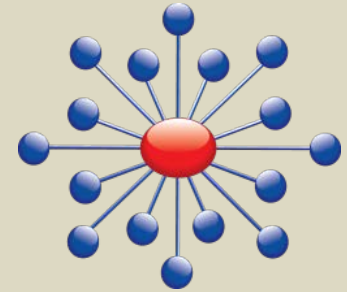


National Drug Abuse Treatment

Clinical Trials Network

*Forging partnerships to improve the
quality of drug abuse treatment
throughout the nation.*



Review Experience

Jay Ford, Ph.D.



January 8, 2015
Rockville, MD



Overview of the PCORI Review Process

James H. Ford II, PhD

Disclaimers

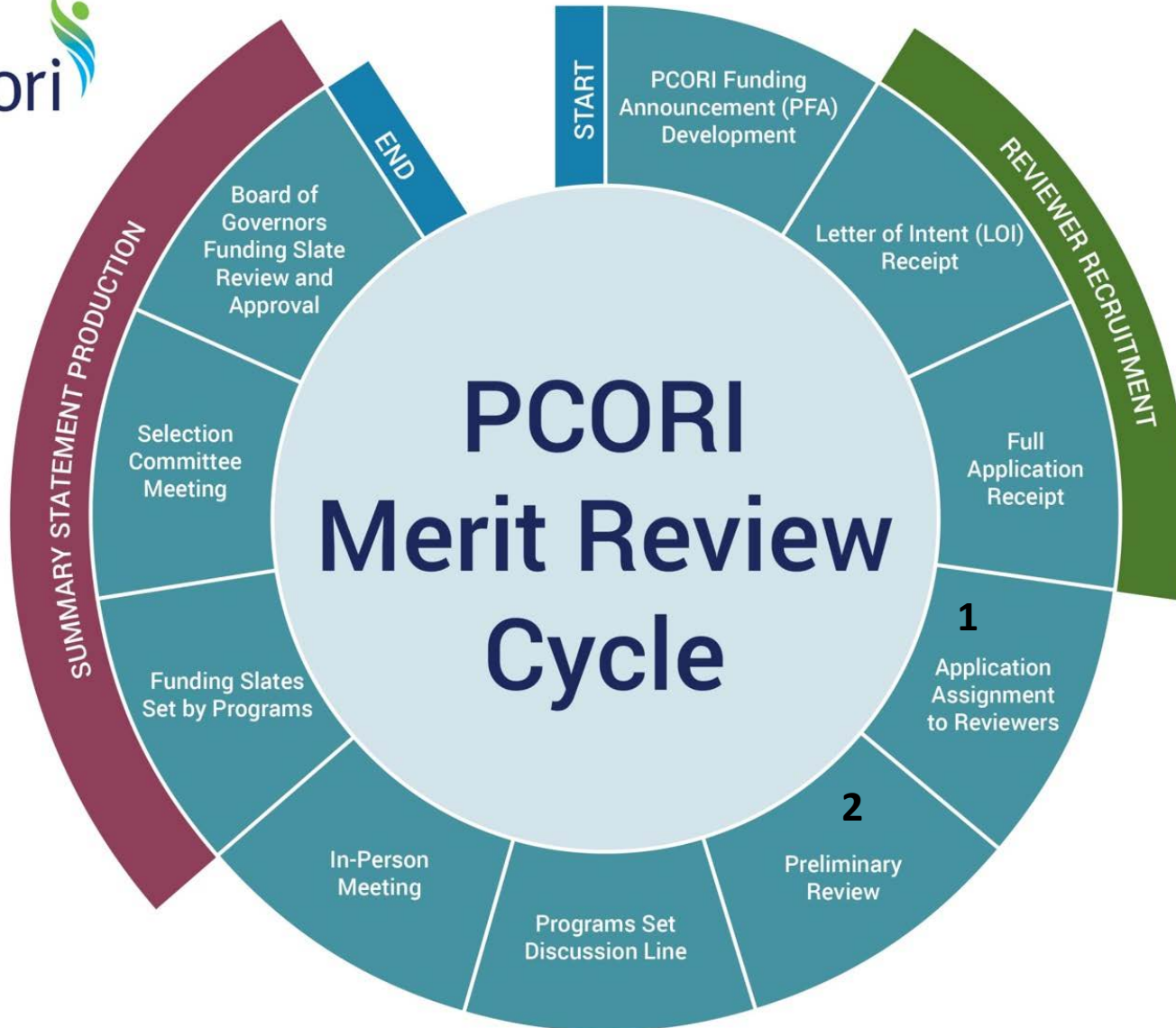
- Reviewed for PCORI Improving Health Systems and Addressing Disparities panels
- I did not review any of the applications presented today
- This session will not discuss any specifics or details from the confidential review process

Review Assignment and Process

PCORI Review: Who Might Participate

- Policy Makers
- Training Institutions
- Researchers
- Clinicians
- Representatives from:
 - Purchasers of Health Services
 - Hospital or Health Systems
 - Payers
 - Industry

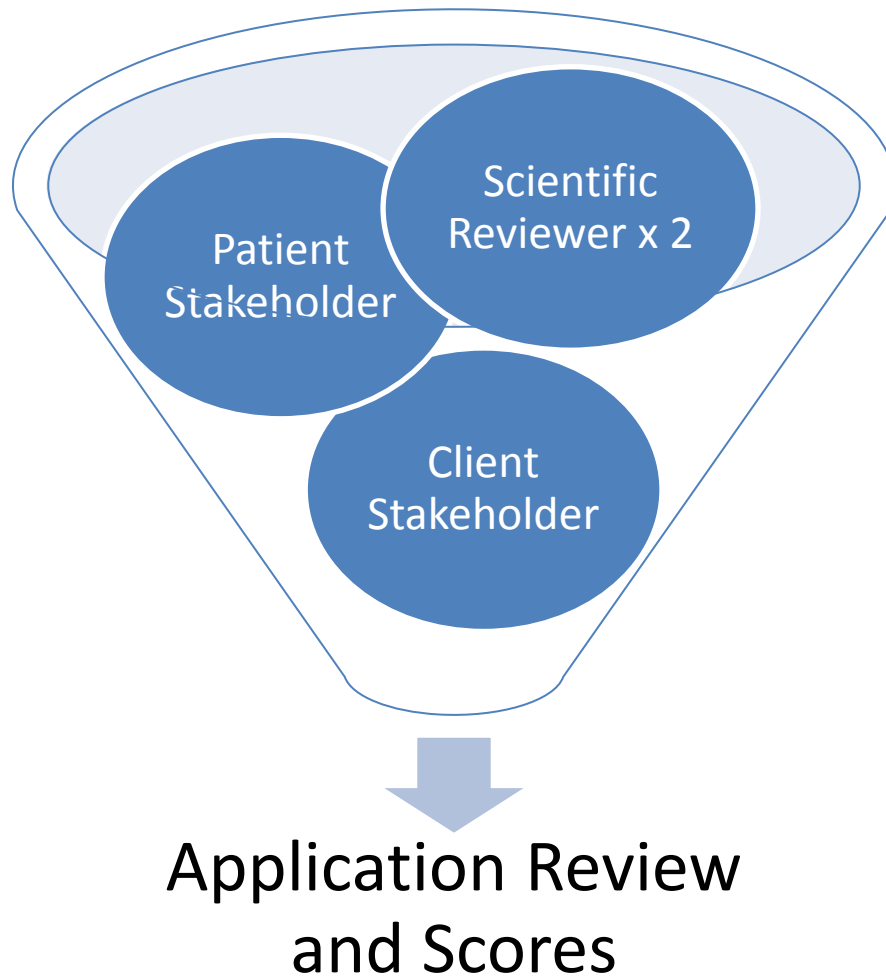
Overview of the PCORI Merit Review Cycle



PCORI: Reviewer Process



PCORI Review Process



During Review

- Each application is reviewed by four individuals
- Strengths and weaknesses identified for each of the five PCORI components.
- A score assigned on a 1 to 9 scale for each section.
- Human subjects is reviewed.
- Overall score and summary is provided.

PCORI Review: Merit Review Criteria

PCORI Merit Review Criteria	Researcher (2)	Patient Stakeholder	Clinical Stakeholder
Impact of the condition	X	X	X
Improve healthcare and outcomes or patient-centered research methods	X		
Technical merit	X		
Patient-centeredness	X	X	X
Patient and stakeholder engagement <ul style="list-style-type: none"> • Engagement Rubric • Dissemination 	X	X	X
Human Subjects	X		

Patient and Clinical Stakeholders can chose to review and score other aspects of the grant application

Learning from Others

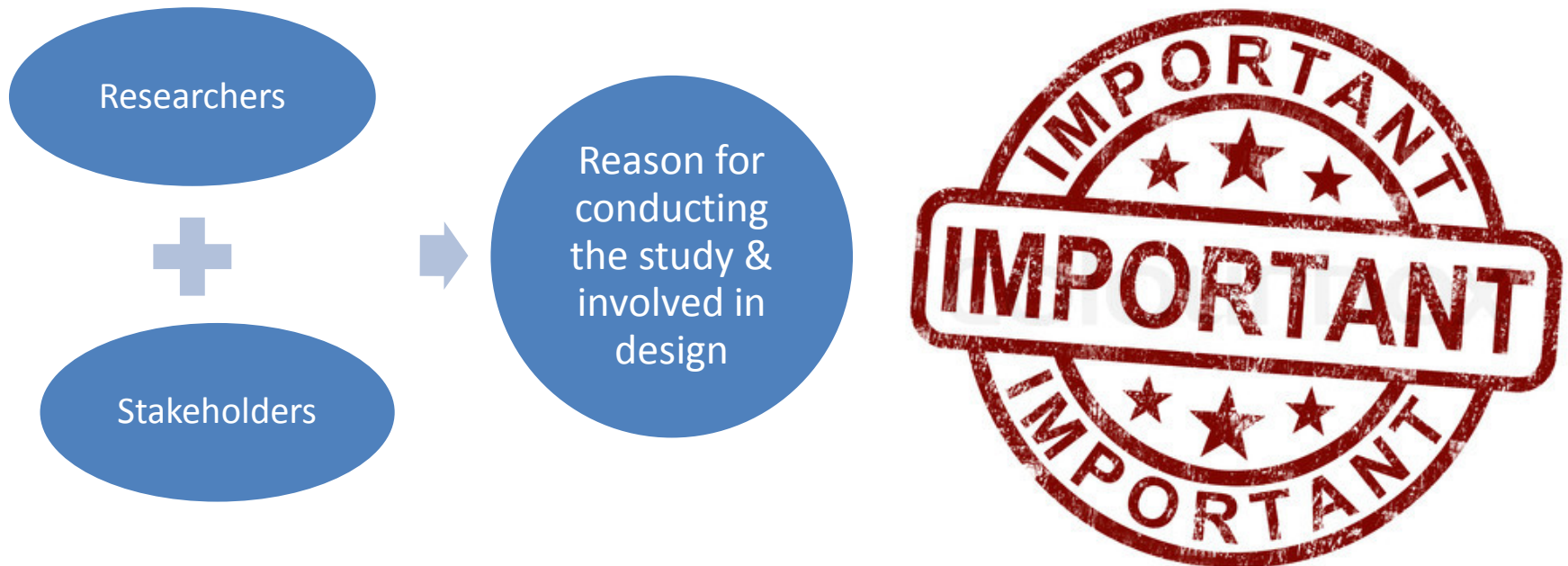
Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only Versus Integrated Behavioral and Medication Interventions (Dr. Aaron Hogue)

What the Application Summary Said	What the reviewers probably liked
<p>Adolescents with ADHD have problems with attention, self-regulation, & social competence that affect school performance & general development</p>	<ul style="list-style-type: none"> • Made arguments for significance of the issue and impact on targeted population • May have been identified as important by stakeholders
<p>Only two proven treatment options: academic training & stimulant medications. Unfortunately, most adolescents w/ ADHD do not receive either treatment</p>	<ul style="list-style-type: none"> • Provided evidence for why it is innovative • Clearly states what will be tested • Provided argument for why it is important to evaluate these two interventions • Clear evidence of what would be involved in each of the interventions • Probably identified as important by key stakeholders
<p>Primary objective is to compare the effectiveness, in OP behavioral services, of academic interventions only versus integrated (academic plus medication) interventions for adolescents w/ ADHD.</p>	<ul style="list-style-type: none"> • Only studying a few outcomes of interest • Clearly states purpose of the study • Strong statistical analysis plan for the outcomes • Incorporated a mixed methods component to understand why the intervention was successful
<p>Study will compare effects of these two treatment options on counseling attendance, medication use, behavioral problems, & quality of life</p> <p>Post-treatment interviews will ask families about their decisions regarding starting medication and their suggestions for improving services.</p>	

Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only Versus Integrated Behavioral and Medication Interventions (Dr. Aaron Hogue)

What the Application Summary Said	What the reviewers probably liked
<p>Randomly assign 140 primarily Hispanic & African-American adolescents with ADHD to academic-only or integrated treatment in community mental health clinics. Half of the study participants will have substance use problems as well as ADHD.</p>	<ul style="list-style-type: none"> • Unique study population • Multiple locations • Stakeholder choice (can opt out) • Adequate samples size • Probably good discussion of why the availability of treatment represents a gap for the proposed study population.
<p>Note that families will retain option of starting ADHD medication if they choose, and no family will be required to start medication at any time.</p>	
<p>Patient & Stakeholder Engagement: To guide the study, we will regularly consult researchers, youth, family advocates (including school officials), therapists & supervisors from counseling centers, & families who have an adolescent with ADHD.</p>	<ul style="list-style-type: none"> • Proposal offer strong evidence of how the engagement will occur. • Strong & <u>individualized</u> letters of support • Stakeholders perhaps had key study role (e.g., co-investigator)
<p>If proven efficacious, the academic-only & integrated treatment protocols could be rapidly shared w/ therapists, treatment programs, & school mental health counselors. W/ minimal additional training, clinicians working w/ adolescents could use protocols to treat ADHD & related problems.</p>	<ul style="list-style-type: none"> • Good evidence of how the study results would be disseminated • Perceived involvement of key stakeholders to help with dissemination efforts. • Perception that results could easily be disseminated.

Why does my idea matter



Pay Attention to the PCORI

Merit Review Criteria

- Impact of the condition on the health of individuals and populations or extent to which the proposed study addresses evidence gaps
- Potential for the study to improve healthcare and outcomes or to improve patient-centered research methods
- Technical merit
- Patient-centeredness
- Patient and stakeholder engagement

PCORI Review: What Else is Important

- Addressing relevant elements of the PCORI methodology report.
- Understanding and addressing elements in the Engagement Rubric.
- Dissemination Plan

PCORI Review: Methodology Standards

- Formulating research questions
- Patient Centeredness
- Data Integrity and Rigorous Analysis
- Preventing and handling missing data
- Heterogeneity of Treatment Effects
- Standards for Specific Study Designs & Methods

Engagement Rubric



Planning the Study



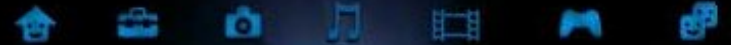
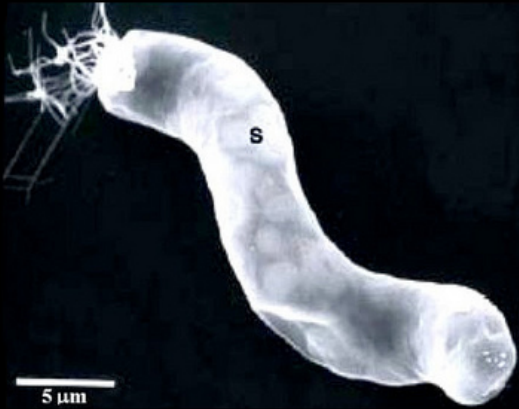
Conducting the Study



Dissemination of Study Results

Reviewer Perspective on Engagement:

**I WANT TO
BELIEVE**



make believe

Dissemination Plan

- Criterion 2: How likely is it that positive findings could be disseminated and implemented quickly, resulting in improvements in practice and patient outcomes?
- Criterion 5: How will patients and other stakeholders be involved in designing plans for dissemination activities?



Don't Forget about Human Subjects

Do not forget about the importance of Human Subjects. It is no different that addressing Human Subjects in an NIH Application including the client demographic table.

Did you really involve the stakeholders?



Questions for Successful Applicants

- How did issues raised in review by the patient and/or clinical stakeholders help improve your overall study design?
- How did you involve patients & stakeholders?
- What advice would you offer a research colleague who is applying for PCORI funding?