University of Alabama at Birmingham

Please complete this checklist and submit to WCG with your submission

Any deviation from the language contained within this document requires pre-approval from the UAB IRB Office. If written approval is not provided the language deviations will be removed.

**Please note: Purple text = site to determine if applicable to study. Please complete fill-in fields if applicable**

**Blue text = WCG IRB can complete for you**

**Black Grey shaded text = must be included verbatim in your consent form as applicable. If different language is submitted to WCG IRB, it must be accompanied by sign-off from UAB IRB Office.**

**Purple Grey shaded text = If language is included in your consent form, it must be verbatim.**

|  |  |
| --- | --- |
| Drug Screening  Is this applicable to your study?    *Yes*  *(if yes, complete the language to the right)*  *No* | If you have used any illicit (street) drug(s) within [site will insert appropriate time frame], we ask that you not participate in this study. |
| Testing for Reportable Diseases  Is this applicable to your study?    *Yes*  *(if yes, complete the language to the right)*  *No* | As part of this study, you will be tested for [site will insert disease]. If the results show that you are positive for [site will insert disease], the study staff will tell you the results. The study staff will be required to give your name to the Alabama Department of Public Health if you test positive because this is the law.  Information obtained during the course of the study which, in the opinion of the investigator(s), suggest that you may be at significant risk of harm to yourself or others will be reportable to a third party and welfare of those at potential risk. If other protocol testing for reportable diseases is conducted, individuals will be informed of the results and told where to obtain counseling and referred to their primary care physician or the state health department. |
| Performing Research Only Imaging  Is this applicable to your study?    *Yes*  *No* | **INCIDENTAL FINDINGS**  We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge. |
| Pregnancy Discussion  Is this applicable to your study?    *Yes (complete information to the right)*  *No* | List specific acceptable methods of contraception if appropriate to the protocol and provide any additional language to be used in this section. |
| Randomization  Does your protocol involve randomization?    *Yes (complete information to the right)*  *No* | Include a paragraph on risks of randomization. All risks of all study arms must be described in detail in this section, even if the procedures in those arms would be standard of care if the participant was not in the study.  The following language will always be included:  You will be assigned to a group by chance which may prove to be less effective or to have more side effects than the other study group(s) or alternatives. |

|  |  |  |
| --- | --- | --- |
| Costs  Make the appropriate selection(s) to the right. | | Option A – Standard Language:  If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.  Option B – If a Category B medical device is used:  Your insurance company may or may not pay for the device(s) used in this study. Blue Cross Blue Shield of Alabama will not pay for Category B medical devices. Other insurance companies may also decline to cover these types of devices. Therefore, it is very important that you provide your current health insurance information to UAB and that you check with your insurance company about the costs of participation. |
| HIPAA  Is HIPAA applicable to your study?  *Yes*  *(if yes, complete the language to the right)*  *No* | Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.  **What protected health information may be used and given to others?**  All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.  Add if your study is a clinical trial:  Your medical record will indicate that you are on a clinical trial and will provide the name and contact information for the principal investigator.  Add if your clinical trial is or will be registered with ClinicalTrials.gov:  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.  **Who may use and give out information about you?**  Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.  **Why will this information be used and/or given to others?**  Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.  Add if genetic testing is applicable:  A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:   * Health insurance companies and group health plans may not request your genetic information that we get from this research. * Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. * Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.   Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.  Add if MSO Billing Compliance Language is applicable, and select appropriate option below -  Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of  UAB only: UAB and UAB Health System affiliated entities  Children’s only: Children’s of Alabama and its billing agents  UAB and Children’s: UAB and UAB Health System affiliated entities, along with Children’s of Alabama and its billing agents  so that claims for clinical services can be appropriately paid for by either the study account or by the patient/patient’s insurance.  The information from the research may be published in scientific journals or presented at medical meetings, but your identity will not be given out.  The information may be reviewed by WCG IRB. WCG IRB is a group of people who perform independent review of research as required by regulations.  **What if I decide not to give permission to use and give out my health information?**  By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.  **May I review or copy the information obtained from me or created about me?**  You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.  **May I withdraw or revoke (cancel) my permission?**  Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.  You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.  When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.  **Is my health information protected after it has been given to others?**  If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. | |
| Voluntary Participation and Withdrawal  Does this apply to your study?    *Yes (complete information to the right)*  *No* | If applicable, include anticipated circumstances under which the PI without regard to the participant’s consent may terminate the participant’s involvement (an example paragraph is below; however you should revise as applicable to the study).  *You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.*  If students or employees of UAB may participate in the study, the IRB recommends using the following language in the consent form:  *If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.*  **Insert Language to be used here:** | |
| Storage of Specimens for Future Use  Does this language apply to your study?    *Yes (complete information to the right)*  *No* | **Storage of Specimens for Future Use**  We would like your permission to keep your private information (data containing personal information) and biospecimens ([site will specify blood/specimen]) collected in this study for future research. The future research may be similar to this study or may be completely different. Your private information and biospecimens will be stored indefinitely or until used.    Your private information and biospecimens will be identifiable. Results of any future research will not be given to you or your doctor    You can take part in this study even if you decide not to let us keep your identifiable private information and identifiable biospecimens for future research.    If you give us permission now to keep your identifiable private information and identifiable biospecimens, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information and biospecimens, we may not be able to take it out of our future research.    We may share your identifiable private information and identifiable biospecimens, so that others can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your identifiable private information and identifiable biospecimens with other researchers, we will not be able to get it back.    [Site will indicate additional risks the future research may pose and describe efforts to minimize them.] Future research use of your identifiable private information and identifiable biospecimens will be conducted in compliance with applicable regulatory requirements.  You will not find out the results of the future research. Allowing us to do future research on your identifiable private information and identifiable biospecimens will not benefit you directly.    The identifiable private information and identifiable biospecimens used for future research may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.    Initial your choice below:    \_\_\_ I agree to allow my identifiable private information and identifiable biospecimens to be kept and used for future research on [site will specify disease or disorder].    \_\_\_ I do not agree to allow my identifiable private information and identifiable biospecimens to be kept and used for future research. | |

|  |  |
| --- | --- |
| Other special instructions | ***If specific language needs to be added anywhere else in the consent form-[Name] will list it out here.***  *[provide additional language, if applicable]* |