# S2212 Study Briefing

| SPECIAL NOTATIONS | REQUIREMENT DETAILS | REQUIREMENT COMPLETED Y/N |
|---|---|---|
| **LAB REQUIREMENTS** | Normal study labs – CBCw/diff, CMP, TSH and T4, ACTH and AM cortisol, Hep testing if needed, and pregnancy test (required if pre/peri-menopausal) | **Kits if patients consent – 20mL streck and 10mL red top tube**<br>**C1D1, C3D1, within 3-5wks of las NAST dose, 6mo post-op, 12mo post-op**<br>**Ship ambient same day, M-F**<br><br>**Kits provided through kit management - ordered** |
| **QUESTIONNAIRES** | Promis fatigue-7a – C1D1, 3-5wk post NAST, month 18<br>Promis-29 profile – C1D1, 3-5wk post NAST, month 18<br>Fact-G GP5 – 3-5wk post NAST, month 18<br>PRO-CTCAE – C1D1 of each cycle | All questionnaires are available in Credit |
| **TISSUE SUBMISSION** | Mandatory – 1 H&E slide after registration<br>Required if consents – 1 block or 10 slides after registration and after surgery if there is residual disease | **Ship Monday - thursday** |
| **RT REQUIREMENTS** | **Adjuvant therapy follows standard guidelines – no credentialing** | |
| **RADIOLOGY REQUIREMENTS** | Breast and axillary imaging and Echo/MUGA required at pre-registration and standard of care imaging is done at surgery | **No credentialed scanners** |
| **TRAINING REQUIREMENTS** | NONE | |
| **FUNDING** | **Study does not cover any drug costs only optional blood samples** | **CREDIT build completed** |

| | | |
|---|---|---|
| **AE ASSESSMENTS** | No solicited AES, no start/stop dates | SAE reporting is only for unexpected grade 4 events that are possible or greater, or grade 5 events |
| **PHI DISCLOSURE** | Standard PHI | Follow Essentia Health Policy EHA3032 |
| **MISC.** | SWOG registration sheet in binder | **DCP study** |
| **OUTREACH** | Complete review for the following:<br>• Lab – Check with Lindsey for outreach kits – need to be able to ship from site<br>• Radiology – Any scanners should work<br>• Radiation – Duluth or Ashland<br>• Treatment – Same as registration sites | Enrollment can go to Duluth, Virginia, Hibbing, Sandstone, Deer River, Moose Lake, Ashland, Fargo, Brainard |

## STUDY BRIEFING ATTENDANCE SIGN-OFF

By signing this debriefing, I attest that I have reviewed all required training modules, protocol, and/or any special requirements listed above for my study role. I agree to follow GCPs and instructions provided in the protocol in the conduct of this study. This briefing was completed prior to any study procedures, and I was given the opportunity to ask questions.

NOTE: The study briefing does not replace the teams (CRC/CRA) responsibility for reading the protocol in its entirety. It is the responsibility of each team (CRC/CRA) to brief/train any staff member who is covering this study in their absence.

| PRINT NAME | SIGNATURE | TITLE | DATE |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |