



## Appendix A Participating Site Community Profile Worksheet

*Instructions to Participating Site: Please complete the information below and return this form to the study Lead PI. Provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) waiver for emergency research would be used.*

<b>Title of Study</b>	
<b>Name of Participating Site</b>	
<b>Participating Site Contact</b>	

**A. Cultural, demographic, geographic, and economic considerations:**

- What is the anticipated geographic area that participants may be recruited from at your site?
  - What is the ratio of rural to suburban to urban populations in this geographic area?
- Do you have any minority populations that should be considered?
- Do you have any particular populations of affluence or poverty that may require special methods of outreach in order to inform them about the research?
- How would you describe your community's access to healthcare and awareness of existing clinical research efforts in the area?

**B. Languages and local educational and/or literacy concerns:**

- Does your site have a large non-English speaking population?
  - If yes, what languages?



**C. Religious, social, and political considerations:**

- What are the predominant religions in your area? Do they have any beliefs that may affect their willingness to participate in research or to accept an EFIC model?
- Has your community experienced any major events (i.e. local/national tragedies, heated social or political issues, etc.) that may require added sensitivity when considering an appropriate community consultation plan for this study?
- What are the dominant political inclinations of your community?

**D. Are there populations being targeted by this study that may be more likely to be enrolled than others?**

- Are there specific patient populations affected by this research that should be specifically consulted?
- Are recruitment procedures designed to ensure a representative sample of participants?
- Will certain disadvantaged or vulnerable groups be over or under represented?
- Will potential risks and benefits be reasonably distributed across the community as a whole?

**E. Other considerations:**

- Overall, is this research appropriate for your community?
- Do you have additional information to provide the IRB?