APPENDICES for “Cultivating a Cycle of Trust with Diverse Communities in Practice-Based Research: A Report from PRIME Net”

APPENDIX I. KEY INFORMANT INTERVIEW GUIDE

We are conducting a study to identify best practices for recruiting and retaining diverse primary care patients into clinical research studies. We are interviewing researchers, like you, who have experience working with underrepresented populations. In particular we are interested in your work with [insert special population(s)]. Your thoughts and ideas about effective practice are important to this effort.

Section I. Summary of research experience

1. Can you briefly summarize your research with underrepresented populations in general; with this [SPECIAL POPULATION] in particular?

   **Probe:** years of experience; types of studies & topic- intervention; prevention; behavioral; surveillance

   a. Has your work involved a primary care setting? Please describe.
   
   b. What specific subpopulations were involved? (gender, age, immigrant/native, other)
   
   c. What study designs (observation; RCT; longitudinal; program evaluation; qualitative) have you commonly used?

Section II. Group and Primary Care-specific Research

The next few questions address recruitment and retention issues in the [special population(s)] community. We define recruitment as processes that include enrollment (including screening & consent), outreach and communication/publicity.

2. Thinking about your involvement in the research studies you just mentioned, can you please share an experience where you feel recruitment went particularly well and describe the strategies and/or processes used that contributed to success.

   **Probe:** How are these strategies similar or different from those used with other populations? [What are unique needs/strategies v. those common across groups]

   **Probe:** Are there specific strategies for particular study designs or conditions? [look for differences and the factors that affect strategic choice: longitudinal study design; randomization; intrusive procedures; complex protocol; perceived threat, others?]

   **Probe:** (If KI has worked with primary care) Have you found that there are unique approaches to recruiting in primary care based studies?
We would now like to talk about retention. We define retention as any activity to ensure that study participants attend required appointments (measurement/tracking, intervention, prescribed medical follow-up) and adhere to study protocols.

3. Again, based on your experience, please describe an example where study strategies and/or processes worked especially well in retaining participants of [SPECIAL POPULATION]?

   **Probe:** How are these strategies similar or different from those used with other populations? [What are unique needs/strategies v. those common across groups]

   **Probe:** Are there specific strategies for particular study designs or conditions? [look for differences and the factors that affect strategic choice: longitudinal study design; randomization; intrusive procedures; complex protocol; perceived threat, others?]

   **Probe:** Have you found that there are unique approaches to retaining participants recruited through primary care settings?

**Section III. Challenges and Adaptations: Recruitment & Retention**

Recognizing that sometimes the best laid plans go awry, we all find ourselves in the position of adapting our study processes to unanticipated conditions.

4. Please think about a study where the initial plans to recruit and retain [SPECIAL POPULATION] failed to work and required adaptation. What adaptations were developed to overcome these challenges? What are your thoughts about why the initial approach was not successful?

   **Probe:** Are these challenges similar or different from those you have experienced with other populations?

Moving from these specific case examples, we have developed a list of other general challenges experienced by researchers.

5. As we review the list, please let me know if these things have been relevant in your work and what, if any, strategies you’ve developed to address them. [NOTE: Skip any discussed previously].

<table>
<thead>
<tr>
<th>Patient/Community Challenges</th>
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<tbody>
<tr>
<td>a. <strong>Follow-up contact</strong></td>
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<tr>
<td>Maintaining contact by telephone, regular mail, or email: bad contact information; cell phone issues, challenges with leaving messages, unanswered/unreturned calls, disconnected lines</td>
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<tr>
<td>b. <strong>Literacy demands:</strong></td>
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<td>Printed material; finding appropriate language to describe complex information; providing simple written and/or oral translations for non-English speakers</td>
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<td>c. Study publicity and outreach:</td>
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<tr>
<td>d. Community Contact:</td>
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<tr>
<td>e. Cultural appropriateness:</td>
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<tr>
<td>f. Historical Trust:</td>
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<td>g. Costs</td>
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<td>h. Other</td>
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Now, we would like your thoughts about the value of a specific set of strategies generally referred to as “participatory research” methods. These include a range of approaches, such as community based participatory research or community-engaged research that involves representatives of the target population in some or all stages of the research process.

Section IV. Participatory Research Methods

6. Have participatory strategies been a part of your research efforts?  
   (If yes) Please tell me about how you’ve used these approaches.

   [NOTE: Skip this question if these methods have already been described in detail. Move to probe question below]

   **Probe:** What kinds of recruitment/retention benefits and challenges have you found using participatory methods? Are there circumstances when a participatory approach is not necessary for effective recruitment and retention?

   (Give examples to help get people going – e.g. if and how people have gone about getting input from diverse communities about the research design and process before it was finalized, and how much shared ownership there is between the researchers and the communities that they are studying)
Thinking about the issues we have discussed, we are interested in your thoughts about the ways that researchers and clinicians can work effectively together.

**Researcher-Clinician Collaboration**

7. What are your thoughts about how to establish and maintain an effective collaborative relationship with primary care clinicians?

**Probe:** level to which they involve the clinicians in the research design process, developing recruitment and retention strategies for the special populations targeted; engaging patients in planning recruitment and retention prior to starting the study

8. We have also developed a list of researcher-clinician challenges. As we did before, I’d like to review the list with you to see which of these issues, and others, impact recruitment/retention efforts in research. [NOTE: Skip any discussed previously].

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<th>Physician/Researcher Challenges</th>
<th>(Robinson &amp; Trochim 2007)</th>
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<tr>
<td><strong>a. Time:</strong></td>
<td>Physician treating underserved populations lack time and staff to participate in clinical research</td>
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<td><strong>b. Academic-Clinician relationship:</strong></td>
<td>“Unbalanced” relationship between academic researcher and clinician; lack of follow-up</td>
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<td><strong>c. Clinician Incentive:</strong></td>
<td>Lack of incentive for overworked physicians caring for minority patients</td>
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<td><strong>d. Clinician awareness:</strong></td>
<td>Lack of adequate clinician education in providing patient’s information about clinical trials</td>
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<td><strong>e. Achieving community buy-in:</strong></td>
<td>Not linking research on community “needs” with perspectives on what community “wants”</td>
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<td><strong>f. Minority scientists:</strong></td>
<td>Insufficient numbers of minority researchers, PI’s, or leaders on research teams</td>
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<td><strong>g. Researcher commitment:</strong></td>
<td>Poor recruitment to trials in minority communities where disease burden is highest</td>
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**Future Directions**

9. As we come to the end of the interview, I’d like you to look ahead over the next several years and comment on any changes you anticipate in recruitment and/or retention strategies for [SPECIAL POPULATION]

For example, changes that may be due to:
- shifts in the composition or characteristics of the [SPECIAL POPULATION] community
- developments related to communication technology—electronic patient registries; connected databases, others

**Probe:** How do you think your approach to recruitment will need to be adapted in response to these changes?
Summary

10. Let’s summarize your top three challenges to recruitment and retention and your top three strategies for success.

Challenges for recruitment
1.  
2.  
3.  

Strategies for recruitment
1.  
2.  
3.  

Challenges for retention
1.  
2.  
3.  

Strategies for retention
1.  
2.  
3.  

Concluding Comments
11. Any final thoughts and recommendations? Is there anything that we haven’t discussed that you feel is important to this discussion?

Thank so much for sharing your views about these issues. We plan to use your input, along with other researchers and patients from some of the communities we’ve been discussing, to assist primary care researchers in their efforts to most appropriately involve underrepresented populations in clinical research.
APPENDIX 2 – FOCUS GROUP GUIDE

I. Warm-up Questions
   1. Impression of research
      a. What does ‘research’ mean to you and your community?
      b. What are some of the reactions or impressions when you heard the word ‘research’?
      c. How about “medical research”?

II. Recruiting/Enrollment Questions
   2. Outreach / recruitment channels for [ethnic/racial group]
      a. How did you hear about this study recruiting participants?
   3. Factors involved in decision-making to participate in a study
      a. How would you decide whether or not you would participate in a research study?
      b. What role do you think your personal doctor and clinic could have in terms of encouraging or discouraging your participation in clinical research?
   4. Other concerns about participating
      a. What concerns might you have about research participation?
      b. Why do you think some patients in the [ethnic/racial group] community are hesitant to participate in research?

III. Retention Questions
   5. Factors involved in staying with a study or withdraw from participation
      a. For studies that involves participation over a period of time, or require you to be interviewed or to complete questionnaires for multiple times, what might encourage/ facilitate you to stay with the study or to continue your participation?
      b. What role do you think your personal doctor and clinic could have in terms of maintaining communication with researchers? How about in helping you decide whether or not to continue in a study after you have enrolled?
      c. Some researchers have used the following strategies to keep people interested in the study (examples: birthday cards, reminder calls, reminder letters, etc), would they help? Why or why not?

IV. Recommendations/Best Practices
   6. Recommendations for researchers
      a. What recommendations would you give to researchers who wish to have a good representation of [ethnic/racial group] participants in their research? The Dos and Don’ts
      b. What methods (people, media sources, etc) would you recommend for researchers to use to spread the word to the [ethnic/racial group] community about the study?
      c. What incentives might be helpful in getting your attention or others’ attention? Other facilitators?
      d. What might turn you off? Other barriers?
7. **Recommendations for [ethnic/racial group]** who are considering about participating in research
   a. What suggestions might you have to encourage members from [ethnic/racial group] community to participate in research studies or to support research projects?
   b. What are good terms or words to use to explain or describe “research”?
   c. What role do you think your personal doctor and clinic could have in terms of encouraging or discouraging you to join a research project like this?

**Probes to consider:**
- **Credibility or reputation of the information source- How do you decide if this person or source is trustworthy?**
- **Recommendations of others- your doctor, other office staff, friends, family**
- **“Hassle-factors”- cost, time, transportation, convenience, trusted place, other people I knew were coming**
- **Benefit to me personally; to my family; to my community**
- **Incentives- what is appealing or acceptable; is money preferred**
- **Bilingual materials, questionnaires, bilingual research staff**

**V. Retention Questions:** Reasons for staying with a study or stopping participation
8. For studies that involve participation over a period of time (like a few years), or require you to complete questionnaires and/or come to a clinic multiple times, what might lead you to stay with the study or to continue your participation?
   a. What do people want to know during the course of research project?
   b. What role do you think your personal doctor and clinic could have in terms of maintaining communication with researchers? How about in helping you decide whether or not to continue in a study after you have enrolled?
9. Some researchers have used the following strategies to keep people interested in the study (examples: birthday cards, reminder calls, reminder letters, etc). How do you feel these things would? Why or why not?

**VI. Recommendations for Researchers**
10. Thinking about the issues we’ve discussed, what recommendations would you give to researchers who wish to ensure that people here in the community participate in a project?
   a. Probes: better ways/methods (people, media sources, etc) for researchers to spread the word to community about the study?
11. Lastly, we’d like you to think about what happens at the end of a research project. What’s important for researchers to do at the end of a project? Are there any other responsibilities the researcher has to participants or the community once the project ends?

**CLOSING:** Thank you very much for your time and your willingness to share your thoughts and ideas with us. Your responses will be very helpful in aiding researchers who design research studies to involve people from all communities. Your thoughts about how to ensure that [ethnic/racial group] families and community are comfortable have been important and will help us to develop standards for clinical research planned for the future.