Clinical Research Oversight Council: IIT Review & Scoring

**Background**:

Clinical Research Oversight Council (CROC) has oversight of clinical research activities at the University of Arizona Cancer Center (UACC). CROC is chaired by the Associate Director of Clinical Investigations and includes clinical research stakeholders across UACC. One of the responsibilities given to CROC by the UACC Director is to support hypothesis-or specification-driven UACC-based research that would result in a grant and/or investigator-initiated trial (IIT) within 2 years of funding.  The requests for proposals are disseminated quarterly (January, April, July, October).

**Guidelines for submission**:

* Principal investigators are required to be UACC members
* CROC typically awards funds up to $50-60,000, enough for a translational add-on to a clinical trial funded by other means, or for a small pilot trial
* Please use UACC IIT template and limit to no more than 5 pages, with preliminary data if available. You could use a different template if you already have one (e.g., from a pharmaceutical company), if it has all the fields requested by the UACC IIT template
* The focus is on NEW concepts. If money is asked for an ongoing study, it has to be for a new aim with a clear deliverable (e.g., a new finding in the course of a trial that could be used to apply for a future grant, or a need for additional data for an R01 application that just missed the funding cutoff)
* Please include a specific description of current and future funding plans
* Proposals should clearly indicate transdisciplinary collaboration within UACC (trans-programmatic collaboration preferred – see description of four UACC Cancer Center Programs)
* A budget should be included. An IIT budget template is provided but other templates may be submitted. Please note: faculty salary, travel, and publication fees are not supported by CROC funds
* Awarded funds are for use within UACC and should not be used to support work at other institutions
* Awarded funds cannot be used for other research without prior CROC approval
* If funds are not spent within 2 years, PI could apply to CROC for a no-cost extension.

**Scoring:**

CROC will assess IIT concepts for resource allocation, taking into account the resources that were already obtained externally from grants and pharmaceutical companies. The concept will be scored and ranked using a 5-criteria scoring system, with a scale of 5-25, with 25 being the highest mark. The average score of the four required committee member reviews is calculated, and trials are placed in ranking order. The evaluation questions in ranking a concept or protocol summary are as follows:

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| **CONCEPT EVALUATION QUESTIONS** |  **SCORE****low high** |
| Does this project promote transdisciplinary collaboration between the Cancer Center Programs and its members? | 1 | 2 | 3 | 4 | 5 |
| Will this project impact patient care? | 1 | 2 | 3 | 4 | 5 |
| Will this project serve the Cancer Center’s defined catchment area? | 1 | 2 | 3 | 4 | 5 |
| What is the potential of this study to obtain additional external funding? | 1 | 2 | 3 | 4 | 5 |
| Is the project scientifically innovative? | 1 | 2 | 3 | 4 | 5 |
| **Total Score:** |  |