

ALZHEIMER'S CLINICAL TRIAL CONSORTIUM: HOW TO PROPOSE A CLINICAL TRIAL

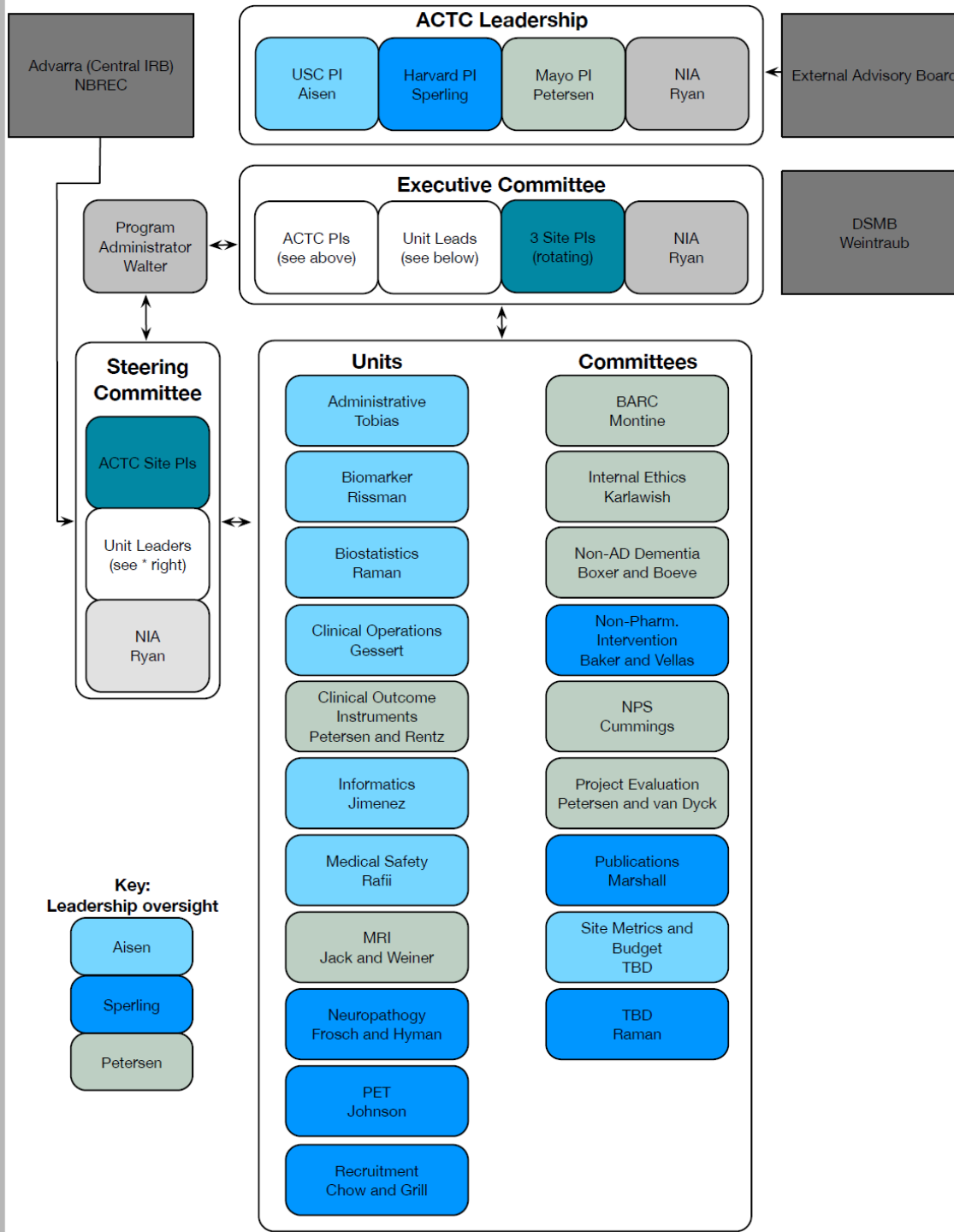
ADC Directors Meeting Oct. 20, 2018

ACTC: overview



- Launched December 2017

- ACT Leadership
 - Paul Aisen, USC
 - Reisa Sperling, HMS
 - Ron Petersen, Mayo
 - Laurie Ryan, NIA



ACTC Project Submission process

contact: Sarah Walter waltersa@usc.edu

- Step 1
 - ▣ Brief proposal
 - ▣ Study synopsis
- Appropriate proposals include
 - Phase 1 (pharmacodynamic), 2, 3
 - Any stage of AD
 - Symptomatic, disease-modifying
 - Behavioral
 - Non-pharmacologic
 - Non-AD dementia
 - Public-private partnerships encouraged

ACTC Proposal

Title:	
Investigator(s):	Institution Name:
Email address:	Date:
NIA funding opportunity: PAR-18-513 Key Dates: LOI: Application Due:	
Can the information provided in this form be circulated within the ACTC program for purposes of determining feasibility?	
<input type="checkbox"/> Yes	
<input type="checkbox"/> No, please provide a brief synopsis of your proposal that can be circulated within ACTC	
All proposals will be required to abide by the ACTC Data Sharing Plan. Please confirm that you are in agreement with this requirement by checking the box. <input type="checkbox"/>	

Scientific Proposal (limited to 4 pages total)

1. Specific Aims

2. Background and Significance

3. Preliminary Studies, Suitability and Feasibility

- a. Briefly describe relevant pre-clinical or clinical evidence used to support this trial.
- b. Describe the fit of the proposal with the strengths of the Consortium

4. Research Design and Methods

- a. Briefly describe the proposed trial design
- b. Participant Selection criteria: inclusion and exclusion

Study synopsis

Study Title	
Principal Investigators	
Study Design	
Study Sponsor	
Objectives	
Population	
Study Participation Duration	
Phase	
Number of Sites	
Description of Intervention	
Estimated Time to Complete Enrollment	
Key Eligibility Criteria	
Primary Outcome Measure	
Secondary Outcome Measures	

ACTC Project Submission process

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- Step 1: Protocol Feasibility Committee (PFC)
 - ▣ Initial screening and feasibility assessment
 - ▣ Aisen, Rafii, Raman, Donohue, Rissman
 - ▣ Other Unit/committee leads (eg MRI, PET, Neuropsychiatric, Non-Pharmacological, non-AD dementia) brought into assessment as needed

- Step 2: Project Evaluation Committee (PEC)
 - ▣ Scientific review
 - ▣ Petersen, van Dyck, Sperling, Hyman, Cummings, Craft, Salloway, Ryan

ACTC Project Submission process

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- Step 3:
 - ▣ Projects approved by the PEC are presented to ACTC Steering Committee for vote

- Step 4:
 - ▣ Projects approved by the ACTC SC advance to NIA application (in collaboration with ACTC Units and Committees)

- Process is interactive: ACTC can provide feedback/guidance to academic and company applicants at any project stage

PROPOSED TIMELINES

2018-2019

FOA Submission Date	Proposal Development Steps and Associated Timelines					
	STEP 1 ACTC Proposal Submission	STEP 2 PFC Review	STEP 3 PEC Review	STEP 4 SC Discussion & Vote	STEP 5 7-8 Project Selection & Grant Development	STEP 6 NIA Proposal Submission
Oct 5, 2018	June 1, 2018	June 8, 2018	June 19, 2018 (Teleconference)	July 13, 2018 (Teleconference)	July 15, 2018	Sept 21, 2018
Feb 5, 2019	Aug 5, 2018	Aug 13-15, 2018	Sept 10-14, 2018	Oct 21, 2018 (F2F)	Nov 5, 2018	Jan 22, 2019
June 5, 2019	Dec 5, 2018	Dec 12-14, 2018	Jan 7-11, 2019	Feb , 2019 (F2F)	March 5, 2019	May 22, 2019

Timeline for COI disclosures: 2 weeks prior to each meeting

ACTC Project Selection

- 12 proposals reviewed to date
- 1 approved and funded by NIA
- There will be 4-6 additional projects this cycle

- 2 proposals to be considered tomorrow at ACTC Steering Committee

ACTC-affiliated projects

- Simpler, shorter process
 - ▣ Review by ACTC leadership
 - ▣ Vote by Steering Committee
- Allows ongoing or planned, funded or unfunded projects to interact with ACTC, to utilize
 - ▣ Consultation
 - ▣ Steering Committee input
 - ▣ Resources (eg, data system, biorepository)



□ Questions?