NRG-GY008
Required Forms and Materials

Form/material *Forms in bold are available to all patients. Forms that are not bolded are rolled out based on entered data.*	Description	Submission
RANDOMIZATION		
Form ENTRY	Collects information on eligibility criteria and patient characteristics needed at patient entry.	Form ENTRY is to be submitted through the NCI Oncology Patient Enrollment Network (OPEN) system.
BASELINE FOLDER *(Following Randomization)*		
• **Visit Information – Baseline** • **Registration Form** • **On Study History Information** • On Study History – Surgery • Pre-Study History Chemotherapy Information • Pre-Study Radiation Therapy Information • **Pre-Treatment Summary** • **Medical History** • **Specimen Consent** • Concomitant Medications • ECG Information • ECHO/MUGA Form • Vitals Form • Labs and Chemistries	Collects information on pre-treatment required assessments	Submit form in Medidata Rave within 14 days of registration
Eligibility Checklist	Displays data as entered at enrollment. Data entry errors at enrollment can be updated on this form	Submit as needed

PATHOLOGY FOLDER		
Form or Report Upload	Collects submission information on required pathology reports	Submit form in Medidata Rave within 14 days of registration
SOLID TUMOR EVALUATIONS		
• **Tumor Assessment Visit Form** • Target Lesions Form • Non-Target Lesions Form • No Target Lesions Form • New Target Lesions Form • Status and Response Form • **Unscheduled Solid Tumor Visit Loader**	Collects submission information on tumor assessments at baseline at scheduled assessment times (see protocol section 4.2)	Submit form in Medidata Rave within 14 days of assessment
TRANSLATIONAL RESEARCH		
Translational Research Management	Collects information related to tissue collection	Submit form in Medidata Rave within 8 weeks of registration (see protocol section 10.4 and appendix XII)
TR FFPE Primary Tumor (FP01)	Collects information related to tissue collection and is printed to accompany the biospecimen shipment (see protocol section 10.4.1)	Print using the "PDF File" link at the top of the form to accompany biospecimen shipment
TF FFPE Metastatic Tumor (FM01)	Collects information related to tissue collection and is printed to accompany the biospecimen shipment (see protocol section 10.4.1)	Print using the "PDF File" link at the top of the form to accompany biospecimen shipment

VISIT FOLDER		
• **Visit Information** • Concomitant Medication • ECG Information • **Vitals Form** • **Blood Pressure** • **Glucose** • **Cycle Drug Information** • **Toxicity Report – Section 1** • Toxicity Report – AEs • Toxicity Report – AE Grades • **Lab Loader**	Collects information on assessments during treatment	Submit form in Medidata Rave after cycle is given
TREATMENT COMPLETION FOLDER		
Treatment Completion	Collects information on treatment discontinuation	Submit form in Medidata Rave when patient ends protocol treatment
FOLLOW-UP FOLDER		
• **Visit Information – Follow up** • **Follow-up** • Non-Protocol Therapy Reporting Form • Follow-up Adverse Event Reporting – Part 1 • Follow-up Adverse Event Reporting – Terms • Follow-up Adverse Event – AE Grades • **Lab Loader**	Collects information during follow-up	Submit form in Medidata Rave from the end of protocol treatment every 3 month for the first. 2 years and then every 6 months for the next 3 years