Phase I+Phase II Clinical Study of PRaG Therapy in Combination With Chemotherapy (AG Regimen) for Neoadjuvant Treatment of Locally Advanced Pancreatic Ductal Adenocarcinoma (PDAC) (NeoPRAG Study) Informed Consent Form

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Applicant: The Second Affiliated Hospital of Soochow University

Research center name:

Patient initials:

Patient study number:

Patient contact number:

Patient address:

Information Disclosure Page

Participant Information Sheet

Dear Patient,

As you are a late-stage solid tumor patient and may meet the inclusion criteria for the " Evaluation of the efficacy and safety of a precise thymalfasin-regulated PRaG regimen for advanced refractory solid tumors: an open-label, prospective, multicenter study (PRaG5.0 Study)". We invite you to participate in this study. Participation is entirely voluntary. If you choose not to participate, all your other rights will remain unchanged and unaffected.

Before making a decision, it is essential that you read and fully comprehend this informed consent document. This document details the study's objectives, methodologies, potential benefits, and associated risks. It also provides an overview of your responsibilities and recommended precautions. This informed consent form is in duplicate. If you decide to participate in this study, you can consult any questions with your research doctor. Upon reaching a clear understanding, both you and your research doctor will sign this document. You will be provided with a copy.

1. Research Objective

Discussing the Safety and Efficacy of PRaG Treatment Model Combined with Chemotherapy as Neoadjuvant Therapy for Locally Advanced Pancreatic Cancer

2. Research Background

Pancreatic ductal adenocarcinoma (PDAC) is one of the major threats to human health due to its high malignancy and aggressive nature. According to GLOBOCAN data, in 2020, there were over 400,000 new cases and deaths from pancreatic cancer worldwide, with an incidence rate of about 6.4 per 100,000 people. The incidence and mortality rates of pancreatic cancer are on the rise globally, with a 5-year survival rate of only 12% in the United States and approximately 7.2% in China. The standard treatment for PDAC is surgical resection combined with chemotherapy. However, real-world clinical data shows that the 5-year overall survival (OS) rate for patients who

undergo resection is about 20% (up from less than 5% in 2011), while it is less than 1% for those who do not undergo surgery (the same as ten years ago). Large cohort studies report that about 20% of patients who undergo surgical resection relapse within six months post-operation, and 40% relapse within the first year, even in cases of R0 (no residual tumor at resection margin) resection. Therefore, more and more views consider that the biological nature of PDAC is different from its early stages, and even resectable pancreatic ductal adenocarcinoma, though in its early stages, is considered a systemic disease. Surgery alone cannot achieve complete tumor clearance, necessitating multimodal treatment methods and a multidisciplinary comprehensive treatment model.

In recent years, neoadjuvant therapy has become a hot topic in the treatment of pancreatic cancer. More and more high-quality evidence-based medical evidence shows that neoadjuvant therapy can inhibit early micro-metastasis, increase the rate of surgical resection, and thereby improve patient prognosis. The advantages of neoadjuvant therapy can be summarized as follows: (1) Early suppression of micrometastases to control tumor recurrence and metastasis. (2) Reducing tumor burden to achieve R0 resection. (3) Enhancing patient tolerance and compliance, addressing postoperative adjuvant therapy intolerance. (4) Pre-screening patients with highly aggressive tumors to avoid meaningless surgery. (5) Offering a multimodal treatment option for all patients, not limited by postoperative complications.

Neoadjuvant chemoradiotherapy is recommended in the American NCCN guidelines for BR-PDCA. Current research is increasingly using Stereotactic Body Radiation Therapy (SBRT) as a neoadjuvant method for BR/LA-PDAC patients. Studies show that chemoradiotherapy benefits local control of the tumor, but the appropriate radiotherapy scheme, intensity, and dosage still need exploration, avoiding severe complications. The impact of radiotherapy on overall survival still needs to be explored in prospective studies.

With the development of precision radiotherapy technology, HypoFractionated Radiation Therapy (HFRT) and SBRT are becoming more widespread in clinical practice. Compared to conventional fractionation doses, hypo-fractionated radiotherapy

can generate an immune activation effect through mechanisms such as direct action on tumor cell DNA, generation of an in situ tumor vaccine effect, and alteration of the tumor microenvironment. It can also cause irreversible DNA damage, leading to apoptosis, necrosis, senescence, or mitotic failure of tumor cells. Additionally, radiotherapy can promote high expression of PD-L1 in tumor cells, thereby increasing sensitivity to PD-1/PD-L1 inhibitors. Combining radiotherapy with PD-1/PD-L1 inhibitors has been shown to enhance patient response rates and prolong survival in many clinical studies. Our center has pioneered the "Prague Protocol" (Prague 1.0), which involves large-fraction radiotherapy combined with a PD-1 inhibitor followed by sequential GM-CSF in patients with advanced solid tumors who have progressed after first- and second-line chemotherapy. The study included 54 patients with a median follow-up time of 16.4 months. The objective response rate was 16.7%, and the disease control rate was 46.3%; the median PFS was 4.0 months, and the median OS was 10.5 months. Patients who received the Prague Protocol generally tolerated it well, with five patients experiencing grade 3 treatment-related adverse events (TRAEs) and only one case of grade 4 TRAE. These results suggest that the Prague Protocol is an effective treatment option for patients with advanced recurrent solid tumors.

Therefore, this study proposes to use the Prague treatment model combined with chemotherapy as neoadjuvant therapy, aiming to increase the R0 resection rate of PDCA patients and prolong their survival.

3. Number of Participants and Expected Duration of the Study

This study is expected to enroll 26 participants in Phase I and 40 participants in Phase II, with the research anticipated to last for 3 years.

4. Research Design

Phase I clinical trials are divided into Phase Ia and Phase Ib. Phase Ia is a dose-escalation study, divided into two cohorts based on radiation dosage, with each cohort comprising 3+3 patients. Phase Ib is the phase of expanding the sample size. For Phase Ia, the regimen with the best safety and tolerability is prioritized, followed by the regimen with a high rate of surgical conversion. A total of 26 patients are enrolled.

Phase II clinical trial: A prospective, single-arm exploratory study. A total of 40 patients are enrolled.

5. Research Procedure

You are introduced to this study and after you understand the entire study and your questions have been answered to your satisfaction, you will be asked to sign this informed consent form if you wish to participate in this study.

This study aims to collect and analyze data from medical information from your standard clinical visits. If you consent to participate in this study, each subject will be assigned a unique identifier, and a medical record will be established.

For study eligibility determination (screening), you will be required to complete specific steps, including signed informed consent, demographic data collection, relevant imaging tests such as CT or MRI within 2 weeks before treatment initiation, and an electrocardiogram one week before treatment. Within 7 days prior to treatment your physician will collect your medical history (including history of previous treatments, surgeries, etc.), measure your vital signs, and conduct a physical examination, score ECOG, PS and quality of life and request you to undergo certain laboratory tests. You will be asked to complete the following labs: complete blood count, urine, and stool tests, liver and kidney function, cardiac enzymes, electrolytes, blood coagulation, tumor markers, thyroid function, glycosylated hemoglobin, and lymphocyte subsets. Check chest X-ray, gastroscopy, cardiac ultrasound will be performed if necessary. For women of childbearing age, a pregnancy test will be conducted to rule out potential pregnancy. For the purpose of identifying novel indicators to evaluate treatment efficacy, approximately 5 mL of your peripheral blood will be drawn for molecular testing before and after the treatment. This is solely for research and you will not receive a report of these findings.

Upon completion of the screening, if you fulfill the criteria, the treatment will be administered as follows:

Phase I: PRaG treatment

Group I n=3+3

First cycle of PRaG treatment

Radiotherapy：24Gy：8Gy*3f d4-d6

GM-CSF treatment: GM-CSF 200 μg subcutaneously daily for 7 days starting on the day of radiotherapy; d1-d7

Immunotherapy: cardunculizumab 375mg within one week after radiotherapy

Second cycle of PRaG treatment

Radiotherapy：24Gy：8Gy*3f d4-d6

GM-CSF treatment: GM-CSF 200 μg subcutaneously daily for 7 days starting on the day of radiotherapy; d1-d7

Immunotherapy: cardunculizumab 375mg within one week after radiotherapy

Group II n=3+3

Radiotherapy：40Gy：8Gy*5f d3-d7

GM-CSF treatment: GM-CSF 200 μg subcutaneously daily for 7 days starting on the day of radiotherapy; d1-d7

Immunotherapy: cardunculizumab 375mg within one week after radiotherapy

Phase II: 3 cycles of neoadjuvant immunotherapy combined with chemotherapy

After 3 weeks of phase I immunotherapy

Cardunolizumab 375mg d1

Albumin-bound paclitaxel 125mg/m2 d1,d8

Gemcitabine 1000mg/m2 d1,d8

Phase III: Surgical treatment

First Surgical Evaluation: After three cycles of neoadjuvant immuno-combination AG regimen, tumor indices and imaging examinations are improved, followed by a multidisciplinary discussion to decide on the feasibility of surgery.

Second Surgical Evaluation: For patients deemed inoperable after the first evaluation, an additional three cycles of the immuno-combination AG regimen are administered. Surgery is re-evaluated upon completion of these chemotherapy cycles.

For patients with preoperative total bilirubin ≤102.6 mmol/L, yellowing can be reduced with the help of PTCD or a biliary stent.

Patients who are resectable after neoadjuvant therapy undergo radical surgical treatment, such as radical pancreaticoduodenectomy, radical paracentesis modular pancreas splenectomy, and radical total pancreatectomy with regional lymph node dissection.

Phase IV: 3 cycles of immuno-combination chemotherapy

Patients who have undergone surgery, as well as those assessed as inoperable after three cycles of chemotherapy combined with immunotherapy, continue with three cycles of immune-combination chemotherapy.

Cardunolizumab 375mg d1

Albumin-bound paclitaxel 125mg/m2 d1,d8

Gemcitabine 1000mg/m2 d1,d8

Imaging Evaluation

Pre-treatment imaging assessment is performed, followed by the first imaging assessment after two cycles of treatment and the second imaging assessment after three cycles of AG combination immunotherapy. The third imaging assessment occurs after completion of six cycles of adjuvant therapy. Multi-stage enhanced CT is preferred, with CT thin-layer reconstruction performed whenever possible. However, imaging often fails to reflect biological attributes such as tumor heterogeneity, activity, blood supply, and immune cell infiltration. As pancreatic cancer is rich in mesenchyme, the tissue around the tumor also produces an inflammatory reaction and fibrosis after neoadjuvant therapy. Even if the therapy is effective, the size of the tumor and the extent of involvement of important blood vessels often do not significantly change. It is often difficult to accurately assess the effect of neoadjuvant therapy for pancreatic cancer and the resectability of the tumor with the RECIST 1.1 criteria. Therefore, dynamic enhanced MRI, PET-CT, and CA199 assessments are combined for comprehensive evaluation.

Pathological evaluation

Pathologists perform post-surgical imaging to assess margins, lymph node status, etc. For patients who do not undergo surgery, re-puncture for pathology retention is

conducted at the end of six chemotherapy cycles.

Collection of specimens

Collection includes 10 ml of fresh pathological tissue and peripheral blood samples before treatment, 10 ml of peripheral blood samples after Bragg treatment, 10 ml of peripheral blood samples after the first immuno-combination chemotherapy, 10 ml of peripheral blood specimens after the fourth cycle of AG-combination immunotherapy, 10 ml of fresh surgical tissue specimens and peripheral blood after the surgery, and 10 ml of peripheral blood specimens after completion of six cycles of adjuvant therapy.

During the enrollment period, we will regularly perform the following examinations on you:

- Vital signs: Heart rate, respiratory rate, body temperature, blood pressure. Once a week.

- Physical examination: Head and face, skin system, lymph nodes, eyes, ears, nose and throat, oral cavity, respiratory system, cardiovascular system, abdomen, genitourinary system, musculoskeletal system, nervous system, and mental state. At the end of each cycle.

- Blood pressure monitoring: Blood pressure during radiotherapy, four weeks after radiotherapy, and at least three times a week during the first cycle. If blood pressure is abnormal, monitor daily; if normal, monitor twice a week from the second cycle. Blood pressure monitoring is completed by the patient and recorded in the patient diary card. Researchers re-measure blood pressure at each follow-up visit. Before each measurement, refrain from smoking and drinking coffee for 30 minutes and rest quietly for at least 10 minutes. Take measurements in a seated position with the elbow at the same level as the heart, and always measure on the same side.

- Routine blood test: Hemoglobin, red blood cells, white blood cells, neutrophils count, lymphocytes count, and platelets count. Once a week after enrollment.

- Urinalysis: Urine protein, urine sugar, urine occult blood (urine red blood cells, white blood cells), urine pH, and urine ketone bodies; if semi-quantitative methods show protein $\geqslant$2+ (e.g., urine test strip), then perform a 24-hour urine protein quantitative test. Every three weeks.

- Blood biochemistry: Total bilirubin, conjugated bilirubin, ALT, AST, AKP, r-GT, total protein, albumin, blood urea nitrogen, creatinine, uric acid, blood sugar, triglycerides, cholesterol, lipase, amylase, potassium, sodium, chloride, calcium, phosphorus. Every three weeks before and after treatment; if abnormal, test every week.

- Stool routine: Occult blood. Every three weeks.

- Coagulation function: PT, APTT, TT, Fbg. Every three weeks.

- Thyroid function: Before treatment and at the end of each cycle. Seek medical attention immediately if abnormal. Ultrasound examination of the thyroid may be necessary.

- Glycated hemoglobin: Test once before treatment.

- Electrocardiogram: 12-lead ECG. Every three weeks.

- Seek medical attention immediately if abnormal. If symptoms such as chest pain or palpitations occur, an ECG should be performed immediately, along with a cardiac enzyme spectrum. Significant ECG abnormalities require additional echocardiographic examination (LVEF).

- Imaging studies: Use the same assessment methods and techniques as the baseline (slice thickness of scans, use of contrast agents, etc.) to describe and evaluate lesion characteristics.

- CT or MRI within 1 week before treatment, CT or MRI or PET-CT after 3 cycles (2 months) for tumor evaluation, imaging study schedule allows a window period of ±7 days; check bone lesions once after 2 months if present at baseline, re-examine after 1 month if suspected progression. If no progression, check every 2 months.

- Unplanned imaging studies can be performed if disease progression (e.g., worsening symptoms) is suspected.

- If the efficacy reaches CR, PR, the subject must be re-examined 4 weeks after the first evaluation.

- Quality of life score: Conducted by the researcher through questioning and answered by the subject. Evaluate before treatment and every 3 weeks during treatment. Seek medical attention if abnormal.

- Tumor markers: Before treatment and at the end of each cycle. Seek medical attention if abnormal.

- ECOG score: Before treatment and at the end of each cycle. Seek medical attention if abnormal.

- Adverse events: Record adverse events from the first administration of the study drug until at least 30 days after the last dose, and follow up until the adverse events resolve or stabilize.

- Concomitant medication: Record concomitant medication and treatment during the study period. Once the subject discontinues the trial treatment, only record concomitant medication and treatment related to new or unresolved adverse events due to the trial treatment.

- Study drug compliance: Calculate the previous cycle's drug dosage, count, and compliance on the first day of each treatment cycle, and record in the CRF. These examinations are recommended for you during the study period. In practice, your treating physician will decide which examinations and tests to perform based on your actual condition.

Throughout the study period, please cooperate fully with the doctor, tell the doctor about any situations that occur, and answer the doctor's questions truthfully. We will record all adverse events from the time you sign this informed consent form until 30 days after the last medication. Your post-treatment follow-up period begins after the last use of the study drug, and we hope you will continue to cooperate with our follow-up.

6. Potential Risks and Discomforts in Participation

There are no additional interventions in this study, so participating in this research will not increase your risk beyond standard medical care.

The study drug may cause some side effects, but we will take all feasible preventative measures and encourage you to report any issues that concern you.

The known side effects of Cadonilimab are as follows:

Based on data from clinical trial subjects with tumors and information from the drug's instructions, the following are listed potential side effects. Please inform your doctor or nurse immediately if you experience any discomfort.

The most common side effects (with an incidence rate of >5% in previous patients) include: fever, abnormal liver function tests, fatigue, and rash.

Less common side effects (with an incidence rate of >1% in previous patients) include: abnormal thyroid function, decreased white blood cells and neutrophils,

abnormal thyroid-stimulating hormone, high uric acid in blood, abnormal liver function tests, decreased appetite, nausea and vomiting, abdominal pain, coughing up phlegm, lung infections, joint pain or stiffness, increased blood sugar, chills, muscle soreness, weakness, stiffness, cramps or paralysis, arm or leg pain, headache, dizziness, palpitations, chest discomfort, and chest pain.

Potential or rare but serious side effects include: reduced red blood cells, fatigue, skin reactions (including itching, hives, redness, and dryness), abnormal blood biochemistry indicators (including low levels of blood phosphorus, magnesium, and potassium), pneumonia (localized pneumonia—see details below), colitis, skin depigmentation, dry mouth, vomiting, numbness, burning or tingling in hands and feet, shortness of breath, altered taste, flushing, high or low blood pressure, allergic reactions during or between infusion of the test drug, increased sensitivity of the skin to sunlight, constipation, difficulty swallowing, heartburn, reduced platelets (increasing bleeding risk), weight loss, palpitations, swollen optic disc, optic neuritis, low blood oxygen levels, acute lung injury or failure, fluid accumulation around the lungs, hepatitis, acute kidney injury or failure, abnormal blood cell production, oral and gastrointestinal mucositis, swelling of the face, arms, and legs, appendicitis, increased inflammatory blood proteins (such as lipase), adrenal abnormalities, pituitary inflammation, vision changes (including blurred vision or vision loss), eye inflammation or bleeding, pancreatitis, inflammation of the heart or its lining, fluid around the heart, increased blood sugar, dehydration, infections (including sepsis, lung infections, and skin infections), reduced intestinal motility, loss of sense of direction, back pain, autoimmune diseases, including Guillain-Barré syndrome (related to progressive muscle weakness or paralysis), chest discomfort, inflammation of the brain and spinal cord membranes or absence, drug reactions including rash, abnormal blood cells, enlarged lymph nodes, involvement of internal organs (including liver, kidneys, lungs), known as drug reaction with eosinophilia and systemic symptoms (DRESS), severe myasthenia (a neurological disease that can cause weakness in the eyes, face, respiratory, and swallowing muscles), potentially life-threatening or fatal encephalitis,

toxic epidermal necrolysis (a potentially life-threatening disease characterized by blisters and peeling of the skin's top layer, similar to severe burns), rhabdomyolysis (muscle fibers released into the blood may harm the kidneys), and polymyositis (chronic muscle inflammation and weakness).

Lung inflammation (pneumonia): This can lead to inflammation of lung tissue. This adverse event is not common but has been reported. While many patients with X-ray or CT abnormalities do not show any symptoms, some experience mild to severe symptoms, and there have been rare cases of pneumonia leading to death. Symptoms and signs of pneumonia include difficulty breathing, pain or discomfort when breathing, chest pain, cough, shortness of breath, rapid breathing rate, fever, low blood oxygen, or fatigue.

Your doctor and nurse will closely monitor changes in your breathing ability and other symptoms and signs that may indicate pneumonia. Routine checks will be conducted, including physical examinations, non-invasive methods (pulse oximetry), blood tests, chest X-rays, and/or CT scans to detect blood oxygen levels.

If you experience any of the following, please inform your doctor or nurse immediately:

- New or worsening difficulty breathing;
- New or worsening chest pain;
- New or worsening pain or difficulty breathing;
- New or significantly changed cough, such as more phlegm or coughing up blood, or these conditions worsening;
- New changes in blood oxygen content;
- Fever, fatigue, or other symptoms accompanying changes in breathing or other lung symptoms.

If you start showing symptoms, the research doctor will ask you to return to the clinic for additional examinations, including physical exams, measuring oxygen levels, blood tests, chest X-rays, and/or CT scans. You will be closely monitored for changes in your entire lung symptoms. Hospitalization may be required during observation.

Specific treatments may be administered to control pneumonia. A pulmonologist, a specialist trained in lung diseases, may treat you.

Sometimes, long-term use of anti-inflammatory drugs (such as corticosteroids) may be necessary to treat side effects, which can reduce the body's ability to resist certain infections (opportunistic infections). Antibiotics or antifungal drugs may be needed to treat these infections, which can be fatal.

We hope that you will follow medical advice, actively cooperate with treatment, maintain contact with researchers, and accept observation and follow-up as required by the trial protocol during your participation in the study.

7、 Management and Compensation for Related Risks and Discomforts

Patients undergoing treatment as part of this research study may experience some degree of discomfort. During radiation therapy, a minority of patients may experience symptoms like poor appetite, nausea, and vomiting, for which symptomatic treatment will be provided based on the severity of the patient's symptoms. During the use of Cadonilimab immunotherapy, a minority of patients (with an occurrence rate of >5% in previous patients) may experience symptoms such as fever, abnormal liver function tests, fatigue, and rash. We will provide appropriate treatment in a timely manner according to the severity of the patient's symptoms. During chemotherapy, symptoms such as bone marrow suppression and allergic reactions may occur. We will follow the instructions of the medication to prepare preventive measures and timely rescue methods for these symptoms. We will adhere to the adverse event management protocols before, during, and after pancreatic cancer surgery, implementing preventive and remedial measures.

For the above-mentioned risks and discomforts, we will actively provide timely treatment to the subjects. However, no additional compensation will be provided for the costs incurred during the treatment process. This study provides insurance policies for enrolled patients, and compensation can be claimed in accordance with the insurance contract if the conditions meet the contract's terms.

8、Possible Benefits

The information obtained from this study will help to further understand the safety and effectiveness of radiation therapy combined with immunotherapy, increase the surgical resection rate, and prolong patients' lives. In addition, all enrolled patients will receive Cadonilimab as a complimentary drug. Each enrolled patient can obtain five cycles of Cadonilimab for free but will need to purchase one cycle of Cadonilimab on their own.

9、 Potential Costs to be Borne

- Costs for pre-treatment imaging studies such as CT/MRI and related hematological tests including routine blood tests, coagulation function tests, and tumor markers.
- Costs for radiation therapy, GM-CSF medication, chemotherapy drugs, and immunotherapy drugs during the neoadjuvant treatment period.
- Costs associated with surgery during the surgical period.
- Costs for chemotherapy drugs and immunotherapy drugs during the adjuvant treatment period.
- Costs for imaging and hematological assessments throughout the treatment process.
- Costs for symptomatic treatment of complications arising from the tumor itself or side effects of the medication during the treatment process.

10、No Additional Compensation

For this study, the biological samples collected for research purposes will not incur any additional costs to the patients, and no test results reports will be provided to the patients. There is no financial compensation for participation.

11、Other Optional Therapeutic or Nursing Interventions

If you decide not to participate in this study, your physician will recommend alternative treatment options based on your specific medical condition.

12、Confidentiality and Privacy Authorization

Pertinent Chinese regulations safeguard your health-related data. By endorsing this informed consent form, you grant permission to acquire, utilize, and disseminate your

health data to the study physician and associated research personnel. Your initials will be coded and provided to the investigators for research purposes.

Your medical records (study chart/CRF, labs, etc.) will be securely retained at the medical facility attending to you. Laboratory test results will be logged by your physician in your medical record. Authorized personnel, including the investigator, ethics committee, and drug regulatory entities, will have access to your medical records. Any publicized findings from this study will ensure your personal identity remains undisclosed, and we pledge to safeguard your privacy.

13、Voluntary Participation and Option to Withdraw

Your involvement in this research is purely voluntary. You reserve the right to decline participation or withdraw your participation at any stage without jeopardizing your medical care rights or facing discrimination from healthcare providers.

14、Inquiries and Updates

Before endorsing this consent document, all research team members are available to address any queries. If you have further questions, insights, or remarks after signing, feel free to consult the investigator. You will remain informed about the study's developments and progress.

For concerns about your rights and interests, please contact the Ethics Committee of the Second Affiliated Hospital of Soochow University at +86-0512-67783682.

Informed Consent

Consent Signature Page

I have been informed verbally about this study by the physician responsible for the study or the appropriate researcher, and I have read the written information above.

I have been given ample opportunity to discuss and ask questions about the above study.

I agree to participate in this study and understand that my participation in this study is completely voluntary and that I will cooperate fully with my physician.

I understand that I can withdraw from the study at any time and that my withdrawal will not affect my future medical visits.

By signing this informed consent form, I agree that my personal information data, including my medical information data, will be used as described above.

I understand that I will be given a copy of this informed consent form.

Patient Name:

Patient Signature: _____Date of Signature: _____

Contact phone number: _____

or

Signature of Legal Representative: _____

Date of Signature: _____ (To be used only if subject is incapacitated)

Relationship to the patient: _____

Contact phone number: _____

Signature of Investigator: _____ Date of Signature: _____

Contact phone number: _____