**Appendix A: Research Plan and Funding**

Title of CRADA

 **Clinical Study(ies) with Formulary Agent(s) Provided by Collaborator**

NIH CRADA Extramural Investigator/Officer(s)

Dr. Jeffrey Moscow and Dr. Margaret Mooney

CRADA Collaborator Principal Investigator

Xxxxx

Term of CRADA

Five (5) years from the Effective Date

**1. Research Goal of CRADA**

The overall goal of this research project is for Collaborator (“Collaborator”) to provide its proprietary Agent(s) (“Formulary Agent(s))” as listed in Attachment A (as may be amended or updated periodically) to support investigator-initiated clinical trials sponsored and conducted by Approved Investigators. The scope of this CRADA is limited to these investigator-initiated clinical Protocols and non-clinical study proposals.

**2. background and contributions of collaborator**

 (collaborator introduction in a couple of sentences,)

**3. Clinical Protocols and NON-CLINICAL Studies using NCI formulary Agents**

 “NCI Formulary” is the Cancer Moonshot initiative that is a public-private partnership with pharmaceutical and biotechnology companies to expedite cancer researchers’ access to investigational agents and approved drugs for their research projects. The researchers will be able to obtain anti-cancer agents from the preapproved “formulary” list and test them for new indications or in new combinations. Ultimately this approach will expedite the start of clinical trials and will bring new treatment options to cancer patients faster.

The investigator-initiated clinical Protocols and non-clinical study proposals using the NCI Formulary Agent(s) approved by Collaborator during the term of the CRADA will be made a part of Appendix A of this CRADA.

During the term of the CRADA and if mutually agreeable by both Parties, Collaborator may provide additional Formulary Agent(s). Additional Formulary Agent(s) and their respective key patent(s) will be added to Attachment A and the updated Attachment A will be incorporated into the CRADA.

**4. Respective Contributions of the Parties**

**A. Collaborator Responsibilities**

1. Collaborator will provide a cross-reference letter of its Investigational New Drug Application (IND) or Master File for each Formulary Agent(s) to FDA with a copy to the Approved Investigator to file in the investigator-sponsored IND for the clinical trial(s).

2. Collaborator, at its own expense, will supply appropriately packaged and labeled Formulary Agent(s) to the NCI Clinical Repository in accordance with NCI Investigational Agent labeling guidelines and the Investigational Agent Material Safety Data Sheet to support the clinical trial(s).

3. Collaborator, at its own expense, will be responsible for ongoing stability testing according to the stability testing protocol defined in the Collaborator’s IND or Master File and provide DCTD with the Investigational Agent stability protocol schedule and test results to support the clinical trial(s). Collaborator will also provide the Investigational Agent lot-release Certificate of Analysis and cGMP-release certificate for each Investigational Agent lot provided to DCTD.

 Collaborator will be responsible for providing a copy of the Formulary Agent Investigator’s Brochure and all updates directly to the PMB who will distribute it to Approved Investigators, as applicable.

**B. DCTD Responsibilities**

1. DCTD will forward the LOIs it receives from Approved Investigators to Collaborator for review and approval, which process shall be completed by the Collaborator within 8 weeks. DCTD will provide assistance to the Approved Investigator(s) and Collaborator to ensure the completion of the review process within the time period above.

1. DCTD will provide Collaborator comments and contacts to the Approved Investigator(s) to support the Protocol development of an approved LOI.
2. DCTD will provide subsequent Protocol(s) to Collaborator for review and comment. Final Protocol approval will be provided by NCI following receipt of the Formulary Agent(s) to support the Protocol, the Collaborator’s concurrence that the Protocol may proceed and all required regulatory filings and agreements are executed by and with the Approved Investigators and the DCTD.
3. DCTD’s PMB will distribute Formulary Agent(s) to U.S. Clinical Research Sites only according to the approved Protocol(s).
4. DCTD will forward to Collaborator for review and approval non-clinical studies (“Proposals”) using the Formulary Agent(s) under this Agreement. Following Collaborator’s approval, DCTD will provide the agents to the Approved Investigators to conduct non-clinical studies.

**6. Funding**

If an Approved Investigator requests and Collaborator approves, Collaborator may provide the funding to NCI under the CRADA to support the clinical trial or correlative studies approved by Collaborator in conjunction with the approved Protocol. A new funding section will be added to Appendix A of this CRADA by an amendment.

*Payment Information*:

Checks for monies payable directly to the NCI should be made payable to the National Cancer Institute and addressed to the individual identified under IC CRADA Notices on the Contacts Information Page.

All checks should be marked with a clear reference to the NCI CRADA Number and Title: CRADA #xxxxx “xxxxxx”. Should NCI require electronic deposit of any monies payable under this CRADA NCI agrees to provide Collaborator with the appropriate account information.

**Attachment A**: Formulary Agents provided by Collaborator and their respective key patent.