Example DTL Signed on 20-Feb-2020

Protocol Information		
Protocol Title A Randomized Phase III Trial of Endocrine Therapy Plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer		
Phase III	**CTEP Document Number** E2112	**Lead Protocol Organization** ECOG-ACRIN
Site Information		
Research Site Name Ohio State University Comprehensive Cancer Center	**Site ID** OH007	**Address** 410 West Tenth Avenue, Columbus, OH 43210 US
Clinical Investigator Information		
Person ID IVR-39855	**Name of Clinical Investigator** Ramaswamy, Bhuvaneswari	
IRB of Record		
IRB # IRB00000781	**IRB Name** National Cancer Inst Central IRB #1 (Adult)	**Address** 401 N. Washington Street, 7th Floor, Rockville, MD-20850
Laboratory Information		
01D1069865, UNITED LAUNCH ALLIANCE, 100 ATLAS AVENUE MAIN BLDG 70, TRINITY, AL 35673		
Delegation of Tasks Log		

#	CTEP Person ID	Person	Research Task
Clinical Investigator			

1	IVR-39855	Ramaswamy, Bhuvaneswari	Consenting Person, Eligibility Assessment, Enrolling Person/Treating Investigator, HP Assessments, Tox Assessment
Sub-Investigators			
1	AP-552557	Camp, Andrea Renee	Rave CRA
2	AP-540434	Gleich, Erica Lynn	Consenting Person, DTL Administrator
3	AP-535497	Laibach Thompson, Megan E.	OPEN Registrar
4	AP-553233	Shegena, Eden	Rave CRA
5	AP-533592	Tolliver, Katlyn	DTL Administrator, OPEN Registrar
Delegation of Tasks Log (Site Added Tasks Not Mandatory for this Protocol)			
#	**CTEP Person ID**	**Person**	**Research Task**
1	AP-552557	Camp, Andrea Renee	Patient Screening/Recruiting
2	AP- 550606	Huhn, Carolyn Jane	RT/Imaging Support
3	A-509751	Jelinek, Kathryn Lynn	Patient Screening/Recruiting

Commitments

- I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
- I agree to personally conduct or supervise the described investigation(s).
- I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.
- I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.
- I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.
- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
- I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.
- I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312

Signature		
Signature	**Date**	**Printed Name**
Bhuvaneswari Ramaswamy	20-Feb-2020	Bhuvaneswari Ramaswamy
I have acknowledged and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.		