

CHAPTER 4. GENERAL RECRUITMENT ISSUES AND STRATEGIES

4.1 Consent Forms

PVDOMICS has three informed consents: (1) main consent for participants with pulmonary vascular disease or those at-risk or suspected to have pulmonary vascular disease, (2) healthy controls consent, and (3) biobank consent for permission to retain and use samples from PVD and controls remaining at the end of the PVDOMICS study in future studies. All participants in PVDOMICS will be asked to sign two consent forms: PVD and at-risk PVD will be asked to sign (1) and (3), and healthy controls will be asked to sign (2) and (3). The main consent (1) and healthy control consent (2) describe the goals of PVDOMICS and are designed to allow sharing of data and samples across centers and with the DCC. The biobank consent (3) requests permission to use samples collected in this study in the future by researchers, who may be other than PVDOMICS researchers and/or possibly studying other diseases.

4.2 Consent Templates for Center Customization

The OSMB approved template consents will be customized by each site into the appropriate format for site-specific Institutional Review Boards (IRB). Once the consents are ready, they will be sent to the DCC for review, followed by NHLBI for review. Changes in consents will be provided to the study site. Once changes are made, consents may be submitted to their IRB. As soon as the site consent forms are IRB approved, they will be provided to the DCC for documentation of approval of the study. Recruitment will start at each site upon IRB-approval.

4.3 Recruitment

Recruitment is essential for the success of this study. Consider the following points when recruiting participants:

- Emphasize the importance of the study.
- Emphasize close follow-up of tests and results during the study, and the availability of findings to the participant.
- Explain that a stipend for participation will be provided.
- Approach potential participants more than once, if necessary.
- Be courteous, attentive and professional.
- Show interest and enthusiasm in the study.
- Make sure that potential participants fully understand the potential risks and benefits of the study. Explain all aspects of the study detailed in the informed consent. Make sure that participants understand the information you present. Allow the participant enough time to consider and sign the informed consent document.
- Emphasize that participation in the study will advance medical knowledge. Potential participants may be told, “We don’t know the answers, but there is a chance to help us all learn more about pulmonary vascular diseases.”

- Consider giving the consent to a potential participant for them to look over and then meet with them after they have had a chance to review the consent at home as this is a detailed protocol with multiple procedures and tests.

Some potential participants will be motivated by stressing that the results may benefit future generations of patients with lung diseases and that they may have a chance to help society.

4.4 Provider Cooperation

Providers are busy, and it is not their responsibility to recruit participants for this study. But you can ask for their support.

- Take the initiative. Do not wait for providers to contact you regarding potential participants.
- Mail a study brochure with a personal letter to providers requesting their cooperation.
- Ask providers for permission to contact their patients and ask them to encourage their patients to enroll.
- Reassure providers that their patients will be seen by investigators for study purposes only.
- Let the providers know that you will inform them of the participant's course in the study.

4.5 Contact with Providers

Direct involvement of site investigators with healthcare providers is important for successful recruitment. Possible strategies include:

- Formal and informal presentations (Grand rounds, research conferences, house staff rounds, clinic in-services)
- Distribution of brochures in clinics
- Direct conversations with physicians and other caregivers, such as physician assistants, nurse practitioners, and nurses
- Consistent and frequent screening in cardiology and pulmonary and other clinics
- Data base and Electronic Health Record searches and mailings

To promote collaboration, investigators should reassure providers that their patients will be seen by investigators for study purposes and that providers will be informed of the patient's status throughout the study if the participant wishes them to be notified.

4.6 The Study Information, Brochures

All participants will complete measurements, study tests, questionnaires, etc. All assessments will adhere to a standardized protocol and techniques. The net result is uniformity of data and adherence to uniform safety precautions. These data and samples are transferred to the DCC for collation and processing, respectively. The centralized data and samples will be utilized to answer questions approved by the Steering Committee.

Information about the study may be referred to online or printed. Study information and contacts will be on the Pulmonary Hypertension's website: www.phassociation.org. Informational brochures describe in easy-to-understand language the purpose of PVDOMICS and what is expected of the participants. This can be used as a tool to briefly review the study requirements with potential participants upon initial introduction, prior to the screening visit and the actual informed consent process. Sample participant brochures will be available on the study website and may be customized to reflect the local site IRB policies and investigators. This brochure requires approval by your local IRB before it can be distributed to potential participants or providers. The complete study is also registered in clinicaltrials.gov allowing widespread information availability to the public.

4.7 Letters to Patients and Providers

Letters mailed to potential participants require approval by your local Institutional Review Board before it should be distributed to potential participants or providers. Emails, telephone calls and letters may also be useful to engage providers in the study. These should be done according to your local policies and procedures.

4.8 Approach to Recruitment

Each site will develop a **recruitment plan** that may use some or all of the following recruitment strategies: clinic-based recruitment; referrals from providers; community-based recruitment campaigns.

Clinic-based recruitment:

After HIPAA waivers and waivers of Informed Consent are obtained, if required by local Institutional Review Boards, electronic medical records will be reviewed to identify potential patients who are eligible for participation.

Study staff will approach patients during their clinic sessions and invite them to learn more about the study. Recruitment letters may also be used instead of verbal contact during the course of providing medical care. Following introduction, study staff will communicate with interested individuals and set up a screening visit.

Referral from providers:

Providers will be introduced to the study and will be provided with a list of inclusion and exclusion criteria. The primary providers will be encouraged to discuss the study with potentially eligible participants, and to either provide the participant with contact information for the study, or alternatively ask if study personnel may contact the participant to discuss the study in more detail. Study staff will initiate contact with interested and potentially eligible patients and describe the study to them. Recruitment letters may also be used instead of phone contact. Following introduction, study staff will set up screening visits with interested individuals.

Community-based recruitment:

The site investigators will initiate contact with community leaders and introduce them to the study. Community leaders will suggest possible ways to disseminate information regarding the study to potential participants in the community. Study staff will respond to contact initiated by interested individuals and briefly describe the study to them. Following introduction, study staff will communicate with interested individuals and set up a screening visit. Additional strategies, including targeted mailings, advertisements within healthcare settings and external promotions will also be considered.

Additional strategies may include:

- provider referrals
- participants referrals
- targeted mailings
- advertisements within local health care settings
- external promotion

Monitoring Recruitment Progress:

Investigators and study staff should meet weekly to discuss progress of weekly goals. Appropriate actions may include:

- Increase number of chart reviews
- Increase time in targeted clinics
- Determine what is working and what is not
- Review barriers and problems
- Revise the plan as necessary
- Consider other means of recruitment, including outside promotion

4.9 Documenting reasons for not approaching participants

Even if screening suggests a participant may be eligible for enrollment to the study, the final decision to approach the individual rests with the site PI and study team. There may be sound reasons to not approach the individual, most important of which is the individual's health stability or ability to safely participate. In every case, documentation of why the individual was not approached should be discussed and recorded by the study team in a local database. The DCC will not collect these data.

4.10 Documenting reasons why a participant did not consent

Study participation is voluntary. Upon understanding the risks of the study, the individual may decline to participate. Attempts to further influence the individual are not recommended. The study team should review and record each individual refusal and the reasons why participation was declined. The number of individuals screened and approached for consent will be recorded by the clinical center and reported to the DCC to determine success of site enrollment.

4.11 Documenting reasons why a participant does not consent to Biobank

Patients with pulmonary vascular diseases, or conditions that place them at risk for pulmonary vascular diseases may participate in this study even if they do not consent to the storage in the biobank and use of their samples after the end of the PVDOMICS study. Likewise healthy controls may participate in the study even if they do not consent to storage in the biobank and use of blood or urine samples at the end of the study. The reason(s) why the participant declined biobanking of samples should be documented and recorded by the clinical center. The DCC will ensure that these individuals' samples are not sent to the biobank. The consent to biobank is separate from consent for use of samples and data across the network during the study, and separate from data sharing (including DNA data) at the end of PVDOMICS. This use during the study, is a requirement for participation, and part of the consenting process in the PVD main consent and the healthy control consent.