Pilot Projects Program

de-ctr.org

The mission of DE-CTR ACCEL Program is to accelerate clinical and translational research that addresses health outcomes of Delawareans.

T0 — BASIC SCIENCE RESEARCH
Preclinical and animal studies
Defining mechanisms, targets, and lead molecules

T1 — TRANSLATION TO HUMANS
Proof of concept Phase 1 clinical trials
New methods of diagnosis, treatment, and prevention

T2 — TRANSLATION TO PATIENTS
Phase 2 and 3 clinical trials
Controlled studies leading to effective care

T3 — TRANSLATION TO PRACTICE
Phase 4 clinical trials and clinical outcomes research
Delivery of recommended and timely care to the right patient
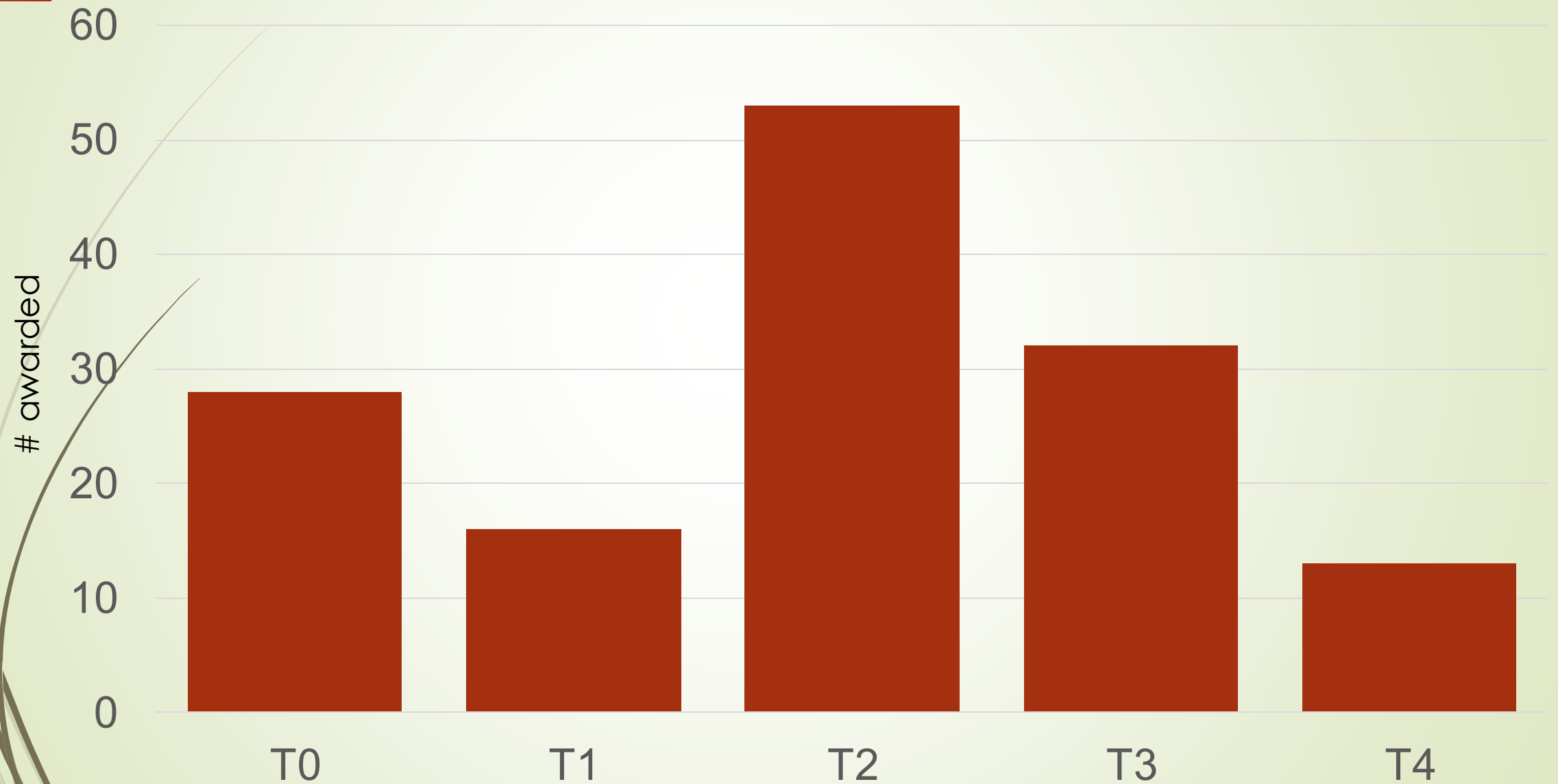
T4 — TRANSLATION TO COMMUNITY
Population-level outcomes research
True benefit to society

Translation from basic science to human studies

Translation of new data into the clinic and health decision making

uams.edu

Integrity, Confidentiality and Conflict of Interest in Peer Review

ACCEL funds pilot awards through its NIH dollars. We are obligated to follow the same rules as NIH regarding the integrity and confidentiality of the peer-review process and minimizing conflict of interest.

Report any issues or concerns in confidence to the

ACCEL Director of the Pilot Projects Program (PPP):

Megan Wenner mwenner@udel.edu.

Confidentiality, Conflict of Interest and Misconduct

Confidentiality:

- *Maintain strict confidentiality throughout and after* the peer review process!!
- All materials and discussions relevant to the applications are privileged communication.
- If you are contacted directly by an applicant, let the PPP director know at once and refer the applicant to the PPP director.

Conflict of Interest (COI):

- Real or perceived!!
- A reviewer feels or appears unable to provide objective and unbiased evaluation of an application.
- If you or your immediate family have a financial, intellectual, or personal interest in an application or there is an appearance of such a conflict, you may not review it.
- Report these situations to the PPP director.

Misconduct:

- A data fabrication, data falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- If you suspect misconduct, contact the PPP director privately so as not to bias the review process. Do not mention your concerns in your critique. Your concerns will be forwarded to leadership for handling.

Details on Confidentiality

Reviewers may not:

- Share review materials, assignments, discussions, scores, or critiques
- Allow applicants to influence evaluation of the applications
- Discuss applications in the absence of the PPP director
- Communicate with applicants regarding their applications
- Allow anyone access to the ACCEL dashboard reviewer system
- Seek expert opinion of a colleague without informing the PPP director

AFTER THE MEETING:

Reviewers **MUST** destroy all paper or electronic documents and records pertaining to applications or reviews immediately after the meeting

Details on COI

Reviewers may not:

- Participate in any reviews or the panel meeting if you have a direct financial interest in any application being reviewed
- Review specific applications in which you have a future planned collaboration with the PI
- Review specific applications in which you have a current or past (last 3 years) collaboration or mentoring relationship with the PI
- Review specific applications for which you have written a letter of support
- Review specific applications for which you have an indirect financial interest

By now, you should have:

- Viewed the preliminary list of applications to check for COIs

- Filled out, signed and returned the pre-meeting Confidentiality and COI forms (return to Karen Hough)

- Received your list of applications to review

Next up, you will:

- As soon as you get these, go into the ACCEL dashboard and check that you:
  - Can open each application
  - Do not have any unforeseen COIs to report (if you do, notify the PPP director asap!)
- Read over the 'Reviewer Tips' document before you start scoring!
- Go to your Teams channel and review the BERD reviews before you start scoring!

Using the Dashboard to Complete Reviews

- In the email with the grant assignment, you can click on the SUBMIT REVIEW button, which will take you to the Dashboard (you must log in).

- You can download the application (blue button, top right) – this will download a zip file. Upon unzipping the file, it will have a number (this is the project ID number) and you can then access the files.

Sections of the Grant Application

- Face Page
- Project Summary Page
- Detailed Budget and Budget Justification (CTR leadership will view)
- Biographical Sketches
  - One for every team member (optional for community and clinical partners)
- Prior IDeA Awards
  - Dates, types and number of prior award(s) and what products have been generated (leadership will assess)
- Specific Aims
- Research Strategy
  - Significance
  - Innovation
  - Approach
  - Community Engagement
- MPI Leadership Plan
- Letters of Support – Chair letter important (no Facilities or Environment)
- Mentor Letter / Compact

- **Human Subjects / Vertebrate Animals are due at JIT if the project is selected so you likely do not have these documents**

Getting Ready to Review: scientific merit reviewers

GOAL: Write a detailed critique with complete set of scores for all assigned applications

- 3 Criterion Scores – using the New NIH Simplified Review
  - Provide comments in each section (i.e., strengths and weaknesses)
    - Importance of the Research(Significance & Innovation)
    - Rigor and Feasibility (Approach)
    - Investigator and Environment (Acceptable / Unacceptable)

- Overall Impact Score:
  - Summary of the score-driving strengths and weaknesses based on the criterion scores
  - Need not be the arithmetical mean of the criterion scores

- Applicants will receive your criterion scores, overall impact score, and your comments

- Your preliminary Overall Impact Scores determine which applications are discussed

Scoring Rubric

- Score each criterion independently

- Assign each a score of 1 to 9

- **<u>Use the entire range of scores!!</u>**

- Scores of 1 and 9 are expected to be used less frequently than the other scores

- A score of 5 represents a good, respectable project

- Overall impact score is your overall impression, considering all relevant factors

- If you give a less than outstanding score on an item, include a clear description of the score-driving weaknesses
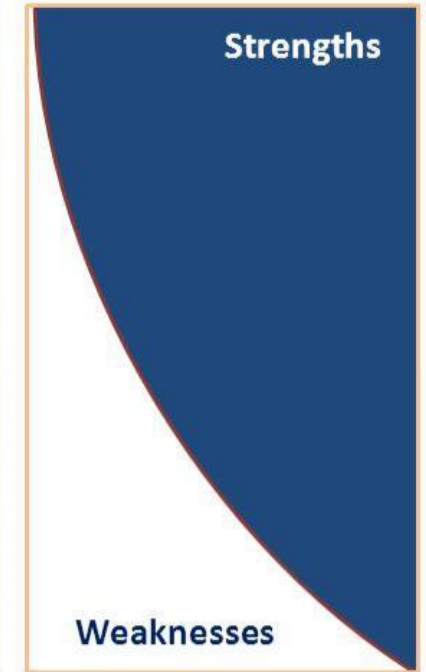
NIH Scoring System

Impact	Full Description	Score	Descriptor
High	Exceptionally strong with essentially no weaknesses	1	Exceptional
High	Extremely strong with negligible weaknesses	2	Outstanding
High	Very strong with only some minor weaknesses	3	Excellent
Medium	Strong but with numerous minor weaknesses	4	Very Good
Medium	Strong but with at least one moderate weakness	5	Good
Medium	Some strengths but also some moderate weaknesses	6	Satisfactory
Low	Some strength but with at least one major weaknesses	7	Fair
Low	A few strengths and a few major weaknesses	8	Marginal
Low	Very few strengths and numerous major weaknesses	9	Poor

Minor weakness: Easily addressable weakness that does not substantially lessen impact.
Moderate Weakness: Impact lessened.
Major Weakness: Impact severely limited.

Strengths

Weaknesses

overall impact score = panel average x 10.
Most scores are then percentiled for comparison across review groups.

Scoring Rubric: Avoiding Score Compression

➡ Remember: we care about rank order, not the raw score!

➡ Score compression occurs when a panel scores most of its applications within a narrow range.

➡ For example, if the panel scores all the applications in the 2-4 range, then it becomes almost impossible to identify the most meritorious ones. The rank ordering loses its value. Now the decision is taken out of the hands of the panel members.

➡ Therefore, it's critical to use the entire range of scores.

➡ A good rule of thumb is to start with a score of 5 (a good, medium impact project) and adjust your score down when you note key strengths and up when you note key weaknesses.

➡ Keep the overall impact scoring rubric (previous slide) in front of you while scoring. Keep track of the strengths and weaknesses and ask yourself whether they are minor, moderate or major. Moderate weaknesses demand a score of 5 or greater.

➡ Also remember: your preliminary scores are not binding! You'll be able to change them during the panel meeting, based on the panel discussion.

Bias in Reviewing

- Avoid translational bias
  - ACCEL values and funds applications across the translational spectrum
  - All types can have high impact
  - Different approaches, metrics, and outcomes are expected from each

- Avoid investigator bias
  - ACCEL funds both established and junior investigators
  - For established PIs, there should be a demonstrated, ongoing record of accomplishment
  - For junior PIs (no prior K or R), expect fewer publications, less preliminary data
  - Independence is not a score-driving criterion
  - But do expect appropriate training and experience

- *Do not score based on your perception of ACCEL priorities!*

Timeline for Completing Reviews: BEFORE THE MEETING

1. Preliminary Review Period
   - Applications assigned/available for review (dashboard)   June 12th
   - BERD and CEO feedback available for review *(Teams)*   ~June 20th
   - Pilot Core panelists written reviews and preliminary scores due in Dashboard   July 15th by 5 pm

2. Read Period
   - All applications and reviews available (masked format) to the entire panel for review *(Teams)*
   - Includes reviews of scientific merit (Pilot Core panelists), experimental design and statistics (BERD Core), and community engagement and impact (CEO Core)
   - All panelists should review and ask, are scores consistent? Where are the discrepancies?

3. Determining Projects for Panel Meeting Discussion
   - Averaged preliminary overall impact scores determine the top 50%
   - Top 50% plus all DSU projects will be discussed
   - Any panel member may also request to bring up others not in the top 50%- contact Megan for this

Panel Meeting to Discuss Applications

- Panel members:
  - Chair, PPP Director, Megan Wenner (non-voting)
  - Panel Administrators, Karen Hough & Jeanne Warrington (non-voting)
  - Voting members
    - Scientific merit reviewers (Pilots Core panelists) n ~13
    - Other core representatives n ~3
      - Biostatistics, Epidemiology & Research Design (BERD) Core
      - Community Engagement & Outreach (CEO) Core

Panel Meeting to Discuss Applications (cont')

- Pilots Core panelists
  - 3 have been assigned as primary reviewers for each app: R1, R2, R3
  - They will review based on scientific merit related to the 3 criterion scores

- BERD and CEO Core panelists will represent the expertise of their individual Core
  - BERD
    - Advise on the strengths or weaknesses related to subjects, design, outcomes, analyses, statistics not already identified by the primary reviewers; help resolve any discrepancies among reviewers regarding design and stats
  - CEO
    - For CE pilots, or any pilot that is community-engaged, provide an evaluation of the written community engagement plan, including the expected community impact as well as the quality and quantity of community engagement throughout the project

Timeline for Completing Reviews: AT THE MEETING

1. Agreement on Projects for Discussion
2. Discussion Order (by institute, for COI reasons)
3. Discussion of each Project (15 min)
   - **Reviewer #1 (~5 min), Reviewer #2 (~2 min), Reviewer #3 (if anything new to add)**
   - BERD Panel Member (if relevant, ~1 min)
   - CEO Panel Member (if relevant, ~1 min)
   - Group discussion (~5 min)

4. Final Scoring of each Project
   - Based on the entire discussion, R1-R3 give their final scores for overall impact, providing the range for the rest of the panel
   - Rest of the panel also scores and should indicate if they intend to vote outside the range (must provide a valid reason)
   - BERD and CEO Panelists may, but are not required to, vote on all applications; they should vote on those most relevant to their Core's expertise

5. Remember:
   - Overall impact score is your overall impression, considering all relevant factors
   - The panel's average overall impact score determines the final score
   - ACCEL leadership will also score on ACCEL priorities

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overall impact score = panel average x 10. Most scores are then percentiled for comparison across review groups.

Your Score Sheet

More on How to Score

- o Merit reviewers (all)
  - ▪ Score 1-9 on all applications
  - ▪ Score based on overall impact, and weighing in considerations from BERD and CEO Cores.

- o BERD & CEO reviewers
  - ▪ We already have your specific BERD/CEO scores.
  - ▪ Here, score 1-9 on the scoresheet based on overall impact, and weighing in considerations from BERD and CEO Cores.
  - ▪ For CEO projects, score all applications that have a relevant component / are CEO applications. You _may but are not required to_ score other applications.

- o If an application is not discussed, score as "**ND**".
- o If you are in conflict (you should be out of the room during discussion), score as "**COI**".
- o If you are not in conflict, but you are not present, score as "**NP**".
- o If you are present, but not voting, score as "**NV**".

Timeline for Completing Reviews: END OF MEETING

1. Turn in Final Score Sheets *(email)*
2. Pilot Core panelists: Make Any Final Revisions to Comments and Resubmit in Dashboard
3. Turn in post-meeting COI form *(email)*

THANK YOU!!