The UC Irvine Consent-to-Contact (C2C) Registry

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Introduction

- Participant accrual is the most important and controllable determinant of total trial duration
- Inadequate recruitment is among the most frequent causes of trial failure

UCI C2C Registry

• New IRB-approved online tool to match adults in Orange County, CA with research studies at UC Irvine
• Year 1 enrollment goal: 1,000 full enrollments
• Current:
  o N=1,211 email addresses
  o N=745 full enrollments (survey completed)
How Participants Came to Enroll (%)

- 29% My doctor told me about the UCI C2C
- 17% I attended a community talk by a UCI researcher
- 16% I saw a newspaper article
- 14% I saw a television story
- 4% I heard a radio story
- 3% I found UCI C2C through an online search
- 2% I connected through social media
- 1% A friend emailed or told me about C2C
- 1% Other
Enrollee Geography

Google Heat Map
UCI C2C Registry Survey

- Open to non-UCI Health patients ≥18 yo
- Self-reported health data (no HIPAA)
- Data collected
  - Demographics
  - Family history of disease
  - Medical history
  - Medications
  - Exercise
  - Diet
  - Sleep
  - Memory
  - Study willingness (investigational drug, approved drug, specific procedures)
**C2C Registrant Characteristics**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median years [Range]</td>
<td>59.77 [18-97]</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>503 (68)</td>
</tr>
<tr>
<td>White race, n (%)</td>
<td>641 (86)</td>
</tr>
<tr>
<td>Ethnicity, Hispanic n (%)</td>
<td>56 (8.6)</td>
</tr>
<tr>
<td>Education, mean years (SD) [Range]</td>
<td>16.9 (6.4) [5-26]</td>
</tr>
<tr>
<td>Medications, mean n (SD) [Range]</td>
<td>2.73 (2.86) [0-20]</td>
</tr>
</tbody>
</table>

### Race and Ethnicity Distribution

- White or Caucasian: 86.3%
- Black or African American: 0.8%
- Asian: 7.8%
- American Indian or Alaska Native: 1.1%
- Native Hawaiian or Pacific Islander: 0.4%
- Other: 2.7%
- Refuse: 0.8%
Participant Interest

% Willing

- Cognitive testing: 99%
- Altering diet: 95%
- MRI: 94%
- Blood draws: 93%
- Approved medication: 86%
- PET: 83%
- Investigational medication: 77%
- Autopsy: 76%
- Lumbar puncture: 41%

Procedure
C2C Engagement (Retention)

• Setting expectations

• Newsletters
  o Opt-in to UCI MIND Newsletter ("MIND Matters")
  o C2C e-Newsletter

• Emails at 3-months re: study participation

• Tokens of appreciation
  o C2C magnets (double as recruitment)

• Opportunities to participate in other studies
  o Other in person studies
  o On-line survey studies
Attitudes toward Potential Participant Registries

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Abstract. Difficult participant recruitment is a consistent barrier to successful medical research. Potential participant registries represent an increasingly common intervention to overcome this barrier. A variety of models for registries exist, but few data are available to assist in their design and implementation. To provide such data, we surveyed 1,110 cognitively normal research participants enrolled in a longitudinal study of aging and dementia. Seventy-four (67%) participants indicated they would be willing to join a registry. Most (76%, CI 0.67, 0.87) participants were likely to enroll through a registry. Willingness to participate was reduced for registries that required enrollment through the Internet using a password (26%, CI: 0.16, 0.34) or through email (36%, CI: 0.27, 0.45). Respondents acknowledged their expectations that the participants’ privacy is protected and that their data would be shared with researchers. Respondents preferred the telephone registry model (77%, CI: 0.67, 0.87) to the Internet registry model (23%, CI: 0.23, 0.50) but had extra precautions to protect registry confidentiality (24% versus 10%, CI: 0.14, 0.26). Compared to those preferring a shared information model, respondents who preferred the telephone registry model were more likely to be concerned about sharing registry data with researchers. Willingness to participate in registries may impact the population enrolled, and hence the population that will eventually be enrolled in clinical studies. Investigators operating registries need to offer particular assurances about data security to maximize registry enrollment but also must carefully manage participant expectations.

Keywords: Clinical trial, recruitment, registries

INTRODUCTION

Slow recruitment to clinical research delays translational science and medical advances, while inadequate recruit can leave studies underpowered and result in bias or scientific error [1, 2]. Accordingly, interventions to improve recruitment are urgently needed, especially in research areas of great activity such as Alzheimer’s disease (AD) [3].

AD is the most common cause of dementia and is increasing in prevalence and cost at alarming rates [4]. Studies suggesting that successful therapeutic intervention will require very early treatment have led to the initiation of a variety of primary and secondary AD prevention trials [5]. Primary AD prevention trials typically enroll large populations (n ~3000) of cognitively normal volunteers who are healthy and able to participate in lengthy (>5 year outcomes) studies [6]. Secondary prevention trials enroll populations most likely to demonstrate cognitive decline, based on biomarker or genetic enrichment [7], enabling shorter (3 year outcomes) smaller (n ~1000) trials. Potential participants of new trials rather than (or in addition) to serially engaging in community outreach, social and popular media campaigns, and other forms of recruitment [9], other registries, or self-reported health information or prospective assessments of cognitive performance. With these data, investigators can prioritize recruitment based on age, family history, previous medical history, or even subjective changes in cognitive performance, all of which may be associated with meeting preclinical AD trial eligibility criteria [11, 12]. Within a given health system, registries may link to electronic medical records to access diagnostic and medication information, allowing investigators to more efficiently exclude ineligible participants [13]. Registries may even perform cognitive, genetic, or biomarker testing to identify participants meeting preclinical AD criteria [14, 15]. For example, an AD prevention trial is underway that is enrolling apolipoprotein E (APOE) ε4 homozygotes specifically [16, 17], and eligible participants could be directly identified in registries that perform genetic testing.
How to Request Queries

• UCI investigators need IRB approval to use the C2C registry as a form of recruitment
  o A) Current version of the stamped (PDF) IRB Protocol Narrative
  o B) IRB approval letter that references the use of the C2C registry for subject recruitment
  o C) IRB approved script/letter template for contacting registry participants

• Once protocol IRB approved, request query based on inclusion/exclusion criteria (e.g., >65 yo, with diabetes, and no cancer diagnosis), receive list of 50 names with contact information
Investigator/CRC Responsibilities

- Investigator/CRC responsible for updating query spreadsheet with contact outcome for each person listed (e.g., unable to reach, declined participation, consented, etc.)
- C2C list to be returned to ARCS team within **30 days** of receipt with contact outcomes completed
- May request a secondary list (N=50) once all registrants contacted
 ICTS Accrual and Retention Consult Service

- Available to any UCI investigator or coordinator conducting human participants research
  - **Protocol review**: Assist investigators in designing studies that reduce barriers and maximize the likelihood of success
  - **Matching services**: Novice investigators may request to be matched with seasoned investigators to offer feedback or guidance toward successful recruitment and retention
  - **Study consult**: Methods to improve recruitment and retention outcomes for studies that are recruiting more slowly than planned or are experiencing greater than expected loss-to-follow-up
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