COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Yale University School of Medicine/Yale-New Haven Hospital

Study Title: Neural indicators of reward processing and inhibitory control associated with Juul use
HIC# 2000025075
Principal Investigator (the person who is responsible for this research): Kristen Morie, PhD
24-Hour Phone Number: 203 737 6473
Funding Source: National Institutes of Health, National Institute on Drug Abuse (NIDA)

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to investigate how using an e-cigarette affects the brain. We will study both Juul users and control subjects (subjects who will not use Juul under this study).
- Study procedures will include: For Juul users: completing tasks after self-administration of Nicotine or placebo (vaping) while functional magnetic resonance imaging (fMRI) and Electroencephalography (EEG) are recorded. Non-smokers control group procedures will include completing a short walk and recording of functional magnetic resonance imaging (fMRI) and Electroencephalography (EEG)".
- 4 testing visits are required if you are a Juul user, and 2 if you are a control.
- Each testing visit will take 2 hours. The Juul vaping group will participate in 4 visits which will equal 8h total, and controls will participate in 2 visits which will equal 4 hours total. If you are a Juul user, on two of the days, you will be given a 0% nicotine pod, and on the other two days you will be given a 5% nicotine pod. The order you will get these is random, and you won't know which day is which until the end of the study.
- There are some risks/inconveniences from participating in this study. These include risk from EEG, MRI, behavioral tasks, and vaping which are further described in this document and include minor discomfort, boredom, inhalation of ultrafine particles including flavoring chemicals that may have risk of lung injury, and the risk of vaping nicotine which includes ongoing addiction.
- The study has no direct benefit to you.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

You are invited to participate in a research study using functional magnetic resonance imaging (fMRI) and Electroencephalography (EEG) to measure activity in the brain post nicotine administration. You have been asked to participate because you use a nicotine vaping device or because you have never used nicotine in any form. We are interested in studying how different parts of the brain work in people who use nicotine vaping devices. We are looking to recruit around 30 vaping subjects and 30 control subjects.

Who is paying for the study?

This study is being paid for by funding from the National Institute on Drug Abuse, a division of the National Institute of Health (NIH).

What is the study about?

The purpose of this study is to examine the effects of vaped nicotine on the brain, and to examine its effects on how people perform certain tasks versus non-users.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen from beginning to end:

Vaping participants:

If you are a Juul user, this study will take up four study days. We will ask you to not vape for 8 hours before testing sessions. On your first testing day, we will ask you to complete interviews and questionnaires about your Juul use and about how you feel about certain things. On all testing days, you will also be asked to complete urine testing for things like cotinine (nicotine) and other drugs (like THC). If you are female, we will also test for pregnancy. The testing will be done at the screening visit. We will also ask you if you are pregnant prior to each visit. Then you will answer some questionnaires about things like your health. Filling out the questionnaires may take about half an hour, and then you will be asked to use your Juul device outside the building and be escorted by study staff.

If you are 18-20 years of age, we will provide a Juul device for your use, which will remain in the laboratory when you leave. All other participants will bring their own Juul device. The device will be loaded with either a nicotine pod (5%) or a nicotine-free pod. We will provide the pods. You will not know which kind of pod your device contains. After you use the Juul device, there will be about one hour of testing while EEG or MRI is recorded. Then your next testing visit will be scheduled, until all four visits are completed. The first two visits will consist of EEG testing, and the final two visits will be fMRI testing. After all the testing is completed, we will give you a call one month afterward to check on your health.

Control Participants:

If you are a control, this study will take two study days. On your first testing day, we will ask you to complete interviews and questionnaires about how you feel about certain things. On all testing days, you will also be asked to complete urine testing for things like cotinine (nicotine) and other drugs (like THC). If you are female, we will also test for pregnancy. The testing will be done at the screening visit. We will also ask you if you are pregnant prior to each visit. Then you will fill out some questionnaires. The questionnaires will take about half an hour, and then you will be asked to take a short walk outside the building and be escorted by study staff. Afterward, you will perform the testing while EEG or MRI is recorded. The first two visits will consist of EEG testing, and the final two visits will be fMRI testing. After all the testing is completed, we will give you a call one month afterward to check on your health.

Description of fMRI:

MRI scans are painless, do not involve the use of radiation, and are used routinely to diagnose neurological problems. You must inform the research staff if you have any metal (for example, shrapnel or surgical prostheses) in your body because having an MRI could be harmful. Some

people feel mildly anxious in the scanner, and if it is too difficult for you to be in it, you may withdraw at any time. The scans will take place in New Haven, at the Yale MRI Research Center.

During the MRI session, you will lie on your back on a comfortable mattress, which is then slid into a large tube until your head and the upper part of your body are inside the tube. Your head will be held still in a cushioned head rest, and you will wear earplugs to reduce the level of noise. You will also be wearing headphones to help communicate with the research staff.

During the MRI session, you will be able to communicate with the research staff with headphones and a microphone. We may tell you when we begin taking pictures of your brain and you will notice a series of knocking noises made by the machine when the pictures start. In addition to pictures taken while you are doing the tasks, another series of pictures will be taken for a more detailed image of your brain. During this time you will be asked to simply lie still.
You may close your eyes during this time. Depending on which tasks you will be asked to complete, the entire imaging procedure may last between 60 and 90 minutes.

Description of EEG:

While you are doing a mental task (such as listening to a sound), small electrical discharges occur inside your brain and these can be recorded by electrodes or small sensors placed on the head. We will record the weak electrical signals produced by your brain on the scalp. The procedure is called electroencephalography, or more commonly, EEG.

Before the EEG, we may ask you to rub your scalp using a disposable hairbrush. You will sit in a chair and a number of small sensors, or electrodes (128) will be placed on your scalp in a kind of hairnet or a nylon cap. These electrodes do not make direct contact with your scalp. To make this connection, there will be gel inserted between the electrodes and the scalp. Once the EEG net is in place, you will be connected to a recording device called an EEG machine. Then you will be asked to sit as still as possible while doing some simple tasks or playing computer games, which will be explained to you.

After you complete the computer tasks we may take several digital pictures of your head from many different angles at the same time. This process is called photogrammetry and it allows us to model, or remember, the sensor locations on your scalp. After the digital photographs are taken, the EEG net will be removed. If your net used wet sponges, your hair will be damp, and a hairdryer will be available for your convenience. There may be some gel left in your hair, but it can easily be washed out with warm water.

Behavioral Tasks in the scanner:

You will be asked to complete any one or more of the following tasks during each MRI scan session and each EEG recording session.

□ *Go/NoGo Task:* Involves you naming colors that you see flashing on a computer screen before, during, and after the scan.

□ *Monetary Incentive Delay Task (MID):* Involves pushing specific buttons after seeing a message on a computer screen. This is sort of like a money-winning game and how well you do on this determines how much you get paid for that scan (either slightly more or slightly less than $95).

We are interested in the possible effects of vaping nicotine on the brain. Therefore, after the first task, if you are a Juul-user we will ask you to use the Juul device the way you normally do. Afterward, you will do the remaining tasks.

You will also be asked to fill out some questionnaires about thoughts, feelings and behaviors before the fMRI scan or EEG recording begins.

What are the risks and discomforts of participating?

EEG

There are no known risks of physical or psychological injury or inconveniences associated with EEG. The EEG techniques are completely safe and pose no risk to you. There may be some gel left in your hair, but it can easily be washed out with warm water.

Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to take pictures of the body. Millions of people have had MRI scans with no known safety issues. MRI uses a strong magnet, which can pull strongly on some metals. These metals must not be brought into the scan room. They could be pulled towards the magnet and cause serious injuries if they hit you. People entering the scan room must remove all metal from their body, clothing and pockets. This includes jewelry, hearing aids, watches, cell phones, keys, coins, and wallets. Some metal objects could also heat up during the MRI, burning you. Electrical devices such as pacemakers could go wrong or stop working. You must also tell us if you are wearing anything that could contain metal. For example, some medication patches have a metal backing. Some clothing can contain metal fibers that could also heat up during the MRI. We will therefore ask you to fill out an MRI safety form to check if you have anything in your body which might be dangerous in the MRI. It is very important that you fill out this form accurately and ask if you are unsure about anything.

During the MRI scan, you may feel uncomfortable or worried. When the MRI scanner is making pictures, it makes loud tapping, buzzing, and beeping noises. Without protection, this could damage your hearing. We will give you with earplugs and/or headphones to reduce the sound to a safe level.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a clinical examination. The scans performed in this study are not designed to find abnormalities. The primary investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a diagnostic evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the primary investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie solely with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The

images collected in this study are not a clinical MR exam and for that reason, they will not be made available for diagnostic purposes.

Nicotine vaping:

Only individuals who are already users of vaping devices will be asked to use their device. You should use your device as you normally would. If you are 18-20 years of age, we will provide a Juul device for your use, which will remain in the laboratory when you leave. You will use the provided device the same way as you normally would. If you feel any sickness or nausea from using your device, inform the research staff and we can stop the experiment.

There have been recent reported cases of severe lung (pulmonary) illness linked to "vaping" or e-cigarette use. These cases included symptoms such as coughing, shortness of breath, chest pain, fever, fatigue, nausea, vomiting, diarrhea, and/or abdominal pain. Some patients reported symptoms to have occurred over a few days and some reported to have occurred over a few weeks. Vaping-related disorders have ranged from mild to severe with hospitalization, intensive care with breathing machines and in some cases death. In most cases, but not all, people experiencing these symptoms were using cannabidiol (CBD) or marijuana (THC) e-liquids, and/or were using e-cigarette devices and e-liquids that were mixed at home or purchased off market (such as purchasing an e-liquid or device on the street, not from a licensed retailer).

The CDC has warned against using vaping e-cigarettes

The Center for Disease Control (www.cdc.gov) has issued the following information on vaping:

- The use of e-cigarettes is unsafe for kids, teens, and young adults.
- Most e-cigarettes contain nicotine. Nicotine is highly addictive and can harm adolescent brain development, which continues into the early to mid-20s.
- E-cigarettes can contain other harmful substances besides nicotine.
- Young people who use e-cigarettes may be more likely to smoke cigarettes in the future.
- Adults who do not currently use tobacco products should not start using e-cigarettes.
- If you do use e-cigarette products, you should not buy these products off the street (for example, e-cigarette or vaping products with THC or other cannabinoids).
- You should not modify e-cigarette products or add any substances to these products that are not intended by the manufacturer.
- Adult smokers who are attempting to quit should use evidence-based treatments, including counseling and FDA-approved medications. If you need help quitting tobacco products, including e-cigarettes, contact your doctor or other medical provider.

The e-cigarettes and e-liquid pods that we use in the current study are purchased only from a licensed retailer and do not contain CBD or THC. The pods we are giving you contain nicotine, solvents, and flavorings. At this time, we don't know what the risks associated with the use of the e-cigarettes and e-liquids, flavors, etc. that we use in this study are, and who might develop symptoms. If you agree to be in this study, it is mandatory, for your safety, that you only use the e-cigarette pods provided and do not attempt to hack or modify the e-cigarette device in any way.

E-cigarettes contain other chemicals besides nicotine including propylene glycol/vegetable glycol/vegetable glycerin. At this time, we do not know the risks associated with the propylene glycol/ vegetable glycerin that may in the fillers in the liquids used in this study.

It is important to note that there may be unforeseen risks (such as allergic reactions). We will be

using e-liquids that are freely available for purchase and the propylene glycol/vegetable glycerin doses will be what is available in these e-liquids. Some research has indicated that in large doses propylene glycol and vegetable glycerin can be harmful. If you experience any side effects, you can stop the session at any point. Research staff will monitor e-cigarette use during the 'lab.' session. If you feel any discomfort or need to stop for any reason, please let the researcher know.

The e-cigarettes and e-liquid pods that we use in the current study are purchased only from a licensed retailer and do not contain CBD or THC. The pods we are giving you contain nicotine, solvents, and flavorings. At this time, we don't know what the risks associated with the use of the e-cigarettes and e-liquids, flavors, etc. that we use in this study are, and who might develop symptoms. If you agree to be in this study, it is mandatory, for your safety, that you only use the e-cigarette pods provided and do not attempt to hack or modify the e-cigarette device in any way. **However, despite these safety measures, it is possible you could still be affected.**

We will assess your health at the intake to make sure you are healthy prior to participating and will continue to monitor your health closely during the study. If you experience any symptoms (such as abdominal pain, nausea, vomiting, diarrhea, cough, shortness of breath, chest pin) or other concerns, please let us know and let your doctor know promptly (right away). Go to the emergency room if your symptoms increase. You can stop the study at any point. If you feel any discomfort or need to stop for any reason, please let the research team know. The CDC requires the hospital to report to the State Health Department and the CDC cases of illness after using e-cigarettes. The report will contain the name and address of the person who is ill.

If you want access to cessation resources during any part of the study, you let study staff know. We can refer you to smoking cessation services at Yale Health.

There have been incidences of vaping devices exploding in the past. However, there has never been a known incidence of a Juul device exploding, and if the researchers or you feel that the device is not working properly, we will stop the study that day.

Other acute risks include irritation of the mouth and throat, dry cough at initial use and potential unpleasant taste if you do not like tobacco.

As with any nicotine product, there is a risk of addiction or progression of addiction due to Juul use.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
This study will not benefit you directly.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of how using Juul affects the brain and performance on certain tasks. These types of studies are beneficial to young adults for they help us better understand the patterns of nicotine vaping and how it may affect the brain.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

You will receive one payment after completion of each scan you are invited to participate in, for a total of 4 payments for Juul users and 2 payments for controls. In some extreme cases, we may partially compensate you for an interrupted session (for example, in case of a power outage at the MRI facility). The payment amounts are as follows:

You will be paid $100 per MRI scan or EEG recording. These payments will be constructed from $10 for completion of questionnaires, $40 from the MRI session plus up to $10 winnable from the MID task, and $40 for your time (and inconvenience and discomfort of nicotine abstinence for 8 hours beforehand). You will be paid a bonus of $10 for completion of all visits.

Payment for completing the full study if you are a Juul user will be approximately $410 for all four visits (depending upon the results of the MID task), and if you are a control, payment will be approximately $210 for the two visits (depending upon the results of the MID task).

What are my choices if I decide not to take part in this study?

If you decide not to take part, it will not affect you in any way. This is not a treatment study. The alternative is not to participate, or to seek other research studies in which you may be interested.

In case of injury:

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine does 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.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

During the course of this study, we will be collecting all kinds of identifiable information including protected health information (PHI) such as your name, pictures of your head from photogrammetry, and contact information, and medical and mental health history.

The information we collect from you such as assessment, pictures, screening, and interview data may be recorded on paper, password-protected computers, and on a shared server with

limited access to approved research staff. While you are participating in this study, some data such as from scans and assessments may, when possible, be identified by your subject number rather than by name. In this case, a 'key' file will record the identity of the subject numbers and is kept in a secure fashion either in a locked cabinet or an encrypted password-protected file stored on a password- protected computer. However, other information such as screening information will remain identified by name indefinitely. After this study is terminated, the data we collected will be de- identified. This means that we will remove all information that may be used to identify you. The pictures of your head will be deleted.

Your identity and information about you will not appear in any publication or be released to anyone without your written consent. Our research group is interested in multidisciplinary research and collaborates with other research groups on a number of projects. If you participate in multiple research studies in which Kristen Morie is involved (either as principal investigator or co-investigator), we may coordinate the sharing of information (data relating to various assessments, demographics, MRIs, etc.) across research studies and with the other research groups involved with your consent. Identifiers might be removed from the identifiable private information or identifiable biospecimens (such as MRI images or EEG data) and, after such removal, this EEG or MRI information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. However, at all times, access to information collected about you, including PHI, will be strictly limited to study personnel and others approved to have access to your data.

Despite the safeguards mentioned above to protect your confidentiality, we may have to release identifying information about you under certain circumstances. For example, medical information may be disclosed in cases of life-threatening medical emergency, or steps may be taken (including notifying authorities) to protect you or someone else (including children and elders) from serious harm.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal,

state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Use of illegal drugs or the study of illegal behavior
    - Records about any study drug you received

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Board (consisting of the PI and associated members of the board)
- The Study sponsor: The National Institute on Drug Abuse (NIDA)
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about Juul involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.

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 website will include a summary of the results. You can search this website at any time."

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Health monitoring for safety:

We will assess your health at the intake of this study to make sure you are healthy prior to participating and will continue to monitor your health via questionnaires during the study. If you experience any symptoms (such as abdominal pain, nausea, vomiting, diarrhea, cough, shortness of breath, chest pin) or other concerns, please let us know and let your doctor know promptly. (right away). Go to the emergency room promptly if your symptoms increase. You can stop the study at any point. If you feel any discomfort or need to stop for any reason, please let the research team know. The CDC requires the hospital to report to the State Health Department and the CDC cases of illness after using e-cigarettes. The report will contain the name and address of the person who is ill.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

However, this is a double blinded treatment study and if you sign this permission form, you will not be allowed to look at or copy your study related information (for example, if you received a nicotine free pod or a nicotine pod an a given day) until after the research is completed.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven Hospital. You may withdraw your permission by telling the study staff or by writing to the principal investigator, *Kristen Morie, Ph.D. 1 Church St 7th Floor, New Haven, CT 06519.*

If you withdraw your permission, you will not be able to stay in this study. When you withdraw from the study, no new health information identifying you will be gathered after that date.

What if I want to refuse or end participation before the study is over?

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future.

The researchers may withdraw you from participating in the research if necessary and if this happens we will advise you of the reasons for the withdrawal.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

This authorization to use and disclose your health information will never expire unless and until you change your mind and revoke it.

What will happen with my data if I stop participating?

Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?

Please feel free to ask about anything you do not understand and please consider this research and the consent form carefully before you decide whether or not to participate. You may take as much time as necessary to think it over. If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203 737 6473

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Permission to Contacted for Future Research

I give permission for Yale research staff to approach me or to contact me in the future regarding other research studies I may be eligible for. (Please initial below your preference).

Yes _____
No _____

I understand that by agreeing to or declining this option in no way affects my eligibility for the present study.

Name of Subject:_____

Signature:_____Date:_____

_____ _____
Signature of Person Obtaining Consent or PI Date

Research Authorization and Permission:

I have read, or someone has read to me this form and have decided that I,

_____(name of participant), will participate in the project described above. The purpose of the study, the procedures involved, and the possible risks and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form or that I have declined the offered copy.

_____
Signature

_____
Date

_____ _____
Signature of Person Obtaining Consent Telephone

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Kristen Morie, at (203) 737-6473. If you have any questions concerning your rights as a research subject, or you have complaints about this research, you may contact the Human Investigation Committee at (203) 785-4688 or hrpp@yale.edu.

If after you have signed this form you have any questions about your rights, please contact the Yale Privacy Officer at (203) 436-3650.