## Pilot Awards – Developing a competitive LOI/Submitting a successful application
Presenters: Michael Avidan, MBBCh, FCA SA and Tammy Hshieh, MD, MPH

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| 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
  - Has parts of a future study
  - 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
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| 32:49 | **Next Steps (findings that came from the pilot grant)**  
- 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 | **Questions/Comments & Answers** |

- Delirium incidence: persons with ADRD = 45%; persons without ADRD = 19%
  - ADRD patients
    - 24% of cohort
    - Higher peak CAM-S scores