Document Coversheet

Study Title: Neurobiological Factors Underlying Sex Differences in Risk for Alcohol Abuse

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KEY INFORMATION FOR NEUROBIOLOGICAL FACTORS UNDERLYING SEX DIFFERENCES IN RISK FOR ALCOHOL ABUSE:

We are asking you to choose whether or not to volunteer for a research study about the influence of sex (male/female), sex hormones, and menstrual cycle phase on the brain's response to alcohol. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to investigate the influence of sex (male/female), sex hormones, and menstrual cycle phase on the brain's response to alcohol. The study will use functional magnetic resonance imaging (fMRI). This technique will allow us to visualize which parts of your brain become active during certain kinds of mental tasks, and under the influence of a moderate dose of alcohol (breath alcohol concentration (BrAC) = 60 mg/dl; 0.06%). By doing this study, we hope to learn about the relationships between sex, sex hormones, and menstrual cycle phase and the brain's response to alcohol. Your participation in this study will consist of 5 lab visits. Your first lab visit is an orientation session and will not involve any alcohol administration. This session requires 1 hour to complete. The 4 brain imaging sessions will require 4 hours each. During each session, you will receive either alcohol or saline through a vein in your arm. If you receive alcohol during a session, your blood alcohol concentration must fall below 0.02% before you may leave. This has been considered in determining the length of your sessions. If you are a female, sessions will be scheduled based on your menstrual cycle. The study will last a maximum of 3 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. You can withdraw from the study at any time. If you experience pain or feel bad during the study, you may stop. Trained medical professionals will perform all tests. For a complete description of potential benefits, refer to the Detailed Consent that follows.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You could experience discomfort during the MRI because you will need to lie still in a small space for one hour. You may also experience pain or discomfort when the catheter is inserted for the blood draws and IV-infusions. There is a possibility that you could feel sleepy or nauseated from the alcohol administration. For a complete description of risks, refer to the Detailed Consent that follows.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. If you decide to take part in the study you still have the right to decide, at any time, that you no longer want to continue. There are no risks to you if you decide to end the study early. However, if you have received alcohol during a session and then decide you no longer wish to continue, you will be required to remain in the laboratory until you no longer feel any drug effects, and your breath alcohol concentration (BrAC) falls to 0.02%, and the research staff judges you safe to leave. Treatment referrals may also be offered at this time and will include psychological services such as the Harris Center at 859-257-6853.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Jessica Weafer, Ph.D. of the University of Kentucky, Department of Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 859-257-4468 (phone) and jweaf2@uky.edu (email).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will be excluded from participation in this study if you have any serious medical or psychiatric condition, including drug or alcohol use disorder, any medical or psychiatric condition requiring medication, or contraindication for fMRI (e.g., metal implants). You will also be excluded if your BMI is greater than 26 or less than 19, and if you are less than 21 or older than 29 years old. You will also be excluded if you smoke more than 5 cigarettes per day, and if you are pregnant, lactating, or using hormonal contraceptives, or if you arrive at the lab with a non-zero blood alcohol level or test urine-positive for other psychoactive drugs.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky in the Department of Psychology (Kastle Hall), the Clinical Research Unit (CRU), and the Magnetic Resonance Imaging and Spectroscopy Center (MRISC). Your participation in the study consists of 5 lab visits. Your first lab visit is an orientation session and requires 1 hour to complete. The 4 brain imaging sessions will last 4 hours each. The total amount of time you will be asked to volunteer for this study is approximately 17 hours over the next 3 months. If you receive alcohol during a session, your blood alcohol concentration must fall below 0.02% before you may leave. This has been considered in determining the length of your sessions. If you are a female, sessions will be scheduled based on your menstrual cycle.

WHAT WILL YOU BE ASKED TO DO?

Screening

You will undergo a brief interview to determine whether you are fully eligible to participate in the study. The interview will consist mainly of questions regarding your health, mental conditions, and substance use. If you are pregnant or breast-feeding, you cannot participate in this study. It will be necessary that you have a urine pregnancy test to determine whether you are pregnant. If you are a female and are sexually active with male partners, you must agree to take precautions to avoid the possibility of impregnation, because the effects of alcohol will affect an unborn child. If you become pregnant during the course of the study, you must notify the principal investigator of this fact as soon as possible. Furthermore, you cannot be taking other drugs such as amphetamine, cocaine, etc. while participating in this study. Therefore, your urine sample will also be tested for illicit drugs and you will be disqualified if you have a positive result.

Orientation Session

During the 1-hour orientation session, you will read and be asked to sign the consent form and to complete the MRI scanner safety questionnaire. You will receive instructions about recreational drug use before the brain imaging sessions, complete questionnaires, and practice study tasks so that you are familiar with the experimental measures. If you are a female, you will complete a guided calendar-based interview to determine the average length of your menstrual cycle. This information will be used to schedule your brain imaging sessions, as they must occur at certain times during your menstrual cycle. You will also be given an at-home urinary ovulation tests and will receive instructions on how to use the tests to monitor your cycle phase at home. You will take pictures of the tests and send the pictures to a member of the research team via text message. Text messaging data rates for these messages may apply.

Brain Imaging Sessions

You will participate in 4 brain imaging sessions that will last for 4 hours each. These sessions will be scheduled in pairs. The two sessions in each pair will be 24 to 48 hours apart, and the pairs will be separated by 7 to 21 days. The sessions will begin in the Psychology Department (Kastle Hall). Prior to each of these sessions, you must abstain from alcohol for 24 hours. You will provide breath and urine samples to detect recent alcohol and drug use and pregnancy. If you test positive for alcohol or drug use or pregnancy you will be withdrawn from the study. You must also fast for 2 hours before each session.

If you are able to participate, you will complete mood questionnaires and computer tasks in Kastle Hall. You will then be escorted to the Clinical Research Unit (CRU) located in the hospital, where a nurse will place a catheter (a hollow, flexible tube) in a vein in your arm in order to administer the substance. The nurse will also collect a blood sample (about 1.5 tablespoons) to assess hormone (estradiol, progesterone, and testosterone) levels.

You will then be escorted to the University of Kentucky Magnetic Resonance Imaging and Spectroscopy Center (MRISC) where you will undergo an fMRI scan that will last for approximately 1 hour. During the scan, you will receive an injection through the tube in your vein that will contain either alcohol or saline. You will perform a reaction time task in which you will be asked to respond as quickly as possible when a 'go' target appears and to stop that response when a 'stop' signal occurs, as well as a resting state task in which you will relax in the scanner while looking at a simple picture for a few minutes. You will also be asked to rate your mood and any drug effects you may be feeling. After the scan is completed, the nurse will collect a second blood sample (about 1.5 tablespoons) to assess change in hormone levels. The nurse will then remove the tube from your vein.

MRI Scanning. There are two parts to the MRI scans. One part is to take a picture of how your brain looks physically. The other part is to visualize which parts of your brain become active while you perform a computer task. For the MRI scans, you have to lie down on a table while a large machine makes images of your brain. You will undergo the MRI scan sessions on a 3T MRI Imaging System at the MRISC at the University of Kentucky. The scan does not hurt, but the machine makes a loud noise and you must lie still on a small table. You will be in the scanner for approximately 1 hour. The scan will be done by staff at the MRISC at the University of Kentucky.

After the scan you will be escorted back to Kastle Hall. If you received alcohol, you will be required to remain in the lab area until your breath alcohol concentration falls to a safe level of 0.02%. This time has been considered in determining the overall session length of 4 hours. You may relax in our lounge area. For your comfort, you will be seated in a room with a couch, TV, DVD player, XBOX, and magazines. You will also be provided with nonalcoholic beverages and snacks.

It is very important that you do not drive after leaving any session. If you live off-campus and are not in walking distance to the study, you should make arrangements for a ride to, and from, the session. You cannot drive to a session because you cannot drive upon leaving the session. If you require transportation home after a session, and do not have a ride, transportation will be provided for you at no cost.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

MRI Scanning: You will be exposed to magnetic fields during this study. Simple exposure to magnetic fields presents very low risk. You will be exposed to approximately the same level of exposure as flying in an airplane on a cross-country trip. There could be risk to you if you have metal inside your body (such as a pacemaker, shrapnel, or artificial valves) or if you are wearing any metal objects during the scan. Metal could be powerfully attracted or heated by the magnet causing injury. You will be asked questions about this possibility in order to make sure that the MRI scan is not a risk for you. For your safety you will be asked to remove any metal before the scan (for example, belts and rings). If you have implanted metal of any kind, you will not be scanned. The scans will be performed in a facility built for these types of studies. You may experience anxiety due to the closed-in space of the scanner or because it makes a loud noise. You will be given noise-dampening headphones to prevent discomfort due to the noise. In rare cases a slight tingling on your skin or on your back has been reported, and if you have this sensation, you are asked to report this immediately. You may discontinue the scan at any time if you are too anxious to continue. You can do this by telling the scanner operator that you would like to end the scanning session.

The MRI scanning procedures are experimental, but they follow the guidelines established by the U.S. Food and Drug Administration for MRI scanning. Care will be taken to avoid all known risks associated with MRI. However, this procedure may involve risks that currently are not anticipated. You will not receive any medications to relax you as part of the scan, nor will the scan involve any X-ray or radioactive materials. The MRI scans being done are designed only for our research purposes and not optimized for finding brain abnormalities. These scans are not a substitute for a medical MRI that a doctor would order. Therefore, our MRI scans may not show problems that would be picked up by a medical MRI scan. Also, the investigators on this project are not trained to find abnormalities on an MRI scan. However, if we believe that we have found a medical problem or something abnormal in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care doctor, we can contact your doctor, with your permission, and inform him or her of the finding on the MRI scan and help him or her get the right follow-up for you. If you do not have a primary care doctor we will provide you with a referral list of physicians in the area. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician.

Alcohol Administration: The risks associated with the alcohol administered in the study do not go beyond those associated with moderate alcohol intoxication (i.e., a little sleepiness at the end of the study). Given the dose used in this study, it is a very rare occurrence that an individual will experience either nausea or vomiting. If you

feel nauseated at any time, you should immediately inform the study technicians by squeezing a signal bulb that we will place in your hand, and the study and substance administration will be stopped.

Catheter Insertion: The risks associated with the catheter insertion and blood draw include soreness, bruising, pain, infection, possible fainting, and bleeding. Great care will be taken to avoid these complications.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect. We will do what we can to alleviate any distress that you might experience as a result of this study. A research staff member will be immediately available to address these issues and you will have telephone contact information to reach the study investigators and the study physician.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, you will have a better understanding of brain and behavior research and knowledge about how such research is conducted.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

Participation in this study involves no financial costs to you or your third-party insurance provider.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. Every effort will be made to maintain the confidentiality of your study records. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential, unless you give prior written approval. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your name, address and social security number will be listed on the receipt for payment that you receive, as required by the Internal Revenue Service; but no information about your participation in this research project will be released. Officials of the Food and Drug Administration, the National Institutes of Health, and the University of Kentucky may look at or copy pertinent portions of records that identify you. However, it is the policy of these agencies and of these investigators that every attempt will be made to resist demands to release information that identifies you. When results of this study are published, your name will not be used.

Certificates of Confidentiality (CoC):

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 specimens 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 specimens 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. 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.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

There are no risks to you if you decide to end the study early. However, if you have been administered alcohol, you will still have to wait in our laboratory until your breath alcohol concentration has decreased to 0.02% and the research staff judges you safe to leave. Transportation home will be provided as needed.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lon Hays, M.D. at 859-323-6021 immediately. Lon Hays, M.D. will determine what type of treatment, if any, that is best for you at that time. If it is an emergency, you should contact the 24-hour on-call physician by calling 859-226-7063 or paging 859-330-2216.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $75 for each brain imaging session that you attend plus a $100 completion bonus, for a total of $400. If you do not complete the study either because you were excluded from participation or because you chose to terminate the procedure, you also will receive payment for sessions completed. Payment will be provided in the form of a check. Record of the payment will be recorded for income tax purposes.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by Lon Hays, M.D. to determine if it is in your best interest to contact you. If so, Jessica Weafer, Ph.D. will contact you using the information you provided. With the help of a medical specialist, she will present possible risks or benefits of receiving the

information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, call Dr. Jessica Weafer (859-257-4468).

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 5 times per year.

Do you give your permission to be contacted in the future by Dr. Jessica Weafer's lab regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 60 people to do so at the University of Kentucky. NIH is providing financial support and/or material for this study.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website 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.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.

STORING AND SHARING YOUR INFORMATION FOR FUTURE USE:

We would like to store, use, and share your study-related health information (i.e., task performance, brain activity, hormonal, and demographic data) for future research. Having information from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information to learn more about risk for addiction or research additional scientific questions.

WHERE WILL INFORMATION BE STORED AND FOR HOW LONG?

The information will be stored at Kastle Hall indefinitely.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION TO BE STORED FOR FUTURE RESEARCH?

Physical:

There is no additional physical risk.

Privacy and Social/Psychological:

There is a risk that someone could get access to the stored information. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Unknown:

There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

We will take careful steps to keep your information confidential. All paper records will be kept in locked file in the Principal Investigator's office, which will remain locked. All electronic data will be stored on password protected databases on secure servers.

We will remove your name or other direct identifiers from your information. We will label your information with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

We will store your identifiable information, in a password-protected database.

The staff follow procedures to keep your identity a secret to the extent allowed by law. In very unusual cases, staff may be required to release your identifiable medical and research information in response to an order from a court of law. Officials of the Food and Drug Administration, the National Institutes of Health, and the University of Kentucky, may look at or copy pertinent portions of records that identify you.

HOW WILL WE SHARE YOUR INFORMATION WITH OTHER RESEARCHERS?

The researchers requesting access to information must sign an agreement. The researchers who receive your information will sign an agreement to use the data responsibly.

Before sharing your information, we will remove identifiers such as (e.g., your name, medical record number, or date of birth). Your de-identified information may be shared with other University of Kentucky (UK) researchers and researchers outside of UK, without your additional informed consent. We will use a process to track information shared without releasing your identity.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION?

You may withdraw your permission to allow your information to be used for future research. To do so, you must send a written withdraw request to Dr. Jessica Weafer, 171 Funkhouser Dr., 205 Kastle Hall, University of Kentucky, Lexington, KY 40506-0044.

We will destroy any remaining information that has been stored. In addition, it may be possible to destroy the code that links you with your information. However, we cannot withdraw the information that has already been used.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

OPTIONAL FUTURE USE:

Do you give permission for Dr. Jessica Weafer to store your information for future research? ☐ Yes ☐ No

Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information stored for this investigator's future research.

AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information, including age, sex, race, and ethnicity
- Hormone levels from blood samples
- Pictures of your brain from the fMRI
- Medical history information related to study. We will not access your medical records directly, but we will request information about your medical history from you during the screening process.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK Hospital;
- Food and Drug Administration (FDA);
- National Institutes of Health (NIH);
- Investigational Drug Service (IDS);
- Center for Clinical and Translational Science (CCTS);
- The primary physician, Dr. Lon Hays, will be contacted if the researcher, in the course of the project, learns of a medical condition that needs immediate attention.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Dr. Jessica Weafer, 171 Funkhouser Dr., 205 Kastle Hall, University of Kentucky, Lexington, KY 40506-0044 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent and HIPPA authorization	_____ Date
_____ Signature of Principal Investigator or Sub/Co-Investigator	