Approaches to Queries for Cohort Identification

Paul Harris, PhD
Professor, Biomedical Informatics
Recruitment

Participant recruitment can be one of the most difficult aspects of conducting human subjects research. Resources are available to help you achieve your study recruitment goals. Use the menu to the right to learn more about the resources available to your research team.

Resources

- **ResearchMatch**
  A national registry of potential research volunteers; to register as a researcher click here. To register as a volunteer click here.
- **VICTR Research Notifications Distribution List**
  Recruit study volunteers via the VICTR Research Notifications Distribution List that reaches over 18,500 Vanderbilt faculty and staff, and members of the Middle Tennessee community.
- **Subject Locator**
  Subject Locator assists researchers recruiting participants at Vanderbilt outpatient clinics by identifying patients with upcoming appointments that meet study inclusion/exclusion criteria. Learn more about how to use this tool to reduce time spent pre-screening potential study participants here.
- **Vanderbilt Clinical Trials Registry**
  All actively recruiting studies in clinicaltrials.gov will be displayed on the Vanderbilt clinical trials website
- **AccrualNet**
  Strategies, Tools, & Resources to Support Accrual to Clinical Trials
- **MyResearch at Vanderbilt (MRAV)**
  A repository of over 17,000 Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas. Investigators may submit a request to contact these patients through MRAV with an IRB approved study description.
- **The Community Engagement Studio** is a guidance session for researchers interested in working in a community setting. Community members serve as experts and provide feedback to enhance the design (including recruitment), implementation, translation and dissemination of community engaged research. For more information contact Tiffany Israel, MSSW, at 615-875-5659 or tiffany.israel@vanderbilt.edu.

- **VICTR Research Notifications Distribution List**
  Recruit study volunteers via the VICTR Research Notifications Distribution List that reaches over 18,500 Vanderbilt faculty and staff, and members of the Middle Tennessee community.
If you are a healthy adult with no history of psychological problems and no history of excessive substance or alcohol use, you may qualify as a normal control subject. This research study is looking at how genes and the brain work together to cause psychological disorders.

We Need:
Men and women ages 18-30 who are physically healthy.
Subjects may be asked to complete a screening survey, undergo a psychiatric interview, provide a blood and urine sample, and complete MRIs. Participants will be compensated for their time.

If you are interested or want more information about the study, please complete the screening survey at this link: https://medapp.wustl.edu/Screening?sid=79894995. Once you have reviewed responses, you will be contacted regarding your eligibility.

If you are interested in more research opportunities in your community, consider joining ResearchMatch.org today. ResearchMatch.org is a collaborative project led by Vanderbilt Institute for Clinical & Translational Research to help “match” you with additional research studies of interest to you.

You are a member of the Research Notifications distribution list. To unsubscribe, send an email to research-notification@listserv@email.com with the command UNSUBSCRIBE to the address in the body of your message.

Tackling the "so what" problem in scientific research: a systems-based approach to resource and publication tracking.
Number of Publications Matched to VICTR Resources by Year

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<thead>
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<td>38</td>
<td>50</td>
<td>44</td>
</tr>
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</table>

291 Publications

- **ResearchMatch**
  A national registry of potential research volunteers; to register as a researcher click [here](#). To register as a volunteer click [here](#).

- **Vanderbilt Clinical Trials Registry**
  All actively recruiting studies in clinicaltrials.gov will be displayed on the Vanderbilt clinical trials website.
Step 1: Potential volunteers (or their parents/caregivers) self-register to indicate a willingness to be contacted for research studies.

Medical discoveries are not possible without volunteers like you. Health research changes people's lives every day. Researchers still need your help. Many studies end early because there are not enough volunteers. We help by matching you with research studies. Researchers need both healthy people and people with all types of conditions. Everyone can be the perfect research match!

Join Now
Potential volunteers (or their parents/caretakers) self-register to indicate a willingness to be contacted for research studies.

**Dashboard / Conditions**

Tell us about your conditions.

Have you been diagnosed with a health or medical condition?
- Yes
- No

Start entering the name of a single condition in the box below. You may enter in as few or as many conditions as you like. Once a condition has been found using the search field make sure you select the condition so that it appears in the list below.

Search for conditions:
- Hypertension
- Hypothyroidism
- ADHD (attention deficit hyperactivity disorder)
- Hyperchloremic acidosis
- Hypothyroid

**Dashboard / Medications**

Tell us about your medications.

Are you taking a prescribed or over-the-counter medication?
- Yes
- No

Start entering the name of a single medication in the box below. You may enter in as few or as many medications as you like. Once a medication has been found using the search please make sure you select the medication so that it appears in the list below.

Search for medications:

Medications list:
- simvastatin

Powered by UNLS®
Registered researchers search database for individuals based on study inclusion criteria and geographical location (Only De-Id Information)

Researchers send IRB approved recruitment message to ‘matched’ volunteers.

Volunteers make final choice to share identifiable information for direct contact.
Researchers contact interested volunteers and follow normal study consent procedures.
It's Early ... No Formal Evaluation Yet for Enrollment, But People are Clicking
Interested in Adopting/Collaborating?  paul.harris@vanderbilt.edu
• MyResearch at Vanderbilt (MRAV)
A repository of over 20,000 Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas. Investigators may submit a request to contact these patients through MRAV with an IRB approved study description.

• Subject Locator
Subject Locator assists researchers recruiting participants at Vanderbilt outpatient clinics by identifying patients with upcoming appointments that meet study inclusion/exclusion criteria. Learn more about how to use this tool to reduce time spent pre-screening potential study participants here.

• An Informatics platform designed to continuously engage patients and offer opportunities to participate in research

• A cohort of ~20,000 Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas

• A convenient and efficient panel of patient representatives for which we have medical record data

• Uses: survey, clinical, interventional research and stakeholder engagement to guide research efforts
MRAV Cohort
Authenticated (MHAV) individuals can use this link to provide information about how they wish to be contacted for recruitment (e.g. e-mail, phone, only by my doctor, etc)

MRAV Cohort Age Distribution

MRAV Cohort Top 5 Conditions

- Hypertension NOS
- Benign Hypertension
- Diabetes Uncomp Type II
- Hyperlipidemia NEC/NOS
- Allergic Rhinitis NOS
How to Recruit Patients From The MRAV Cohort

- Obtain IRB approval for use of MRAV recruitment tool and email contact language
- Submit a MyResearch Access Request
  - Reviewed for participant burden and availability of programmers
- Self-Service Identification through RD Discover Interface
- - or - submit a Research Derivative Request to identify eligible patients based on study criteria, if applicable (IDAS Core, $120 per programming hour)
- Once approved, Data Coordinating Center Core programmers send email notifications to participants including approved language ($82 per programming hour)

Expression of Interest / Pre-Screening Survey
- Enables more efficient screening and recruiting of patients versus traditional methods of manually reviewing upcoming appointment lists and cross-referencing EMR.

- Based on a list of upcoming appointments in a predetermined set of clinics, Subject Locator searches patient’s EMR via the research data warehouse for commonly used, discrete inclusion/exclusion criteria to significantly narrow down the number of patients that require screening.
  - Criteria includes ICD-10 and CPT codes, demographics, vitals, keywords, medications.

### Snapshot – Pilot Studies

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<tr>
<th>Department</th>
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<th>Candidates</th>
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<tr>
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<td>Cleft Palate</td>
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<tr>
<td>Cardiology (2 studies)</td>
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<td>95%</td>
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**Start Here → Filtering Criteria**

**Clinics of Interest**

- **Nephrology**
- **Cleft Palate**
- **Cardiology**

**Study Work Queue (Daily Review)**

<table>
<thead>
<tr>
<th>Clinics of Interest</th>
<th>Review List</th>
<th>Starting Here → Filtering Criteria</th>
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<td>1388 VUH Clinics</td>
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<tr>
<td>215 VUH Pediatrics</td>
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</table>
Subject Locator

Subject Locator is available to those with:
- VUerdin
- IRB-approved research study
- IRB approved to use Subject Locator in conducting the study
- Access to Elasticsearch
- A UAN

Begin here to Become a Registered User:
- Obtain IRB approval
- IRB-approved study, a Subject Locator-specific amendment should be submitted
- Search by name of institution

Access Subject Locator (registered users only)

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<tr>
<th>Data types available in the RD Discover:</th>
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<th>Data Export</th>
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<td>Demographics (age, sex, race, deceased status)</td>
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<td>ICD Codes</td>
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<td>CPT Codes</td>
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<td>PheWAS Codes</td>
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<td>Medications</td>
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<td>Lab Values</td>
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<td>Documents (search for keyword text strings)</td>
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<td>Vital Signs (BMI, BP, weight, height, pulse, RR)</td>
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<td>Departments (inpatient, outpatient, provider name)</td>
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<td>MRNs</td>
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<td>My Research at Vanderbilt (MRAV) cohort</td>
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<tr>
<td>Contact information</td>
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</tbody>
</table>
BioVU
- Links DNA extracted from discarded blood samples to de-identified EMR
- ~177k DNA samples, over 20k pediatric
- 74 BioVU projects approved to date

Synthetic Derivative
- Research tool to enable studies with de-identified clinical data
- Contains 2.5 million records; highly detailed longitudinal clinical data for ~1 million

Research Derivative
- Identified clinical data warehouse
- Tools (e.g. Subject Locator)
- Services (Fee for Service)
- New REDCap extraction toolkit
Recommendations for clinical data representation to support phenotyping

1. Structure clinical data into queryable forms.
2. Recommend use of a common data model, but also support customization for the variability and availability of EHR data among sites.

Recommendations for phenotype representation models

4. Implement set operations and relational algebra.
5. Represent phenotype criteria with structured rules.
6. Support defining temporal relations between events.
7. Use standardized terminologies, ontologies, and facilitate reuse of value sets.
8. Define representations for text searching and natural language processing.
9. Provide interfaces for external software algorithms.
10. Maintain backward compatibility.
Vision and purpose

Our goal is to positively impact human health by improving participant enrollment and retention in multi-center clinical trials.

Achieving this goal will require sophisticated informatics-based recruitment tools and novel engagement approaches to accelerate recruitment and retention.
Key Principles

- Respecting CTSA autonomy and diversity
- A focus on minority and underserved populations
- Making the most of electronic health records
- Preserving a disease neutral approach
- Focus on cost efficiency
- Respecting and returning value to participants
- Build on best practice (avoid reinventing the wheel)
- Evidence based.... What works? (test bed)
- Finite resources – scalability / tools
- Home for recruitment experts (across + beyond CTSA)

EHR-Based Site Feasibility

BE OPPORTUNISTIC

"If I have seen further than others, it is by standing upon the shoulders of giants."

- Sir Isaac Newton

Do what you can, with what you have, where you are.

Theodore Roosevelt
EHR-Based Feasibility

Secondary use of clinical data: The Vanderbilt approach

Clinical and Translational Science Award (U54)

Informatics

The challenge for the next phase of the CTSA Program will be to establish a more integrated and collaborative national network for the development of new diagnostics, therapeutics, and preventive interventions while driving innovation in clinical and translational research methods, policies, and leveraging the ever-expanding capabilities of health informatics tools and other research technologies.

Biomedical Informatics is a critical CTSA focus for enabling and advancing translational research, which is increasingly data intensive, and requires collaborating across communities, including healthcare, research, and public health. Additionally, the increasing amounts and types of data (e.g., genetic, imaging, clinical, economic, environmental, behavioral, patient reported) need to be integrated to generate knowledge. Cooperation and coordination among the data providers in various organizations and institutions on policy issues, and among the managers of these data systems on technical issues are critical. This section should describe how the applicant will facilitate exchange of data among various sources required by translational researchers. Organizations, policy, and technical issues should be addressed. This section should explain how electronic or other medical records interface with clinical research data systems.

CTSA hubs should offer researchers a user-friendly data management system along with training on its use and some basic support. CTSA applicants should encourage compatibility of their research systems with broadly accepted content and technical standards including those adopted by the Department of Health and Human Services for use in U.S. health care and public health operations. In addition, as NIH Institutes and Centers adopt common data elements in their domain areas, CTSA hubs should ensure their research tools are compatible (see http://www.nih.gov/for_more_information). Maintaining the security of study data, particularly in studies involving human subjects, is critical. Many clinical and translational researchers manage such data in systems, processes, and formats that lack appropriate security. Academic institutions vary in the availability of low cost and user friendly infrastructure to assist investigators in ensuring the security of their data or in their requirements for its use by faculty, staff, and students. Applicants must describe their plan for ensuring the security of research data on all studies involving human subjects at all participating institutions. This plan should address policy, workflow, technical, and enforcement issues. The plan should outline challenges and feasible alternative approaches for overcoming them.

CTSA hubs should work towards a flexible, sustainable digital enterprise where digital assets are interoperable as that, for example, data from the electronic health record (EHR) can be used for research purposes. This will require informatics solutions that are embedded in HIPAA regulations and other measures to safeguard patient privacy and autonomy. CTSA hubs should support a research-friendly integrated IT environment where information on applicable research opportunities is presented to clinicians and patients via EHR at the time of the clinical encounter. Other useful services might include notifying a patient's participation in a research study in the clinical EHR for the benefit of the treating clinician, and efficient routing of laboratory results. Applicants should describe any solutions they currently have to integrate health care and research data, as well as plans for the future. Applicants should indicate any concerns they may have about regulatory, privacy, and security issues. The plan should encompass the privacy and security safeguards that ensure that information is not shared without the patient's consent.

Inaccurate translation CTSA hubs should work towards data sharing and reusing data across, and processes. Applicants should indicate whether they have initiatives at their hub that support data sharing, how they promote broad use of data, and how they encourage researchers to submit data to repositories (see for example NIH Data Sharing Regulations). In this context, applications should also describe how they train researchers to prepare for downstream data sharing, such as by providing training and sample language for research-friendly consent forms that support broad data use (not limited to time, place, or purpose), and that avoid complex medical formats to the extent possible. This is based on the observation that patients consenting to research participation are often information abusers who welcome the secondary use of research data so long as appropriate measures have been taken to protect their privacy. Applicants should also describe how they might collaborate with other CTSA hubs in using common data standards in multi-site projects.

CTSA hubs attach importance to assessments of informatics performance and goal setting across the entire CTSA community. Therefore informatics leadership from each CTSA is expected to participate in national CTSA network informatics activities, and the application should indicate an informatics point person that can serve as liaison to the network. The CTSA hubs are encouraged to share their informatics tools, and to adopt and utilize tools developed by others to avoid duplication and redundancy. The CTSA hub must be committed to working toward standards and integration of standards and practices employed by the CTSA program.
EHR-Based Feasibility

Secondary use of clinical data: The Vanderbilt approach

Informatics / Platforms

EHR-Based Feasibility Assessment

Efficient Use of the EHR for Research
EHR-based Cohort Assessment

Non-federated strategic approach to cohort identification by utilizing established network resources to inform various components of the clinical trial process.

Key features:
3 stages facilitated by RIC Concierge
Tiered algorithms
Custom phenotypes vetted on multiple platforms

EHR-based Cohort Assessment
Stage 1: Defining the ask
One-on-one discussions with study team to define need for cohort identification, assess inclusion/exclusion criteria, identify proxy data points to satisfy unique study criterion

Inclusion criteria: 10% or greater ischemia on stress testing

Substitute criteria: CPT codes or keyword mention AND diagnosis code during same time period

No specific data element or standardized reporting of the magnitude of ischemia

Investigator, phenotyping expert, and cardiology programmer identified proxy criteria to satisfy inclusion
EHR-based Cohort Assessment
Stage 1: Defining the ask

Creating tiered phenotypes show attrition rates

EHR-based Cohort Assessment
Stage 2: Vetting

During vetting, institutions can ask questions, make suggestions, and determine limitations. Changes in algorithm are communicated to PI for approval before re-vetting.
EHR-based Cohort Assessment
Stage 3: Network query

- PI can choose sites to query.
- Sites can ‘opt-out’ for any reason.
- Initial feedback is positive; lessons learned

Framing The EHR Request to CTSA Hub
Request to be made to Hub Liaison POC from TIC (or RIC)

- Protocol Summary + Investigator Team Information
- Project Status (Recruiting/Funded – or - Prospective)
- Expected Number of Sites
- Timeline for Information + Expression of Interest Request
- General Contact information for questions
- Connection information for a 1-time webinar (recorded)
- Instructions for EHR-based data interrogation
  - Connect with your local informatics core
  - Deliver query algorithm (algorithm will most likely be multi-tiered to accommodate data diversity at CTSA hubs)
  - Post-Query Aggregate Data Collection - REDCap Survey
  - Specific point of contact (from RIC) questions
- Instructions for Expression of Interest
  - Contact PI + Contact Information
EHR-based Cohort Assessment
Stage 3: Network query

Submitting Results:

- Simple submission process
- Ability to save and return if needed
- Ability to upload supporting documentation
- Option to opt-out
- User-friendly well-known REDCap platform
EHR-based Cohort Assessment
Stage 3: Network query

Example results; detailed site information included in separate tabs, including demography, race, and ethnic breakdown (if provided by site).

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<thead>
<tr>
<th>EHR Institution</th>
<th>Count</th>
<th>EHR Institution</th>
<th>Count</th>
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EHR-based Cohort Assessment
Results of Network Queries

**STUDY 1-9/14**
4 counts requested at 29 sites
Response rate: 72%
Average Response: 6 days

Study 1: actively recruiting study needing additional sites

**STUDY 2-9/15**
3 counts requested at 60 sites
Response rate: 50%
Average Response: 8 days

Study 2: newly funded study for site selection

**STUDY 3-10/20**
3 counts requested at 60 sites
Response rate: 20%
Average Response: 8 days

Study 3: pilot study selecting additional sites
Related Results

### Federated

<table>
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<tr>
<th>Count</th>
<th>TriNetX Counts</th>
<th>Difference between counts</th>
<th>TriNetX (CTSA sites)</th>
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<td>1</td>
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<td>172,480</td>
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<td>2</td>
<td>233,310</td>
<td>2.28%</td>
<td>168,730</td>
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<td>3</td>
<td>214,630</td>
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<td>4</td>
<td>181,630</td>
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### Non-Federated

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<td>9,106</td>
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<td>7,302</td>
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<td>16.76%</td>
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</table>

The change in the counts is virtually the same between Federated and Non-Federated.

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EHR-based Cohort Assessment

Lessons Learned

Non-Federated approach works

Feedback during RIC vetting and Network Query Request stages have provided valuable information about data limitations and site uniqueness.

Examples:
- Epic slicer/dicer tool allows one code occurrence in record, not 2 or more - not a limitation but supports inconsistencies
- 6 Hub sites need LOINC codes for lab criteria

\[+ \text{Need Federated to do sophisticated sensitivity analysis of inclusion/exclusion rules}\]
EHR-based Cohort Assessment Uses

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<th>Study</th>
<th>Site Selection</th>
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<th>Budget Planning</th>
<th>Study/Protocol Design</th>
<th>Rescue/flow enrollment</th>
<th>Recruitment Planning/Materials</th>
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</tbody>
</table>

We’re working on joining ...

We’re working on leveraging ...

WHAT ABOUT...
"Perfect is the enemy of good." — Voltaire

“We’re working on joining ...”

“We’re working on leveraging ...”

“We’re working on joining ...”

“Perfect is the enemy of good enough.” — Anthony

“DON'T JUST COUNT”
RESEARCH

The use of electronic medical records for recruitment in clinical trials: findings from the Lifestyle Intervention for Treatment of Diabetes trial

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Results: A total of 1102 telephone screens were conducted, resulting in randomization of 260 participants (61.5% from EMR, mean age 56.3 years, 66.2% women, 48.1% non-Hispanic black) over a 21-month period, with a yield of 23.6%. Recruitment yielded differed by recruitment method, with referrals having the highest yield (27.5%). A history of cardiovascular disease was the main health reason for exclusion from the study (16.5%). An additional 8.9% were excluded for BMI <25 kg/m² (<27 kg/m² for insulin users), 5.4% could not exercise, 5.2% had an HbA1c >11%, and 34.9% were excluded for other non-medical reasons. Exclusion criteria did not appear to differentially affect enrollment in terms of race or ethnicity.

Conclusions: Future clinical studies should tailor their recruitment strategies based on the participant demographics of interest. Efficient methods such as using the EMR system and referrals should be prioritized over labor-intensive, low-yielding methods such as community screenings and mass mailings.

Fig. 1 Flowchart of the recruitment process for the LIFT Diabetes trial. Community screenings refers to screenings during health and church fairs. Media refers to television, radio, and print advertisements. Referrals were from healthcare providers, study staff, participants’ friends and relatives, and other studies. Unknown refers to participants whose source of recruitment was either unknown or from the Wake Forest Be Informed website, Clinical Trials.gov website, and other online advertisements, DSM diabetes self-management, (AU) lifestyle weight loss.
Recruitment methods for survey research: Findings from the Mid-South Clinical Data Research Network

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**Purpose:** The objective of this study was to report survey response rates and demographic characteristics of eight recruitment approaches to determine acceptability and effectiveness of large-scale patient recruitment among various populations.

**Methods:** We conducted a cross-sectional analysis of survey data from two large cohorts. Patients were recruited from the Mid-South Clinical Data Research Network using clinic-based recruitment, research registries, and mail, phone, and email approaches. Response rates are reported as patients who consented for the survey divided by the number of eligible patients approached.

**Results:** We contacted more than 90,000 patients and 13,197 patients completed surveys. Median age was 56.3 years (IQR 40.5, 67.4). Racial/ethnic distribution was 84.1% White, non-Hispanic; 9.9% Black, non-Hispanic; 1.8% Hispanic; and 4.0% other, non-Hispanic. Face-to-face recruitment had the highest response rate of 94.3%, followed by participants who “opted-in” to a registry (76%). The lowest response rate was for unsolicited emails from the clinic (6.1%). Face-to-face recruitment enrolled a higher percentage of participants who self-identified as Black, non-Hispanic compared to other approaches (18.6% face-to-face vs. 8.4% for email).

**Conclusions:** Technology-enabled recruitment approaches such as registries and emails are effective for recruiting but may yield less racial/ethnic diversity compared to traditional, more time-intensive approaches.
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