INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Study Title: A Study to Assess the Safety Tolerability and Effectiveness of NUEDEXTA (Dextromethorphan 20mg/Quinidine10mg) in the Treatment of Pseudobulbar Affect (PBA)

Protocol / Study #: 12-AVR-401

Sponsor: Avanir Pharmaceuticals, Inc.
20 Enterprise, Suite 200
Aliso Viejo, California 92656
Study Phone: 855-468-3339

Investigator Name: **RicardoR.PardoMD**

Research Site Address(es):
Jacinto Medical Group PA
2800 Garth Rd
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Daytime telephone number(s): 281-425-3805

24-hour phone number(s): 281-425-3800

Note to Participant

- In this Informed “ConsentForm,” “you” and “your” always refers to the study participant.
  If you are a legally authorized representative, please remember that “you” and “your” refers to the study participant.
- If you are the legally authorized representative and the caregiver, please be aware you will need to sign both this InformedConsentForm as well asthe CaregiverInformedConsentForm.
- This InformedConsentForm may contain words that you may not understand. Please ask the study doctor or other study staff to explain any words that you may not clearly understand.

- Before agreeing to take part in this research study, you should take your time to carefully read this InformedConsentForm.
- You may take an unsigned copy of this InformedConsentForm to review and discuss with your family and friends before making your decision.
- Before you decide to take part in this research study, it is important for you to understand why the research is being done and what it will involve. Take time to decide whether or not you wish to take part.
- If you sign this form, it means that you agree to take part in this study. This form describes what the study is about and what will happen. It also tells you about the risks and benefits of the study.
- You can change your mind about taking part in this study at any time. You may leave the study at any time, even if you have signed this form. You do not have to give a reason.
- You will receive a signed and dated copy of this InformedConsentForm for your records. Keep it in a safe place as you may wish to refer to some of the information during your participation in the study.

Invitation to Take Part

You are being asked to take part in a research study of NUEDEXTA because you have had a Stroke, have Dementia, or have had a Traumatic Brain Injury and have also been diagnosed with probable Pseudobulbar Affect. NUEDEXTA has been approved for the treatment of Pseudobulbar Affect symptoms by the U.S. Food and Drug Administration (the "FDA"). Pseudobulbar Affect symptoms of uncontrollable crying or laughter can be difficult to manage and can impact your quality of life.

This "Consent Form" describes the study and your role in it. The Investigator (the "study doctor" whose contact information is noted on the first page of this Consent Form) has reviewed the study and has agreed to participate as a study investigator. The Investigator will answer any questions you have about this study or this Consent Form. You are to read this form carefully and ask any questions you have regarding the information it contains.

Your decision to take part is voluntary and you may refuse to take part, or choose to stop taking part, at any time. A decision not to take part or to stop being a part of the research study will not change the services that are available to you from the Investigator. The Investigator or Avanir may also stop your participation in the study at any time (e.g. if you fail to follow your doctor's instructions, if you experience a serious study treatment side effect, if your medical condition gets worse). Avanir may stop this study at any time for reasons it determines are appropriate. If you decide to withdraw from the study you should contact the Investigator immediately.

If during the course of this study, new information is discovered about the study medication that could influence your willingness to take part, the Investigator will let you know about it in a timely manner and discuss it with you.

Study Purpose

NUEDEXTA is developed and marketed by Avanir Pharmaceuticals (the sponsor of the study) for the treatment of Pseudobulbar Affect ("PBA"). This study will add to the current clinical evidence which was gathered in amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS) patients and reaffirm NUEDEXTA is effective, safe and well tolerated.

Approximately 750 participants at approximately 150 study centers in the U.S. are expected to participate in this research study. If you agree to participate in this study, you will take NUEDEXTA capsules for 3 months (90 days). You will be allowed to continue taking other medications required to manage your Stroke, Dementia or Traumatic Brain Injury while you are participating in this study.

If you are deemed eligible and agree to participate in this study, you will be assigned at the Baseline visit to receive NUEDEXTA (the "study medication"). You will take one capsule of the study medication orally (by mouth) daily from Day 1 through Day 7. You will take 1 capsule twice daily for the remainder of the study (total of 3 months). All participants receiving study medication will start at NUEDEXTA (20mg of dextromethorphan and 10mg of quinidine) once a day and be escalated up to NUEDEXTA (20mg of dextromethorphan and 10mg of quinidine) twice a day. All 3 months of the study medication NUEDEXTA will be provided for you free of charge.

Known Information about the Study Medication and Related Drugs

The study medication, NUEDEXTA, is a combination of two drugs called dextromethorphan and quinidine. Dextromethorphan is a drug that is available without prescription as an over-the-counter cough medication and has been in use for over 50 years.

Quinidine is one of the oldest prescription drugs still in use. It is used to treat abnormal heart rhythms (arrhythmias). The usual dose used to treat arrhythmia is 600mg to 1600mg per day. The total daily dose of quinidine in this study is 20mg per day, which is much lower (30-80 times lower) than the dose normally used to treat cardiac arrhythmias.

A Description of Study Participants

To be considered for participation in this study you must meet certain criteria. You must:

- Be at least 18 years old;
- Give written informed consent;
- Have a diagnosis of probable Pseudobulbar Affect and have received a screening score of 13 or greater on the CNS-LS,PBA symptom screen; and
- Understand the study instructions, and be able to follow the study instructions.

If you are a woman who can have children, the study doctor will talk to you about the risk of becoming pregnant while being treated with NUEDEXTA. Also, if you become pregnant while participating in the study, the sponsor of the study may need access to your medical records regarding your pregnancy and the outcome of your pregnancy.

There may be other reasons for your ineligibility to participate in the study. The study doctor or the study staff will discuss these reasons with you, your legally authorized representative and your caregiver.

Study Procedures

This section describes in detail the tests and procedures that will occur at each of the 4 study visits over a period of approximately 3 months.

You understand that if you currently use any medications (including vitamins, over the counter medications or herbal supplements) you need to tell the study doctor about them.

After you and/or your legal representative give consent to take part in the study, you will be examined by your study doctor to see if you qualify for the study. Before entering the study, as well as during the study, you will undergo a number of examinations (tests).

You and/or your caregiver will also be given instruction on what constitutes (signs and symptoms) a "PBA episode". Each visit you and/or your caregiver will need to recall the number of PBA episodes over the course of the previous week.

Screening / Baseline Visit

Your first screening or baseline visit will last up to 1 hour and the study doctor will assess your illness. The following tests will be performed*before* you receive study medication:

- Review and sign the Informed Consent Form (the form you are currently reading).
- Recording of your medical history and current medications.
- Vital Sign collection and recording (measurements such as blood pressure, body temperature, heart rate, height and weight).
- The CNS-LS test questions will be completed by either the patient or the caregiver.
- Patient PBA Episode count from the previous 7 days (patient or caregiver recall).
- A Patient Health Questionnaire (PHQ-9) and exploratory diagnostic question will be completed by patient or caregiver and measured.
- The Quality of Life (QOL) Visual Analog Scale (VAS) will be completed by patient or caregiver.
- Disease specific functional questionnaires (stroke – SIS; TBI – NFI) will be completed and the results will be recorded.
- Cognitive function measures (MMSE) will be completed and the results will be recorded.

If you are eligible to take part in the study based on the results from this screening visit, the study doctor will schedule your Visit 1 appointment within 4 weeks of this screening.

You will receive your study medication.

Visit 1 (Day 30)
Visit 1 will last up to one hour. The following tests will be performed:

- Patient History and Vital signs will be measured and recorded.
- You and your caregiver will be asked about any adverse events (AEs) and concomitant medications use (including OTC medications, vitamins, and supplements).
- The CNS-LS form will be completed.
- The previous week's PBA episode count will be recorded.
- PHQ-9 (the health questionnaire) will be completed and measured.

You will be asked if you have taken your study medications as instructed. You will receive your study medication for the next 60 days.

You will receive a telephone call in 30 days and this telephone call will be your second study visit (Visit 2 - Day 60).

Visit 2 (Day 60) – Telephone Visit
This telephone call visit should last about 5 minutes. The following will be performed at this visit:

- You and/or your caregiver will be asked if you had taken your study medications as instructed.
- You and/or your caregiver will be asked about any adverse events (AEs) and concomitant medication use (including OTC medications, vitamins, and supplements).

You will return to the clinic 4 weeks later for your final study visit (Visit 3 - Day 90).

Visit 3 (Day 90)
This visit should last approximately 1 hour. The following tests will be performed at this visit:

- You and/or your caregiver will be asked if you had taken your study medications as instructed.
- Patient History and Vital signs will be measured and recorded.
- You will be asked about concomitant medications (including OTC medications, vitamins, and supplements).
- You and or your caregiver will complete a CNS-LS form.
- You and or your caregiver will be asked to recall the previous week's PBA episode count.

- PHQ-9 (the health questionnaire) will be completed
- You will be asked to complete a Quality of Life Visual Analog Scale (QOL VAS).
- You or your caregiver will be asked to complete a Patient Global Impression-Change questionnaire.
- The Clinician Global Impression-Change measure will be completed and recorded.
- You or your caregiver will be asked to complete a Patient Treatment Satisfaction Survey.
- You and or your caregiver will be asked about any adverse events (AEs).
- Disease specific functional questionnaires (stroke – SIS; TBI – NFI) will be completed and the results will be recorded.
- Cognitive function measures (MMSE) will be completed and the results will be recorded.

For a full schedule of visits and procedures, see Table 1 below.

Table 1 Study Schedule

Procedure	**Visit:**	**Baseline**	**Visit 1**	**Visit 2**	**Visit 3**
	Study Day:	**Day 1**	**Day 30**	**Day 60**	**Day 90**
	End of Study Week:		**Week 4**	**Week 8**	**Week 12**
Informed Consent Form(s) Signed		**X**			
Medication History		**X**			
Review of Inclusion and Exclusion Criteria		**X**			
Patient History		**X**			
Capture Vital Signs		**X**	**X**		**X**
PHQ-9		**X**	**X**		**X**
CNS-LS		**X**	**X**		**X**
Episode Count		**X**	**X**		**X**
Exploratory Diagnostic Question		**X**			
MMSE		**X**			**X**
QOL VAS		**X**			**X**
Review Concomitant Medication		**X**	**X**	**X**	**X**
Clinical Global Impression-Change					**X**
Patient Global Impression-Change					**X**
Patient Treatment Satisfaction Survey					**X**
Dispense Study Medication		**X**	**X**		
Review of Adverse Events			**X**	**X**	**X**
Disease Specific Functional Questionnaires					
Stroke- SIS		**X**			**X**
TBI – NFI		**X**			**X**

You and your caregiver will be instructed to contact the study doctor whose name is on the first page of this Informed Consent Form, if you experience any sickness or health problem within 30 days after the final clinic visit.

After this study is completed, you and your caregiver should talk to your doctor about your future and ongoing treatment.

Early Termination

If you stop taking the study medication before completing the last treatment visit for any reason (such as, the study doctor feels it is in your best interest, you decide not to continue, or the study is stopped) you will be asked to return to the study site for a final visit to undergo the procedures described in Visit 3 (Day 90). You will be required to return all unused study medication.

Your Responsibilities

While you are in the study you should:

- Keep all scheduled appointments.
  You may be asked to return to the clinic for more visits and/or tests as determined by your study doctor.
- Take the study medication exactly the way the study doctor tells you and call the study doctor if you have any questions about how to take the study medication. You should not stop taking the study medication without talking to the study doctor first.
- Do not give the study medication to anyone else. Only the study participant can take the study medication.
- Keep the study medication out of the reach of children and persons who may not be able to read or understand the label.
- Tell your study doctor or study staff about any changes in your health even if you think they are not important.
- Tell the study doctor or study staff about any other medicines that you take, even if it is medicine that you buy without a prescription, vitamins, and supplements.
- Inform the study doctor or study staff you move or change your phone number during the study.
- Tell the study doctor of study staff if you want to stop being in the study.
- If you think you are or might be pregnant during the study, you must tell the study doctor or study staff immediately. The study doctor will again explain the risk of NUEDEXTA treatment during pregnancy. The study doctor may share this information with the sponsor.

Risks and Discomforts

Your symptoms of PBA may not improve or may worsen if you take part.

Participation in this study involves some possible risks or discomforts, which are outlined below.

NUEDEXTA

Side effects reported in people who have taken NUEDEXTA were similar to those that might be expected from taking either drug (dextromethorphan or quinidine) by itself. The side effects reported in people who have taken NUEDEXTA are listed in Table 2.

Table 2 List of Side Effects Reported in People Treated with NUEDEXTA

Most Common >10%	**Common 5-10%**	**Uncommon, but related 1-5%**
Dizziness	Cough	Urinary tract infections
Diarrhea	Vomiting	Influenza
	Asthenia (weakness)	Flatulence (gas)
	Peripheral Edema (swelling)	

Dextromethorphan Alone

The most commonly reported side effects of dextromethorphan alone are similar to the most common effects seen with NUEDEXTA and are captured in Table 2 above.

Rare but severe, side effects of dextromethorphan alone include:

- Respiratory depression
- Seizures
- Coma

A rare but severe, life-threatening side effect of dextromethorphan is serotonin syndrome, a potentially life-threatening reaction that causes the body to have too much serotonin, a chemical produced by nerve cells. This risk is increased if taken with other medications known as serotonin-specific reuptake inhibitors (SSRIs) or tricyclic antidepressants.

Quinidine Alone

The most common reported side effects in people given doses of quinidine to treat arrhythmia which are not listed in Table 2 above include:

- Headache
- Chest pain or discomfort
- Rash
- Visual disturbances
- Poor coordination (difficulty moving)
- Hearing loss
- Change in sleep habits

Rare but severe, side effects of quinidine include:

- Jaundice (yellowish color pigmentation of the skin)
- Decrease of platelets in the blood
- Vasculitis (inflammatory destruction of blood vessels)
- Lupus-like syndrome

Rare but severe, life-threatening side effects of quinidine include complications affecting the heart, liver, joints, blood, or other organs such as:

- Swelling and inflammation of the liver
- Changes to your heart rate

Quinidine can also cause serious cardiac complications possibly resulting in death in people who have certain ECG abnormalities such as prolonged QT interval (a measurement related to heart rate). Should you be at risk for QT prolongation you will be given an ECG screening in advance of your inclusion in the study.

Other medications may interact with the study medication that may change the study or lead to unexpected side effects. Because of this, some medications may not be allowed to be taken during the study.

The study doctor should be contacted before you take any non-study medications including prescription medications, over-the-counter medications and herbal products available without a prescription.

Allergic reactions are possible. If you have any symptoms of an allergic reaction, such as rash, hives, or difficulty breathing, notify your study doctor immediately.

Precautions to reduce the risk of falls should be taken, particularly if there is impaired gait or history of falls.

Unforeseeable Risks

Participating in this study may also involve risks that are currently unknown due to the investigational nature of this study. If any new risks become known you will be informed of them by your study doctor.

As with any research study, there may be unforeseeable risks associated with participation in this clinical study.

Reproductive Risks

The effects NUEDEXTA might have on an embryo, fetus or nursing infant is unknown. It is not known whether dextromethorphan and/or quinidine are excreted in human milk.

If you are a woman and miss a period (or your period is late for 5 days or more) or think you might be pregnant during the study, you must notify the study doctor immediately. If you become pregnant, you will be withdrawn from the study. Your study doctor will need to follow the course of your pregnancy and delivery, as well as be informed of the condition of the newborn baby.

New Information

During the study, you will be told of any significant new findings that are learned about the use of NUEDEXTA. The sponsor may make changes to the study tests or procedures at any time. If changes occur prior to the start of the study; reasonable attempts will be made to notify you prior to the study check in. Changes made after the study has started will be communicated to you as soon as possible. You can use this information to decide whether you would like to continue to take part in the study.

Potential Benefits

Your symptoms of PBA may improve while participating in this study, however, this cannot be guaranteed. You may not receive any direct medical benefit from taking part in this study. However, your taking part in this study may help other people in the future to benefit from the results of this study. The knowledge gained from the study may help in understanding more about the treatment of PBA.

Alternative Treatments

Currently,NUEDEXTA is the only FDA-approved medication for the treatment of Pseudobulbar Affect.

In addition, you have the option of choosing no therapy. You should talk about other options with your study doctor. Make sure that you understand all of your choices before you decide to take part in the study.

You do not have to participate in this study to receive treatment for your condition.

Study medication will not be available after you have completed this study.

Confidentiality

All information that you give will be kept strictly confidential. The information collected about you usually will not directly identify you (for example, by name, address, or social security number). Instead, you will be assigned a participant identification code number and this number will be used on your study forms.

Your records may be reviewed by:

- the study sponsor (Avanir)
- people who work with the sponsor on the study (the Study Team)
- healthcare professionals or research staff conducting the study
- Government agencies, such as the FDA
- Copernicus Group Independent Review Board (IRB). The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects or participants.

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

The Study Team may use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication.

There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible.

If the study doctor is not your normal primary care provider, it is recommended that the study doctor inform your normal primary care provider that you are taking part in this study. If you have any concerns about this, please discuss them with the study staff.

Payment for Participation

You will not receive any payment or compensation for taking part in this research study.

Cost of Study

The procedures carried out in this study are free of charge for you. The sponsor is paying the study doctor to conduct this study and for all clinical tests, procedures and study medication needed for the study. These procedures may include a physical and neurological examination and vital signs. All the questionnaires used in this study will be administered free of charge. The sponsor will provide the study medication to you free of charge.

Compensation for Study-Related Injury

If you are injured during your study participation, you should seek medical help immediately.

In the event of a serious physical or bodily illness or injury that is determined to be directly related to the use of the study medication or properly performed study procedure, the sponsor, Avanir Pharmaceuticals, Inc., agrees to pay reasonable and necessary medical expenses to treat such illness or injury. Payment will not be made for an illness or injury that is not a direct result of the appropriate/authorized use of the study medication or properly performed study procedure for the collection of data.

The sponsor has no plans to make any other payments.

However, you do not give up any of your legal rights by signing this consent form.

Voluntary Participation/Withdrawal

Your participation in this study is entirely voluntary. You may decide not to take part in the study or you may withdraw from the study at any time for any reason without any consequences and without affecting your medical care or benefits to which you are otherwise entitled. If you decide to no longer participate in the study please notify the study doctor.

Your study doctor, the study sponsor (AvanirPharmaceuticals), Copernicus Group IRBor the FDA (or any other regulatory agency) may decide to terminate this study for medical or other reasons (such as the research is not beneficial, the study resources are no longer available, your overall welfare is determined to be at risk, or for any other reason determined by the study doctor) at any time and without your consent. Your study doctor will notify you should this occur. The study doctor will talk with you about other options for your continued care.

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.

Study Contacts

If you or your legal representative have any study questions or if you have any injury or illness during the study, you or your caregiver should call:

Study Doctor/Contact Name: **RicardoR.PardoMD**

Daytime telephone number(s): 281-425-3805

24-hour contact number(s): 281-425-3800

If you have questions about your rights as a research participant or questions, complaints or concerns about the study, you may contact the IRB. The “IRB” is a group of people who perform independent review of research.

Copernicus Group IRB at 1-888-303-2224.

Copernicus Group IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff. Please visit the Copernicus Group IRB website ***www.cgirb.com*** for more information about research studies and the role of a research participant.

PARTICIPANT'S STATEMENT OF CONSENT

A Study to Assess the Safety Tolerability and Effectiveness of NUEDEXTA (Dextromethorphan 20mg/Quinidine10mg) in the Treatment of Pseudobulbar Affect (PBA)

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I have been told and read that I may contact the study doctor if I have any more questions about taking part in this study. I have been told and read that the study doctor or the company he/she is employed by is being paid by the sponsor for my participation in this study.

I have been told and read that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I also have been told and understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

By signing this form, I have not waived any of my legal rights.

I have read and been told the above information. I agree to participate in this study. I have been told that I will be given a copy of this signed and dated form for my own records.

_____ _____
Signature of the Participant Date

_____ _____
Print Name of Participant Time

I certify that I am the legally authorized representative of the participant named above. I am permitted under state law to sign this form on behalf of the participant.

_____ _____
Signature of Legal Guardian/
Legal Representative Date

_____ _____
Print Name & Relationship
of Legal Guardian/Legal Representative Time

_____	_____
Signature of the Investigator	Date
_____	_____
Print Name of Investigator	Time

The information about the study was described to the participant and/or legally authorized representative in a language he/she understood.

_____	_____
Signature of the Person Obtaining Consent	Date
_____	_____
Print Name of Person Obtaining Consent	Time

PARTICIPANT'S ASSENT **(minimum 18 years of age)**

A Study to Assess the Safety Tolerability and Effectiveness of NUEDEXTA (Dextromethorphan 20mg/Quinidine 10mg) in the Treatment of Pseudobulbar Affect (PBA)

- I have read this form or had it read to me.
- I don't have to be in this study if I don't want to.
- I can stop at any time.
- My doctor will still take care of me.
- I have asked any questions I have about the study.
- My questions have been answered.

I agree to take part in this study.

_____
Participant's Name, as able (please print)

_____ _____
Signature of Participant, as able Date

I explained the study in language understood by the participant.

_____
Printed Name of Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

HIPAA Authorization

A federal regulation known as the Privacy rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

If you sign this Authorization Form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to participate in the study.

Who Will Use and Disclose Your Health Information?

The investigator and his or her research staff (the Study Team) may use your health information to conduct, review, and determine the results of the study. The Study Team may disclose your information to others, as discussed below.

What Health Information will be Used and Disclosed?

The Study Team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. Your name will not appear on the study forms. Instead, you will be assigned a participant identification number. The Study Team will send the completed study forms to the study sponsor. This type of information may also be shared with others, as described below.

Your medical records may include other health information about you and may include documents that directly identify you. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is completed.

Who Will Receive Your Health Information?

Your study information may be shared with the following people or groups:

- The study sponsor (Avanir) or its representatives, including companies it hires to provide study-related services
- Researchers who are conducting this study at other study centers
- The Copernicus Group Independent Review Board, the (ethics committee) and any other committees responsible for overseeing the research
- Government health agencies (such as the Food and Drug Administration) in the U.S. or other countries

Representatives from these groups may receive information from your study forms or may review your medical records (as describe above) or both.

Will Your Information be Protected by the Privacy Rule After it is Disclosed to Others?
The study center is required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research and regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study date at a later date or combine your information with information from other studies for research purposes not directly related to this study.

The goal of any such research would be learn more about drugs or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services. This could result in transfer of your information outside the United States. However, your name will never appear in any sponsor reports or publications, or in any future disclosures by the sponsor.

What Happens if You Leave the Study Early?
If you stop participating in the study early for any reason, the Study Team will tell the sponsor why. If the Study Team asks you to come to any more study visits and you agree, the Study Team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will Your Authorization Ever Expire?
This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. The Study Team may need to correct or provide missing information about you even after your study participation is over. The review of your medical records (described above) may also take place after the study is completed.

May You Take Back Your Authorization?
You have the right to take back (revoke) your Authorization at any time by writing to the study doctors whose information is listed on page one of this form. If you revoke your Authorization, the Study Team will not collect any new health information about you unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. However, they can continue to use and disclose any already collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

May You Look At Your Study Information?

You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Authorization

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, healthcare professionals or their research staff taking part in this study, the Copernicus Group Independent Review Board, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

_____ _____

Signature of the Participant Date

_____ _____

Print Name of Participant Time

I certify that I am the legally authorized representative of the participant named above. I am permitted under state law to sign this form on behalf of the participant. I am the responsible person legally permitted to sign this Authorization to release the participant's medical records and health information as described above.

_____ _____

Signature of Legal Guardian/
Legal Representative Date

_____ _____

Print Name & Relationship
of Legal Guardian/
Legal Representative Time