



## CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

**TITLE:** Use of Xtampza ER to overcome difficulties in swallowing opioid pills

**PRINCIPAL INVESTIGATOR:**

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**SOURCE OF SUPPORT:**

Collegium Pharmaceuticals

***About this consent form***

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form. If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

***Why is this research study being done?***

We are doing this research study to determine if the ability to open up the Xtampza ER capsules and put the pellets in food or drink will make it easier to swallow opioid pain medications.

***Who is being asked to take part in this research study?***

We will ask adult individuals who have been prescribed opioid medications for chronic pain and who have trouble swallowing these pills to participate in this study. You are expected to have access to a mobile phone that can send and receive text messages and access the internet.

Your physician may be the investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with the research study. You are not under any obligation to participate in any research study offered by your physician.

***How long will I take part in this research study?***

It will take you 6 weeks to complete this research study. Everyone who participates in this study will attend 4 study visits at the UPMC Pain Medicine Clinic at Centre Commons. These visits will be approximately 1-2 hours long.

***What will happen in this research study?***

**Study Visit 1 (Week 1)**

The Screening Visit will take about 2 hours at the UPMC Pain Medicine Clinic at Centre Commons. At this visit, we will:



- Ask about your medical history and review your medical records
- Give you a urine pregnancy test if you are a woman of child-bearing age. Pregnant women cannot take part in this research study.
- Give you some online questionnaires to fill out about your general health and well-being, quality of life, pain, and how much trouble you have swallowing pills.
- Check that your mobile phone can receive the daily text messages for the study.

### **Text Messages**

- After Study Visit 1, you will receive daily text messages to track your pain and medication use. These texts will ask you to respond to simple questions. For example, you will receive a text that says “What is your level of pain now? Text 0-10. 0 = no pain, 10 = pain as bad as you can imagine.” You would then text the number that corresponds to your current pain, such as “5” if you are experiencing moderate pain.
- These messages will count towards your text and data usage on your mobile phone plan. Please contact your mobile phone carrier for more information.

### **Study Visit 2 (Week 2)**

Visit 2 will take about 1.5 hours at the UPMC Pain Medicine Clinic at Centre Commons. At this visit, we will:

- Give you some online questionnaires to fill out
- Begin the conversion of your current opioid medications to Xtampza ER.

You will take the study drug by mouth for the entire study. Every time you take Xtampza ER, you will open the capsule, sprinkle the drug microspheres onto soft food such as applesauce or pudding, and then eat the food with the microspheres. You will need to take the drug with the same amount of food every time. It is important for you to follow our instructions about how to take the study drug. Bring any unused study drug with you to your next study visit.

### **Visit 3 (Week 3)**

Visit 3 will take about 1 hour at the UPMC Pain Medicine Clinic at Centre Commons. At this visit we will:

- Ask you questions about side effects or health problems since your last visit
- Give you some online questionnaires to fill out
- Refill your medication or change the Xtampza ER dose if appropriate

After this visit, you will be emailed or texted a link to take a survey on a weekly basis. This is separate from the daily text messages you have been receiving.

### **Visit 4 (Week 6)**

Visit 4 will take about 1 hour at UPMC Pain Medicine at Centre Commons. At this visit we will:

- Ask you questions about side effects or health problems since your last visit
- Give you some questionnaires to fill out
- Return to your usual medication regimen and follow up with your pain physician. You can also discuss whether to switch over to Xtampza ER long-term.



## ***What are the risks and possible discomforts from being in this research study?***

### **RISKS OF TAKING XTAMPZA ER:**

#### **(1) Xtampza ER is Addictive**

Xtampza ER contains oxycodone, an opioid drug controlled by the United States Drug Enforcement Administration (DEA). Taking any opioid drug can lead to addiction, abuse, and/or misuse. There is no way to determine whether you will become addicted to, abuse, or misuse an opioid drug. You may develop an addiction to this drug even if you take it as directed by the researchers and/or your doctor.

The specific risks related to addiction, abuse, and/or misuse of Xtampza ER are:

1. A risk of overdose and death. Xtampza ER is an extended-release product and carries a higher risk of overdose and death due to the larger amount of oxycodone present.  
Possible symptoms of an overdose are:
  1. Respiratory depression (slow breathing)
  2. Somnolence (sleepiness) progressing to stupor or coma
  3. Muscle weakness
  4. Cold and clammy skin
  5. Constricted (tiny) pupils or dilated pupils
  6. Pulmonary edema (fluid in the lungs)
  7. Bradycardia (slow heart beat)
  8. Low blood pressure
  9. Partial or complete airway obstruction
  10. Unusual snoring
  11. Death
2. Abuse or misuse of Xtampza ER by snorting or injecting the dissolved product can result in overdose and death.
3. Someone may try to steal this drug from you.

At each study visit, the study doctor will check whether you are showing any signs of addiction, abuse, or misuse by asking you questions and having you fill out forms. If you are showing signs of addiction, abuse, or misuse, you will be referred to an appropriate treatment program.

#### **(2) Xtampza ER Can Slow Down Breathing to Dangerous Levels**

Xtampza ER and other opioid drugs can slow down your breathing, a condition called “respiratory depression.” This can happen even if you take the drug as directed by the researchers and/or your doctor.

1. Respiratory depression caused by Xtampza ER and other opioid drugs can be fatal.
2. The highest risk of respiratory depression is during the first 3 days after you start taking Xtampza ER.

#### **(3) Xtampza ER is Dangerous to Newborn Babies**

It is not safe to take Xtampza ER or other opioid drugs while pregnant. Babies born to women who take opioid drugs will develop a condition called Neonatal Opioid Withdrawal Syndrome. This condition can be fatal to newborn babies.



Because of these risks, women cannot take part in this study if they are:

1. Pregnant
2. Trying to become pregnant
3. Breastfeeding

If you are a menopausal woman and have not had a period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female subjects must have a negative pregnancy test before starting the study drug.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for the entire study. Acceptable birth control methods for use in this study are:

1. Hormonal methods (birth control pills, patches, injections, vaginal ring, or implants)
2. Barrier methods (condom or diaphragm) used with a
3. Spermicide (a foam, cream, or gel that kills sperm)
4. Intrauterine Device (IUD)
5. Abstinence (no sex)

If you miss a period or think you might be pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you must stop taking the study drug and stop taking part in the study.

#### **(4) Stopping Xtampza ER Too Quickly Can Lead to Withdrawal**

Stopping the use of Xtampza ER or other opioid drugs too quickly can lead to withdrawal syndrome. Some of the effects of withdrawal syndrome are:

1. Restlessness
2. Lacrimation (watery eyes)
3. Rhinorrhea (runny nose)
4. Yawning
5. Perspiration (sweating)
6. Chills
7. Myalgia (muscle pain)
8. Mydriasis (dilated pupils)
9. Irritability
10. Anxiety (nervousness)
11. Backache
12. Joint pain
13. Weakness
14. Abdominal cramps
15. Insomnia (trouble sleeping)
16. Nausea (upset stomach)
17. Anorexia (decreased appetite)
18. Vomiting
19. Diarrhea
20. Increased blood pressure
21. Increased heart beat
22. Faster breathing

It is important to follow the doctor's directions for discontinuing Xtampza ER in order to prevent these side effects.

#### **(5) It is Dangerous to Drive or Operate Machinery While Taking Xtampza ER**

Taking Xtampza ER can impair your ability to think and to drive a car or operate heavy machinery. We advise that in switching to Xtampza that you should not drive or operate other heavy machinery until you are used to the medication and feel confident that you are safe to drive.

#### **(6) Xtampza ER Can Have Dangerous Interactions with Alcohol and Other Drugs**

Taking Xtampza ER with some types of medications or with alcohol may have harmful effects.



There are certain medications that interact with the breaking down of oxycodone in the body. Oxycodone is the active ingredient in Xtampza used in this study. If you are on one of these medications, we will let you know because you might be at risk of developing too high or too low of a level of oxycodone in your bloodstream. We will also take this issue into account when prescribing the dose of Xtampza. Notify Dr. Wasan if you are taking any of the following types of medications:

1. Drugs that inhibit the Cytochrome P450 3A4 enzyme may cause potentially fatal respiratory depression when taken with Xtampza ER or other opioid drugs. These drugs include some antibiotics (**erythromycin**), antifungal agents (**ketconazole**), and protease inhibitors (**ritonavir**).
2. If you are taking a drug that induces the Cytochrome P450 3A4 enzyme while taking Xtampza ER or other opioid drugs, you may experience withdrawal symptoms if you stop taking the Cytochrome P450 3A4 inducing drug. These drugs include **rifampin, carbamazepine, and phenytoin**.
3. Drugs or substances that depress the central nervous system (CNS) can cause severe sedation, respiratory depression, coma, and death when taken with Xtampza ER or other opioid drugs. These drugs and substances include **alcohol, benzodiazepines, sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, and other opioid drugs**.
4. Drugs that affect the neurotransmitter serotonin can cause serotonin syndrome when taken with Xtampza ER or other opioid drugs. Drugs that affect serotonin include **selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, mirtazapine, trazodone, tramadol, and monoamine oxidase inhibitors (MAOIs)**. Serotonin syndrome is a potentially fatal condition, and its symptoms include:
  1. Confusion
  2. Agitation or restlessness
  3. Dilated pupils
  4. Headache
  5. Changes in blood pressure
  6. Changes in body temperature
  7. Nausea and/or vomiting
  8. Diarrhea
  9. Rapid heart rate
  10. Tremor
  11. Loss of muscle coordination or twitching muscles
  12. Shivering and goose bumps
  13. Heavy sweating
1. Xtampza ER and other opioids drugs can reduce the effects of **diuretic drugs** that increase urination.
2. Taking anticholinergic drugs with Xtampza ER or other opioids may increase the risk of urinary retention and constipation. Examples of anticholinergic drugs include **hyoscyamine and atropine**.

### (7) Xtampza ER May Be Especially Dangerous If You Have One of These Conditions

People with certain conditions are especially vulnerable to harmful effects of Xtampza ER and other opioid drugs.

1. There is a higher risk of severe or life-threatening respiratory depression in people with **chronic pulmonary disease** and in **elderly, cachectic, or debilitated persons**.
2. Patients with **increased intracranial** (inside the head) **pressure, brain tumors, head injury, or impaired consciousness** who take Xtampza ER or other opioid drugs are at risk for reduced breathing and increased carbon dioxide retention.



3. Xtampza ER and other opioid drugs may cause spasm of the sphincter of Oddi and increases in the serum amylase in patients with **gastrointestinal obstruction**, including **paralytic ileus**.
4. Xtampza ER and other opioid drugs may increase the frequency of seizures in patients with **seizure disorders**, including **epilepsy**.

### **(8) Xtampza ER May Cause Adrenal Insufficiency**

Prolonged use of Xtampza ER and other opioid drugs may cause adrenal insufficiency, a condition characterized by the following symptoms:

- |             |              |                       |
|-------------|--------------|-----------------------|
| 1. Nausea   | 4. Fatigue   | 7. Low blood pressure |
| 2. Vomiting | 5. Weakness  |                       |
| 3. Anorexia | 6. Dizziness |                       |

### **(9) Xtampza ER May Cause Severe Low Blood Pressure**

Xtampza ER and other opioid drugs may cause severe low blood pressure, especially in people with reduced blood volume or who are taking certain CNS depressant drugs such as phenothiazines or general anesthetics.

## **POSSIBLE DISCOMFORTS FROM TAKING XTAMPZA ER:**

**The most common side effects of Xtampza ER reported in clinical trials are:**

- |                                   |                              |
|-----------------------------------|------------------------------|
| 1. Nausea (upset stomach) -16.6%  | 5. Pruritus (itching) – 7.4% |
| 2. Headache - 13.9%               | 6. Vomiting – 6.4%           |
| 3. Constipation – 13.0%           | 7. Dizziness – 5.7%          |
| 4. Somnolence (sleepiness) – 8.8% |                              |

**Less common side effects of Xtampza ER reported in 1 - 5% of patients in clinical trials are:**

- |   |  |
|---|--|
| 8. Blurred vision                       | 23. Back pain                          |
| 9. Abdominal pain                       | 24. Musculoskeletal pain               |
| 10. Upper abdominal pain                | 25. Myalgia (muscle pain)              |
| 11. Diarrhea                            | 26. Migraine (severe headache)         |
| 12. Gastroesophageal reflux disease     | 27. Tremor (shaking)                   |
| 13. Chills                              | 28. Anxiety (nervousness)              |
| 14. Drug withdrawal syndrome            | 29. Insomnia (sleeplessness)           |
| 15. Fatigue (tiredness)                 | 30. Withdrawal syndrome                |
| 16. Irritability                        | 31. Cough                              |
| 17. Edema (fluid build-up)              | 32. Oropharyngeal pain (sore throat)   |
| 18. Pyrexia (fever)                     | 33. Hyperhidrosis (excessive sweating) |
| 19. Excoriation (scratches on the skin) | 34. Rash                               |
| 20. Decreased appetite                  | 35. Hot flush                          |
| 21. Hyperglycemia (high blood sugar)    | 36. Hypertension (high blood pressure) |
| 22. Arthralgia (joint pain)             |  |

**Uncommon side effects of Xtampza ER reported in less than 1% of patients in clinical trials are:**



- |   |   |
|---|---|
| 37. Increased gamma-glutamyl transferase (a liver enzyme) | 41. Poor-quality sleep                    |
| 38. Increased heart rate                                  | 42. Abnormal dreams                       |
| 39. Lethargy (lowered consciousness)                      | 43. Euphoric mood (feeling of well-being) |
| 40. Memory impairment (trouble remembering things)        | 44. Restlessness                          |
|   | 45. Dyspnea (shortness of breath)         |
|   | 46. Night sweats                          |

### **Risks of Questionnaires**

We will ask you to fill out a set of questionnaires about your pain and mental health. If you feel uncomfortable about answering a question, you can choose not to answer it. Dr. Ajay Wasan, a psychiatrist and pain physician as well as the study investigator, will be available to answer any questions you may have.

### **Risks of Breach of Confidentiality**

There is a potential risk of breach of confidentiality that is inherent in all research protocols. There is a possibility that if research data were to become known to others, this knowledge could potentially impact a subject's future or have a negative impact on family or social relationships.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

The text messages you will receive as part of this study are sent from a secure, encrypted system, and all of your responses are stored in this secure system. However, the text messages you send are not encrypted or secure during transmission and could be intercepted. These text messages will include information about pain medication that you may be currently taking. Therefore, it is important to understand your text message response is not protected, and it is possible that it may be viewed by others. It is important to note that depending on your cell phone carrier, even if you delete the text message from your phone, your cell phone carrier will retain those messages for an extended period of time. Additionally, depending on your specific device or carrier, copies of those messages may be stored on multiple devices and/or related cloud storage services. You are responsible for the security of any information that is stored on your cell phone or mobile device. We suggest you periodically check for and delete any sensitive information that may be contained in these text messages.

### **Unknown Risks**

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe or life-threatening.

### ***What are the possible benefits from being in this research study?***

It is possible that your pain management may improve with this new method of ingesting medication. Other people with chronic pain and difficulty swallowing pills may also benefit in the future from what we learn in this study.



***What other treatments or procedures are available for my condition?***

You do not have to take part in this research study in order to receive treatment for chronic pain. Several opioid and non-opioid medications, treatments, and procedures are available to treat chronic pain. There are other opioid pain medications that can be opened and sprinkled onto food, including Kadian and morphine ER. Talk with the study doctor if you have questions about any of these treatments or procedures.

You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in this study.

***What if I want to stop taking part in the study?***

You can, at any time withdraw from this research study; you can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

1. To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.
2. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.
3. If you decide to withdraw from study participation after you have received the study drug, you should participate in additional monitoring follow-up procedures that are being conducted.

**Stopping the Study Early**

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. You will need to return all unused study drug at this visit. The final study visit will take about 2 hours at UPMC Pain Medicine at Centre Commons. At this visit, we will:

- Ask you questions about side effects or health problems since your last visit
- Give you some questionnaires to fill out
- Give you a schedule for tapering off of the study medication

Also, the study doctor may take you out of the study without your permission. This may happen because:

- The study doctor thinks it is best for you to stop taking the study drug
- You cannot make the required study visits
- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study. We will ask you to come in for a final study visit as described above.



***Will I be paid to take part in this research study?***

You will receive a total of \$120 for completing the study, detailed as follows:

Week 1 (Initial Evaluation): \$20

Week 6 (End of Study): \$100

This totals \$120 if you complete the study.

If you are participating in other research studies and your total compensation for research is greater than \$600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

***How much will I have to pay to take part in this research study?***

The study medication is paid for by Collegium Pharmaceuticals and provided at no cost to you during the 6-week study. If you choose to keep taking Xtampza ER after the end of the study, your insurance might not cover the cost of this drug. We will reimburse you for your parking in the clinic parking lot during study visits or bus fare to and from the study site.

Although study funds will pay for certain study-related items and services, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will not be billed for any study-related procedures or services.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff.

***What happens if I am injured as a result of taking part in this research study?***

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Collegium Pharmaceuticals, the manufacturer of Xtampza ER, has agreed to compensate research subjects for all medical expenses incurred for the emergency and/or long-term treatment of any injury that is directly a result of Collegium's manufacture, packaging, or labeling of Xtampza ER, or negligence of willful misconduct on the part of Collegium.

Emergency medical treatment for injuries solely and directly related to your participation in this research study, and not related to the manufacturer, packaging or labeling of Xtampza, will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

***Will this research study involve the use or disclosure of my identifiable medical information?***

We are requesting your authorization or permission to review your medical records. This research study will involve the recording of past, current and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (for example,



your physician's office) records. This information that will be recorded will be limited to information concerning the study (for example, diagnostic information, lab and scan results, medications, medical history). This information will be used to determine your eligibility for this study and to follow you once you are enrolled in the study. This authorization is valid for an indefinite period of time.

This research study will also result in identifiable information that will be placed into your medical records held at UPMC. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes medications prescribed and a note that you are or have participated in this study.

***Who will have access to identifiable information related to my participation in this research study?***

In addition to the investigator listed on the first page of this consent form and the research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

1. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.
2. In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
3. Authorized representative of the U.S. Food and Drug Administration (FDA) and other regulatory agencies may review and/or obtain your identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of monitoring the accuracy of the research data.
4. Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

The data from this study may be shared with other investigators; however, only data without identifiers (such as your name) will be shared.

We will protect your privacy and the confidentiality of your research records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.



***For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?***

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 7 years following final reporting and publication of the study and for as long (indefinite) as it may take to complete this research study.

***Your rights as a research subject***

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described below, is completely voluntary. Note, however, that if you do not provide your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will not be allowed, in general, to participate in the research study.

You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The researchers will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effects on your current or future relationship with the University of Pittsburgh, your current or future medical care at a UPMC hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider.

To formally withdraw your consent for participation in this research study, you should provide a written and dated notice of this decision to the principal investigator at the address listed on the first page of this form.

If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the **University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668**.

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**VOLUNTARY CONSENT**

The above information has been explained to me, and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed on the first page of this consent document at the telephone number given.



I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the **Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668)** to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Date/Time

**CERTIFICATION of INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Role in Research Study

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date/Time

