# Manual of Procedures (MOP)
# Section 5. Recruitment Strategy and Materials

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## 5.1 RECRUITMENT OVERVIEW

Recruitment of potential participants cannot begin until approval from the site IRB has been obtained. *However, the planning and recruitment strategy should be fully developed and ready to deploy upon IRB approval.*

This section provides suggested recruitment strategies and tools. Sites are expected to incorporate these strategies and tools into those that have worked locally in the past and evolve new strategies as needed.

The pre-screening phase is site-specific and may take place in one or two stages (e.g. over the phone or web-based pre-screening [pre-screening-stage 1], followed by a visit [pre-screening-stage 2]). Each site, based on their prior experience, will develop a detailed site-specific recruitment plan that includes a pre-screening recruitment strategy to identify individuals with high likelihood of pre-diabetes that will be invited in for the formal screening visit, which will be identical for all sites. The intent of the staged pre-screening phase is to allow collaborating sites flexibility in their approach of recruiting participants, while maintaining a uniform study-specific set of inclusion/exclusion criteria. Publicity and recruitment efforts are the responsibility of the sites; however, the Coordinating Center (CC) will assist with centrally prepared and disseminated publicity and recruitment procedures and tools (e.g. brochures, flyers, and posters) that need to be modified to meet the needs of the sites. To maximize efficiency, the recruitment strategy must clearly target people at risk for diabetes (with pre-diabetes).

Active recruitment will take place year round at regular rates of enrollment to ensure equal exposure of all participants to UV-B.

Each site has provided the CC with a target number of participants to be randomized. At each site, the research coordinator or designee responsible for recruitment will work with the site PI to develop a written site-specific recruitment plan, based on what has worked well for the site in the past, and refine the plan during the course of the trial, as needed. The Recruitment and Retention Subcommittee (RRS) will review the site recruitment strategy prior to study initiation. The subcommittee may make suggestions to the site or may ask for modifications to the plan. During recruitment, sites will report regularly to the RRS on their methods and to identify areas for improvement. Successful recruitment methods from sites will be posted to the Recruitment Resource Center on the portal.

## 5.2 RECRUITMENT RESOURCE CENTER

The Recruitment Resource Center (RRC) on the D2d web portal (D2dStudy.org) compiles examples of successful D2d recruitment materials and strategies, and makes them available for other sites to use. The material on RRC is continuously updated, so sites are encouraged to visit RCC frequently for new or revised recruitment methods.

## 5.3 RECRUITMENT PROGRESS & MONITORING

Recruitment is expected to take place over a 2-year period. Recruitment will be closely monitored and short-term site-specific recruitment goals will be established and reviewed weekly at each site by the

CC, quarterly by the RRS, semi-annually by DSMB and NIDDK and annually by the local IRB. A site-specific recruitment goal will be based on the target number of enrolled participants. For instance, if a site plans to enroll a total of 150 participants, the goal will be 6 enrolled participants per month. The initial target will be to enroll at least 50% of the total enrollment during the first 12 months. Based on review of recruitment progress, changes in the site-specific recruitment plan and pre-screening strategy may be required.

## 5.4 RECRUITMENT STRATEGIES

Each site should utilize strategies that have worked in the past and incorporate new strategies as needed. To increase efficiency, recruitment efforts (especially pre-screening) should be targeted to people who have a greater chance of being eligible for the study than the general population. The following are risk factors to consider when targeting populations and communities at risk for diabetes:

1. Family members of people with type 2 diabetes (adult children, spouses, parents).
2. People who are overweight.
3. Ethnic groups at highest risk: African Americans, Hispanic Americans, Asian Americans, and Native Americans.
4. Women with a history of gestational diabetes.

Below are some recruitment ideas, strategies, and tools. All means of communication with potential participants (advertisements, letters, brochures etc.) must be reviewed and approved by the local IRB prior to use.

### 5.4.1 Database Review

Use of databases to identify potentially eligible volunteers is the most efficient and cost-effective recruitment strategy. Below are examples of databases that may be available at the sites.

#### 5.4.1.1 Electronic Medical Record Systems (EMR)

After IRB approval, the system can be queried for variable ranges that indicate a person could be potentially eligible, e.g.:

1. Age (≥ 30 years) and one or more of the following:
    a. Recent HbA1c: search for people with levels 5.7-6.4%.
    b. Recent fasting glucose: search for people with levels 90-125 mg/dL
    c. BMI search for people with BMI of 24-42 kg/$m^2$ (22.5-42 kg/$m^2$ if Asian)
2. Exclusion of people with a diagnosis of diabetes or who are known to take diabetes medications.
3. Depending on the system, other inclusion/exclusion criteria may be used to develop the query.

Examples of successful EMR searches can be found on the RRC on the d2d portal.

Institutional policies should be followed to contact potentially eligible people or their primary care provider. In general, a recruitment letter followed by a phone call 1-2 weeks later is the best approach to recruit patients following an EMR search (please see appendix for examples of letters). Sending

letters on behalf of the primary care physician is also another successful way to capitalize on the use of EMR (see section below).

#### 5.4.1.2 Research Participant Databases/Registries

Several institutions have databases of people who have previously participated in research, or expressed an interest in participating in research studies. These databases can be queried in the same manner as EMR systems. Typically, people have agreed to be added to the database so after IRB approval of the D2d study and recruitment plan, they can be contacted directly. A recruitment letter followed by a phone call, 1-2 weeks later, has proven to be a successful approach to recruit patients following a database search.

#### 5.4.1.3 Research-specific Websites

A number of websites exist that serve dual purposes: 1) to help people interested in volunteering in research studies learn more about the clinical research process and about trials that are actively recruiting and 2) to help researchers recruit potential participants.

##### *5.4.1.3.1 ResearchMatch.org*

ResearchMatch (www.researchmatch.org) is an online database that allows willing volunteers to enter relevant information and make it available to researchers who can then search for potential research study participants. In order to register and use the database, investigators must have an IRB-approved study and be affiliated with a Clinical and Translational Science Award (CTSA) institution. The database can be searched for potential volunteers based on criteria entered into the ResearchMatch search builder program, which yields a list of non-identifiable user profiles that fit the search criteria. Researchers can choose one of two search types: feasibility or recruitment. A feasibility search yields an estimated number of volunteers within the ResearchMatch database that match search criteria, and can be done without IRB approval. Researchers cannot contact volunteers via a feasibility search. A recruitment search is available only after IRB approval and allows researchers to contact volunteers within the database that match search criteria. In a recruitment search, the potentially eligible volunteers can be contacted via an IRB-approved initial recruitment message, which is sent to the anonymous volunteer via the ResearchMatch server. Once a volunteer responds to the recruitment message and authorizes ResearchMatch to release their contact information to the researcher, the volunteer may be contacted according to the IRB-approved protocol.

Below are the steps required [choices selected for the D2d study]

a. Login as a researcher on www.researchmatch.org/researchers
b. Under 'Find Volunteers' choose 'Search/Contact,' which opens a new search query based on the following criteria:
    i. Search type: feasibility or recruitment.
    ii. Location: distance to institution *[e.g., 50 miles]* or state
    iii. Demographic:
        - Age *[≥ 25]*
        - BMI *[22.5 – 42 kg/m$^2$ inclusive]*

The following demographic parameters are available, but will not be used to exclude participants for the D2d study.

- Ethnicity
- Gender
- Height
- Multiple-birth Status
- Race
- Tobacco User
- Weight

iv. Conditions:

- Healthy
- Exclude Condition Set # 1 *[diabetes]*
- Exclude Condition Set *[kidney disease, kidney stone, stroke]*

v. Medications: *[will conduct 2 searches]*

- No Reported Medications
- Exclude Medication Set *[diabetes medications]*

c. Finish search.
d. ResearchMatch displays results of search query, IRB-approved initial recruitment message sent to eligible volunteers via ResearchMatch server.

* Although ResearchMatch is free, the tool is in its early development phase and may not result in a large number of potential participants, so the opportunity cost of searching in ResearchMatch.org should be weighed against the likelihood of successful recruitment. However, ResearchMatch.org is a tool whose importance may grow over time.

#### *5.4.1.3.2 Centerwatch.com*

Centerwatch.com is a commercial research information clearinghouse. A potential volunteer can search by disease category, therapeutic area, or site location. The posting contains contact information so the volunteer contacts the clinical site directly. People can also register to be notified if a study is listed that meets their criteria. The registry charges to post information on studies, so the cost should be weighed against the likelihood of successful recruitment.

#### *5.4.1.3.3 Clinicaltrials.gov*

Clinicaltrials.gov is a federally funded database that list studies funded by NIH and other foundations or organizations. The D2d study will be included in the database and as sites obtain IRB approval, the CC will add new sites to the list of participating sites in clinicaltrials.gov. For each participating site, a contact name will be listed. People interested in finding a clinical trial can search the site by medical condition (i.e. diabetes), intervention (i.e. vitamin D) and site location.

### 5.4.2 Other Publicly Available Databases

Potential volunteers will be identified through use of other publicly available lists (e.g. ActOne, voter registration) generated based on major inclusion and exclusion criteria (e.g. age, BMI, presence of diabetes). These lists can be purchased and invitation postcards (see appendix) can be sent to people on the lists.

### 5.4.3 Referrals from Primary Care Providers and Other Clinicians

Primary care colleagues and community primary care providers (PCP) can be asked to refer patients for study participation. A recommendation from a personal physician can strongly influence one's decision to enroll in a research study. The keys to success with this method are:

- Ensuring the PCP maintains responsibility for the patient's care (i.e., she would not "lose" the patient).
- Providing the PCP with enough information about the study, including information on the protocol and procedures to be followed, study rationale and past studies.
- Engaging and updating the PCP throughout the study.
- Making it easy for the PCP to refer patients.

Obtaining referrals from PCP and other clinicians in the area can be challenging given their increasing demands but can be accomplished during in-person meetings, by sending letters and including relevant attachments, sending annual updates regarding the referred participant, and providing general study status updates in the form of a letter (see MOP section 5 Appendix for sample letters). A brochure may be attached to the letter (see MOP section 17 Appendix). To attract participants from minorities, consider targeting PCPs whose offices are in neighborhoods with a high density of minority populations.

In addition, to make it easier for the PCP, sites may do an EMR search as described above and either 1) request the PCP send out a letter drafted by the site to potential participants (see MOP section 5 Appendix) or 2) site research staff offers to send the letter on behalf of the PCP (see MOP section 5 Appendix). All institutional policies should be followed to contact potentially eligible people or their primary care provider. A recruitment letter followed by a phone call, 1-2 weeks later, has proven to be a successful approach to recruit patients following a database search.

Another approach is to perform a chart review of all patients coming into a particular clinic ahead of the scheduled clinic time. Individual records can be flagged for the physician to explain the study to patients and refer them to site staff. Alternatively, potentially eligible patients could be approached in the waiting room by research staff.

Working with physicians that have established relationships with the site PI and co-investigators is the best approach. However, a list of local physicians may be rented from several services (e.g. Medical Marketing Service, Inc.).

### 5.4.4 Referrals from Participants ("word-of-mouth")

Participants, whether they qualify or not, can be encouraged to refer other potential participants (family members or friends who may be at risk for diabetes). Participants can be provided with study information pamphlets and asked to share them with friends and family members who may be at high risk for type 2 diabetes. Word-of-mouth recruitment can be very effective.

### 5.4.5 Publicity and News Media

- The institution's public relations department can distribute a press release to news outlets in the area. The press release can generate news stories and request for interviews with site investigators. Typically there are no costs associated with this form of publicity. A sample press release that can be modified to your site is located in the appendix.
- The site may increase visibility of the study through presentations in endocrinology, nutrition or medical grand rounds in local hospitals.

### 5.4.6 Print and Media Advertisements

Advertising can be an effective recruitment method if targeted to the study population. Print advertisements can be placed in newspapers, organization newsletters, on public transportation, and in fliers. Radio and TV advertisement is very expensive, and care must be taken to accurately target the intended audience. Below are some examples of advertisements (see appendix for samples). Print and media advertisements tend to be expensive.

1. Flyers
2. Newspaper advertisements
    - Metro
    - Medical Center newsletter
3. Direct mail postcard
4. Subway or bus advertisements

### 5.4.7 Web-based

#### 5.4.7.1 D2d Public Website

The D2d public website, www.D2dstudy.org, will present general study information to the public. All participating sites and their contact information will be listed on the site. Potential participants can review study information on the website and obtain contact information for a site in their area. In addition, the website URL will be included in printed advertisements, and can be given to interested people verbally. Brief information about the study may also be posted on the institution's website, which can link interested volunteers to the D2d study's web page.

The website provides tools to encourage pre-screening by participants themselves, e.g. diabetes risk score, inclusion/exclusion criteria, etc.

#### 5.4.7.2 Craigslist

Craigslist.org is a free community-moderated forum that hosts classified ads and discussion forums. Study participant volunteer recruitment ads can be posted on Craigslist. A sample ad is included in appendix.

A few things to note when posting on Craigslist:

1. Choose the geographical location in Craigslist that is closest to the site.

2. Craigslist postings appear listed by the date posted, so you may want to consider re-posting the recruitment advertisement a few times a week, depending upon how many postings there are in your area.
3. Consider posting the ad as a Community posting, in the category volunteers.

#### 5.4.7.3 Twitter

There is a D2d twitter account that is managed by the CC, which can be used for recruitment purposes. Additionally, twitter messages (which may need to be approved by IRB) may be sent from the institutional official twitter account (e.g. @TuftsMedicalCtr). These messages will advertise the study and promote the D2d public website. These tweets will target D2d-related topics (e.g. prevention of type 2 diabetes, vitamin D). The D2d site coordinator will need to contact the medical center's twitter administrator to provide suggested "tweets."

#### 5.4.7.4 Facebook

There is a D2d Facebook account that is managed by the CC, which can be used for recruitment purposes. Additionally, the Facebook page of the hospital may be used to post a message regarding the D2d study. Sites need to work with the hospital administrator and IRB regarding postings on their institution's Facebook account. Examples of a successful Facebook approach can be found on the RCC on the d2d portal.

### 5.4.8 Recruit from "Within"

Medical centers and universities employ thousands of adults and have thousands more walk through their doors each day, not only as patients, but also as visitors, caregivers, faculty, students, and vendors. These medical centers often have multiple resources that can be utilized to recruit study participants. These may include employee newsletters, hospital TV, intranet, employee health services, and bulletin boards for posting recruitment fliers.

Many companies, including medical centers, perform biometric screenings on their employees as a way to lower health care costs. Recruitment efforts may target such screenings so that employees with potentially eligible values (BMI, glucose) can be referred to a nearby recruiting table.

### 5.4.9 Recruit from Local Companies

Large local companies can serve as additional pool of potential participants.

Many companies, including medical centers, perform biometric screenings on their employees as a way to lower health care costs. Sites can contact the company's employee wellness or human resources department to see if an invitation letter could be sent to potentially eligible employees.

Alternatively, companies frequently distribute employee newsletters on a weekly or monthly basis. Posting a recruitment advertisement or article in these newsletters can ensure distribution to a large group of people.

### 5.4.10 In-Person

Health fairs, community events, and community gathering places (houses of worship, bingo events, etc.) often present opportunities to set up a table and do community outreach while recruiting for the study. During these events people can be provided information on the study and if appropriate some pre-screening activities may be done (see MOP section 6).

⇒ Do not actively seek out or recruit volunteers who are participating in weight-loss or intensive lifestyle programs. Participants can be recruited from such studies or programs, if they dropout or after the completion of a program if their weight has been stable.

## 5.5 APPENDICES (TOOLS AND MATERIALS FOR RECRUITMENT)

The following materials may be customized by the site and used to assist in recruitment. Recruitment materials should be submitted to the CC for review prior to IRB submission.

**Appendix 1a Brochure, general info**

**Appendix 1b Brochure, general info (Spanish version)**

**Appendix 2a Letter to physician, general info**

**Appendix 2b Letter to patient from MD**

**Appendix 2c Letter to patient from D2d (EMR, opt-out)**

**Appendix 2d Letter to volunteer from D2d**

**Appendix 2e Researchmatch.org message**

**Appendix 3a Ad pull tab flyer (2 versions)**

**Appendix 3b Ad newspaper 1/12 page**

**Appendix 3c Flyer (2 versions)**

**Appendix 4 Official Press Releases (NIDDK)**