

Part 6: Preparing for a Randomized Controlled Trial (RCT) in a Tribal Community



Staffing and Personnel

School settings in tribal communities vary and are reflective of the economic, political and ethnic characteristics in relationship to their physical location. Interventions implemented in an American Indian school setting involving sexual and reproductive health requires personnel that have an understanding of the culture and environmental context of the community. Training should be provided to staff and personnel involved in implementing this knowledge and practices. Successful implementation requires buy-in by everyone involved at every level including school administrators, school personnel, and parents.

The NE RCT included two full-time staff in the community, one researcher at Montana State University, and many cultural mentors and teachers.

The NE intervention was structured as a Randomized Controlled Trial (RCT), allowing researchers and partners to compare outcomes between groups receiving the intervention. RCTs can be adapted and implemented in any community; preparation is key for successful implementation. Preparing for a RCT in a tribal community takes staffing and personnel, partnerships, and funding. This section outlines considerations for tribal communities as they prepare for a RCT.

It's helpful to do focus groups or focused interviews with the community to determine the topics that your RCT will address. A lot of the topics we have addressed and found helpful were based on the CBPR process. You have to constantly engage the community.

To understand our communities are vastly different. Our barriers are different, we are not negating that process. We are giving an amazing tool that worked- the biggest reason it was successful is that we engaged the community.

Engagement did take constant communication with tribal leadership. Our leadership is a revolving door sometimes. It requires you to stay engaged.

We have been talking about this. It has evolved since my son was in Head Start and is a senior now. That is how long it took.

- Adriann Ricker



Preparation is essential for implementing an RCT in a Tribal community. Staffing and personnel can be hired locally to implement and support an RCT.

The number of staff and personnel you will need depends on where you live, the number of sites that you will be implementing the intervention with, and the levels of support you have within the CAB, elders, and community.

Their roles and responsibilities were...
Beth is from Bozeman. She is the Principal Investigator and has knowledge from an academic / western way of knowing.

Olivia and Paula deal with the students and work with them and teachers and parents and staff at school.

Marty Reum and other cultural mentors deliver cultural lessons and support cultural adaptations of the intervention.

We gather data from them, the parents. We just started gathering data from teachers. We give parents and teachers information. It is just the two of us. We have cultural mentors that do cultural lessons.

Those are elders in the community. They speak to the students. It is probably about 25 to 30% of the curriculum is cultural stuff.



- Paula Firemoon

Building Your Team

Your team will consist of both core personnel to implement the project, and community members to guide and support efforts.

Core Team

The core team consists of key personnel who administer, implement, and evaluate NE in the community. Roles and responsibilities for each staff member should be identified prior to implementation. Within the team, diversity mirrors the community. A variety of backgrounds, perspectives, and expertise help create a well-balanced team.

Community Support

Build a support system around the core team with people and resources to support and guide NE activities.

Cultural Consultants

The project needs cultural leaders, elders, cultural guides who can provide consultation on cultural teachings and ways.

Support Staff

Who are the champions and change-makers in your community; the ones who know how to get things done? Bring them on as support staff.

Local Resources

Identify relationships with local resources; people, goods, and services. The nature of community research is that you are creating the resources, understanding the balance between online and local resources and the distinction between formal and informal resources. Identify cultural networks to reach out to if assistance is needed.

Advisory Board

Create an advisory board (CAB or AB) that includes a variety of key stakeholders with education and local/cultural knowledge. The CAB knows their community the best and plays a critical role in guiding research efforts and bringing unique perspectives to the table.



We used the CAB to link elemental pieces of the community. Gayopi (Dakota) sometimes this has a negative connotation. We are talking about things that may not be good to talk about, but it's the method of how we share info about our community. It's a natural part of how we come together. When we visit with our relatives, there is an element of Gayopi. How we share info. It's a way of connection.

- Adriann Ricker



Here are some things to consider when building your team and creating your network of supporting resources:

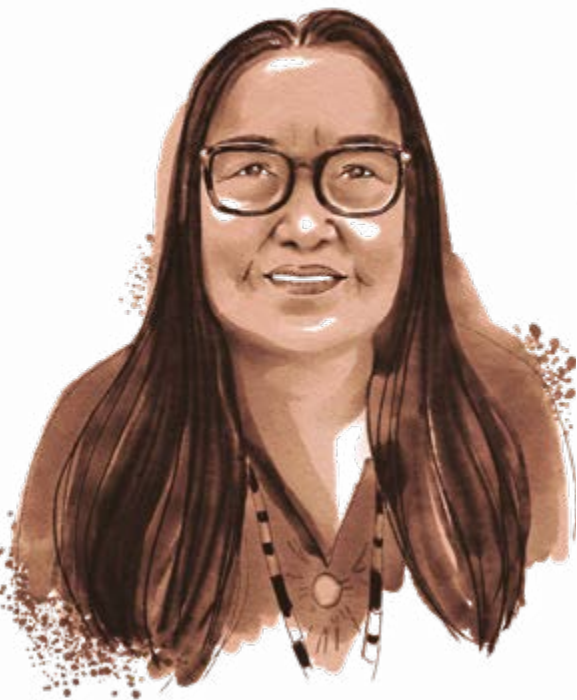
Community Characteristics

Gain an understanding of the physical, economic, political, and cultural characteristics of your community and how these factors may influence and affect the implementation of a RCT.

There are lots of things in Native American culture, even different from tribal. Each tribe has their different culture. It has to do with protocols. It's important to... I could not tell you what the protocols are at Navajo or how we get things done. With the staffing, we cannot say, we need a person with this type of educational background. They need to be more involved in understanding the cultural ways of anything.

That is what they need to know the most. When you are working with Native American children in the schools, they have a school structure, but when they go home, they are being raised by grandparents, or they are the parents in their house, the older kids. We have a big gap, almost a two generational gap, where a lot of kids in school are either kids born with FAS or Drug Affected, homeless kids because on our reservation, kids are dropping out by 8th grade. They are becoming younger parents now.

- Paula Firemoon



There can be someone sitting in the room that doesn't say anything but be very powerful and have a lot of influence on these kids. I struggle with this kind of stuff. There is a Native way of knowing things. We have a way of knowing things. We have cultural mentors who have been involved. They understand you cannot misbehave or be disrespectful. There is something about a traditional elder when they come into the room. Instinctively as a Native American you don't make fun of them, you don't speak unless you are spoken to, or asked to speak. A lot of the kids know that, even though they may not have the best family lives or have different privileges. But they know that. When you bring in a tribal elder, the kids get quiet.

- Paula Firemoon

Leadership Characteristics

Decisions are made from a variety of sources including tribal leaders, elders, cultural teachers, or families and systems. Who are the leaders and decision-makers in your community? How are important decisions made and how do power dynamics influence decision making? These dynamics should be gauged and can be discussed early in the RCT process.

Cultural and Political Relationships

Each tribe has its own All the Relations Network; a cultural and political history with years of relationships that provide a foundation for RCT work. This is not hierarchical or merit-based decision-making that comes from a typical distribution of power within academic research settings.

School Relationships

Schedule planning meetings with schools to develop partnerships and shared understanding before applying for funding. NE met with school administrators and leaders nine months before the research proposal was submitted. Ongoing meetings with schools are essential to address questions and concerns that come up during the intervention. Utilize every opportunity possible to educate schools, teachers, and parents about your work.

Figure 7. Working With Schools





You run into parents who don't want their kids to be a part of this. The majority of families think this is good.

If you are facilitating, be open, be willing to be vulnerable. When you show openness as an adult, it helps youth open up.

I am not afraid to tell my story. If they are living in a tough situation, we can see the light in the dark tunnel we are in.

Be transparent with the students, parents, administrators, about the goals of this process. We've had great reception from all schools.

- Marty Reum



Community Based Participatory Research (CBPR) - Involving the Community at Every Step


Developing community capacity in a tribal community to address sexual and reproductive health requires capacity building, community engagement, collaboration, and infrastructure development.

From the beginning, I was with this project. I supported focus groups and advisory capacity. This topic was stigmatized in our community, we had a high incidence of teen pregnancy, STIs, etc. this idea was birthed in response to how school systems were asking Kris and me if we would teach sexual health lectures in middle school and high school because we were doing that as part of the male sexual health project we had. It was a taboo topic.

The teachers were nervous. That birthed the ideas of this project. Talking about not just basic sex ed, we wanted elements of relationships and cultural pieces.

-Adriann Ricker





The systems intervention, I feel, is unique in the sense of working on the reservation. We have learned over time, working in this intervention on the reservation, it is not what you know but who you know in order to get things done. To get people to look at a sex education curriculum. It is about knowing who to talk to, how to talk to them, and your connection. This started at the time of the pilot. When the pilot came out, I was a teacher at Brockton School. When Paula brought the intervention to pilot in Brockton, I believed in it. We discussed it. It did not take much convincing because our board knew it was something positive for our community. It makes red tape a lot easier; it is not there because of who we know and the relationships we develop. Paula knows everyone. She has a long history of working with the tribes and attending college. She's built a nice network of connections. Our connection is with families in general, knowing people, their kids, and who they are.


About Capacity Building:

Now we have project officers coming to Fort Peck and our tribal council leaders are able to talk about sex openly. A once taboo topic in public and professional policy settings, is now a comfortable topic. This speaks to 20 years of work that we have all done. Everyone.

The comfort level with a historically traumatizing taboo topic is now normalized. You even see that in the schools, with the leadership in the schools. There is a recognition that if we want young people to be healthy when they choose to have families, we as adults have to model responsible healthy behavior. We are seeing that across the board. There is lots of joking, the use of humor, but there is also seriousness.

- Olivia Johnson

On Development of a Community Advisory Board (CAB):



This current CAB has been together for 12 years or so. We all know and trust each other. That is a gift. It's not like we don't disagree. There will be times when someone mentions we should do something and I say it won't work... Or we have to do this because of research... they will say no it won't work but they give me another idea.

We have learned how to resolve differences in agreement in a respectful way and find solutions. The strength of the relationship is the relationships' ability to resolve conflict. If you are in a relationship that cannot resolve conflict in a mutual reciprocity way- there is something wrong. We have incredible support.

- Beth Rink



People from different programs and ages. I was identified as someone who could teach this, but I got older. How it's been successful is that the research team and the CAB are open to the fact that the community is dynamic, the work should reflect that. We had original ideas we thought would work. It wasn't hard for us to switch directions. Beth, Paula, and Oliva would meet and gather our CAB and let us know what was going on. We collected feedback from them. Constantly being engaged in the process of moving with the flow and dynamics of the schools. Being responsive to changes of leadership in the schools. Different cultures, within a few years, the culture is different with student groups. The approach has been to be resilient and dynamic. In response to the community the whole time.

- Adriann Ricker



Change and Maintenance of CAB

If something isn't working, change it. NE utilizes a regenerative community engaged research/regeneration process. We implement NE within existing structures and attached funding. This provides sustainability and maintenance of efforts, including support of the CAB.

Our CAB

meetings are tons of fun.

There is tons of laughing and the food is really good. Paula gets her sister to cook, the food is incredible. I remember a CAB meeting two years ago where Paula and I worked up the agenda for a 1.5 hour meeting.

We were laughing so hard for an hour and 15 minutes ... laughing and eating. We got a huge agenda done in 15 minutes. It's because it's fun, We like other.

We feel comfortable with each other. It doesn't feel like work. It feels like talking about a community and a people that we are all passionately invested in. We are passionately invested in this work.

- Beth Rink



Working with Tribes, it is necessary to create relationships. Data is situated within the community. If you are working with a statistician, the analyst needs to be in the community and spend time with them or be from the community. If analyses are done, community members and tribal research partners need to work alongside you. A lot of the stuff you see in analyses is unknown.

It is risky if you don't have a tribal partner working with you, you might make false assumptions that are incorrect. A lot of people believe that quantitative analysis is objective- it is truly not. You need to make sure that every decision you make is in line with the community values. You cannot ensure that unless you are working with tribal research partners throughout the process.

- Jeffrey Thiele,
Graduate Research Assistant



Budgeting a RCT

When conducting the intervention, the budget will vary depending on the capacity and the needs of the community. Below is a general budget template that outlines some of the key costs of a RCT. A budget justification is also included to support these costs and detail key job duties.

This template can be used and adapted when preparing funding applications.

Personnel	Details	Budget
Salaries/Wages		
a. Principal Investigator (0.10 FTE)	\$100/hr x 208 hrs	\$ 20,800
b. Research Coordinator (1.0 FTE)	\$40/hr x 2080 hrs	\$ 83,200
c. Data Analyst (0.50 FTE)	\$40/hr x 1040 hrs	\$ 41,600
d. Cultural Constultant (0.25 FTE)	\$30/hr x 520 hrs	\$ 15,600
	Total Salaries	\$ 161,200
Fringe Benefits		
	20% Rate	\$ 32,240
	Total Personnel	\$ 193,440
Supplies		
Program Supplies		\$ 1,810
Participant Supplies	50 participants x \$30/ participant	\$ 1,500
Computer	\$2500/computer x 2	\$ 5,000
Projector		\$ 500
	Total Supplies	\$ 8,810
Other Costs		
Printing Manuals	50 participants x \$50/ participant	\$ 2,500
Printing Classroom Materials	Posters, flyers, etc.	\$ 750
Classroom Incentives	Snacks, stress balls, etc.	\$ 1,500
	Total Other Costs	\$ 4,750
Total Direct		\$ 207,000
IDC	10% de minimus	\$ 23,000
Total		\$ 230,000

Budget Justification

Principal Investigator (0.10 FTE): The Principal Investigator will be responsible for the overall integrity of the program. This individual will work closely with the program staff to ensure the program is meeting all goals, objectives, and deliverables.

Research Coordinator (1.0 FTE): The Research Coordinator will be responsible for implementing the entire program. This individual will work closely with program staff, present each learning module to classroom participants, and conduct any follow-up with the funding agency.

Data Analyst (0.50 FTE): The Data Analyst will work closely with the Project Coordinator to collect data from participants during each session. This individual will be responsible for entering the data into the program computer, conducting any necessary analysis, and preparing for dissemination. .

Cultural Consultant (0.25 FTE): The Cultural Consultant will work closely with the Project Coordinator and Principal Consultant guide development and adaptations of all cultural teachings and content.

Fringe Benefits: Employees will receive fringe benefits according to the policies and procedures of the organization. An average rate of 20% is estimated.

Program Supplies: General office supplies will be needed to conduct the program. These supplies include paper, pens, staples, paper clips, and tape.

Participant Supplies: Supplies are needed for each individual participant to journal in and reflect on the lessons given.

Computer: Two computers are needed for the Project Coordinator and Data Analyst. This cost would be a one-time expense.

Projector: A projector will be needed to share program materials to the whole class at one time.

Printing Manuals: Online materials are available for downloading and printing. These materials are worksheets for students to write on and learn during class time. These can be put into a binder to create a manual for students to bring home.

Printing Classroom Materials: Online materials are available for downloading and printing. These materials are large posters, flyers, or educational materials.

Classroom Incentives: The program can purchase classroom incentives for participants of the program. These items can be used to recognize a job well done or to be used to keep students' hands busy while talking about subject matter.

IDC: A 10% de minimus indirect cost is included and used for organizational administrative costs for items such as rent, utilities, financial services.

Agreements and Institutional Review Board (IRB)


Tribes have the right to govern collection, ownership, and application of their own data. This is called **Indigenous Data Sovereignty**.

When beginning a research project, it is important to follow tribal protocols for conducting research and collecting information from participants. Ideally, the Institutional Review Board (IRB) process would begin before the research begins. If your research is funded by a specific agency like the National Institutes of Health (NIH), they have specific requirements for IRB reviews and approvals.

The most important thing to remember is that the NE should not begin until all necessary agreements and approvals are in place and documented.

Every tribal process for conducting research is unique to the population being served and the target population. Tribes are sovereign nations and honoring this I've been on the IRB since its inception. I dropped out because I had a huge grant from the Department of Labor. I went back... I am the IRB Administrator and we went through MSU. MSU has said when it involves Tribal programs at Fort Peck it just goes through us.

-Paula Firemoon



We are pretty unique with having our own IRB board. Our tribe is trusting our IRB board to lead us in the right way. This is important for people to know, if they are doing research, these are the steps we had to take.

- Olivia Johnson

Here are some additional resources related to IRBs:

Exemptions to IRB processes

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1>

Data and Approvals

<https://natedata.npaihb.org/wp-content/uploads/2021/09/Handout-12-Planning-for-the-Approvals-Process.pdf>

Research Ethics

<https://www.hhs.gov/sites/default/files/supporting-ethical-al-an-research-508.pdf>

Social media research guidance from the Social Media and Adolescent Health Research Team

<http://smahrtresearch.com/use-our-methods/>

Native Data Main Portal

<https://natedata.npaihb.org/>

Ethics of Social Media Research

Ethics of Social Media Research: Common concerns and practical considerations.

