

Pre-Application Webinar for Molecular Profiling to Predict Response to Treatment (MP2PRT) Program

Retrospective Characterization and Analysis of Biospecimens
Collected from NCI-Sponsored Trials of the NCTN and NCORP



a National Cancer Institute program

January 30, 2018

Pre-Application Webinar Topics for MP2PRT

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Program Purpose – MP2PRT

- Program comes out of the Beau Biden Cancer MoonshotSM Initiative and is supported by dedicated funds from the 21st Century Cures Act
- Targets a scientific priority designated by the Blue Ribbon Panel
 - Retrospective analysis of biospecimens already collected from patients enrolled on completed NCI-sponsored clinical trials of the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) that have outcome results available
- Focus of MP2PRT is on the response of specific tumors/cancers to treatment
- Successful proposals will be those that are hypothesis-driven, hypothesis-generating, or exploratory in a key population, and that propose studies where comprehensive molecular analyses could answer a key clinical question

Timeline – MP2PRT

- Release Date: December 4, 2017
- Webinar: January 30, 2018, 2-3 PM ET
- Letter of Intent: February 15, 2018 (Required)
- Receipt Dates for Proposals: March 15, 2018

Special Eligibility Criteria – MP2PRT

- Limited Competition
 - Currently funded NCTN Network Groups: NCTN Operations Centers in conjunction with the NCTN Tissue Banks, NCTN Statistics & Data Management Centers (SDMCs), and relevant group of NCTN investigators (*can include Canadian NCTN Group if Canadian Group can accommodate biospecimen access and data sharing requirements of MP2PRT*)
 - Currently funded NCORP Research Bases
- Biospecimens collected from NCI-sponsored NCTN or NCORP trials in which:
 - Clinical data have already been presented or published
 - Publication or presentation at a major scientific meeting is planned by July 1, 2018
- Must include letters of support from:
 - Statistical Investigator verifying the availability of the relevant data for sufficient patients with the relevant consent under standard DUA terms in a timely manner
 - Tumor Bank verifying the availability of the specimens for transfer for the project under standard MTA terms in a timely manner

Application Components – MP2PRT

- Cover letter signed by NCTN Network Group Chair or NCORP Research Base PI
- Proposal using provided proposal form (should not exceed 10 pages)
- Budget
- Parent trial protocol (may request accommodation for an NCTN trial by providing only trial number and version date if full protocol electronically available on file at Cancer Therapy Evaluation Program's Protocol and Information Office)
- Letters of support from Statistical Investigator and Biospecimen Bank PI

Funding Mechanism – MP2PRT

- Funding for approved proposals will be provided via a contract mechanism, rather than a grant supplement. Proposal budgets should be prepared accordingly.
- Contracted laboratories will conduct necessary biospecimen preparation or extraction and perform molecular characterization.
 - Biospecimen preparation or extraction and molecular characterization should not be included in the proposed budget.
- Data analysis will be performed as a collaboration between the Group/Research Base and the investigators at the contracted laboratories who characterize the samples.
- Funding for approved proposals will be provided via a subcontract mechanism to the NCORP Research Base or via separate subcontracts to the NCTN Group Operations, SDMC, and Bank components.

Budget Issues – MP2PRT

- Separate budgets sections should indicate which costs would be paid to each NCTN Group grant component. A single budget can be used for NCORP Research Bases.
- The budget may include:
 - Biospecimen bank costs for locating, assessing, preparing, and shipping of biospecimens to the contracted laboratory
 - Statistical center costs for preparation and transfer of relevant patient-level clinical and outcome data from the trial(s) to the appropriate data repositories and costs to support reasonable biostatistician involvement in the proposed research project
 - Operations center costs to support reasonable lead investigator and operations staff involvement in the proposed research project
- Budget must NOT include costs covered any NCTN or NCORP grant
- Budget should use the Form PHS 398 with narrative justification for each cost

Select Review Criteria – MP2PRT

- Proposals will be reviewed by NCI for scientific merit, feasibility of the work, and potential for benefiting patients and guiding future treatment decisions
- Highest priority will be given to hypothesis-driven proposals with detailed statistical plans
 - Exploratory or hypothesis-generating projects will be considered, particularly in cases of good clinical opportunity, high diversity sample representation, or building on data generated from prior analysis projects
- Additional criteria:
 - Comprehensive molecular analyses of malignant and patient-matched normal samples could answer a key clinical question(s)
 - Feasibility given number and quality of biospecimens available
 - Acceptable timelines for provision of biospecimens and data
 - Appropriate consent for use of specimens and appropriate data sharing plans

Terms for Approved Proposals – MP2PRT

- Timely completion of contract agreements with the program contractor
- Timely submission of:
 - Fully executed MTA
 - Certification of consent
 - Biospecimens and associated data
 - Clinical and outcome data

Contact Information – MP2PRT

Announcement and Webinar Slides (to be posted):

<https://ctep.cancer.gov/initiativesPrograms/nctn.htm>

Scientific Contacts:

Margaret Mooney, M.D.

Program Director, National Clinical Trials Network
Chief, Clinical Investigations Branch
Cancer Therapy Evaluation Program
National Cancer Institute

NCINCTNRFA@mail.nih.gov

Irina Lubensky, M.D.

Chief, Pathology Investigation and Resources Branch
Cancer Diagnosis Program
National Cancer Institute

NCINCTNRFA@mail.nih.gov

Administrative Contact:

Grace Mishkin, MPH

NCTN Operations

Clinical Investigations Branch

Cancer Therapy Evaluation Program

National Cancer Institute

NCINCTNRFA@mail.nih.gov



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