

Clarification of Guidelines Relevant to Protocol Specific Research Support

This Guidelines component provides support for short term, feasibility (e.g., pre-phase I, pilot) and phase I clinical trials originating from scientific investigators within the Cancer Center. Preliminary data generated from these trials, which historically were rarely funded through other mechanisms, could be used as the basis for support of later phase trials through competitive grant applications or industry. Criteria for support are as follows:

- 1) Trials should be high priority, innovative, feasibility (i.e., pre phase I, pilot) and phase I institutional clinical interventions focusing on initial early-phase testing of a candidate agent or device for the diagnosis, prevention detection or treatment of cancer. This support is not meant for *all* early phase trials, for later phase trials, or for studies that do that do not involve testing of an agent or device.
- 2) Trials must be conceptualized/designed by investigators in the Center's Research Programs.
- 3) Trials should typically be of short duration (e.g., less than one year).
- 4) Trials can not be receiving support through other peer reviewed research grants, cooperative agreements, or contracts. They may receive partial support from industry, assuming all other criteria are met.
- 5) The Center's PRMS must be approved or conditionally approved by peer review for funding of positions requested.
- 6) Trials must be approved by the PRMS.
- 7) Funding is restricted to support of research nurses and data managers *directly* involved in the conduct of these trials. No other positions are eligible for support via this component (e.g., pharmacist). Center leadership must oversee these funds (i.e., no funds are allowed for a core director or other supervisory functions).