Community-Based Potential Participant Registries

Ed Core Meeting

October 11, 2013

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Disclosures

- Site investigator on clinical trials sponsored by the Alzheimer's Disease Cooperative Study (NIA), Janssen AI, Pfizer, Bristol Myers Squibb, Genentech, Avanir, Biogen Idec.
- Principal investigator of single site study sponsored by John Douglas French Foundation for which the medical food is generously donated by Accera Inc.
- Consultant to Avanir Pharmaceuticals, Phloronol, Inc (more than 12 months prior)
- Funding: NIA AG016570, Alzheimer's Association NIRG 12-242511, NACC JIA

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Why Study Recruitment?

- Most AD research fails to meet recruitment goals
- Failure to meet recruitment goals
  - Delays learning/treatment advances
  - Threatens internal validity
  - Raises concerns about generalizability of results
  - Could lead to disparities in disease treatment
- Two action items (1.B.2 and 1.B.3) in the National Plan to Address Alzheimer's disease (AD) aim to increase enrollment to AD clinical trials

Who Participates in Alzheimer's Disease Clinical Trials?

Characteristic	Community Study[1]	DHA Trial[2]
Age	84 ± 3.7	76 ± 8.7
Non-Hispanic White	78%	90%
Education > 12 yrs	13%	63%
% with spouses	29%	65%

[1]Data from the Aging Demographics and Memory Study. Fisher et al., *JAGS.* 2011. [2]Quinn et al. *JAMA* 2010.

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How Can We Increase Trial Enrollment?

- Appeal to previous participants
- Increase community referrals
  - Initiate satellite clinics
- Mailing lists
- Advertising campaigns
- Community outreach/ Community based participatory research
- Initiate potential participant registries

Grill and Galvin, *submitted*

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What is a Potential Participant Registry?

- IRB-approved source of research participants
- Distinct from AD Center's Clinical Core
- Enrollees agree to be contacted about new studies for which they might be eligible

Grill and Galvin, *submitted*

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Types of Registries

- National
  - Alzheimer's Association's TrialMatch®
  - Banner Institute's Prevent AD
  - Research Match
- Local
  - UCLA
  - NYU

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National Registries

- Strengths
  - Large campaigns to increase awareness
    - E.g. Alzheimer's Association chapters
    - Prevent AD partnership with AlzForum
- Weaknesses
  - Low interaction with local researchers
  - Low yield participants
    - E.g. 1% of TrialMatch enrollees have participated in research

Grill and Galvin, *submitted.* Petersen et al. *Neurodegen Dis Manag* 2010.

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Local Registries

- Strengths
  - Direct interaction with researchers
  - ‘Hands on’ approach may lead to increased research enrollment across a variety of studies
- Weaknesses
  - Resource intense

Grill and Galvin, *submitted.*.

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IRB Considerations

- May have unique application (separate from human subjects study)
- Minimal risk = expedited review
- Length of ‘participation’
- HIPAA considerations
- Listed as recruitment source for subsequent new studies

Registry Modalities

- Paper consent form that collects data
- Consent-to-be-contacted form
  - Telephonic follow-up, consent, data collection
- Electronic enrollment

Grill and Galvin, *submitted*

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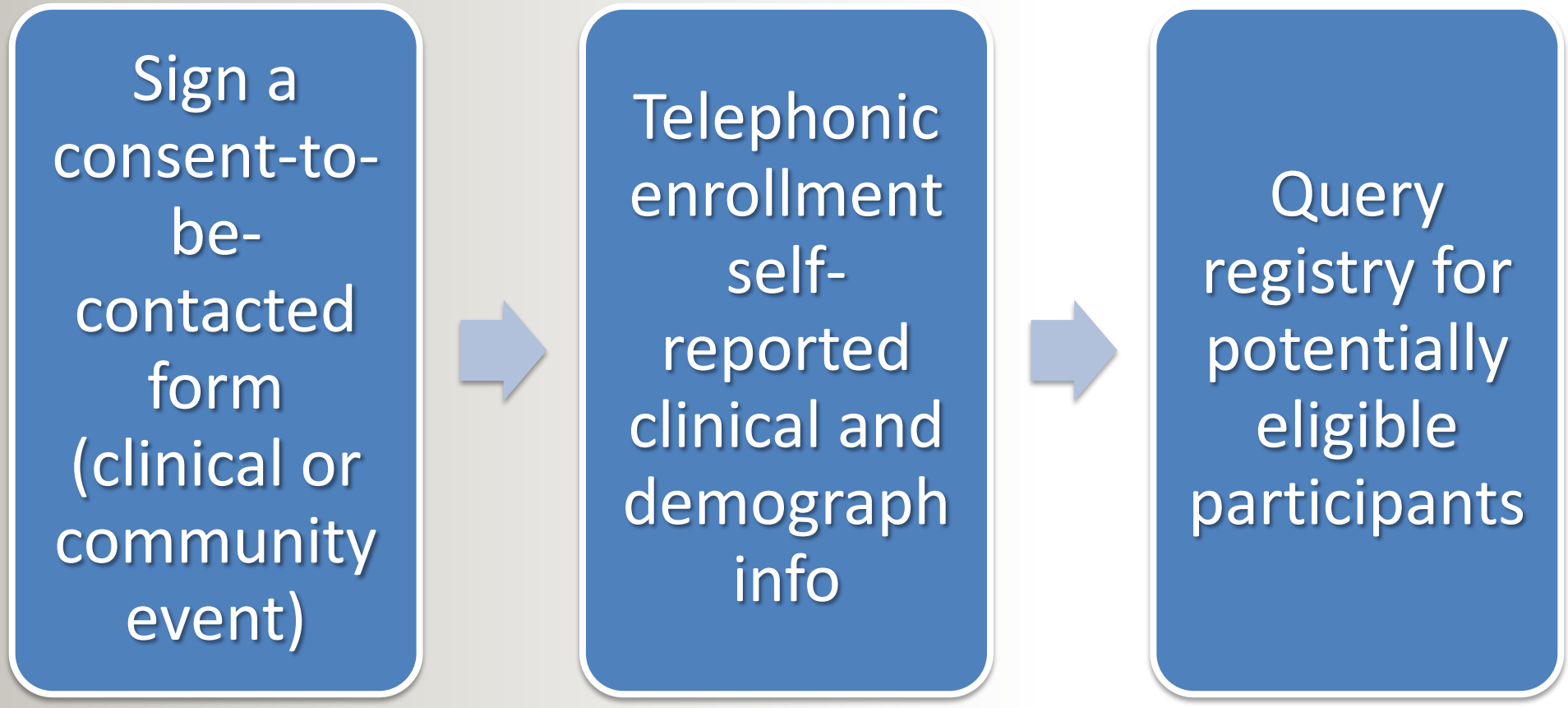
Potential Subject Flow



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David Geffen School of Medicine at UCLA
Department of Neurology

INFORMATION AND SIGN-UP SHEET FOR PARTICIPATION IN RESEARCH

Lay Title: UCLA Easton Alzheimer's Disease Center Potential Subject Pool

Technical Title: **UCLA Easton Alzheimer's Disease Center Potential Subject Pool**

Principal Investigator: Joshua Grill, PhD
Co-investigators: John Ringman, MD, Liana Apostolova, MD, Po Lu, PsyD, Ellen Woo, PhD, Kathleen Tingus, PhD, Mario Mendez, MD, PhD, Jill Shapira, RN, PhD, Sarah Kremen, MD, Edmond Teng, MD, PhD, Zaldy Tan, MD, Verna Porter, MD, Aaron McMurtray, MD

INTRODUCTION and PURPOSE
The Mary Easton Center for Alzheimer's Disease (AD) Research conducts clinical research studies related to AD. Signing this form indicates that you are willing to have someone from the Center call you and discuss research opportunities. Signing this form does not obligate you to volunteer for any research program and you can change your mind and refuse discussion with Center staff if you desire.

ANTICIPATED BENEFITS TO POTENTIAL SUBJECTS and SOCIETY
The studies conducted at the Center aim to improve diagnosis and find a cure for AD.

PRIVACY AND CONFIDENTIALITY
Information captured in this form or in the follow-up phone call will be confidential and will be shared with no one outside of research staff at the UCLA Easton AD Center.

PARTICIPATION AND CONSEQUENCES OF WITHDRAWAL
I understand that I am not obligated to sign this form or to participate in research. It has been communicated to me that I may withdraw any recorded information at any time and that doing so will have no impact on the care I receive or my relationship with the staff at UCLA.

SIGNATURE OF RESEARCH SUBJECT
By signing this form I am granting permission to the research staff of the Mary Easton Center for AD Research to call me and discuss research projects.
I understand that if I grant permission during this phone call, the staff will record basic information about me that will be stored in case future studies for which I might be eligible become available.

Name_____ Phone number_____

Signature_____ Date_____

David Geffen School of Medicine en UCLA
Departamento de Neurología

INFORMACIÓN Y HOJA DE REGISTRO PARA PARTICIPAR EN INVESTIGACIONES

Título para el Público: Agrupación de Posibles Participantes en el UCLA Easton Centro de Trastorno de Alzheimer

Título Técnico: **Agrupación de Posibles Participantes en el UCLA Easton Centro de Trastorno de Alzheimer**

Investigador Principal: Joshua Grill, PhD
Investigadores Colaboradores: John Ringman, MD, Liana Apostolova, MD, Po Lu, PsyD, Ellen Woo, PhD

INTRODUCCIÓN y PROPÓSITO
El Centro Mary Easton para Investigaciones del Trastorno de Alzheimer (The Mary Easton Center for Alzheimer's Disease [AD] Research) realiza estudios de investigación clínica relacionada con AD. La firma en este formulario indica que usted consiente que alguien de este Centro le llame para hablar acerca de oportunidades de investigación. La firma en este formulario no le obliga a usted a ser un voluntario en algún programa de investigación y si usted lo desea, usted puede cambiar de opinión y negarse a hablar con el personal del Centro.

BENEFICIOS ANTICIPADOS PARA LOS POSIBLES PARTICIPANTES y para la SOCIEDAD
Los estudios realizados en el Centro tienen el objetivo de mejorar el diagnóstico y encontrar una cura para el Trastorno de Alzheimer.

PRIVACIDAD Y CONFIDENCIALDIAD
La información que se obtiene en este formulario o en la llamada telefónica de seguimiento será confidencial y no se compartirá con nadie que no sea parte del personal de la investigación en el UCLA Easton AD Center.

PARTICIPACIÓN Y CONSECUENCIAS DEL RETIRO
Yo entiendo que no tengo ninguna obligación de firmar este formulario para participar en investigaciones. Me han informado que puedo en cualquier momento retirar la información registrada y que no habrá impacto en el cuidado que recibo o mi relación con el personal en UCLA.

FIRMA DEL SUJETO BAJO INVESTIGACIÓN
Al firmar este formulario permito que el personal del Mary Easton Center for AD Research me llame para hablar acerca de estudios de investigación.

ID del Protocolo: IRB#10-001189 Aprobado por el IRB de UCLA Fecha Aprobación: 9/13/2011 Hasta 9/12/2012 Comité: IRB Médico 3
Versión en español: 2/10/2012

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Consent-to-be-Contacted Venues

- Clinical
  - Direct recruitment (physicians, neuropsychologists)
  - Facilitate referral
- Community
  - Targeted community outreach
  - Quantifying success

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“Data” in Registry

- Demographics
  - Contact information
  - Age
  - Race
  - Ethnicity
  - Education
  - Family history
- Availability of study partner

Grill and Galvin, *submitted*

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“Data” in Registry

- Medical history
  - Neurologic conditions
  - Psychiatric conditions
  - Other comorbidities (hypertension, hypercholesterolemia, diabetes, etc)
  - MRI compatibility
  - Medications

Grill and Galvin, *submitted*

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“Data” in Registry

- Study preference
  - Drug trials
  - Non-drug studies
  - Any
- Preferred mode of contact

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Demographics of the Registry

Characteristic	Summary
Mean Age + SD	70.3 + 13.9
Diagnosis MCI/AD/Dementia	33%
Family history AD	52%
African American	18%
Latino	8%
Study Interests:	
• All studies	67%
• Observational studies only	31%
• Drug studies only	2%

Results

567 signed consent

282 (49.7%) enrolled

45 (16%) participated

Since 2010 (as of July 2013)

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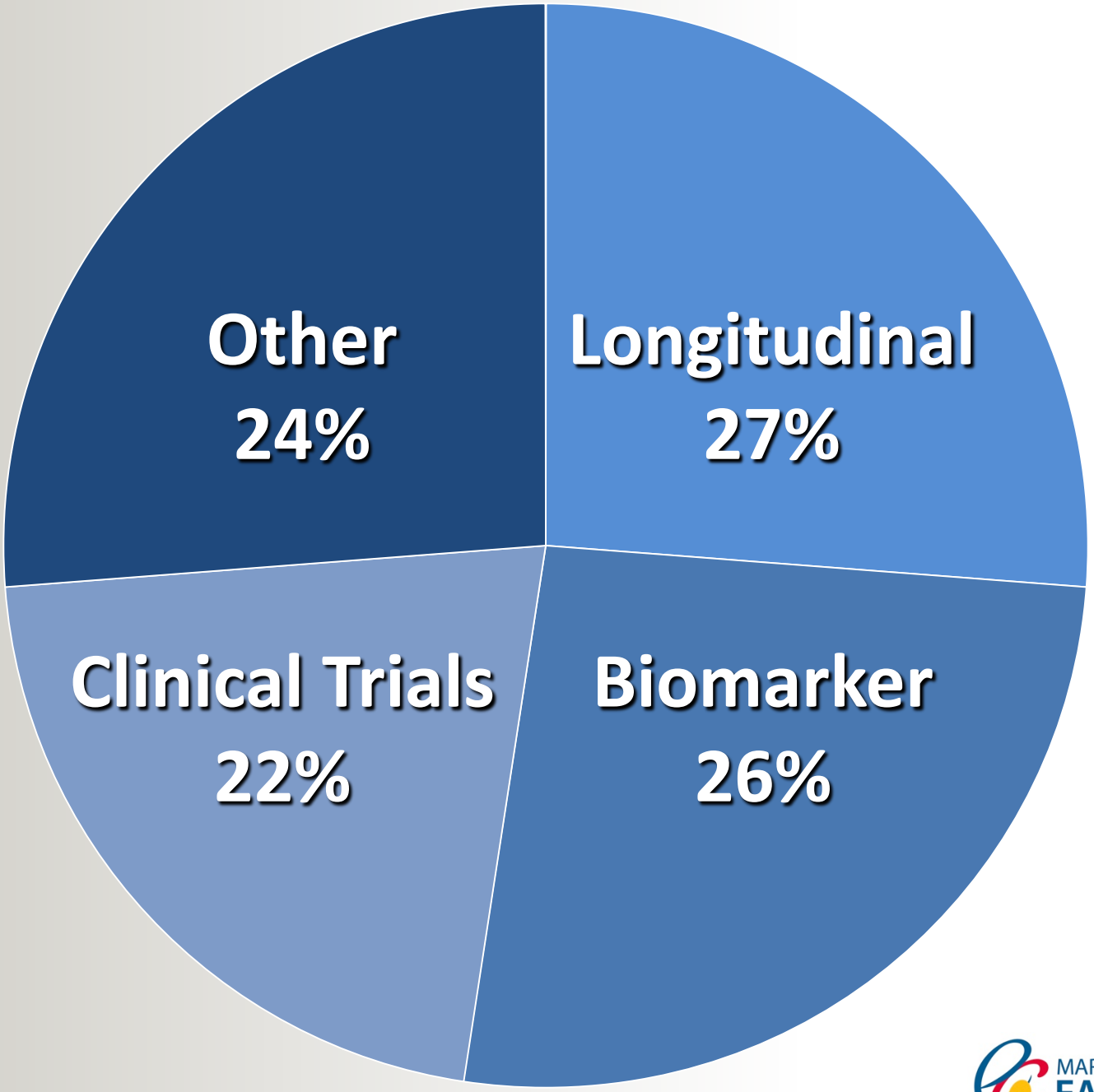

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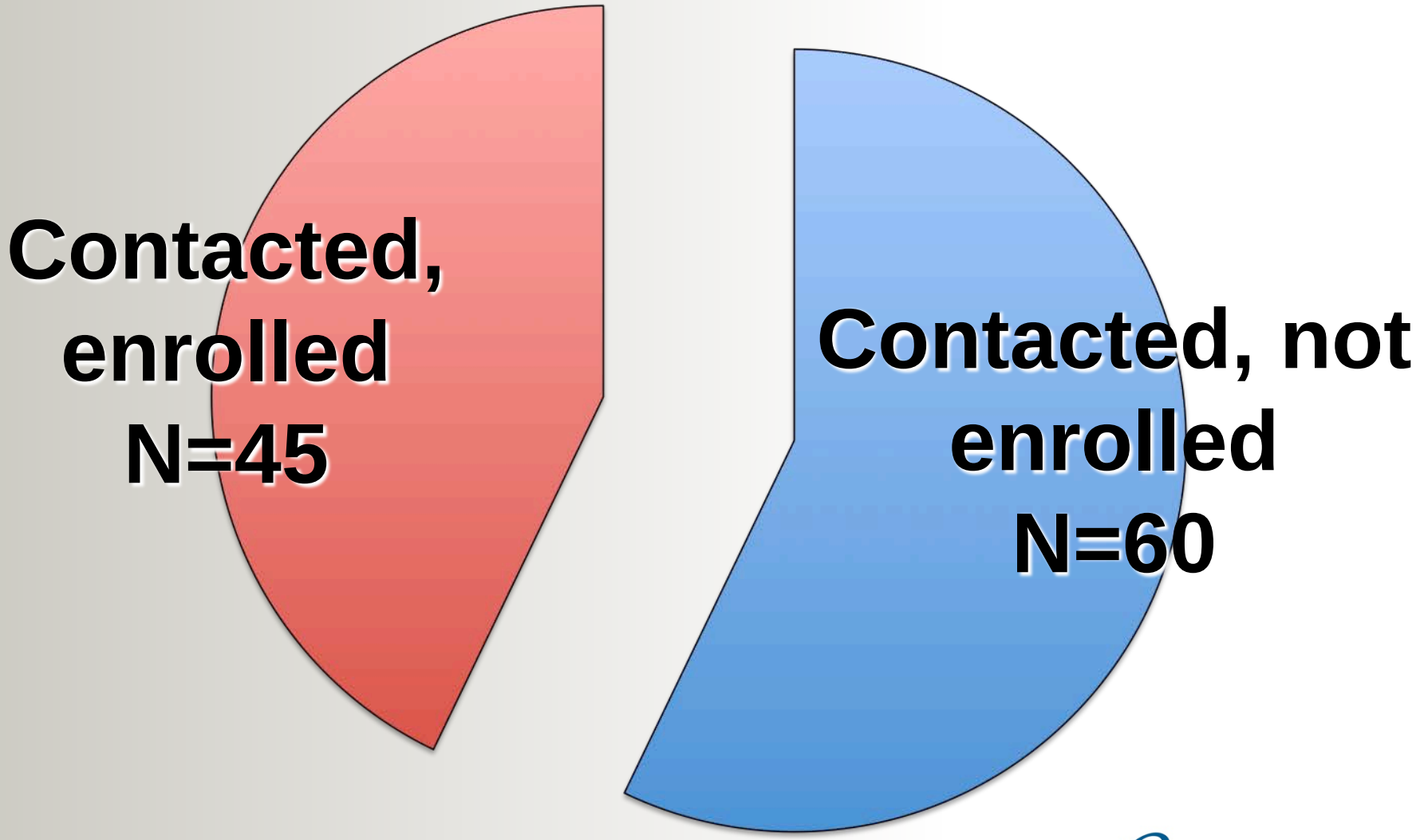
Efficiency of the Registry



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Future Directions

- Electronify
  - Increase sophistication of data entry, query, outcome assessment
- Increase enrollment
  - UCLA student group (RENOUS): 16 undergraduates trained on Alzheimer's disease biology, risk factors, and research and public speaking

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Acknowledgements

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- Sidell-Kagan Foundation
- The Alzheimer's Disease Cooperative Study (NIA UO1-AG10483)
- NACC (UO1 AG016976)

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Summary

- AD research recruitment is slow and fails to represent the disease-suffering population
- Potential participant registries are IRB-approved modes to enhance enrollment
- Potential participant registries may provide
  - Improved enrollment at study initiation
  - More efficient use of research staff time
  - Avenues to increase diversity and representativeness of research samples

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