## **FAST FACTS**

# URCC 16092: Phase II Study of Low-Dose Ibuprofen for Cognitive Impairment in Cancer Patients Receiving Chemotherapy

#### **Inclusion Criteria**

Study participants must:

- 1. Be  $\geq$  18 years of age
- 2. Have a diagnosis of cancer and are now receiving cytotoxic chemotherapy or have received cytotoxic chemotherapy within the last 6 months (i.e. are within a 6 month window of completion of chemotherapy).
- 3. Report cognitive difficulties or respond YES to the question: "Have you noticed any problems in your memory, attention, concentration, multi-tasking, or other cognitive functions?" NOTE: If a participant does not report cognitive difficulties or answers NO, they should be re-approached multiple times. Patients should be re-screened at all subsequent chemotherapy treatments and multiple times during the six months following completion of chemotherapy via phone and in person.
- 4. Be able to swallow medication.
- 5. Be able to read English.
- 6. Be able to give written informed consent.

### **Exclusion Criteria**

Study participants must not:

- 1. Have a confirmed brain tumor or confirmed brain metastases.
- 2. Be taking regular daily doses of an NSAID. Note: Daily doses of 81 mg aspirin are permitted and higher doses of an NSAID on an 'as needed' basis are permitted.
- 3. Be diagnosed with dementia or severe neurodegenerative disease that would prohibit the ability to complete cognitive testing.
- 4. Have a contraindication to ibuprofen per physician or physician's designee (e.g., allergy, worsening of ongoing medical problem due to NSAID, very low platelet count from chemotherapy, full-dose anti-coagulation/high risk of bleeding, as well as uncontrolled conditions such as hypertension, asthma, or peptic ulcer disease).
- 5. Have a hospitalization for treatment of a major psychiatric illness within the last five years.
- 6. Be pregnant.
- 7. Have a serum creatinine above 1.5 ULN. ULN is per institutional definition. If currently receiving chemotherapy, lab test must be collected within the 4 weeks prior to study enrollment. If not currently receiving chemotherapy, most recent labs tests may be used.
- 8. Be colorblind.
- 9. Have active substance abuse (e.g. alcohol, drugs) that would interfere with participation in this study per self-report or medical record.

#### Schema

