

Example DTL Signed on 20-Feb-2020

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

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	CTEP Document Number	Lead Protocol Organization	
III	E2112	ECOG-ACRIN	
Site Information			
Research Site Name	Site ID	Address	
Ohio State University Comprehensive Cancer Center	OH007	410 West Tenth Avenue, Columbus, OH 43210 US	
Clinical Investigator Information			
Person ID	Name of Clinical Investigator		
IVR-39855	Ramaswamy, Bhuvaneshwari		
IRB of Record			
IRB #	IRB Name	Address	
IRB00000781	National Cancer Inst Central IRB #1 (Adult)	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, Bhuvanewari	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			
<ul style="list-style-type: none"> 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>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.</i>		