What is the timeline for approval of a P&F that will involve a clinical trial or other human subjects research involving greater than minimal risk?

If a DDRCC's Pilot and Feasibility Program will consider projects that include human subjects research, they should include a Human Subjects section for delayed onset studies. Otherwise, the DDRCC's P and F Program will only support research that does not involve human subjects research. If they are also going to allow projects that include a clinical trial, they also need to address delayed onset for clinical trials.

Before a funded DDRCC can award a Pilot and Feasibility Project that involves a clinical trial or other human subjects research involving greater than minimal risk, preapproval by NIDDK is required. The preapproval process generally takes a week or less.

The FOA indicates that 4 P&F examples should be described and for renewals should be from the currently funded group. If we have <4 should we move backward one year?

Yes, this is appropriate. The intent is to provide more information and the most recent information available.

Will the reviewers receive specific instructions regarding how to view enrichment activities during COVID?

Yes, we have NIH-specific policies for reviewers regarding activities during the pandemic.

The Biomedical Research Core have a minimum of 2 and maximum of 6. What, in your opinion, is a happy medium and/or necessary amount?

There are usually between 3-4 Biomedical Research Cores in a DDRCC. This will vary between centers. You can find a description of all currently supported DDRCCs, including their Biomedical Research Cores [here.](#) The number of cores and the services offered will depend upon the needs of your research base and should reflect the center's cohesive theme. Budget constraints should also be considered.

I see the designation of "P" in the Progress Report Publication List (renewal applications only) was preserved to enable sorting. Can you comment on this, as publications involving several cores can be challenging to segregate according to which was "most important?"

It will be the responsibility of each center to make the determinations regarding which core to designate as "P" for Primary contribution.