you to the Yale Smoking Cessation Program.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able. Yale School of Medicine and Yale New Haven Health System do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional

financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Yale New Haven Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask in writing to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number (203) 737-3347.

If you experience an emergency during your participation in this research, call 911.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.

- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Yale New Haven Health System reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research, will collect information about your health that includes:
- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Medications
- Questionnaires

The researchers will also get information from your medical records, including:
- Name
- Gender
- Date of birth
- Medical Record Number
- Telephone Number
- HIV / AIDS
- Hepatitis infection
- Sexually transmitted diseases
- Physical exams
- Laboratory and other test results

- Sexual practices
- The diagnosis and treatment of medical and psychiatric conditions
- Tobacco and alcohol use
- Drug use

During the study the researchers will gather information from you through questionnaires. We will also collect information from your electronic medical record. This will include medical and psychiatric diagnoses, medications, visits, procedures and lab test results. We are collecting this information so we can better asses how treatments in this study impacts health outcomes.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Yale New Haven Health System.

The research team and other authorized members of Yale University workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Yale University Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Yale New Haven Health System workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies and the Office of Human Research Protection.

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Yale School of Medicine, SUNY Downstate School of Medicine and the Icahn School of Medicine at Mount Sinai.

- The Yale Human Research Protection Program and the Yale Human Investigation Committee, the Human Research Protection Program at the Icahn School of Medicine at Mount Sinai and the Institutional Review Board at SUNY Downstate Medical Center (the committees that review, approve, monitor research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Those providers who are participants in the Electronic Medical Record (EMR) system.

- The Principal Investigators overseeing the study: Drs. E. Jennifer Edelman and Steven L. Bernstein

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: The National Cancer Institute (NCI)

- Health care providers who provide services to you in connection with this study.

- Co-Investigators and other investigators

- Study Coordinator and Members of the Research Team

- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

In almost all disclosures outside of Yale University you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary*

to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Yale University be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside of Yale University, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Yale University has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the Connecticut Commission on Human Rights and Opportunities at 860-541-3400.

Certificate of Confidentiality:
To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____
Signature of subject	Printed Name of Subject	Date

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time