**LUNG CANCER MASTER PROTOCOL (LUNG-MAP) DRUG SELECTION COMMITTEE**

APPLICATION FORM

The intent of this form is to provide the Independent Drug/Biomarker Selection Committee with background information regarding drugs/drug combinations to be considered for the Lung-MAP trial. This application is divided into two sections: **Part A** requests summary information on the candidate drug/drug combination and **Part B** requests more detailed information on its development status.

Information contained in this document will not be shared with individuals who are not a part of the Selection Committee or project staff of Friends of Cancer Research, the Foundation for the NIH, or the Investigational Drug Branch of NCI. Information provided will be treated with confidentiality by all of the parties previously listed. In addition, prior to submission and discussion of more detailed information in **Part B**, formal CDAs will be executed between the applicant and Lung-MAP project team because of the proprietary nature of the information requested. Representatives that have applied for participation in Lung-MAP will not have access to information supplied by other applicants.

Please fill out **Part A o**f this form and return to the Lung-MAP Drug Selection Committee electronically at the address shown at the end of this application. Following submission, applicants will be contacted by a member of the project team to talk about submission of **Part B** and to schedule a time for an introductory discussion of the application with a member(s) of the Selection Committee.

**Part A**

**Drug/Drug Combination Name:**

**Manufacturer(s):**

**Primary Target:**

**Primary Contact Information**

 Name:

 Title:

 Phone:

 Email:

 Assistant Name and Email:

 Assistant Phone:

**LUNG-MAP DRUG SELECTION COMMITTEE**

APPLICATION FORM

**General Information:**

 Drug/Drug Combination Target(s) (list all known):

Mechanism(s) of Action:

Drug Type(s) (Small Molecule or Antibody):

Current Phase of Development:

Biomarker(s):

Type of Assay(s) Required:

The intent of the Master Protocol is to use Foundation Medicine’s Next Generation Sequencing Assay as a broad screening tool, to be supplemented, in some cases, by immunohistochemistry or other methodologies as the patient selection tool for trial enrollment. The supplemental testing could, for example, be a proprietary methodology developed by the company. Is this procedure acceptable to you?

**Brief Narrative Summary of Development Status Relevant to Lung-MAP** (≤ 1 page; focus on items listed under **Data Requirements** in **Part B**)

**Part B**

**Data Requirements** (Including available Phase 1-2 data, toxicity and efficacy)

Please describe current evidence of clinical activity:

Please provide a summary of clinical data. This should include number of patients treated with single agent and in combination (list partner drug(s) tested to date); if already tested in NSCLC, indicate if squamous cell carcinoma patients have been treated, in particular, and please describe this group separately:

Please provide a summary of the current or potential toxicity profile of the agent (including high grade toxicities):

Please provide in brief a summary of preclinical/cell line/tissue/animal data:

Please provide a summary of pharmacokinetic and pharmacodynamic (PK/PD) data for the agent:

Please describe the existing assay status (if any) for selecting patients to receive the drug. If you plan to seek approval for this co-Dx, are you willing to share methodology for the assay, so that it can be performed centrally by Foundation Medicine if appropriate:

Please provide an update of your clinical development plan (studies relevant to Lung-MAP):

Please include additional relevant data and reports as needed (including, but not required, Investigator’s Brochure, if available):

Submission of Application. Completed application forms (**Part A** only or full application, **Part A** and **Part B)** should be submitted electronically by email (in PDF format) or by fax to:

 Lung-MAP Drug Selection Committee

 Attn: Dr. Caroline Sigman, PhD

 Phone: 650-691-4400

 Fax: 650-961-4410

 Email: csigman@ccsainc.com