Information for investigators interested in submitting a UG3/UH3 grant application in response to PAR-20-306

As you prepare your application in response to PAR-20-306, you will need to consider which items to include in your budget. Items to include for the National Dental PBRN Administrative & Resource Center (ARC) and the National Coordinating Center (NCC) comprise those listed in the Excel file entitled "PBRN-Descript-Resources-Grant Applicants" (see link from the NIDCR website).

So as to ensure equitable treatment of all potential applicants, the ARC and NCC cannot provide a budget or assist with writing your budget justification narrative. In your application there is no need to have a subaward from your institution to either the ARC or NCC institutions at this phase of the process. If your UG3/UH3 application is ultimately funded, the ARC and NCC may work with you during the UG3 phase to develop a UH3 application that may include funding to the ARC and/or NCC, but it would be premature to engage in those discussions at this point in the process.

ARC

As explained in the excel file (PBRN-Descript-Resources-Grant Applicants), you may include salary support for a Principal Node Coordinator (row 8) and Node Coordinator(s) (row 9). Per the FOA, you can budget allocations as stated in the file. Based on the project scope, Node Coordinator effort allocations may need to be modified prior to the start of the UH3 phase pending discussions between the project team, NIDCR, and the ARC. For budgeting purposes, you can use a 1.0 FTE salary of \$75,000, plus 50% fringe benefits and 60% F&A rates. Actual amounts will vary by region and personnel assigned to the study, which can be addressed as a final UH3 application is developed during the UG3 phase.

You also may include funding to remunerate patient-participants and practitioners for participating in or conducting the study, as stated in row 11. The dollar amounts for this remuneration will vary based on the time required of the participant or practitioner. Remuneration amounts from the network's previous studies have been mentioned in several of its peer-reviewed publications (http://nationaldentalpbrn.org/publications/peer-reviewed/) and for some studies are stated at http://nationaldentalpbrn.org/study-results/.

You also may include funding to pay for travel and food/beverage costs for Node Coordinators to conduct protocol training in practices and study monitoring or closeout visits. The typical dollar amounts are specified in row 12.

Questions about the ARC component can be directed to Gregg Gilbert (ghg@uab.edu).

NCC

In the Excel file (PBRN-Descript-Resources-Grant Applicants), there is text under columns C, E and F that describes the roles of the Study Manager, the NCC Data Manager and the NCC biostatistician. If you choose to include NCC staff besides the NCC Data Manager, you can use this text for creating your budget justification. In addition, the NCC can provide you with the biosketch for the biostatistician you have been working with during the concept development phase, if you have already engaged one. It is important to note that this may not be the biostatistician you will ultimately be assigned if you are funded.

Data collection for clinical studies can vary depending on study complexity. Participant (patient) registration and consent will need to use a PC, laptop or tablet located in the practice. All other data collection forms can be administered on a cellular telephone or tablet. However, complex chair side data collection (e.g., dental examinations) will need to be captured via a PC, laptop, or tablet. Cellular telephones are not appropriate for visually complex data due to limited screen space. See details below around study team expectations regarding tablets.

If a study team chooses tablets for data collection, the study is responsible for the selection, purchase, distribution, and management of the tablets used to collect data in both the UG3 and UH3 phases. The National Dental PBRN NCC will provide recommendations on type of device if needed. You can budget between \$200-\$400 per tablet/practitioner depending on the tablet operating system and capabilities needed for the study. Studies should plan to purchase additional tablets to serve as a backup in the event an assigned tablet is lost, stolen, or otherwise broken. Studies may also consider purchasing a warranty for tablets to insure against drops, spills, and malfunctions.

The study team should plan for technical assistance with the tablets to be covered through their institutions' IT department. It is the study teams' discretion whether this needs to be accounted for in the budget proposal and should be consistent with standard procedures at the institution.

The NCC is responsible for the development of all study-specific data collection systems unless a study-defined application (e.g., training app) is needed. Study budgets should include time for working with the NCC to extract data from the study-specific applications since study data will ultimately be housed in the NCC-supported study data collection system. The data collection Information-for-potential-UG3-UH3-applicants-to-National-Dental-PBRN-FOA-2022-02-02 v4.0

systems via the NCC-supported "Hub" and REDCap will be accessible via a URL which can be accessed via a web browser. More specifications related to data collection systems can be discussed further between the NCC and study team as needed.

If you have any questions about the NCC, please contact Reesa Laws (<u>Reesa.Laws@kpchr.org</u>) or Mary Ann McBurnie (<u>MaryAnn.McBurnie@kpchr.org</u>).