

LAY LANGUAGE PROTOCOL SUMMARY

Principal Investigator: **Charles Thomas, MD** IRB#: **4236**

Study/Protocol Title: **Timing of Rectal Cancer Response to Chemoradiation**

Please answer all of the following questions using lay language, similar to the language used in a consent form. Please number your responses.

1. Briefly describe the purpose of this protocol.

Subjects in this study will get chemoradiation and chemotherapy followed by surgery at different intervals. The purpose of this study is to see if extending the interval between chemoradiation, chemotherapy and surgery will result in better outcomes for subjects with rectal cancer.

2. Briefly summarize how participants are recruited.

Potential subjects who have been diagnosed with rectal cancer will be seen by the investigator in clinic. They will be asked if they would like to take part in the study and given the chance to look over the consent and ask questions.

3. Briefly describe the procedures subjects will undergo.

The following tests and procedures will be done to see if the subject can be in the study: Medical history, chest x-ray, abdominal CT (Computerized Tomography scan - x-ray pictures of the inside of the body using a computer), proctoscopic exam (involves placing a hollow tube in the rectum), EUS (Endorectal Ultrasound – creates images of the inside of the body) or MRI (Magnetic Resonance Imaging – uses a magnetic field to produce detailed pictures of inside the body), blood tests (CBC and CMP), and a pregnancy test (if the subject is female and able to have children).

Chemoradiation:

If the tests and procedures show that the subject can take part in the study, they will be placed in one of three groups and receive radiation therapy and Fluorouracil (5-FU) chemotherapy intravenously (through a vein in the arm) for approximately 6 weeks.

Post-chemoradiation chemotherapy:

After receiving radiation therapy and chemotherapy, subjects will have tests and procedures similar to those listed above to see if they can continue to the next part of the study.

If the tests and procedures show that the subject can continue on the study, they will receive modified FOLFOX-6 (mFOLFOX-6) chemotherapy intravenously (through a vein in the arm) for 2 to 6 cycles, depending on which group they are in.

Surgery:

One week after receiving their final mFOLXFOX-6 therapy, subjects will have surgery to remove their tumor.

Follow up:

Subjects will stay on the study and be followed for 30 days after their surgery. After this 30 day period is over they will be considered off-study.

Optional tissue collection:

Subjects will be given the chance to take part in an optional part of the study that will take two tissue samples from their tumor. The first sample will be taken before the study starts, and the second will be collected during surgery.

4. Briefly describe how the data will be analyzed to address the purpose of the protocol.

The goal of the study is to measure pCR (pathologic Complete Response) at the time of surgery. This will be decided by looking at how the study exams, tests and procedures affects subjects' tumors (i.e., did the subject's tumor shrink, get bigger, or disappear after receiving the study treatment?) The data will be analyzed to figure out if patients might benefit from surgery for their rectal cancer in the future.

Note: For GCRC studies, this abstract is submitted to the NIH/NCRR and may be entered into the publicly available CRISP database.