Pilot Awards – Developing a competitive LOI/Submitting a successful application

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Time	Section
02:49	**Objectives**

04:32	**Pilot and Feasibility Studies**
	• Pilots are subsets of feasibility studies
	• A feasibility study asks whether something can be done, should we proceed with it, and if so, how.
	• A pilot study asks the same questions but also has a specific design feature
	  o Has parts of a future study
	  o Conducted on smaller scale
	• Shows conceptual model of these ideas

06:57	**Areas of Focus in Feasibility Studies** • Acceptability • Demand • Implementation • Practicality • Adaptation • Integration • Expansion • Preliminary Data • Limited Efficacy
08:31	**Key References** • Example: Non-Randomized Pilots • Provides a lot of useful links on the slides • Example: Pilot and feasibility studies for pragmatic trials • CONSORT Extension (check lists when designing trials—items to help you think about the design)
13:41	**Using NIDUS Resources to Advance your Research** • Provides useful links to NIDUS website resources
16:05	**Goal of NIDUS II Pilot Studies** • Support studies related to delirium that provide key preliminary data, exploratory or proof-of-concept pilot work, feasibility studies, or secondary analyses that define a clear pathway to future large-scale studies and grants
17:01	**NIDUS II Priority Areas** • Inter-Relationship of Delirium and ADRD • Measurement of Delirium • Pathophysiology • Clinical Trials—Intervention Development
17:55	**Developing a Feasibility/Pilot Study** • Assemble a team (utilize NIDUS Collaboration Communication Site) • Develop a protocol—NIDUS Delirium Bibliography • Data sources—NIDUS Research Hub • Data Collection/Synthesis of data—NIDUS Measurement Core • Develop the pilot—Collaborative Working Group
18:43	**Keys to Success** • Don’t be overly ambitious in your aims • Do be specific in what you hope to accomplish • Consider the scoring criteria • Be explicit regarding the next steps, including large funding proposal

	• Use figures or infographics creatively • Use simple language and avoid abbreviations • Understand what type of feasibility study you are proposing • Set clear and realistic deliverables for the feasibility study • Do focus on feasibility outcomes • Do use NIDUS II resources • Take full advantage of NIDUS II Methods Consultations • Do demonstrate your commitment to delirium research
20:24	**Infographic Describing a PCORI Funded Study** • Delirium is a key outcome in this study • Feasibility version of this study: enroll about 30 patients for a trial; focus on simple aims (not all those outcomes)
22:13	**NIDUS II Collaborative Awards** • Letters of Intent (LOI) • $1,000 each for method consultations to refine pilot grant application
22:48	**Requirements for NIDUS Pilot Proposals** • Approved pre-application (LOI) and NIDUS II methods consultation. A NIDUS II Collaborative award is NOT required to apply for a NIDUS II pilot grant • Must complete 4-page brief NIH style proposal • Priority to projects relevant to the NIDUS II priority areas and lay the groundwork for future collaborative grants and papers • Utilize our NIDUS Cores and resources to accomplish the work • Involve 3-6 investigators from multiple disciplines • Preference for projects that involve multiple sites and include junior investigator(s).
23:23	**Review Criteria for NIDUS Pilot Grants** • Scored on NIH review criteria: significance, investigators, innovation, approach, environment • Relevance to aging and delirium research in a priority area • Feasibility/likelihood that the proposed study can be completed within one year • Use of NIDUS Core resources (e.g., measurement/harmonization core, research hub) • Involvement of multiple disciplines • Involvement of a junior investigator • Commitment to diversity, equity, and inclusion • Likelihood that the proposed study will lead to a future large grant proposal and/or major scientific publication that will help to advance delirium treatment
25:15	**Tammy's Project that was funded as a Pilot Award: Key Areas** • Feasibility of assessing delirium severity • Feasibility of determining who has ADRD
26:06	**Scope** • In scope vs. Out of scope for a pilot grant
27:33	**Refining Methods** • Cognitive status→ brief cognitive testing • Delirium→ Confusion Assessment Method (CAM) • Delirium severity→ CAM-Severity (CAM-S) ○ What to use? Peak CAM-S? Sum of all CAM-S scores? Categorical vs. continuous? • ADRD status determine by cognitive testing, chart review and expert consensus • 197/352 participants needed chart review by expert clinicians to determine ADRD status
31:53	**Outcomes** • Used peak CAM-S categorically

	○ Delirium incidence: persons with ADRD= 45%; persons without ADRD= 19% • ADRD patients ○ 24% of cohort ○ Higher peak CAM-S scores
32:49	**<u>Next Steps (findings that came from the pilot grant)</u>** • We need a tool that better assesses delirium severity in ADRD patients (external and local expert panels; DEL-S-AD) • We need to incorporate more ADRD patients into clinical studies
34:27	**<u>Questions/Comments & Answers</u>**