

## E. Protection of Human Subjects

### 1. Risks to the Subjects.

1.1. Human Subjects Involvement and Characteristics. Participants in this study will be healthy, community dwelling individuals, aged 18-75 years. The population to be studied is from Multnomah County, Oregon. N CHWs will be included who are paid to participate in the project. 100 individuals from each of the African American and Latino communities will be recruited to complete a yearly questionnaire. Subjects will be required to meet the following selection criteria: (1) 18 years of age or older and (2) a resident of Multnomah County, Oregon.

1.2. Sources of material. Data collection methods will include data obtained specifically for research purposes, including: in-depth interviews with CHWs and community residents; focus groups with community residents; and face-to-face surveys with 100 African American residents and 100 Latino residents. In addition, we will make use of existing records and data, including: weekly documentation of CHWs' activities; meeting minutes and field notes from trainings; materials from publications and presentations; newspaper and document reviews; and evaluation forms from trainings.

1.3. Potential risks. Overall, potential risks associated with participation in the study are unlikely and of low risk.

1.3.1. Physical. There is little likelihood of any physical risk as a result of participation in this research project. Interview subjects, including CHWs and community members, are not asked to perform any tasks as a part of interview schedule that could result in physical harm. As part of the intervention, in the course of their paid duties CHWs will engage in activities including participation in training activities, driving, and visiting clients in their homes, that have a small likelihood of low physical risk.

1.3.2. Psychological. Participants will be asked to provide information about their self-reported physical and mental well-being, their neighborhood environment, and demographic data (age, gender, income, education, race/ethnicity, and home ownership). These questions have a small likelihood of low psychological risk if participants are upset by questions that ask them to think about their own poor health or problems in their neighborhoods that are disturbing.

1.3.3. Social. The process of Popular Education is designed to use collective reflection and discussion techniques to develop a critical consciousness of one's culture and society, including immediate health-related needs as well as longer-term issues, including improving socioeconomic position of participants, namely discrimination (Bosch, 1998). Bringing these social issues to a conscious level has a considerable likelihood of moderate social risk in terms of conflicts with cultural beliefs, traditions, and social order. We propose that this risk can be managed and channeled in a positive way through careful attention and training which will be a part of this intervention. Additionally, there may be a perceived risk among CHWs that participation in the research aspect of this project may impact their employment status in a negative way. Community members may perceive a risk that participation in the research aspect of this project may impact the quality or existence of services they receive (currently or in the future) from the CHWs, the County, or other involved CBO's. There is no likelihood of these social risks.

### 2. Adequacy of Protection Against Risks.

2.1. Recruitment and informed consent. “Units of identity” will be identified within the two communities. These may include: neighborhoods, churches, sororities, soccer leagues, people from same region or town in Mexico, etc. For recruitment for the questionnaire, we will randomly sample units of identity identified by the focus groups and interviews with steering committee and exploratory focus groups with community members. After selecting a random sample of units of identity, we will count all individuals in the selected identity units to create a sample frame for each unit of identity. Finally, we will use the list of individuals to draw a random sample. Trained teams of two interviewers will go in person to the sampled individual to request participation in the research study. Participants for the in-depth interviews will be recruited using purposive sampling (Patton 1990). Prior to conducting any interviews, all participants will be given a formal Statement of Consent Form to read and the form will be verbally explained by the interviewer. Participants will sign the form indicating that they understand that they are being asked to participate in a research study, that they understand the risks involved in participating, that they can refuse to answer any question that they are not comfortable with, and that the information they provide will be kept strictly confidential. In the case of the CHWs, their informed consent form will also provide assurances that their participation in the research aspect of this project will in no way affect their employment status either positively or negatively. In the case of community residents, their informed consent form will also provide assurances that their participation in the research aspect of this project will in no way affect their current or future receipt of services from CHWs, the County, or involved CBOs.

## 2.2. Protection Against Risk.

2.2.1. Minimizing physical, psychological, and social risks. Participants are free to refuse to respond to any question that may result in psychological disturbance. Written information collected for research purposes only will not become part of CHWs’ personnel records. Individual responses to community questionnaire will not be linked to identifying information, except for purposes of following-up with respondents in subsequent years of data collection, and will not at all influence current or future receipt of services from County or participating CBOs. These precautions are expected to be completely effective in eliminating risks associated with participation.

2.2.2. Minimizing risks to confidentiality. Identifying information from any of the participants in the community survey will be kept separately from the forms on which they record their responses to the questions. Records will be linked to individuals only through a unique identifier and the information used to link records with identifying information will be kept in a securely locked file drawer only accessible to project staff. Names and any other identifying information collected from the subjects of the in-depth interviews will be kept in a locked file drawer only accessible to project staff. References to names or other identifying information will be eliminated from the written transcript of the interview in preparation for analysis of qualitative data. Names and any other identifying information on evaluation forms from the trainings, weekly documentation of CHWs’ activities, meeting minutes and field notes from trainings, materials from publications and presentations, and newspaper and document reviews will be eliminated in preparation for analysis of these records. These precautions are expected to be completely effective in eliminating risks to confidentiality.

3. **Potential Benefits of Proposed Research to Subjects and Others.** Benefits may accrue to community residents who participate in the interviews beyond those of the knowledge generation: participation may build community understanding and greater awareness of community assets, as well as enhance buy-in for community project implementation, health promotion programs, and policy changes. Benefits may accrue to CHWs who participate through awareness raising leading to greater individual and community empowerment, enhanced knowledge of community assets as well as health concerns and needs, and enhanced skills related to performance of duties as CHW. Outside of participants in research, all community members may also benefit from enhanced trust and reciprocity within the community.
4. **Importance of Knowledge to be Gained.** The information gained in the course of this research may be used to improve CHW programs within this community as well as to inform CHW programs in other communities. Additionally, the information gained in the course of this research may be used specifically to enhance social capital and overall health in other similar communities.

### **Inclusion of Women and Minorities**

There are several different types of participants in this study. The first category of participants will be the CHWs who are paid to participate in the project. The second category of participants will be community members (100 surveys to be completed in the African American and Latino community) who may or may not have interacted with CHWs and who are selected for participation in the survey in Years 1, 2, and 3. A fourth group of participants will be staff members of the project partnership, including salaried, hourly or volunteer staff members. A fifth group will be those community members, decision-makers, or stakeholders who become involved in [project name] to improve the health of affected communities.

It is anticipated that subjects will range in age from their mid-teens to their mid-sixties. Given the focus and nature of this CHW and Popular Education intervention, many of the participants will be women. Additionally, participants will be predominantly African Americans or Latinos.