

ClinicalTrials.gov Data Entry Cover Sheet

**Today's date:** May 15, 2024

**Document date:** November 15, 2023

**Protocol ID:** 21287

**Clinical Trials.gov ID:** NCT05129501

**Project Title:** *The Impact of an Adapted Version of the Strengthening Families Program on IPV Among Caregivers and ACEs Among Children*

**Principal Investigator:** Katie M. Edwards, PhD, University of Nebraska-Lincoln

## **Recruitment and Retention Plan**

Careful efforts will be made to **maximize participant enrollment** and **minimize attrition** in the survey and programming portions of the project. As described in the Statistical Design and Power Analysis section of this proposal (referenced in C.14 of the Research Strategy), we will enroll a total of 320 families (160 per condition). Based on previous similar research, including the PI's work, we anticipate that we will retain 75% of the sample at the 8-month follow-up for a final sample size of 120 families per condition (160 youth and 160 caregivers per condition x 2 conditions for a grand  $N = 640$  youth and caregivers across conditions at the pretest, and 480 across conditions at the 8-month follow-up).

### **Recruitment**

We will recruit from multiple agencies/organizations/schools in Rapid City, including Youth and Family Services; Children's Home Society; Department of Social Services; Rural America Initiative; Rapid City Area Schools; Working Against Violence, Inc.; Girls, Inc.; Rapid City Police Department; Pennington County Sheriff's Office; and Ellsworth Air Force Base. (See enclosed letters of support from these partners.) These partnering agencies/organizations/schools will do the following as detailed in their letters of support: (1) post project information on their social media sites; (2) allow the project team to have a table at events hosted by the school/agency/organization; (3) send recruitment letters to families that are involved with or attend the school/agency/organization; (4) share information about the project with staff so that they can pass along information to the youth and families they serve; and/or (5) encourage families to personally invite other families to the project. We will follow the recommendations for recruitment suggested by the Iowa State University Extension (e.g., use positive language when describing the project, personalize invitations). In addition to these efforts we will also "boost" posts on social media to advertise the project, place an advertisement in the local newspaper with project information, saturate the community with fliers advertising the project, and attend numerous community events (e.g., Black Hills Pow Wow, Lakota Nation Invitational, Black Hills Pride). Dr. Edwards (PI) has used these recruitment methods in another federally funded study (5U01CE003168) in South Dakota (SD) with success (as evidenced by over 80% returned consent forms in schools, for example). Also, as part of this same study, Dr. Edwards (PI) was able to recruit more than 50 adults (e.g., caregivers, teachers) to participate in interviews and/or focus groups within a 2-week period. We will also advertise the study in other ways as recommended by the Research and Practice Advisory Board (RPAB). In addition, we will offer informational sessions that incorporate culturally grounded "feeds" (dinners to be covered by Dr. Edwards's discretionary funds), which our previous work suggests increases community buy-in and enrollment. Finally, like previous studies in SD, we will engage in "door knocking" on the north side of Rapid City where the vast majority of residents are low income and/or American Indian. Door-knocking includes identifying areas within a community that have a large proportion of the target population. Once identified, members who live within the targeted neighborhoods are recruited and trained to go door to door and explain the nature of the study to potential participants, assess eligibility, and enroll families that are interested and meet inclusion criteria. We have had great success using this method in previous studies, especially with American Indian communities.

Participants will have multiple ways to **enroll** in the study. They will have the option of attending informational sessions in addition to enrolling by phone, email, an online portal on a project website, or in person at various locations across Rapid City (i.e., we will have a strong presence at community events, especially those targeting American Indians and/or low-income individuals). We will also offer to go to the homes of interested participants to enroll them in the study. Interested families will first be asked if they have at least one child between the ages of 10 and 14. Families will also be required to answer "YES" to one or more of the following questions: (1) *Is your child American Indian/Alaska Native/Lakota?*; (2) *Does your family (including all people who work and contribute to the finances of the household) make less than \$25,750 a year (for family of four)?*. Additionally, at least one caregiver and one child must commit to both the research and programming components of the project to be eligible to participate.

### **Retention**

Intense efforts will be made to **retain** participants. First, at all programming sessions, a culturally tailored meal (e.g., buffalo, fry bread) will be served (paid for by the PI's discretionary funds). Second, we will provide

families with a gift card for each session that they attend (a gift card will be given to each family member who attends). We will also call, text, and email participants of upcoming programming and survey sessions and include reminders on our project social media sites. At the baseline survey, we will collect detailed contact information as well as social media account information. We will use this information to directly contact participants who do not show for a program and/or survey session and are not responsive to our initial contact attempts. We will engage in monthly check-ins with participants in order to keep them engaged and more likely to complete follow-up surveys. During these check-ins we will determine if any contact information has changed. We will also maintain relationships with families by sending them branded goods (e.g., a University of Nebraska–Lincoln T-shirt for the child) and by sending birthday cards. We will also seek participants' approval to locate them via Intelius in the event we are not able to locate them using the contact information provided. Intelius is a database that allows the user to enter an individual's name and/or contact information to receive updates about new contact information (e.g., new address). We have used this in a previous, federally funded study (grant number 2016-SI-AX-0003) with women who have histories of criminal offending, victimization, and addiction to retain over 85% of the sample, and there have been no negative impacts of using this service on participants. Also, widespread community support for this project will likely help with retention. Finally, we recognize the transient nature of the American Indian population in Rapid City, SD. More specifically, some American Indian families in Rapid City, SD, spend some of their time on one of the nearby reservations. We will work with families to enroll them in the study when they anticipate being in Rapid City for the duration of the project. We will also provide options for families to complete the follow-up surveys remotely in addition to having research staff make occasional visits to the nearby reservations for follow-up survey procedures.