**General Information**

|  |
| --- |
| 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**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **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.) | |

**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** | |