

ACTC:
ALZHEIMER'S CLINICAL TRIAL CONSORTIUM



Multiple PI Project

- Paul Aisen, USC
- Reisa Sperling, HMS
- Ron Petersen, Mayo Clinic

Investigators at 3 primary institutions

- USC

- ▣ Aisen, Raman, Donohue, Rafii, Gessert, Jimenez, Chow, Jenkins, Toga

- HMS

- ▣ Sperling, Johnson, Rentz, Hyman, Frosch, Cudkowicz, Selkoe, Walsh, Arnold

- Mayo

- ▣ Petersen, Jack, Knopman, Dickson

ACTC: overview

- Launched December 2017
- Aims to build on our collective academic contributions to the field over many years
 - E.g., instrument development, biomarker utilization, pre-dementia and sporadic preclinical trial designs
- Aims to improve on prior procedures and practices, emphasizing:
 - transparency and collaboration
 - effective communication among sites, cores, investigators
 - sharing of data and methods
 - trial efficiency and data quality

Some key aspects of ACTC

- U24 award funds infrastructure for trials; no projects
 - ▣ Separate PA for project R01s has been released
- 35 member sites (this number may grow); many other participating sites
- Focus on:
 - ▣ rapid development and implementation of protocols
 - ▣ central IRB and master contract language
 - ▣ innovative trial design methods, outcomes, analyses
 - ▣ recruitment/diversity

Coordinating Center: USC ATRI units

- Administration: Tobias, Pizzola, Shaffer
- Biostatistics: Raman, Donohue
- Clin Ops: Gessert, Harless
- Informatics: Jimenez, Hong, Toga
- Medical safety: Rafii, Chow, Muranevici
- Recruitment: Chow, Moore, Bowman (many external)

Biomarker repository

- New facility in San Diego
- Robert Rissman, Director

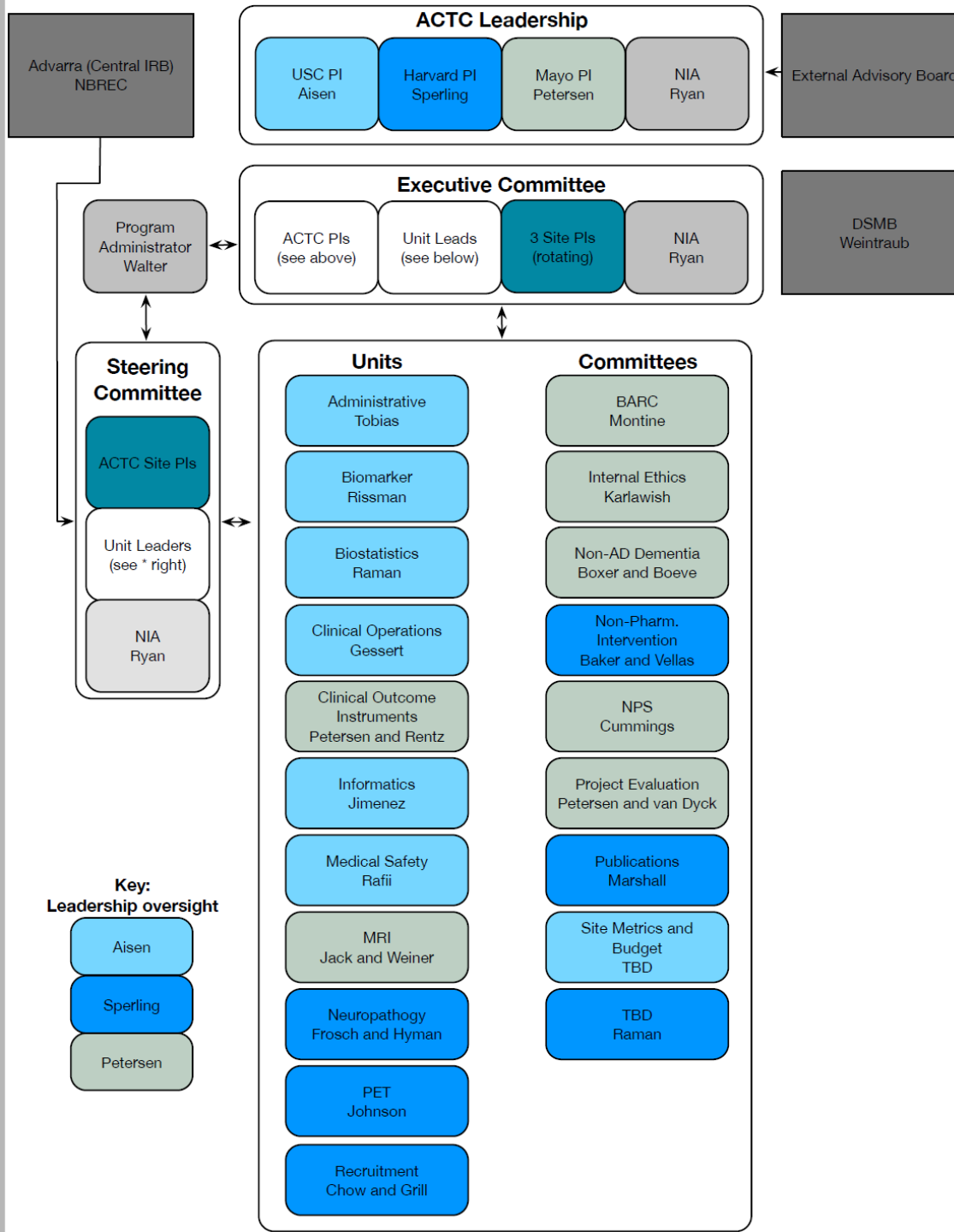
- AD biofluid assays, PK, APOE
- Specimen processing, storage and distribution

Other key units/committees

- PET: Johnson, Koeppe, Jagust
- MR: Jack, Weiner
- Recruitment: Chow, Grill, Karlawish, Baker, Monroe, Carrillo, Snyder, Weiner, Monroe, Langbaum ...
- Neuropath: Hyman, Frosch, Morris, Cairns
- NeuroNEXT liaison: Cudkowicz

Other key units/committees (cont)

- Instruments: Petersen, Rentz, Jenkins, Ferris, Marson, Weintraub, Amariglio, others
- Non-AD dementias: Adam Boxer, Brad Boeve, Steve Greenberg, Brad Dickerson
- Non-pharmacological interventions: Baker, Vellas
- Neuropsychiatric symptoms: Cummings, Mintzer, Portseinson, Tariot
- Ethics: Karlawish
- Publications: Marshall
- BARC: Montine



ACTC Project Submission process

contact: Sarah Walter waltersa@usc.edu

- Initial screening and feasibility assessment: Aisen, Rafii, Raman, Donohue
- Project Evaluation Committee (PEC): Petersen, van Dyck, Sperling, Hyman, Cudkowicz, Cummings, Craft, Salloway
- Projects approved by PEC are presented to ACTC Steering Committee for vote
- Approved projects advance to a collaborative NIA application with ACTC Units and Committees
- Process is interactive: ACTC can provide feedback/guidance to academic and company applicants at any project stage

ACTC and ADCs

- Increase interactions at fall and spring meetings
- Early discussions on potential project submissions
- Sharing of methods (including data system), data, specimens
- Collaboration on biomarker/assessment development
- Recruitment approaches
- Training of investigators and staff

- *The ACTC is a resource for trials in AD and other age-related dementias*