**General Information**

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| --- |
| Name: Institution/Affiliation: Email: Phone Number:  |
| **Individuals involved in Concept, and their Role, Institution/Affiliation, and Email Addresses**Individual to Complete Assay, if applicable:Individual to Complete Biomarker Data Analysis:Individual to Complete Clinical Data Analysis: |
|  |
| **Purpose (underline all that apply):** Grant Manuscript Abstract |

**Research Proposal (Not to exceed 1-2 pages)**

|  |  |
| --- | --- |
| **Title:** |  |
| **Background:** **(not to exceed 10 lines)** |  |
| **Preliminary Results:****(not to exceed 10 lines)** |  |
| **Relevant Own Publications:****(up to 5)** |  |
| **Primary Objective:** |  |
| **Secondary Objective:** |  |

**Research Request**

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| **Specific Data Requested:** **(clinical, biomarker, demographic- detail for each)** |  |
| **I-SPY 2 Specific Biomarker Patient Population:****(specific treatment arm)** |  |
| **Biospecimen Type if applicable** |  |
| **Timepoint (T0, T1 etc)** |  |
| **Sample Type, i.e. sections, DNA, RNA** |  |
| **Quantity per Sample** |  |
| **Quality Metrics of Samples** |  |
| **Biospecimen Contact Name, Shipping Address, Phone Number, Email Address** |  |
| **Underline the type of research that will be performed, if applicable.** | Exploratory Qualifying 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**

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| **General Analysis Overview*****(Not to exceed more than 1 page)*** | (A concise, clear, and brief summary of the Statistical Analysis Plan for a broader scientific audience.) |
| **Statistical Analysis Plan:**  | (Indicate template used- these can be obtained from the ISPY 2 trial, or state Own, modified etc) |
| **Detailed Analysis Plan:** | (Include primary endpoints, variables of interest, sample size justification, and statistical plan used) |
| **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:** | **I-SPY 2 DAPC Project Manager****Email: ispy2dapc@quantumleaphealth.org****Phone: 415-353-7743****DO NOT FAX** |

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