



I-SPY 2 TRIAL: Concept Proposal for Data Access and/or Biospecimen

General Information

Name:

Institution/Affiliation: UCSF

Email:

Phone Number:

Institution/Affiliation:

Individual to Complete Biomarker Data Analysis: Amrita Basu, PhD

Individual to Complete Clinical Data Analysis:

:

Purpose (underline all that apply):

Grant

Manuscript

Abstract

Research Proposal (Not to exceed 3 pages)

Title:	
Background: (keep to half a page)	
Preliminary Results: (not to exceed half a page)	
Relevant Own Publications: (up to 5)	
Primary Objective:	
Secondary Objective:	

Research Request

Specific Data Requested: (List the biomarker, and clinical specific variable details for each category from I-SPY data dictionary and attach the variable spreadsheet)	<i>Clinical Variables from data dictionary:</i> Biomarkers:
I-SPY 2 Specific Biomarker Patient Population: ClinicalTrials.gov ID NCT01042379	Arms: Subtypes:



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(list specific treatment arm(s), and/or sub-types, or any closed arms etc)			
Timepoint (T0, T1 etc)			
Biospecimen Type as applicable (tumor/buffy coat/plasma/serum and/or Sub-Sample Type, i.e. sections, DNA, RNA)			
Quantity per Sample			
Quality Metrics of Samples eg >30% cellularity			
Biospecimen Contact Name, Shipping Address, Phone Number, Email Address			
Underline the type of research that will be performed, if applicable.	Exploratory	<u>Qualifying</u>	Standard
Will the platform or assay be performed in a CLIA certified Lab?	(If so, submit the associated standard operation procedures.)		



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Analysis, Budget, Funding, and Timeline

General Analysis Overview (Please keep to 1 page)	
Statistical Analysis Template Used (ISPY provided) or describe own below:	
Detailed Analysis Plan:	
Deliverables (data types, variables)	
Timeline for Completion once Data/Biospecimen are Received: (biospecimen distributed immediately prior to use only)	(Include time for contracting, assay completion, and data analysis completion)
Budget for Concept Work, as applicable: (Platform or Assay cost per sample, etc.)	
What is the funding source for this work?	
Other Relevant Information/Comments:	

Submission

Please Submit in MS WORD To:	Biomarker Liaison (Data and Specimen Access) Gillian Hirst PhD Email: gill.hirst@ucsf.edu DO NOT FAX
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