

NCI's Office of Cancer Nanotechnology Research Pre-application Question/Answer Meeting Details and FAQ's for U01 and U54 Submissions

NCI's OCNR recently announced new funding opportunities: the *Centers of Cancer Nanotechnology Excellence – U54* ([RFA-CA-14-013](#)) and the *Innovative Research in Cancer Nanotechnology – U01* ([PAR-14-285](#)). In order to help all applicants in the process of submitting their applications, we will hold two** “pre-application” question and answer meetings, which will be publically accessible, on **Friday September 5th, 2014**.

**Each meeting will be specific to only one grant type (e.g. U01 or U54)

Please read the following information carefully. It includes the times for each meeting, the three ways to attend / communicate during each meeting, and a frequently asked question (FAQ) section to help answer a few commonly asked questions before the meeting.

--For all NIH VideoCast links please test your browser prior to the meeting [here](#). The VideoCast will allow for questions to be written in the **Live Feedback Form** during the meeting ([FAQs pertaining to NIH VideoCast](#)). The questions will be immediately relayed to the panel.--

Pre-application Informational Webinar for RFA-CA-14-013 CCNEs (U54) **September 5, 2014, 2:30–4:00 pm EDT**

NIH VideoCast: [U54 Q&A Meeting live link here](#)

Teleconference Call-in: **1-(866)-692-3582** and use conference passcode **6705578**

NIH Campus Bethesda, MD Natcher Auditorium, Rm. H*

Pre-application Informational Webinar for PAR-14-285 IRCNs (U01)-Domestic Applicants

September 5, 2014, 1:00–2:00 pm EDT

NIH VideoCast: [U01 Domestic Q&A Meeting live link here](#)

Teleconference Call-in: **1-(866)-692-3582** and use conference passcode **6705578**

NIH Campus Bethesda, MD Natcher Auditorium, Rm. H*

* Due to the limited seating available in this room, we strongly encourage applicants to attend remotely via VideoCast, teleconference, or both simultaneously.

Frequently Asked Questions (FAQs)

A good place to start, for applicants who are unfamiliar with the application process at the National Cancer Institute, is on the NCI website at [this link](#) for general NCI research and funding FAQs. FAQs specific to the funding opportunities being discussed in this meeting are as follows:

FAQs for IRCNs (U01)

- **Q - What are the objectives of the U01s (IRCNs) under this PAR?**
- A - The IRCNs are expected to expand the fundamental understanding of the processes pertinent to the use of nanotechnology in cancer. Clinical translation is NOT a goal of IRCNs.

- **Q - What nanotechnology devices and constructs qualify under this PAR?**
- A - Please carefully review the definition of nanotechnology included in PAR. For example, microfluidic devices (*unless they have nanometer range channels*) do not qualify.

- **Q - What is the maximum award budget and project period allowed?**
- A - Application budgets are limited to \$450K in direct costs per year; Applications may request up to 5 years of support.

- **Q - Can the application include multiple PDs/PIs?**
- A - Given the need for integration of multi-disciplinary efforts in IRCN projects, applicants are encouraged to take advantage of the multiple PD/PI option with one PD/PI representing biology or oncology fields and another PD/PI representing the fields of chemistry, physics, or engineering.

- **Q - Can one institution submit more than one application to the same submission date of this PAR?**
- A - Yes – providing that research areas and teams on both applications are significantly different.

- **Q - What are the differences between the PAR for these U01s (e.g. IRCNs) versus the RFA (CA-09-013) published in 2009, which also solicited U01s (e.g. CNPPs)?**
- A - The primary differences and similarities are:
 1. This PAR does NOT have set aside funds allocated as it did for the previous phase's U01 RFA. The funds to support U01 awards will be drawn from RPG (Research Project Grant funds) pool, similarly to standard R01 submissions.

2. This PAR has multiple receipt dates, on a rolling basis, versus the previous U01 RFA, which designated a single receipt date. Please see the announcement ([PAR-14-285](#)) for the specific receipt dates.
3. Scientific review of the current PAR U01 application does remain within NCI and does not go to the NIH Center for Scientific Review (CSR) for peer review, which is the same as the previous RFA U01.

- **Q - Can the PD/PI be a PD/PI on both an IRCN (U01) and the Cancer Nanotechnology Training Center (T32) application at the same time?**
- A - **Yes** – a PD/PI may submit an application for and, if awarded, serve as the PD/PI for both the U01 and T32 (relevant to the Cancer Nanotechnology Training Centers), simultaneously.

- **Q - Can the PD/PI be a PD/PI on both an IRCN (U01) and the Centers of Cancer Nanotechnology Excellence (U54) application at the same time?**
- A - **No** – although, technically, one applicant may apply for an IRCN on the 2nd (or later) due dates while also having applied for the U54, they may NOT serve as the PD/PI, if awarded, simultaneously. However, IRCN applicants/holders can serve as Project leaders, Core directors, or other key personnel within a U54 CCNE application.

- **Q - Is there a particular focus on selected tumor types to be investigated in the U01 and how many of them should be included in the application?**
- A - All IRCN applicants are expected to concentrate their proposed efforts on **one or two rationally selected tumor types**. The PAR does not make any recommendations when it comes to the selection of tumors under investigation.

- **Q - How does one incorporate a nanomaterial repository into the required data-sharing plan?**
- A – In the Data Sharing Plan, all applicants are expected to address the sharing of nanomaterial data through appropriate publically accessible databases. At least one scientifically qualified person is expected to be designated as the nanomaterial data sharing coordinator after an award has been made. For the purposes of this Funding Opportunity Announcement (FOA), applicants should detail plans for data submission into NCI's cancer Nanotechnology Laboratory ([caNanoLab](#)) data portal, as described in the Cooperative Agreement Terms and Conditions of Award. Standardized text describing data deposition into caNanoLab will be provided on [the caNanoLab FAQ Wiki page](#).

FAQ's for CCNEs (U54)

- **Q - What are the objectives of the U54s (CCNEs) for this phase of the Alliance?**
- A - U54s are expected to enable the development of nanotechnology-based comprehensive solutions to significant problems in cancer biology and / or oncology and to produce cancer care relevant applications with clinical utility.

- **Q - How are these objective different than the previous phase's U54s (e.g. RFA-CA-09-012)?**
- A - They are similar, however the number of required translational projects is increased to two.

- **Q - What nanotechnology devices and constructs qualify under this RFA?**
- A - Please carefully review the definition of nanotechnology included in RFA. For example, microfluidic devices (unless they have nanometer range channels) do not qualify.

- **Q - What is the maximum award budget and project period allowed?**
- A - Application budgets for each Center may not exceed \$2.6 million in total costs per year and need to reflect the actual needs of the proposed project : applicants may request up to 5 years of support.

- **Q - How many research projects should be included within the application?**
- A - Each CCNE is **required** to include **3 - 5 Research Projects** (no more than 5 and no less than 3) closely pertinent to the research objectives (outlined in [Section I](#) of the FOA) and in combined support of the overarching problem in cancer biology and/or oncology selected as the theme for the Center. It is required that: (i) at least two projects are clinically-relevant translational projects with the ultimate goal of technology commercialization and (ii) at least one project is oriented mainly to basic research/discovery.

- **Q - What components will be required for these multi-component applications?**
- A - Components required include: *Overall* (12 page limit), *Admin Core* (6 page limit), *Research Projects* (12 page per project limit), and *Developmental Program* (6 page limit). Components not required but recommended include: *Shared Resources Core* (6 page per core limit with no more than 2 cores allowed).

- **Q - Must the Center PD/PI also be a Project Lead for a project?**
- A - No – The Center PD/PI is not required to be a Project Lead for a project within the Center.

- **Q - Can we indicate two or three Project Leads (Co-Project Lead) for each project?**
- A - Yes – it is allowed to have more than one Project Lead per project.

- **Q - Can one person participate as a Co-Project Lead on more than one project?**
- A - Yes – Although, the consideration needs to be given to over-committing one investigator to too many projects.

- **Q - Can the PD/PI for the CCNE (U54) also be a PD/PI on an application to the companion funding opportunities (e.g. IRCN-U01 or Cancer Nano Training Center-T32)?**
- A - PDs/PIs submitting a U01 application in response to the IRCN FOA [PAR-14-285](#) or T32 application (through Parent T32 FOA [PA-14-015](#)) for the first due dates in October and September 2014, respectively, are NOT eligible to apply for the U54 CCNE award under this FOA as PDs/PIs. However, these individuals can serve as Project leaders, Core directors, or other key personnel within a U54 CCNE application.

- **Q - Should the *Developmental Program* section of the application describe the actual science with respect to potential pilot projects?**
- A - No – Specifically, applicants are to outline their vision on strategies and mechanisms for developing Pilot Projects and Auxiliary Projects and the process for projects evaluation / approval. Applicants may indicate potential research directions to consider, but *are not to propose any specific projects in this section.*

- **Q - Can the application include multiple PDs/PIs leading the Center?**
- A - Multiple PDs/PIs are **required** for this FOA. Applicants should identify at least one senior investigator (PD/PI) to lead clinical translational oncology and another senior investigator (PD/PI) to lead the applied nanotechnology.

- **Q - Is there a particular focus on selected tumor types to be investigated and how many of them should be included in the application?**
- A - All CCNE applicants are expected to concentrate their proposed efforts on **one or a few rationally selected tumor types.** The RFA does not make any recommendations when it comes to the selection of tumors under investigation.

- **Q - How does one incorporate a nanomaterial repository into the required data-sharing plan?**
- A - In the Data Sharing Plan, all applicants are expected to address the sharing of nanomaterial data through appropriate publically accessible databases. At least one scientifically qualified person is expected to be designated as the nanomaterial data sharing coordinator after an award has been made. For the purposes of this Funding Opportunity Announcement (FOA), applicants should detail plans for data submission into NCI's cancer Nanotechnology Laboratory ([caNanoLab](#)) data portal, as described in the Cooperative Agreement Terms and Conditions of Award. Standardized text describing data deposition into caNanoLab will be provided on [the caNanoLab FAQ Wiki page.](#)

- **Q - Are clinical trials or *in vivo* studies in human subjects eligible to be covered under this RFA?**
- A - **No** – this RFA will not support clinical trials. However, *in vitro* investigations that employ clinical biospecimens or the theoretical modeling of human systems are within the scope of activities and will be considered for support by this initiative.

- **Q - Can applications be submitted as paper and / or electronic submission?**
- A - Electronic submission of application is **required** for this RFA.

- **Q - Will submissions from groups which were awarded in the previous phase of the Alliance program be considered as renewals?**
- A - **No** – all submissions are viewed as new submissions. Prior research experience (whether originating from previous Alliance award or previously performed research) should be described in the Overall section of the application.