Clinicaltrials.gov: Cover page

Official title of study:
Improving Chronic Illness Management With the Apsaalooke Nation: The Baa Nnilah Project

NCT number: NCT03036189

Date of the document: 10/2019
(note: this is a compilation of documents dating from 7/2017-10/2019)

Full Committee Review ☐
Expedited Review ☐

MONTANA STATE UNIVERSITY
Institutional Review Board Application for Review
(revised 06/01/15)

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Application Number: Approval Date:
Disapproved: IRB Chair's Signature:

****

Date: July 13, 2017

I. Investigators and Associates (list all investigators involved; application will be filed under name of first person listed)

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DATE TRAINING COMPLETED: 1/2016. *[Required training: CITI Training; see website for link]*

SIGNATURE (PI or ADVISOR): x Suzanne Held

NAME: Alma McCormick TITLE: Executive Director
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DATE TRAINING COMPLETED: 10/2015. *[Required training: CITI Training; see website for link]*

NAME: Jim Becker TITLE: Assistant Professor
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DATE TRAINING COMPLETED: 10/2016. *[Required training: CITI Training; see website for link]*

Do you as PI, any family member or any of the involved researchers or their family members have consulting agreements, management responsibilities or substantial equity (greater than $10,000 in value or greater than 5% total equity) in the sponsor, subcontractor or in the technology, or serve on the Board of the Sponsor?
_____ YES xx NO

If you answered Yes, you will need to contact Kellie Peterson, Assistant Legal Counsel-JD at 406-994-3480.

II. Title of Proposal: *The Báa nnilah Project*

III. Beginning Date for Use of Human Subjects: 8/1/2017

IV. Type of Grant and/or Project (if applicable)
Research Grant: xx
Contract:
Training Grant:
Classroom Experiments/Projects:
Thesis Project:
Other (Specify):

V. Name of Funding Agency to which Proposal is Being Submitted: funded from the National Institutes of Health, U01MD010619, Co-PIs: Suzanne Held & Alma McCormick

VI. Signatures

Submitted by Investigator
Typed Name: Suzanne Held
Signature:
Date: 7/13/2017 Suzanne Held

VII. Summary of Activity. Provide answers to each section and add space as needed. Do not refer to an accompanying grant or contract proposal.

A. RATIONALE AND PURPOSE OF RESEARCH. (What question is being asked?)

Urgent attention is needed to address the significant disparities between whites and American Indians (AIs) in age at death for those with chronic illness (CI). In our state of Montana, AIs die 14 years earlier for those with heart or kidney disease, 12.5 years for those with diabetes, and 11 years for those with cerebrovascular disease(1). Existing programs addressing CI management, which can lead to lower mortality rates and a higher quality of life, fail because they are not consonant with the AI culture. To address this failing, we developed *Baa nnilah*, an innovative and unique program to improve capabilities for CI management among Apsáalooke (Crow) Indians in Montana.

The study is based on methods and findings from a 19-year community-based participatory research (CBPR) partnership between members of the Apsáalooke Nation and faculty and students at Montana State University. Community members asked the partnership to develop an effective intervention for CI management. The development, implementation, and evaluation of a culturally centered intervention for improving CI management can serve as an important model for other communities and tribal nations looking to improve CI health disparities and has implications for management of acute conditions.

Using a CBPR approach, we completed qualitative interviews with 20 AI men and women on the Apsáalooke Reservation who had a CI diagnosis. After we developed a culturally consonant method for co-analyzing the data with our community advisory board (CAB), we analyzed the data and used the findings to develop a conceptual framework and intervention for understanding and improving CI management, something that had not existed for this population. Our intervention will be tested across multiple CIs, as our analysis findings matched other CI management interventions in that "people with chronic conditions have similar concerns and problems"(2-4). The intervention is titled *Baa nnilah*, which translates to advice or instructions for life that are received from others, often in a story form. The method for *Baa nnilah* is centered on Apsáalooke cultural strengths. The content of *Baa nnilah* is based on our conceptual framework of influencers of CI management gleaned from the interview data. The measured outcomes flow directly from the conceptual framework and intervention content. *Baa nnilah* is a group intervention comprised of 10 groups of 11 tribal members: a trained facilitator, who is considered a successful manager of his/her CI, and 10 mentees, who are not managing their illness well. Each 11-member group will meet 7 times covering content and using methods outlined in our intervention manual that include a mini-discussion (lecture), talking circle and skill-building activity. The mentees will be partnered into supportive pairs who will connect a minimum of once per week outside of group meetings. Topics include those found in both our interview data and existing evidence-based self-management programs (e.g., developing a positive relationship with a healthcare provider) and Apsáalooke-specific topics

from our interview data (e.g., coping with historical and current grief and loss). Consistent with the stages of behavioral therapy research(5) and using a CBPR approach, we will pursue the following Specific Aims:

Aim 1: Refine and strengthen the community-based, culturally appropriate *Baa nnilah* intervention and study protocol.

Involved will be the CAB, the Apsáalooke-based and MSU-based research team, and four potential *Aakbaabaaniilea* (facilitators). This aim will be accomplished in Year 1 and will result in a finalized training and intervention manual that will be utilized to train *Aakbaabaaniilea* and deliver the intervention.

Aim 2: Test the effects of the *Baa nnilah* intervention versus usual care using a wait-list control group effectiveness trial among 200 randomly assigned AI men and women 25 and older who have CI on the Apsáalooke Reservation.

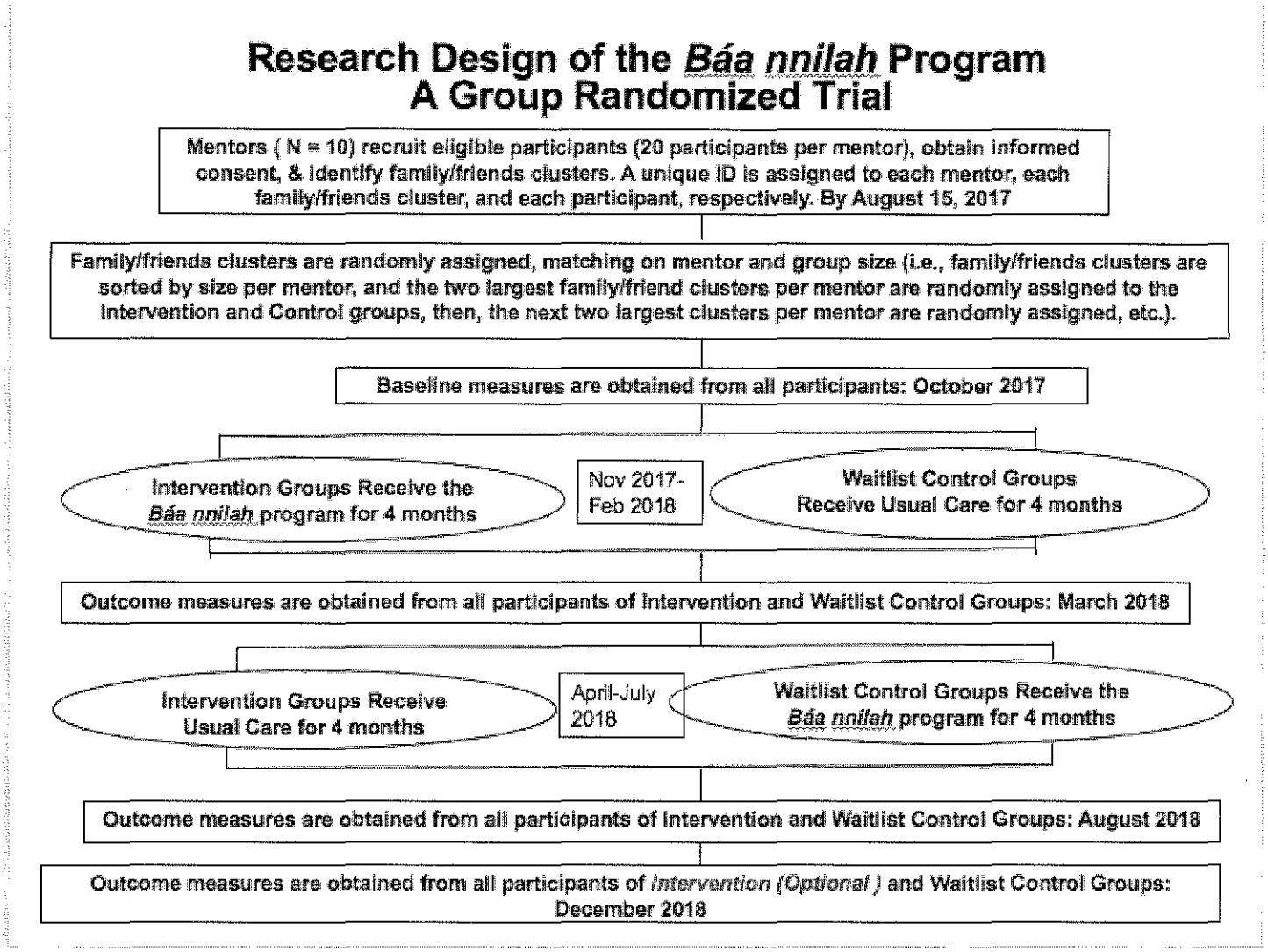
Primary hypothesis: Those AI adults on the Apsáalooke Reservation participating in the *Baa nnilah* intervention will have significant improvement in quality of life using the SF-12 measure compared to a wait-listed control group immediately following the intervention and at 6 and 12 months post-intervention.

Secondary hypothesis: Those AI adults on the Apsáalooke Reservation participating in the *Baa nnilah* intervention will have significant improvement in measures of satisfaction in and participation with social roles and activities, social isolation, patient activation, health care relationship, physical function, and depression compared to a wait-listed control group immediately following the intervention and at 6 and 12-months post-intervention. Our mixed-methods design includes a qualitative evaluation of fidelity and acceptability immediately post-intervention.

This study is considered a Phase 3 clinical trial. Please see the attached document, "Protection of Human Subjects" from our grant application that contains human subjects information (some overlap with what is below) and our Data Safety and Monitoring Plan, which is required for Phase 3 clinical trials. This clinical trial has been registered at Clinicaltrials.gov with the following NCT identifier: NCT03036189.

As this project takes place on a reservation, please see the attached letter of support/approval from the Crow Nation.

See picture below for a graphic depiction of our study design:



B. RESEARCH PROCEDURES INVOLVED. Provide a short description of sequence and methods of procedures that will be performed with human subjects. Include details of painful or uncomfortable procedures, frequency of procedures, time involved, names of psychological tests, questionnaires, restrictions on usual life patterns, and follow up procedures

There are three different groups from whom data will be gathered. Answers to the questions below are grouped according to who is providing the information.

1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

1. Participants of intervention: all participants: 200 Crow community members will be recruited by other community members (described below under D5), provide informed consent (form attached), and be randomly assigned by family/friend cluster to an intervention or wait-list control group (both groups will receive the intervention). Random assignment will occur via cluster so that family members or friends who are interested in participating in the intervention together will remain in the same group. During the month of October 2017, groups of approximately 10 community members will attend an orientation and data collection session – this is the baseline data collection. The groups are based on the community in which they will attend the intervention meetings and include: Wyola, Lodge Grass, Crow Agency, Hardin, and Pryor, MT.

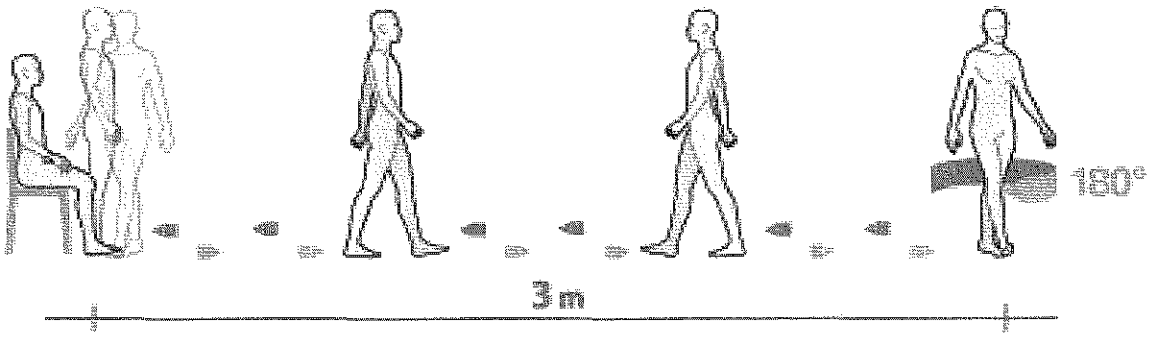
During the orientation/data collection session, participants will complete a survey and 3 exercises. All measures in the survey that are in an index form (one measure with multiple questions) come from the NIH PROMIS measure bank (http://www.healthmeasures.net/index.php), are other validated measures, or are demographic or fidelity measures used in other studies. All measures

are included with the application and begin with the page labeled "Measures". The survey responses and results of the exercises will be on a tablet computer and will look similar on the computers (the measures attached are in different formats at present).

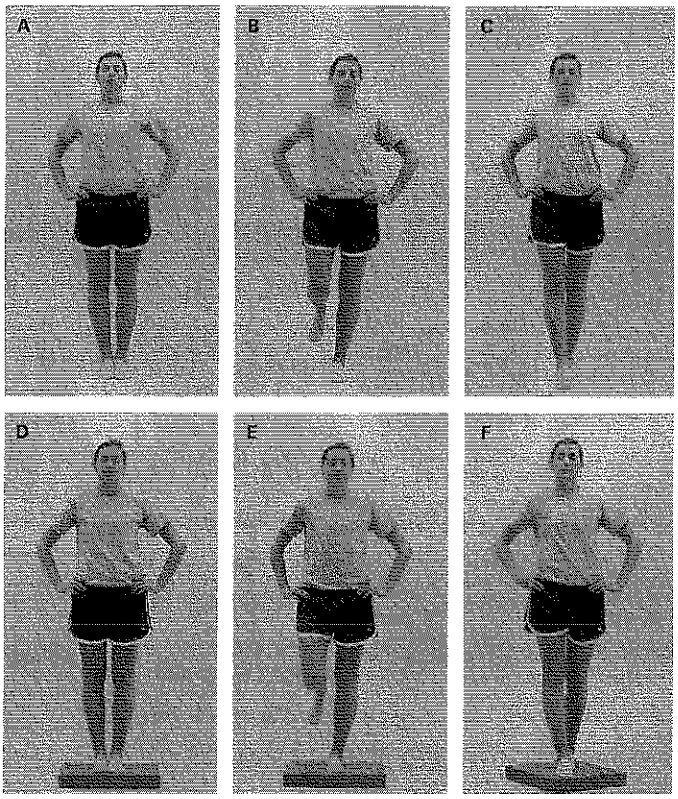
The survey questions will be read out loud by a project staff member. Participants will be seated so that they do not see the responses being entered into other computer tablets by other participants. We are working with the MSU HELPS lab to facilitate data collection. Survey respondents will provide their responses on tablet computers using Qualtrics offline software and unique identification codes. Once a respondent has submitted the survey, those answers will not be viewable by subsequent research participants. The responses will upload to the secure Qualtrics servers once the tablets are again connected to a wi-fi network. Data will not be maintained on the tablet computers in the long term.

Three basic physical function tests will be performed: timed up and go (TUG), static balance assessment (BESS), and 6 minute walk. Brief descriptions of the tests are below. Responses will be entered into the computer tablets.

Timed Up and Go (TUG) Test: This test is commonly used in clinical settings to assess strength, mobility, and balance control in older adult populations. The test starts with the participant sitting in a chair. Examiner ensures that they are sitting all the way in the chair, i.e with their hips at the back of the seat and their back resting against the chair upright. When the examiner says go, the participant rises from the chair, walks forward to a tape placed on the ground, turns around, walks back to the chair, and sits down. The tape is placed 3 meters in front of the chair. The participant is instructed to "rise from the chair, walk to the tape and back, and sit back down as quickly as possible while still walking safely." Including "as quickly as possible" in the instructions ensures the assessment will appropriately challenge the participant, while including "while still walking safely" ensures that the participant knows not to go so fast that they risk losing their balance or falling as they try to sit back down. The outcome measure recorded from this test is the time taken from first movement out of the chair until they sit back down. The image below shows a schematic of the test.



Standing Balance Assessment. To assess static balance the balance error scoring system (BESS) will be used. This test is commonly used in clinical setting where one needs to assess an individuals' balance control but does not have access to force plates or pressure pads. The test includes standing in three different positions, on both a solid and deformable surface. The positions are: feet together on solid surface, on a single foot on solid surface, and in tandem stance (one foot in front of the other) on a solid surface. These are then repeated while standing on a foam pad. Each position is held for 20 seconds and participants are instructed to keep their eyes closed for all tests. The test is scored based on the number of errors made. An error includes if the participant opens their eyes, moves their hands from their hips, takes a corrective step, or makes other significant postural corrections during the 20 seconds (i.e. flexes or abducts the hip beyond 30 degrees or raises the heel or forefoot off the floor). The image below shows the six different positions.



6 Minute Walk. To assess cardiovascular fitness, participants will walk as far as possible in six minutes. Depending on the space available, this can be around the outside of a large room or could be back and forth in a hallway. A step counter is used to record the number of steps the individual takes in the six minutes. Distance walked can then be calculated based on the length of an individual step.

See the research design graphic above: Next, participants in the intervention group will attend the intervention. The intervention consists of 7 group education sessions (called gatherings), conducted every other week in the local communities and led by community mentors. A manual for the mentors for the education sessions is being finalized at this time so that the sessions remain consistent across mentors and across the intervention and wait-list control groups; all mentors have been recruited and are meeting monthly with project staff to co-develop the intervention materials and receive training. Next, all 200 participants will attend another data collection session in their same groups in March 2018. Next, the waitlist control group will attend the 7 intervention sessions, which will be identical to the intervention group via the mentor manual. All 200 participants will provide outcome measures again in August 2018 and December 2018. The measures will be the same for each data gathering session with the exception of a few questions that will be asked after the intervention only (as noted in the attached measures handout) and are focused on measuring outcomes related to intervention content.

2. Participants of intervention: subgroup. A random sample of 20 participants will be selected – 10 from the intervention group and 10 from the wait-list control group. These participants will be invited to participate in a qualitative interview. Alma McCormick, Co-PI of this grant will conduct the interviews, which are expected to last approximately one hour. The interview will be audio-taped and transcribed verbatim. Qualitative data analysis methods used in our prior studies will be conducted on this data. Participants will select a location to be interviewed where they are comfortable and where confidentiality will be assured. The questions for the qualitative interview are included with this application and are titled: "Báa nnilah program qualitative interview questions"

3. Intervention facilitators: 10 members of the Crow Nation will be facilitating the intervention meetings and will provide fidelity evaluation information. The questions for the fidelity evaluation are included with this application and are titled "Facilitator measures of fidelity." Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions. Facilitators will complete a form for each gathering that includes a check list of completed activities, 2 closed-ended questions, and 1 open-ended question. An example is included

with the application and is titled "Mentor Gathering Check list"

C. DECEPTION - If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary and attach debriefing statement.

1, 2, 3: No deception will be conducted.

D. SUBJECTS

1. Approximate number and ages
   How Many Subjects: 1: 200; 2: 20; 3: 10
   Age Range of Subjects: 1, 2, & 3: 25 and older
   How Many Normal/Control: 0
   Age Range of Normal/Control: 0

2. Criteria for selection:

1. Participants of intervention: all participants: criteria include 25 and older, American Indian living on or near the Crow reservation, and with a diagnosed chronic illness.
2. Participants of intervention: subgroup: criterion is being a member of the intervention participant group.
3. Intervention facilitators: criterion is being one of the 10 facilitators of the intervention

3. Criteria for exclusion:

1. Participants of intervention: exclusion criteria include an advanced terminal condition that precludes participation.
2. Participants of intervention: subgroup: exclusion criteria include not being a member of the intervention participant group.
3. Intervention facilitators: these individuals have already been selected

4. Source of Subjects (including patients):

1. Participants of intervention: all participants: The Crow Indian Reservation and outlying areas including Hardin, MT.
2. Participants of intervention: subgroup: The Crow Indian Reservation and outlying areas including Hardin, MT.
3. Intervention facilitators: these individuals have already been selected and are members of the Crow Nation who live on or near the reservation.

5. Who will approach subjects and how? Explain steps taken to avoid coercion.

1. Participants: Local community members from the Crow Reservation who will serve as intervention facilitators and local community members from the Crow Reservation who are staff members of the grant project will talk with potential participants about the project to assess their interest. They will approach community members they already know – family members, friends, clan members. Potential participants will be given a brochure that explains the project and one of two handouts that graphically depict the activities in which they will participate. The facilitator or staff member will review the handout, describing the study design and expectations of being enrolled in the project. If the community member expresses interest in being a part of the study, the facilitator or staff member will record their name and contact information. The project will also hold community meetings and tabling events to recruit potential participants and post information that is on the brochure in public locations in the community. As Messengers for Health has a positive record in the community, community members also are asking project staff members to be included in this intervention. There will be no coercion to participate. A copy of the brochure and graphic handouts are included with these materials.

2. Participants of intervention: subgroup: these participants will already be enrolled in the study. After the names are randomly selected, a project staff member or facilitator/mentor will ask the participant if they are interested in taking part in the qualitative interview after they have completed the

intervention.

3. Intervention facilitators: these individuals have already been selected and are members of the Crow Nation who live on or near the reservation.

6. Will subjects receive payments, service without charge, or extra course credit? **Yes** or No
(If yes, what amount and how? Are there other ways to receive similar benefits?)

1. Participants: Participants will receive a $40 gift card each time they complete the surveys and exercises. Participants will receive a $10 gas card for each of the 7 intervention meetings/gatherings.

2. Participants of intervention: subgroup: will receive a $30 gift card for their participation.

3. Intervention facilitators: will receive a $225 payment each month leading up to and through the intervention.

1, 2, & 3: There are no other ways to receive similar benefits.

7. Location(s) where procedures will be carried out.

1, 2, & 3: On the Crow Indian Reservation and in Hardin Montana in public community sites such as community centers, senior citizen centers, churches, and schools.

E. RISKS AND BENEFITS (ADVERSE EFFECTS)

1. Describe nature and amount of risk and/or adverse effects (including side effects), substantial stress, discomfort, or invasion of privacy involved.

1, 2, 3: While there is always a possibility that participants may experience discomfort completing the measures, there is a low possibility of this occurring as the result of the proposed project because a) Apsáalooke community members have approved of all measures through a collaborative process and they do not believe that the measures involve an invasion of privacy or would provoke discomfort and b) all of the measures used in this study have been used in other populations. We do not anticipate that the three exercises that participants will be performing would cause stress or discomfort. Participants are encouraged to do the exercises as a pace and level that is comfortable for them. The consent form states that they do not have to answer any question they are not comfortable answering and do not have to do any exercises that they do not want to do.

During one of the gatherings, there will be a discussion of grief, loss, resilience, and healing. Should any participants experience an adverse psychological reaction, intervention facilitators and project staff involved in data gathering will be trained by Dr. Earl Sutherland (a psychologist from our clinic partner, Big Horn Valley Health Center), to evaluate the situation and, if necessary, make appropriate referrals. Referrals will be made to BVHC, Indian Health Service or other mental health providers in the community for psychological assistance. Participants will be provided with a list of resources available in the local communities.

2. Will this study preclude standard procedures (e.g., medical or psychological care, school attendance, etc.)? If yes, explain.

1, 2, & 3: No.

3. Describe the expected benefits for individual subjects and/or society.

1, 2, & 3: Participants in the *Baa niilah* intervention groups may receive benefits of learning from each other and from the intervention facilitator on how to improve their chronic illness management. Our hope is that the proposed intervention will lead to improved management and that this intervention can be disseminated to other Native American communities in order to assist with chronic illness self-management strategies. The intervention methods are built upon strengths of the Apsáalooke culture and are culturally sensitive to ways of knowing and interacting. As a result of our culturally sensitive approach, the intervention meetings are likely to be a pleasurable experience for the

participants.

Health statistics of Montana's Native American populations show significant health disparities that require effective interventions; however, intervention strategies with Native Americans that focus on chronic illness self- management are severely lacking. By adapting, testing, and disseminating an effective intervention that is based in the Apsáalooke Indian culture, there will be a reduction of negative consequences of chronic illness in this population, as well as meaningful information gained, which will inform other research and practices.

F. ADVERSE EFFECTS

Information for F, ADVERSE EFFECTS, is the same for participant groups 1, 2, & 3.

1. How will possible adverse effects be handled?

   By investigator(s):

Referred by investigator(s) to appropriate care: xx. It states in the consent form: "In the event your participation in this research supported by the National Institutes of Health results in injury to you, medical treatment consisting of referral to Indian Health Services or Bighorn Valley Health Center will be available. If it is an emergency, a project mentor or staff member will call 911. This treatment will be at your expense. Further information about this treatment may be obtained by calling Alma McCormick at 665-5492 or Suzanne Held at Montana State University at 994-6321."

   Other (explain):

2. Are facilities/equipment adequate to handle possible adverse effects? **Yes** or No
   (If no, explain.)

3. Describe arrangements for financial responsibility for any possible adverse effects.

   MSU compensation (explain):
   Sponsoring agency insurance:
   Subject is responsible: xxxx – this is stated in the consent form.
   Other (explain):

G. CONFIDENTIALITY OF RESEARCH DATA

1. Participants: For all data collected, the HELPS Lab at MSU will manage the uploaded data. All HELPS Lab personnel have completed the appropriate CITI human subjects training. Once the data are downloaded from the secure Qualtrics servers, they will be stored on Box, which is password protected. Any index files that link individual names or addresses to identification codes will be stored separately on Knox, which has an even higher degree of security. Transfer of data to other researchers affiliated with the project will happen by granting subfolder access via Box. All participants will be assigned ID numbers with names that will be maintained in locked and secure files.

2. Participants of intervention: subgroup: As is standard protocol for qualitative interviews with our project, we will ask each participant if they would like their name attached to their interview or if they would like to remain anonymous. The interviews will be recorded and transcribed and kept confidential or no according to the wishes of the participant. The recordings and transcriptions will be kept in Box.

1. Will data be coded? **Yes** or No

2. Will master code be kept separate from data? **Yes** or No

3. Will any other agency have access to identifiable data? Yes or **No**
   (If yes, explain.)

4. How will documents, data be stored and protected?

Locked file:

Computer with restricted password: xx – Data will be stored on computer tablets, which will be password protected. The computer tablets will be stored together in two locked traveling cases.

Other (explain):

VIII. Checklist to be completed by Investigator(s)

A. Will any group, agency, or organization be involved? **Yes** or No
(If yes, please confirm that appropriate permissions have been obtained.)

This grant has subcontracts with, 1) Messengers for Health, which is a 501c3 non-profit organization located on the Crow Reservation, 2) University of Nevada Las Vegas, where our biostatistician is located, and 3) University of Hawaii, where a mentor is located. We also partner with Big Horn Valley Health Center, a community health center and clinic partner just off the Crow Reservation. BVHC is primarily involved to provide training to intervention facilitators.

B. Will materials with potential radiation risk be used (e.g. x-rays, radioisotopes)? Yes or **No**

1. Status of annual review by MSU Radiation Sources Committee (RSC). Pending or Approved
(If approved, attach one copy of approval notice.)

2. Title of application submitted to MSU RSC (if different).

C. Will human blood be utilized in your proposal? Yes or **No**
(If yes, please answer the following)

1. Will blood be drawn? Yes or No
(If yes, who will draw the blood and how is the individual qualified to draw blood? What procedure will be utilized?)

2. Will the blood be tested for HIV? Yes or No

3. What disposition will be made of unused blood?

4. Has the MSU Occupational Health Officer been contacted? Yes or No

D. Will non-investigational drugs or other substances be used for purposes of the research? Yes or **No**

Name:
Dose:
Source:
How Administered:
Side effects:

E. Will any investigational new drug or other investigational substance be used? Yes or **No**
[If yes, provide information requested below and one copy of: 1) available toxicity data; 2) reports of animal studies; 3) description of studies done in humans; 4) concise review of the literature prepared by the investigator(s); and 5) the drug protocol.]

Name:
Dose:
Source:
How Administered:
IND Number:
Phase of Testing:

F. Will an investigational device be used? Yes or **No**
(If yes, provide name, source description of purpose, how used, and status with the U.S. Food and Drug Administration FDA). Include a statement as to whether or not device poses a significant risk. Attach any relevant material.)

G. Will academic records be used? Yes or **No**

H. Will this research involve the use of:
Medical, psychiatric and/or psychological records Yes or No
Health insurance records Yes or **No**
Any other records containing information regarding personal health and illness Yes or **No**

If you answered "Yes" to any of the items under "H.", you must complete the **HIPAA worksheet**.

I. Will audio-visual or tape recordings or photographs be made? **Yes** or No

1 & 3: NO

2. Participants of intervention: subgroup: Yes. As is standard protocol for qualitative interviews with our project, we will ask each participant if they would like their name attached to their interview or if they would like to remain anonymous. The interviews will be recorded and transcribed and kept confidential or not according to the wishes of the participant. The recordings and transcriptions will be kept in Box.

J. Will written consent form(s) be used? (**Yes** or No. If no, explain.) (Please use accepted format from our website. Be sure to indicate that participation is voluntary. Provide a stand-alone copy; do not include the form here.)

Protection of Human Subjects

This Human Subjects Research meets the definition of a clinical trial.

The protocols for the project will be submitted for primary review to the Little Big Horn College (LBHC) Institutional Review Board and secondarily to the Montana State University (MSU) Institutional Review Board. LBHC will be the primary IRB of record. The investigators for the *Baa nnilah* project may be interested in applying for a Certificate of Confidentiality through NIH and will investigate this possibility prior to applying for human subjects approvals.

One metric of partnerships in community-based participatory research is "who owns the data?" The data gathered from this study will be housed at Montana State University, as it has the ability to securely store the data. At this time, the Apsáalooke Nation does not have the capacity to securely store the data. The PDs/PIs from this project are involved in a separate project that has the goal of enabling secure ownership, control, access, and possession of data on the reservation site. We will work with the Apsáalooke Nation to provide useful data from this project, which may be used to assist the tribe with their current and future health projects.

Risks to human subjects

a. Human subjects involvement, characteristics and design

Participants in this study will consist of American Indian (AI) community members who live on or near the Apsáalooke reservation, age 25 and older who have a chronic illness. Two hundred (200) participants shall be enrolled, 100 male participants and 100 female participants. Inclusion criteria for screening of participants include a) ≥ 25 years, b) AI, and c) diagnosed with diabetes, hypertension, osteoporosis, liver disease, chronic lung disease (asthma, chronic bronchitis or emphysema), heart disease (coronary artery disease or congestive heart failure), stroke (completed cerebrovascular accident with neurologic handicap and normal mentation), or chronic arthritis. In addition to at least one of the above conditions, they could have other conditions. CAB members were strong in their desire to be inclusive in the list of CIs for which individuals will be eligible to be in the study. This list matches other widely accepted evidence-based self-management programs in the US. Potential participants will be excluded if they have an advanced terminal condition that precludes participation.

The Bighorn Valley Health Center (BVHC), a Federally Qualified Health Center located in Hardin, Montana, represents the primary site where the research will be performed.

Recruitment and study orientation: Intervention mentors (*Aakbaabaaniilea)* will take the lead in participant recruitment, using the strength of *Iishamaaalaxxia*, the Apsáalooke clan system, of which everyone is a part. The *Aakbaabaaniilea* will meet as a group with Ms. McCormick and bring to the meeting a list of potential participants of the same gender, in keeping with respectful kinship relationships. Since the community is very close knit, *Aakbaabaaniilea* will know who has or does not have a CI. Use of *Iishamaaalaxxia* and care in *Aakbaabaaniilea* selection will ensure that there will not be overlap among the list of potential participants. The meeting between the *Aakbaabaaniilea* and Ms. McCormick will cover participant recruitment, which includes contacting potential participants to explain the study and asking if they wish to be involved in the project. The *Aakbaabaaniilea* will be trained to randomly assign participants to the intervention group or wait-list group using a permuted block randomization protocol with 10 groups in each condition and 10 participants per group. The 10 groups (per condition) will be conducted at the same time, for a 4-month period to allow for 7 meetings approximately every two weeks (See Tables 5 and 8 of the Research Strategy section). *Aakbaabaaniilea* will keep a log of refusals and reasons for refusing, and will recruit until they have 10 participants (each) in the intervention and wait-list group. Building the groups in this manner is also appropriate as clan relatives mentor each other and visit often. This team used a culturally-based survey recruitment procedure in another intervention study that yielded a 98% participation rate. We also anticipate a very high acceptance rate for this project due to multiple community members reaching out to Ms. McCormick and asking to be involved in the study. Also, the tradition of having compassion, empathy, and respect for relatives and a 19-year history of working in the community will lead to successful recruitment and retention.

Participant retention: *Aakbaabaaniilea* will check in with participants via telephone on a weekly basis to remind them of upcoming intervention meetings and to problem-solve any issues. It is estimated that the current community-based leadership role of the *Aakbaabaaniilea* in the community and the relationships established through the intervention will contribute to participant retention. We will provide incentives that have worked in our past intervention research with the Apsáalooke Nation, including gas vouchers to assist with transportation to and from the intervention site and by holding a graduation at the end of the intervention where participants who complete the program will receive a larger gift incentive. Our CAB believes that the culturally consonant intervention and the long-standing partnership will be strong incentives to keep program participants engaged. In our Messengers for Health study, community members consistently attended monthly meetings for the entire intervention period, which was 5 years.

b. Sources of materials

Data will consist of:

1. Quantitative measures of: demographic information, quality of life, physical function, satisfaction with participation in social roles, satisfaction with social roles and activities, social isolation, psychosocial impact of illness, emotional distress, health care relationship trust and patient activation.
2. Qualitative data on fidelity and acceptability of the *Baa nnilah* intervention. Data that has individually identifiable private information about human subjects will be managed primarily by the PI/PDs (Dr. Suzanne Christopher and Ms. Alma Knows His Gun McCormick). The faculty at the Montana State University Human Ecology Learning and Problem Solving (HELPS) Lab will receive the data in order to de-identify all data before the analysis phase is initiated. The PI/PDs and faculty of the HELPS lab have undergone Collaborative IRB Training Initiative (CITI) training for human subjects research. Further, research team members will have completed a research ethics training course required by the IRBs prior to contact with potential project participants.

c. Potential risks

While there is always a possibility that participants may experience discomfort completing the measures listed above, there is a low possibility of this occurring as the result of the proposed project because Apsáalooke community members have approved all measures in advance of the study through a collaborative process. However, should any participants experience an adverse reaction, intervention *Aakbaabaaniilea* (Mentors) and project staff involved in data gathering will be trained by Dr. Earl Sutherland and other mental health staff from our clinical partner, BVHC, to evaluate the situation and, if necessary, make appropriate referrals. Referrals will be made to BVHC or other mental health providers in the community.

Adequacy of protection against risks

a. Recruitment and informed consent: For all data points, we will seek and obtain fully informed consent by each participant before she/he takes part in the proposed intervention. Montana State University requires the Collaborative IRB Training Initiative (CITI) online course; as stated above, all per Montana State University requirements, research team members will have completed a research ethics training course required by the IRBs prior to contact with potential participants. We will write all consent forms and explanatory scripts in plain language English at an eighth-grade reading level. Project partners have co-written multiple human subjects consent forms for prior studies, which are attuned to the Apsáalooke culture. No one will be coerced or pressured to take part in the proposed project. If any research team staff believes a person does not fully understand the project or rights as a research participant, we will explain further until the person understands, or we will not permit the person to take part. The content of the verbal explanation, consent process, and consent form will fully disclose our project's purpose, procedures, and requirements, and describe the potential risks of our project as noted above. That consent will also inform the person of his/her rights as a research participant, including:

1. Participants do not have to participate; their participation in the research project is voluntary;
2. Participants do not have to answer any questions or participate in any procedure they do not want to;
3. Participants can stop the process at any time, and continue later or not continue at all;
4. All information they share will be strictly confidential. Their names will not be given out or connected with any information shared publicly about the project by the PIs or members of the research team; and,
5. Their care at Bighorn Valley Health Center will not be impacted by agreeing or not agreeing to participate in the study.

Once they have read the consent form (or had the form read to them) in English, understand their rights, and agree to participate, we will ask them to sign the consent form and we will give them a copy.
b. Protections again risk: Community partners have reviewed and edited or revised all questionnaires and surveys in order to increase protection against risk. Should any participants experience an adverse reaction during the assessments or intervention in spite of this collaboration, intervention *Aakbaabaaniilea* and other project staff will be trained to evaluate the situation and, if necessary, make appropriate referrals. Our clinical partner, BVHC, has agreed to accept referrals from this study and to train our community intervention Mentors on how to evaluate their mentees for mental health referral needs (see their letter of support). BVHC has mental health specialists on staff, including Dr. Earl Sutherland, who is a part of our research team. We will follow rigorous methods to insure participant confidentiality. The co-investigators and all assistants have had or will receive training on confidentiality and ethical research conduct.

Confidentiality of data will be maintained by the numerical coding and stripping of identifying information of all data upon transfer to Montana State University and the University of Nevada-Las Vegas. As stated above, the Montana State University HELPS lab will be responsible for this action as well as for secure transmission of data to Dr. Feng at University of Nevada-Las Vegas. The data will be kept in the private offices of Dr. Christopher and Dr. Feng. Data will be entered into tablets and the tablets will be secured in a locked cabinet at Ms. McCormick's office. Data from the tablets will be downloaded onto a disk and personally transported to MSU. After the study is completed, the tablets with the data files will be personally transported back to MSU by one of the PIs and secured in a locked cabinet. All subjects will be assigned ID numbers with names that will be maintained in locked and secure files by Dr. Christopher. Additionally, all data will be stored in locked file drawers at each stage of data transfer. Moreover, all data obtained will be accessible only to the research staff, and no subject will be identified in any report of the project. The intervention Mentors, Project Assistant, and research assistants will be thoroughly versed in ethical issues associated with this research, with specific attention to confidentiality, and will be IRB certified by MSU. All research staff will sign a formal oath of confidentiality as part of their employment contract.

We will only disclose information we receive from subjects about intended physical harm to potential victims to the responsible authorities. We consider it our responsibility to inform authorities and to protect the well-being of potential victims; this is also the state law in Montana.

Potential benefits of the proposed research to human subjects and others
Participants will share their health stories with their *Aakbaabaaniilea* and with other members of their intervention group. In our preliminary study, we found that this was perceived by participants to be a beneficial experience. Participants in the *Baa niilah* intervention groups may receive benefits of learning from each other and from their Mentor on how to improve their chronic illness management. Our hope is that the proposed intervention will lead to improved management and that this intervention can be disseminated to other Native American communities in order to assist with chronic illness self-management strategies. The intervention methods are built upon strengths of the Apsáalooke culture and are culturally sensitive to ways of knowing and interacting. As a result of our culturally sensitive approach, the intervention meetings are likely to be a pleasurable experience for the participants.

Importance of the knowledge to be gained
Health statistics of Montana's Native American populations show significant health disparities that require effective interventions; however, intervention strategies with Native Americans that focus on chronic illness self- management are severely lacking. By adapting, testing, and disseminating an effective intervention that is based in the Apsáalooke Indian culture, there will be a reduction of negative consequences of chronic illness in this population, as well as meaningful information gained, which will inform other research and practices.

Data safety and monitoring plan (DSMP)
Using definitions and information in the June 10, 1998 NIH Policy for Data Safety and Monitoring, we consider this study to meet the criteria for a Phase III clinical trial as we are conducting an effectiveness trial where we are comparing a new treatment (*Baa niilah* intervention) to usual care and in which participants will be followed for 12-months post-intervention. This is a single-site study. We agree to work with the IC that will be funding this study regarding their roles and responsibilities listed in the policy, to include:

- Prepare or ensure the establishment of a plan for data and safety monitoring for all interventional

trials;
- Conduct or delegate ongoing monitoring of interventional trials;
- Ensure that monitoring is timely and effective and that those responsible for monitoring have the appropriate expertise to accomplish its mission;
- Oversee monitoring activities; and,
- Respond to recommendations that emanate from monitoring activities.

The website listing specific institute/center policy and guidance (http://grants.nih.gov/grants/policy/hs/data_safety.htm) does not include guidance for NIMHD, so we used the 1998 Policy document and the *Policy of NINR for Data and Safety Monitoring of Extramural Clinical Trials* dated 2014 to prepare this DSMP.

Data Safety and Monitoring Plan (according to NINR 2014 guidance):

A.1 Monitoring entity or who will monitor the study: The Principal Investigators, Dr. Christopher and Ms. McCormick will be responsible for knowing the policies of the Apsáalooke Nation community and the Institutional Review Boards (IRBs) for LBHC and MSU. The PIs will adhere to IRB policies and maintain accurate documentation of IRB correspondence and reports (e.g., annual report). Dr. Christopher will be the lead on IRB correspondence and reports.

A.2 Purpose of the Data Safety Monitoring Board: In accordance with NINR policy and procedures, the *Baa nnilah* Project is required to establish a DSMB to serve as an independent group that will evaluate the data on an ongoing basis to assure participant safety and study integrity. The *Baa nnilah* Project DSMB will provide a data monitoring function above and beyond that traditionally assumed by the institutional review boards that oversee the project, that is, the LBHC and MSU – Committee on Human Studies. Although this is a relatively "low risk" intervention, we recognize the need to monitor all patients in this study to ensure the safety of participants and assure the quality of the research.

A.3 Members of the *Baa nnilah* Project DSMB: According to the NIH Policy for Data Safety and Monitoring, "A monitoring committee is usually required to determine safe and effective conduct and to recommend conclusion of the trial when significant benefits or risks have developed or the trial is unlikely to be concluded successfully." Upon funding, we will recruit a minimum of three (3) members for the DSMB in accordance with NIH and IC policies. We will recruit individuals to ensure representation of the appropriate areas of expertise to consider patient safety and proper study conduct. Areas of expertise will include: a) chronic illness management; b) clinical trials; and, c) research with American Indian populations.

Supporting members of the DSMB include: 1. Dr. Suzanne Christopher (PI), 2. Ms. Alma McCormick (PI), 3. Dr. Du Feng, (Co-investigator and project biostatistician), 4. Dr. Jillian Inouye, (Co- investigator), and 5. Dr. David Mark (Co- investigator and clinical partner).

A.4 Roles and Responsibilities: We will abide by the NIH 1998 policy guidance and have our board perform the following activities:
- Review the research protocol and plans for data and safety monitoring;
- Evaluate the progress of interventional trial(s), including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study;
- Make recommendations to the IC, IRB, and investigators concerning continuation or conclusion of the trial(s); and,
- Protect the confidentiality of the trial data and the results of monitoring.

We will abide by NIH policy, and have the data and safety monitoring board (from the 1998 policy guidance):
- Meet first in open session, attended by selected trial investigators (Dr. Christopher and Ms. McCormick) as well as NIH program staff or project officers (as available) and perhaps industry representatives, and then in closed session where they review emerging trial data;

- When "masked" data are presented or discussed, no one with a proprietary interest in the outcome will be allowed. Participants in the review of "masked" or confidential data and discussions regarding continuance or stoppage of the study will have no conflict of interest with or financial stake in the research outcome. However, if there is an open session, they could be present; and,
- Confidentiality will be maintained during all phases of the trial including monitoring, preparation of interim results, review, and response to monitoring recommendations. Besides selected NIH program staff, other key NIH staff, and trial biostatisticians, usually only voting members of the DSMB will see interim analyses of outcome data. Exceptions may be made under circumstances where there are serious adverse events, or whenever the DSMB deems it appropriate.

B.1 Procedures for monitoring study safety: *Aakbaabaaniilea* (Mentors) and PIs will hold weekly teleconference meetings in order to discuss intervention meetings and to monitor study safety. The community PI (McCormick) will be available via cell phone to intervention mentors in between teleconference calls in the case of an event that requires discussion. Intervention Mentors will be trained in this manner.

B.2 Procedures for minimizing research-associated risk: Community partners have reviewed and edited or revised all questionnaires and surveys in order to increase protection against risk. Community partners have also co-developed all study protocols with minimization of risk in mind. We will also hold community meetings in the first 6-months of the study to gather input and suggestions and will include minimizing risk as a subject of discussion. Should any participants experience an adverse reaction during the assessments or intervention in spite of this collaboration, intervention Mentors and other project staff will be trained to evaluate the situation and, if necessary, make appropriate referrals. Our clinical partner, BVHC, has agreed to accept referrals from this study and to train our community intervention Mentors on how to evaluate their mentees for mental health referral needs (see their letter of support). BVHC has mental health specialists on staff. We will follow rigorous methods to ensure participant confidentiality. The Co-investigators and all assistants have had or will receive training on confidentiality and ethical research conduct.

B.3 Procedures for protecting the confidentiality of participant data: Confidentiality of data will be maintained by the numerical coding and stripping of identifying information of all data upon transfer to MSU and the University of Nevada-Las Vegas. The MSU HELPS lab will be responsible for this action and for secure transmission of data to Dr. Feng at University of Nevada-Las Vegas. The data will be kept in the private offices of Dr. Christopher and Dr. Feng. Data will be entered into tablets and the tablets will be secured in a locked cabinet at Ms. McCormick's office. Data from the tablets will be downloaded onto a disk and personally transported to MSU. After the study is completed, the tablets with the data files will be personally transported back to MSU by one of the PIs and secured in a locked cabinet. All subjects will be assigned ID numbers with names that will be maintained in locked and secure files by Dr. Christopher. Additionally, all data will be stored in locked file drawers at each stage of data transfer. Moreover, all data obtained will be accessible only to the research staff, and no subject will be identified in any report of the project. The intervention Mentors, Project Assistant, and research assistants will be thoroughly versed in ethical issues associated with this research, with specific attention to confidentiality, and will be IRB certified by MSU. All research staff will sign a formal oath of confidentiality as part of their employment contract.

C. 1. Procedures for identifying, reviewing, and reporting adverse events and unanticipated problems to the IRB and NIH IC.

Procedures and timeline for reporting Adverse Effects to the IC

Reporting Procedure for Serious Unanticipated Adverse Events: In the event of an unanticipated serious adverse event, the project PIs will ensure that these events are reported to the IC Program Official within hours by phone, fax, and/or email and will submit a written report to the Program Official no more than two days later. The project personnel will also utilize the following reporting procedures:

1. When the research team, project personnel and /or PIs become aware of a serious adverse event, reporting requirements must be implemented in a timely manner;
2. The PIs complete an "Adverse Event Reporting Form" and submit the form to the Human Subjects Officer at MSU and LBHC;

3. The Human Subjects Officer immediately distributes the form to the following individuals or groups as required: Division of Sponsored Research; the Data and Safety Monitoring Committee;, and, the MSU and LBHC IRB Officials;
4. The Human Subjects Officer will convene an expedited meeting of the IRB. The IRB, with input from the PIs and the Data and Safety Monitoring Committee, will review the study protocol and determine what further action should be taken based on the best interests of the participants and of the research; and,
5. The PIs will report any actions taken by an IRB.

Critical problems: A protocol for identifying, reviewing, and reporting will be put into place in the event of any of the following critical problems:

1. Increased morbidity and/or mortality related to the study intervention;
2. Adverse reactions to the educational intervention;
3. Unsatisfactory performance of the study;
4. Suspicion of fraud;
5. Failure to comply with recruitment criteria; and/or
6. Any other issues that would require an important protocol change

Notification of any critical problems may be done initially through telephone but must be subsequently documented in writing either through e-mail or postal mail correspondence.

D. For multi-site studies, procedures to ensure compliance with monitoring plan and reporting requirements across study sites: This does not apply as this study is a single-site study.

E. Assessment of external factors or relevant information that may have an impact on the safety of participants or on the ethics for the research study: The Apsaalooke community-based PI, Ms. McCormick will take the lead on this assessment.

F. Advanced plans for interim and/or futility analysis as appropriate: This is not appropriate.

Inclusion of Women and Minorities

1. Describe the planned distribution of subjects by sex/gender, race, and ethnicity for the proposed study and complete the format in the Planned Enrollment Report: Planned enrollment report is complete and in the application. There will be an estimated 100 men and 100 women who are all American Indian enrolled in the study. Additional guidance for research utilizing existing datasets: We are not using existing datasets

2. Describe the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design: The description may include, but is not limited to, information on the population characteristics of the disease or condition under study. The study is being conducted on an American Indian reservation, thus the subjects will be American Indian. Inclusion criteria for screening of participants include a) ≥ 25 years, b) Chronic Illness diagnosis, and c) American Indian. Men and women will be recruited equally.

3. Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study (see examples below): There are no exclusions of sex/gender, racial, or ethic group that comprises the population under study. The population under study consists of American Indians. The partnership for this research grant consists of a university and a tribal nation, so it is appropriate that the population under study consists of members of the tribal nation partner.

4. Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects: Members of the tribal nation will conduct the recruiting of subjects. Also, as appropriate to this tribal nation, same gender tribal members will recruit same gender subjects.

5. Regarding clinical trials: To meet the requirements of section 4.2.1, we plan to conduct valid analyses of the intervention effect on men and women separately. Prior studies neither support nor negate significant

differences in intervention effect among subgroups. We will not conduct valid analyses by racial or ethic subgroups as all subjects will be American Indian.

Inclusion of children
There will be no data gathered from children.

Justifications for Exclusion of Children: The justification for exclusion of children is #1 of the list of justifications, "the research topic to be studied is not relevant to children."

Measures

Data Gathering Meeting

Program staff member – introduce self and other staff members:

First of all, I would like to welcome each one of you and thank you for participating in our Báa nnilah program. Your being here shows the commitment to your health and our community. This program grew from the desires and interests of the Crow community to encourage and support people with ongoing health conditions to take good care of ourselves and in turn to support each other. We would like to ask one of the elders to provide an opening prayer to bless the gathering and the meal.

While people are eating, have them introduce each other and where they are from and one thing they are looking forward to receiving from the program. Provide the handout with the topics and dates of the 7 gatherings.

Here is a handout that shows the topics and dates for our 7 gatherings. We encourage you to come on time, stay until the end of each gathering, and to attend each of the 7 gatherings. The gatherings will be about 3 hours long. The success of Báa nnilah in improving our health and the health of our communities comes from each of us dedicating ourselves to working together and supporting each other.

In the Báa nnilah program, you will:

- Gain knowledge and tools for healthy living and self-care to improve your quality of life.
- Learn from mentors and other program members.
- Share and apply Crow cultural strengths to address ongoing health concerns.
- Learn about nutrition and physical and emotional health tools and exercises through hands-on activities.
- Gain support and help from program staff and other participants to apply what is learned to your self-care.

Today we will complete a survey using computer tablets and we will do 3 exercises. The purpose of the survey and exercises is to help us learn how the program is progressing and what we can do to make it better. We will be reading the questions on the survey out loud and you will see the questions on the computer screen. You will respond to the questions by touching the screen. If you have a question, please raise your hand and someone will come to help you.

We thank you very much for sharing with us today. We hope you will share your true feelings, for there are no right or wrong answers to these questions. The information you share with Messengers for Health will be kept confidential and your name will not be on this survey. We have arranged the computer tablets so that no one will see your responses.

Arrange participants so that their computer screens are private and other participants cannot see their screens. A staff member will be at the front and will read each question out loud. Other staff

members will remain located so that they do not see the participant's computer screens and will remain ready to assist as needed.

The first questions ask some information about you.

Q1. Which community do you live in?
1. Lodge Grass
2. Fort Smith (Big Horn District)
3. St. Xavier (Big Horn District)
4. Pryor
5. Crow Agency (Reno District)
6. Wyola
7. Garryowen (Reno District)
8. Hardin
9. Dunmore (Black Lodge District)
10. Other _____

Q2. What is your current marital status?
1. Married or living in a marriage-like relationship
2. Separated
3. Divorced
4. Widowed
5. Single, never married
6. Other _____

Q3. What was the highest grade or year of school that you completed?
1. Eighth grade or less
2. Some high school
3. High school graduate or diploma
4. Some technical/vocational school
5. Technical/vocational school graduate
6. Some college
7. 2-year college graduate (associate's degree)
8. 4-year college graduate (bachelor's degree)
9. Post graduate or professional degree

Q4. What is your year of birth?_____

Q5. Employment Status: Are you currently…?
1. Employed for wages, full time (40 hours or more per week) and not a student
2. Employed for wages, part time (less than 40 hours per week) and not a student
3. Out of work
4. A homemaker/Carrying for family
5. A student and not working
6. A student and employed for wages, full time (40 hours or more per week)
7. A student and employed for wages, part time (less than 40 hours per week)

8. Retired
9. Unable to work

Q6. Please select the number that shows how much your total household income was for the past 12 months. Household means all of the people who live with you and share income and expenses.
1. Under $10,000
2. $10,000-$19,999
3. $20,000-$29,999
4. $30,000-$39,999
5. $40,000 and over

Q7. Including yourself, how many people are living in your household at this time? ____

Q8. Where do you receive most of your health care?
1. Indian Health Service
2. Bighorn Valley Health Center
3. Hardin Clinic/St. Vincent's Health Care
4. Billings Clinic
5. Other

Q9. About how many miles do you travel to get to the clinic where you receive your health care?
____

Q10. Please select the type of health insurance or health coverage that pays for your health care. Select all that apply:
1. Medicare/Medicaid
2. Private insurance
3. IHS only
4. Other _____

Q11. Does anyone in your household receive benefits from a food assistance program such as WIC, Commodities, SNAP, EFNEP?
1. Yes
2. No

Q12. Please select the ongoing illness(es) that a doctor has told you that you have. Please select all that apply.
1. Diabetes
2. Arthritis
3. Heart disease
4. High blood pressure
5. Asthma
6. Cancer
7. Chronic pain
8. Other (they can type in others)

Q13. What is your gender?

1. Female
2. Male
3. Other _____

This question is for the wait-list control group to be included with the March 2018 data gathering
Q. The Messengers for Health Báa nnilah program consists of 7 gatherings in the local Crow communities and Hardin that are led by a community member mentor. Have you taken action for your health based on something you have learned from a friend or family member who has attended the gatherings?

1. Yes
2. No

These questions are for after participants have completed the intervention:

I felt like my mentor cared about or was concerned about me.	very much	somewhat	a little	not at all
I felt like the other participants in my Báa nnilah group cared about or were concerned about me.	very much	somewhat	a little	not at all
I felt safe and comfortable to openly express my feelings in my group.	very much	somewhat	a little	not at all
I trusted that what I shared in my group would be kept confidential and not shared with others.	very much	somewhat	a little	not at all
After participating in the Báa nnilah program, I feel more hopeful.	very much	somewhat	a little	not at all
I would recommend the Báa nnilah program to friends or family members	definitely would	probably would	probably would not	definitely would not
The Báa nnilah program was helpful to me	Very helpful	Somewhat helpful	A little helpful	Not at all helpful
Gathering 1, with the purpose of sharing how the program grew from the desires and interests of the Crow community to provide support to community members with ongoing illnesses, to become familiar with the	Very helpful	Somewhat helpful	A little helpful	Not at all helpful

program, and to foster and encourage an atmosphere of safety and hope was helpful to me.				
Gathering 2, with the purpose of gaining knowledge of ongoing health conditions and self-care was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful
Gathering 3, with the purpose of better understanding the personal impacts of historical and current trauma and loss and how traditional cultural values and resilience help to heal and overcome loss and trauma was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful
Gathering 4, with the purpose of learning about healthy food and physical activity was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful
Gathering 5, with the purpose of showing how to establish a healthy relationship with our healthcare providers and that we have to do our part in taking care of ourselves outside of the doctor's office in order to stay healthy was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful
Gathering 6, with the purpose of learning about how to speak and act for ourselves and our families for better health including understanding our personal communication style and discovering ways to find our voice and communicate our needs directly, openly and honestly with others was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful

Gathering 7 with the purpose of planning for the future and celebrating our program was helpful to me.	Very helpful	Somewhat helpful	A little helpful	Not at all helpful

at end of all surveys: Aho. We really appreciate your participation with this survey. The information you shared will help us to make this program successful. I would like for you to know that the information you shared will be kept confidential and your name will not be on this survey. We thank you very much for sharing with us and look forward to seeing you at the first gathering.

SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer.** If you are unsure how to answer a question, please give the best answer you can.

1. **In general, would you say your health is:**

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. Moderate activities: such as pushing a vaccuum cleaner, carrying a small child, walking for exercise, or round dancing/push dancing.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	YES	NO
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	YES	NO
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual**.	☐1	☐2

8. **During the <u>past 4 weeks</u>, how much <u>did pain interfere</u> with your normal work (including work outside the home and housework)?**

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the <u>past 4 weeks</u>.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

12. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?**

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

Patient name: Date: PCS: MCS:

Visit type (circle one)
Preop 6 week 3 month 6 month 12 month 24 month Other:_____

Physical Function – Short Form 8b

Please respond to each question or statement by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA63	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Not at all	**Very little**	**Somewhat**	**Quite a lot**	**Cannot do**
PFC12	Does your health now limit you in doing two hours of physical labor?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB1	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA5	Does your health now limit you in lifting or carrying groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA4	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Self-Efficacy for Managing Symptoms – Short Form 8a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSX010	I can manage my symptoms during my daily activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX014	I can keep my symptoms from interfering with relationships with friends and family.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX009	I can manage my symptoms in a public place	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX011	I can work with my doctor to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX017	I can keep my symptoms from interfering with my personal care	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX008	I can manage my symptoms when I am at home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX015	I can keep my symptoms from interfering with the work I need to do	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX027	I can find the information I need to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last Updated: 5 August 2016

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

COPE - U of Miami (http://www.psy.miami.edu/faculty/ccarver/sclCOPEF.html)

Please respond to each statement by making one box per row.

Related to my ongoing illness(es),

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
I say to myself "this isn't real."				
I refuse to believe that it has happened				
I pretend that it hasn't really happened.				
I act as though it hasn't even happened.				
I get used to the idea that it happened.				
I accept that this has happened and that it can't be changed.				
I accept the reality of the fact that it happened.				
I learn to live with it.				

Key reference:

Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: A theoretically based approach. Journal of Personality and Social Psychology, 56, 267-283. http://129.171.58.17/media/college-of-arts-and-sciences/content-assets/psychology/documents/faculty/p89_COPE.pdf

13-item Short Form Patient Activation Measure (PAM) by Insignia Health(1)
(Item responses scored by proprietary scale available following licensing)

1. When all is said and done, I am the person who is responsible for managing my health condition

2. Taking an active role in my own health care is the most important factor in determining my health and ability to function

3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition

4. I know what each of my prescribed medications do

5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself

6. I am confident I can tell my health care provider concerns I have even when he or she does not ask

7. I am confident that I can follow through on medical treatments I need to do at home

8. I understand the nature and causes of my health condition(s)

9. I know the different medical treatment options available for my health condition

10. I have been able to maintain the lifestyle changes for my health that I have made

11. I know how to prevent further problems with my health condition

12. I am confident I can figure out solutions when new situations or problems arise with my health condition

13. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress

1. Hibbard J, Mahoney E, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Services Research 2005;40(6):1918-1930.

Emotional Support – Short Form 8a

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
FSE31053x2	I have someone who will listen to me when I need to talk	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31059x2	I have someone to confide in or talk to about myself or my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SS12x	I have someone who makes me feel appreciated	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSQ3x2	I have someone to talk with when I have a bad day	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31069x2	I have someone who understands my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSE-CaPS6	I have someone I trust to talk with about my feelings	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31066x2	I have someone with whom to share my most private worries and fears	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSQ4x2	I have someone I trust to talk with about my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Self-Efficacy for Managing Emotions – Short Form 8a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMEM015	I can handle negative feelings.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM018	I can find ways to manage stress	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM016	I can handle upsetting situations	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM012	I can avoid feeling discouraged	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM017	I can keep emotional distress from interfering with things I want to do	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM010	I can bounce back from disappointment	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM003	I can relax my body to reduce my anxiety.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMEM019	I can handle the stress of going for treatment of my medical conditions	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Positive Affect and Well-Being - Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Never	Rarely	Sometimes	Often	Always
NQPPF14	I had a sense of well-being……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF12	I felt hopeful……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF15	My life was satisfying……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF20	My life had purpose……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF17	My life had meaning……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF22	I felt cheerful……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF19	My life was worth living……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF16	I had a sense of balance in my life……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF07	Many areas of my life were interesting to me……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Self-Efficacy for Managing Social Interactions – Short Form 4a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence...	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSS014	I can talk about my health problems with someone.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSS024	If I need help, I can find someone to take me to the doctor's office.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSS013	I can get emotional support when I need it.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSS012	I can ask for help when I don't understand something.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction with Participation in Social Roles – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT07	I am satisfied with how much work I can do (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT24	I am satisfied with my ability to work (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT47	I am satisfied with my ability to do regular personal and household responsibilities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT49	I am satisfied with my ability to perform my daily routines	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT50	I am satisfied with my ability to meet the needs of those who depend on me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT39	I am satisfied with my ability to do household chores/tasks	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT06	I am satisfied with my ability to do things for my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT38	I am satisfied with the amount of time I spend performing my daily routines	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Báa nnilah program qualitative interview questions

Hello. I am Alma McCormick. Thank you for agreeing to talk about your experiences with the Báa nnilah program. We plan to use the information shared in the interviews to improve the program for the future. We hope you will share with us your true feelings, for there are no right or wrong answers to these questions. We will be tape-recording our conversation so that we make sure to receive everything that you have to share. Participation in this interview is voluntary and you can choose to either share your name or have the information you share be anonymous, meaning that your name will not appear anywhere. You can stop the interview at anytime or not answer any question. The interview will take about one hour of your time and you will be paid a $30 gift card to thank you for your help. Let's begin.

- How did participating in the Báa nnilah program impact your life?
- How did your Báa nnilah program mentor impact your life?
    - What information did you learn from your mentor?
    - How did the mentor's teaching style impact your learning?
- What have you shared about the program with community members and others?
    - How have you shared about this program?

(Give participant the list of gathering topics for the next set of questions.)

- What have you changed about your self-care after participating in the Báa nnilah program?
    - What information/tips/techniques from the Báa nnilah program did you apply or are you applying to your own life?
- If you think about how you talked with others about your health before and after being in Báa nnilah – how has it changed?
- What has changed in your relationships with your family and friends since being in Báa nnilah?
- What has changed in your relationship with your doctor since being in Báa nnilah?
    - How has the communication between you and your doctor changed?
    - How has your doctor's attitude changed since being in Báa nnilah?
        - Ask about concern and thoroughness if they don't mention these
    - How has the doctor's behavior and treatment toward you changed?
- Which parts of the program (which gathering) were most helpful?
- Which parts of the program (which gathering) was least helpful?
- What would you change to make the program better for the future?
- Since starting with the Báa nnilah program, what other support in addition to being in the program has made a difference for your health?
- In your observation, what changes have you noticed in the community as a result of this program?
- What do you see for yourself for the future?
    - What information/tips/techniques from the program will you use in the future?

- What ideas do you have for the future of the Báa nnilah program in the Crow community?

Aho. Thank you for your time today. You are helping us to make the Báa nnilah program most effective.

Facilitator measures of fidelity

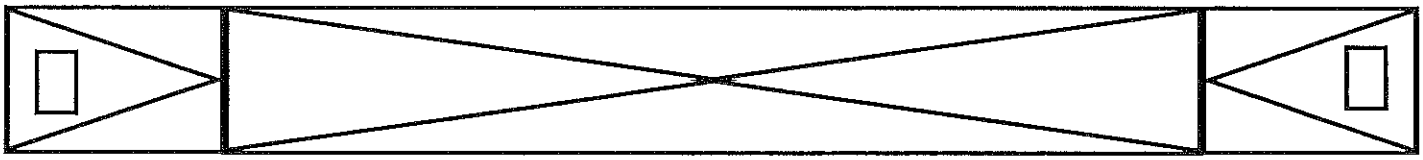
1. Recruitment: Mentor will have a "Participant Notebook" where they keep track of names and contact information of community members they recruited, location of recruitment, and date of recruitment. We will also gathering information on emergency contacts for each participant. We will use this notebook to track recruitment efforts. Note: The Participant Notebook will not be linked to the outcome data in order to protect confidentiality of participant information.
2. Entry into study: The Participant Notebook will also have information on the date the mentor consented the participant and the date they held a meeting with the participant to hear their health story.
3. Retention:
    a. Each gathering will include a mentor check list of participant attendance, which the mentor will transfer into the Participant Notebook, which will be changed to number of gatherings attended by each participant in the database.
    b. For gatherings missed by participants, the mentor will indicate if the participant provided a reason for missing the gathering
    c. Participants who drop out of the study will be contacted by project staff (not the mentor who is leading their gatherings) and asked for their reasons for drop out.
4. Dose: Each gathering will include a mentor check list of which components of the gathering they facilitated and the length of the gathering in minutes. An example is included in the materials. The evaluation will consist of the number of manual-based intervention components delivered divided by the total number intended. The checklist also includes three questions:
    a. How comfortable were you in leading this gathering?

    Not at all comfortable to Very comfortable on a scale of 1-10

    b. How confident were you in leading this gathering?

    Not at all confident to Very confident on a scale of 1-10

    c. Please share any comments you have about leading this gathering.



Mentor Gathering Check List

Please complete this check list after the gathering has taken place. Please check the box to the right to show which activities you were able to complete during the gathering and answer the questions below. Return the completed check list to Alma or Lucille. Thank you!

Mentor name: _____

Date of gathering: _____

Length of gathering: _____ minutes

Gathering 1: *Beginning the Báa nnilah Journey* Outline

Welcoming, prayer, meal	
Story	
Mentor provides information: introduction/purpose of gathering	
Supportive partnerships activity	
Closing	
How comfortable were you in leading this gathering? Circle one number: Not at all comfortable 1 2 3 4 5 6 7 8 9 10 Very comfortable	
How confident were you in leading this gathering? Circle one number: Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident	
Please share any comments you have about leading this gathering.	

Spirituality is the foundation and guide of the Crow Indian culture. It is incorporated in every aspect of the Crow way of life.

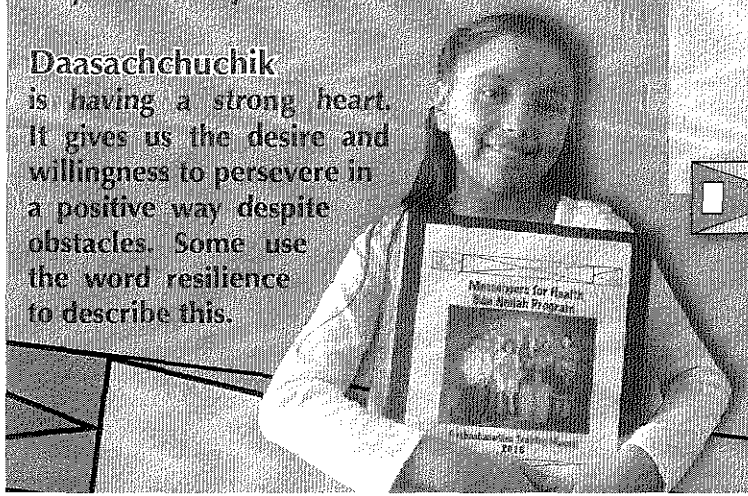
Our Báa nnilah program is based on Crow cultural strengths:

Báa nnilah, *advice that we all receive from* others, is often shared through story and gives us instructions for life.

Babaxuaiitchik, the belief that every day is a good day and that life is more valuable than anything else. Entails having a positive approach to life.

Itchik diiawakaam and itchik de baanaum mean it is good to see you and good to talk with you. When individuals see each other, it is never with a quick hi and goodbye. This reflects the importance of spending quality time with others, of real listening and exchange, and understanding that others are special and what they share is important.

Daasachchuchik is *having a strong heart.* It gives us the desire and willingness to persevere in a positive way despite obstacles. Some use the word resilience to describe this.



For more information or to sign up to take part in the program, contact:

Program staff
Alma McCormick: 665-5492
Lucille Other Medicine: 679-1644

Mentors

Hardin
Laura He Does It: 696-3777
Mike Bear Claw: 696-3777

Lodge Grass
Beldine Crooked Arm Pease: 620-1339
Anthony Pisano: 638-1788

Crow Agency
Pam Garza: 679-1027
William Falls Down: 665-7173
Lois Rides Horse: 620-1478

Pryor
Sampson DeCrane: 281-1014

Wyola
Valencia Crooked Arm: 679-4131
Tye Backbone 638-1559

LEARN MORE:
MessengersForHealth.org
and find us on FaceBook

Messengers for Health

photo by Cabel Noteboom

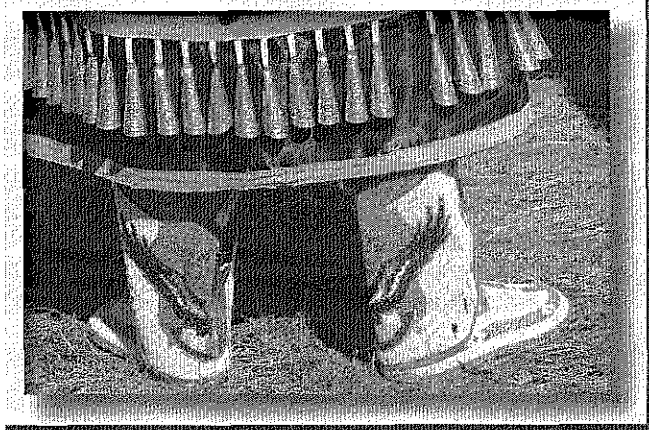
Báa nnilah program

Improving the health and wellness of Crow families.

Join us!

Alma McCormick, Lucille Other Medicine and mentors who have ongoing health concerns (see back) will lead the Báa nnilah program. Messengers for Health is collaborating with all Tribal entities, MSU – Bozeman and Big Horn Valley Health Center in Hardin.

Báa nnilah Program Gatherings will begin in 2017

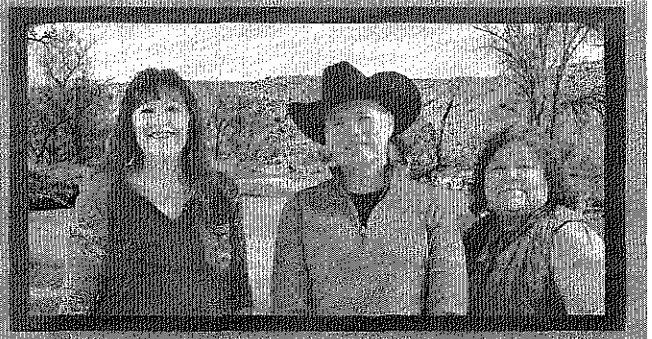


Messengers for Health is expanding our programming to serve both men and women living with chronic illness and recurring health concerns including but not limited to arthritis, cancer, diabetes and heart disease.

Our Báa nnilah program was inspired from personal stories that community members shared with Alma McCormick about what helps and what makes it harder for them to manage their ongoing health concerns.

Crow community members who have been living with chronic health concerns and are doing well with their self-care, known as mentors, will in turn encourage others who are facing similar medical challenges. Báa nnilah mentors provide real-life experience, knowledge and cultural strength for our Crow brothers and sisters with on-going health concerns that may not be available in most medical services.

Messengers for Health will work to keep the program going long-term to help inspire a healthier Crow People.



Báa nnilah Program at a Glance

This program is free for any Crow men and women who are living with on-going health concerns and consists of a total of 7 gatherings. Participants will attend all 7 gatherings which include a free meal. Family members are welcomed to be involved and attend the gatherings.

- Gain knowledge and tools for healthy living and self-care to improve your quality of life.
- Learn from mentors and other program members.
- Share and apply Crow cultural strengths to address ongoing health concerns.
- Learn about nutrition and physical and emotional health tools and exercises through hands-on activities.
- Gain support and help from program staff and other participants to apply what is learned to your self-care.

Messengers for Health will also host Báa nnilah community meetings to receive input and share our progress so we can better serve our Crow People.

Together let's take back our health!

Journey through the *Báa nnilah* Program

Our 10 mentors will each recruit 20 participants. Eligible participants have an ongoing illness and are 25 and older. Participants sign forms & identify family members and friends who want to be in a group together. By August 15, 2017.

Family members and friends who want to be together are randomly assigned to Fall (Nov 2017-Feb 2018) or Spring (April-July 2018) groups. There will be about 10 participants per group and 10 groups each in Fall and Spring.

Fall and Spring group participants come to orientation and fill out health surveys in local communities. October 2017

10 Fall groups attend 7 *Báa nnilah* gatherings in local communities

Nov 2017-Feb 2018

10 Spring groups stay in contact

Fall and Spring group participants fill out health surveys in local communities. March 2018

10 Fall groups stay in contact

April-July 2018

10 Spring groups attend 7 *Báa nnilah* gatherings in local communities

Fall and Spring group participants fill out health surveys in local communities. August 2018

Fall and Spring group participants fill out health surveys in local communities. December 2018

Báa nnilah information

- This program is for Crow men and women who have an ongoing illness.
- It is a partnership with MSU-Bozeman.
- There will be 7 gatherings in local communities - everyone will attend all 7 gatherings.
- Local mentors will lead the program.
- You will gain knowledge and tools for improving your health.
- You will learn from other members and use cultural strengths to address ongoing health concerns.
- There will be hands-on activities to learn about and apply physical activity, nutrition, and emotional health information.
- Members will support and help each other to apply what is learned to your every day life.
- Family members are welcomed to be involved.
- Meals will be served.
- Participants will receive a $10 gas voucher for each gathering to help with transportation.

Program staff

Alma McCormick: 665-5492

Lucille Other Medicine: 679-1644

Gathering Topics

1. Beginning the Báa nnilah journey
2. Self-care with an ongoing illness
3. Daasachchuchik (Strong heart): Overcoming trauma and building resilience
4. Healthy food and physical activity
5. Positive healthcare experiences
6. Healthy communication and overcoming challenges
7. Graduation, honoring, and next steps

Mentors

Hardin

- Laura He Does It: 696-3777
- Michael Bear Claw: 696-3777

Lodge Grass

- Beldine Crooked Arm Pease: 620-1339
- Anthony Pisano: 638-1788

Crow Agency

- Pam Garza: 679-1027
- William Falls Down: 665-7173
- Lois Rides Horse: 620-1478

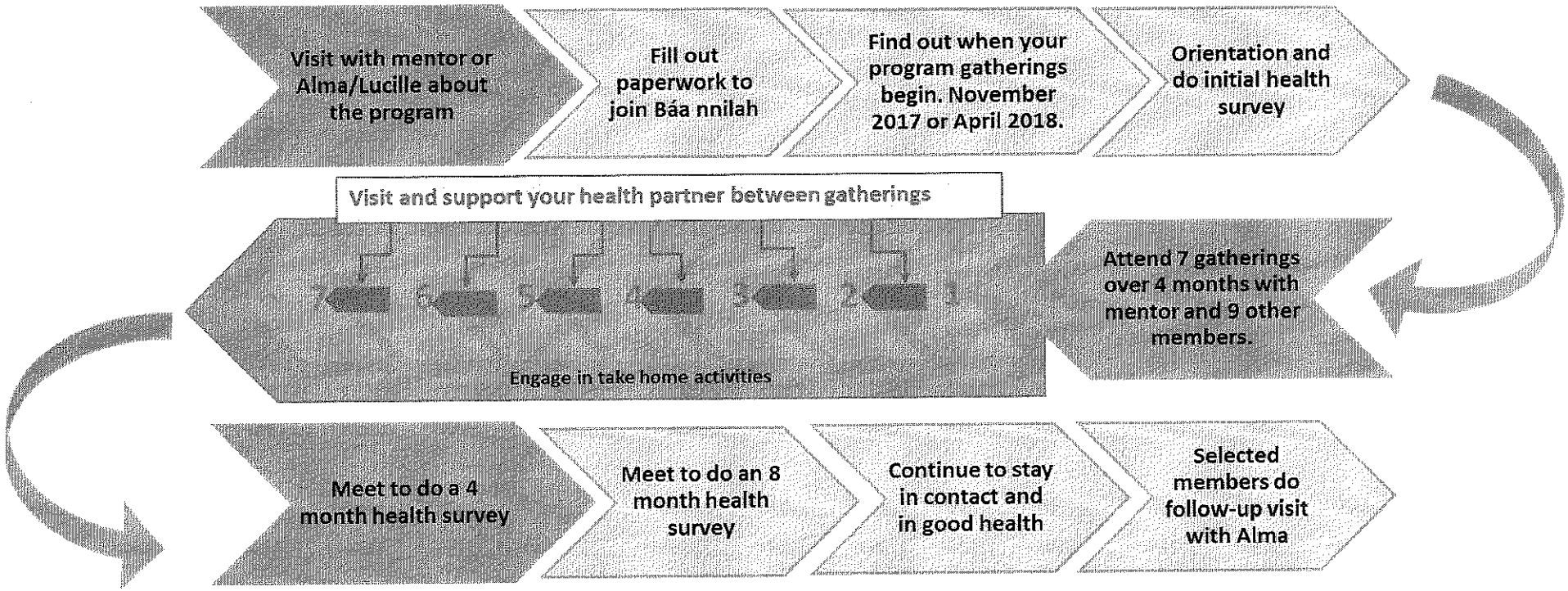
Pryor

- Sampson DeCrane: 281-1014

Wyola

- Valencia Crooked Arm: 679-4131
- Tye Backbone: 343-2006

Journey through the Báa nnilah program



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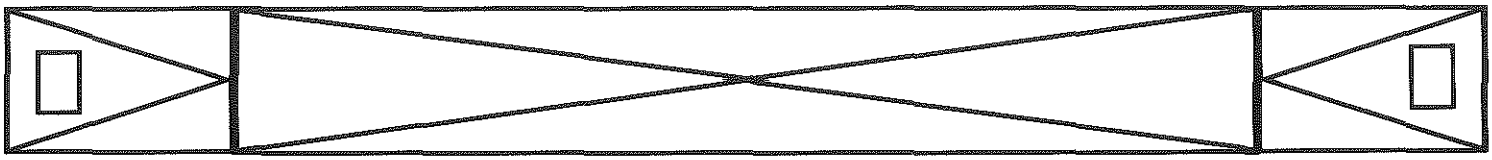


Subject Consent Form for Participation in Human Research at
Montana State University

Would you like to participate in the Messengers for Health Báa nnilah project?

You are being asked to participate in a research study called the Báa nnilah project. Why am I being asked to participate in the Báa nnilah project?

- This project is being done to teach Crow men and women about ongoing health concerns. The project will give you the opportunity to discuss your experiences and knowledge about ongoing health concerns.

- The goal of the project is to increase the amount of information that Crow men and women have about ongoing health concerns and to increase the number of men and women who take steps to keep themselves healthy. This could mean improving the health and wellness of Crow families. Community members who have an ongoing illness and who are 25 years old and older are welcome to participate.

What will I be asked to do? How much time will it take?

- Participation is voluntary. If you choose to participate in the project, you will:
  - Come to an orientation meeting for the program. The meeting will last 2-3 hours, held in a community on the reservation (Wyola, Pryor, Lodge Grass, Crow Agency) or in Hardin and be led by project staff members including Alma McCormick and Lucille Other Medicine. During the meeting, we will have a meal, share information about the program, take a survey that asks questions about ongoing health concerns, and perform 3 exercises including walking for 6 minutes, standing up from a chair and walking 10 feet and walking back to the chair to sit, and standing for balance. These exercises will be used to develop an exercise program for you. For the survey, a member of the Báa nnilah team will read the survey questions to you and you will enter your answers on a computer privately so that no one will see your answers. You will come to another group meeting where you will take the same survey and complete the same exercises 4 times over the next 18 months.
  - Fill out a form that lists your ongoing health concerns.
  - Attend 7 gatherings with about 10 other people where you will learn about ongoing health concerns. These gatherings will take place in local communities (Wyola, Pryor, Lodge Grass, Crow Agency, Hardin) and be led by a community mentor. Each of the 7 gatherings will last for 3 hours and include a meal and hands-on activities.

Project staff members such as Alma McCormick and Lucille Other Medicine may also attend the gatherings.

- 20 participants will also be asked to complete an hour-long interview with Alma McCormick or another staff member after the gatherings are completed. The interview will help us to make the Báa nnilah program better for the future.

Do I have to take the survey or do the exercises?

- No. You do not have to take the survey or do the exercises. Participation is voluntary and you can choose to not answer any questions you do not want to answer and/or you can stop anytime. There will be no penalty if you decide not to take the survey or do the exercises.

How did you get my name for this survey?

- You expressed interest in participating in the Báa nnilah project. You may have met with a project mentor or staff member in the community.

Are there any risks involved with taking part in the project? Will I feel uncomfortable?

- Taking part in the project *should not* put you at risk for physical harm. You may feel uncomfortable answering certain questions on the survey. You can perform the 3 exercises as you feel comfortable. You will never be required to answer any questions that make you feel uncomfortable or do any exercises that you do not want to do.

- During one of the gatherings, there will be a discussion of grief, loss, resilience, and healing. You will be provided with a list of resources available in the local communities for you to access if you desire.

- In the event your participation in this research supported by the National Institutes of Health results in injury to you, medical treatment consisting of a referral to Indian Health Services or Bighorn Valley Health Center will be available. If it is an emergency, a project mentor or staff member will call 911. This treatment will be at your expense. Further information about this treatment may be obtained by calling Alma McCormick at 665-5492 or Suzanne Held at Montana State University at 994-6321.

What will I get out of taking part in the project? Will I get paid?

- You will be provided with a $40.00 gas card each time you come to the meeting where you will complete the survey and exercises. This is to thank you for taking your time to do these things. You will also help us learn about ongoing health concerns among women and men in the Crow community. This information will help us learn if our Báa nnilah program is helping people and how to make it better for others.

- At each of the 7 gatherings, you will also receive a meal, incentives that encourage healthy living, and a $10 gas card to help with transportation to the gatherings.

Is there any cost for me to participate in the Báa nnilah program?

- No, there is no cost for you to participate in the program.

Will people know that I took part in the project?

- To ensure *confidentiality*, you will be entering your answers to the survey into a computer tablet. The tablet does not have your name included. The information from the computer tablets will be transferred securely and stored on computers that have a password that only people working on this project can have access to. The mentors and project staff who will be giving you the survey have signed a form agreeing not to share any information.
- This project is a clinical trial. A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

Who is paying for this project?

- The National Institutes of Health is paying for this project.

Why do you have me signing this form?

- This type of form is used any time people gather information for a research project. It is done to make sure that you understand any risks of taking the survey and completing the exercises and to give you people to contact in case you have any questions about the Báa nnilah project.

What if I have any questions about the project or my participation?

- If you ever have any questions about this project, please feel free to contact the project coordinator, Alma McCormick at 665-5492 or Suzanne Held at Montana State University at 994-6321.

What if I have any questions about my rights regarding this project?

- If you ever have any questions about your rights, you can contact Mark Quinn, the Chair of the Human Subjects Committee at Montana State University. His number is (406) 994-5721.

If you are interested in being a part of the Báa nnilah project, please read the following agreement statement and sign your name below the statement.

Agreement statement:

By signing this consent form, I agree to participate in the Báa nnilah project. I have read the above information and understand the discomforts, inconvenience, and risk of this study. I, _____ (name of participant) agree to be a part of the Báa nnilah project. I understand that I may later refuse to participate, and that I may withdraw from the project at any time. I have received a copy of this consent form for my own records.

Participant signature _____ Date _____

Mentor Signature _____ Date _____

CROW TRIBE EXECUTIVE BRANCH

Bacheeitche Avenue
P.O. Box 159
Crow Agency (Baaxuwuaashe), Montana 59022
Phone: (406) 638-3732/638-3786
Fax: (406) 638-7301

June 13, 2017

Mark Quinn, Chairman for MSU-IRB
P.O. Box 173610
Bozeman, MT 59717

Dear Mr. Quinn,

On behalf of the Crow Tribe, I am honored and pleased to support Messengers for Health (MFH) in their efforts to improve the health and wellness of the Crow people. MFH under the leadership of Crow tribal member, Alma McCormick, a long-standing community-based project on the Crow Indian reservation that provides effective culturally appropriate health outreach services among the Crow people.

MFH began as a research project in 2001 funded by the American Cancer Society and worked in partnership with the Montana State University (MSU) Bozeman in Bozeman, Montana and the Crow Nation. In 2010, MFH became a 501 (c) (3) American Indian nonprofit organization in order to continue their outreach services and address other health needs in the Crow community.

At this time, MFH is again working collaboratively with MSU-Bozeman to develop and implement a culturally appropriate intervention known as, the "Baannilah" Program to improve the self-care management of Crow people with chronic illnesses. Diabetes is prevalent in our community and many people are in need of support services so they are able to better themselves. The Baannilah intervention will utilize Crow cultural strengths and values combined with the expertise of research to implement a mentorship intervention to encourage and support individuals with chronic health conditions toward improved self-care and well-being.

The Crow Tribe fully supports MFH and their efforts and goals to improve chronic illness management amongst the Crow people. If you have any questions, please call (406) 638-2059.

Sincerely,

Carlson Goes Ahead
Vice-Chairman, Crow Tribe

Montana State University
Institutional Review Board
Request for Minor Modifications/Amendments

Instructions: E-mail completed form and all revised and/or new study documents to: cherylj@montana.edu

Note: The project's IRB-approved Research Protocol must be kept current and followed throughout the life of the project with yearly renewals. Protocols approved in the Exempt category do not require yearly renewals. All study documents are subject to review.

1. **IRB approval number:** SH082017

2. **Project Title:** The Báa nnilah project

3. **Principal Investigator:** Suzanne Held
   Contact information (phone/e-mail): 994-6321; Suzanne@montana.edu

4. **Requesting modification/amendment to:**

   ☐ Research protocol
   X Consent form
   ☐ Recruitment materials
   ☐ Survey instrument, interview questions
   ☐ Research personnel
   ☐ Other, please explain:

   _____

   _____

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.)

In response to a recent National Institutes of Health policy update regarding Certificates of Confidentiality, we have a prepared an Addendum to our Informed Consent for our IRB approval for "The Báa nnilah project," approval SH082017. The policy update provides all NIH funded human subjects research with a Certificate of Confidentiality, which provides additional privacy protections for data collected during the *Baa nnilah* project. More information regarding the policy update is available within NOT-OD-17-109 and at https://humansubjects.nih.gov/coc/index.

We are seeking your approval to add the attached document to our informed consent form. We would like to provide the information to participants who were already consented and attended the data collection meetings (10 people) and add it to our form for those who have not received consent or who have not attended the data collection meetings (about 190 people).

6. **Have these requested changes been initiated?**

□ No

X Yes

We had a data collection meeting last night – October 24, 2017 and we handed out the additional information below to 5 participants.

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

   This will provide further protections to participants of their confidentiality.

Additional Form for Informed Consent:

Certificate of Confidentiality Covering Participation in Human Research at Montana State University

What is a Certificate of Confidentiality?

- A Certificate of Confidentiality helps us protect your privacy.

What does the Certificate of Confidentiality do?

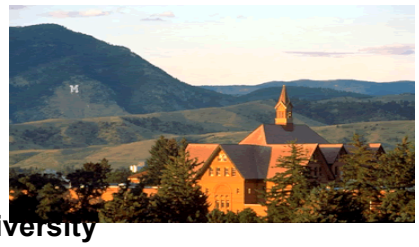
- It lets us legally refuse to release information you share through the Báa nnilah program that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Are there limits to what a Certificate of Confidentiality can do?

- It cannot be used to resist a demand for information from personnel from the agency that gives us funding, which is the National Institues of Health, for auditing or program evaluation purposes.
- We must share information you share about reports of child abuse and neglect, or active, specific threats of harm to yourself or others.

What if I want to share my information?

- The Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.



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2. **Project Title:** The baa nnilah project

3. **Principal Investigator: Suzanne Held**
   Contact information (phone/e-mail): 994-6321/suzanne@montana.edu

4. **Requesting modification/amendment to:**

   X Research protocol
   ☐ Consent form
   ☐ Recruitment materials
   X Survey instrument, interview questions
   ☐ Research personnel
   ☐ Other, please explain:

   _____

   _____

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.)

We would like to make amendments to our IRB application that was approved last fall. In the application, we have three different groups of people from whom data will be gathered.

1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

1. Participants of intervention: all participants. There are two changes – one to the timeline and one to add a data collection element.

For this group, the actual timeline for group data collection is different from what was proposed in the application. The application has data gathering events occurring in March 2018, August 2018, and December 2018 for the intervention participants. The actual months will be April/May 2018, October/November 2018, and April 2019.

We are proposing to add a data collection element for the intervention participants. All participants attend 7 gatherings as a part of the intervention. The intervention is led by facilitators who are members of the Crow community. Project staff members will send postcard reminders the week before each gathering and text or phone call reminders to participants on the day of each of the 7 gatherings. Project staff will save participant phone numbers only by participant ID number versus by name. Any responses to the text or phone reminders will be archived, again only by participant ID. Additionally, we would like to add questions to the post-intervention survey to ascertain how well each of the retention strategies helped participants to keep attending each of the gatherings (to improve and track participant retention). The questions are below and will be answered on computer tablets with the already approved surveys.

Please check how much each of the following helped you to keep coming to the gatherings

	Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
Newsletter					
Gifts received at gatherings					
Gas cards received at gatherings					
My supportive partner					
Information I learned at the gatherings					
My personal motivation					
Collecting my feathers (goals)					
Healthy meals at gatherings					
My relationship with my mentor					
My bonding with other participants					
Location of gatherings					
Postcard reminders					
Phone texts/calls from MSU team members					
Phone texts/calls from my mentor					
Other (please explain):					

Please check how much each of the following prevented you from attending the gatherings

	Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
Weather					
Lack of transportation					
My personal health					
Deaths in the community					
Death in the family					
Personal or family crisis					
Community events					
Work schedule					
Not being informed of gathering times and locations					
Changing schedule of gatherings					
Location of gatherings					
Family member care					
Atmosphere and feeling of gatherings -Please explain any gathering issues:					
Other (please explain):					

2. Participants of intervention: subgroup – no changes at this time

3. Intervention facilitators. We are adding a data collection element.

There are 10 intervention facilitators who are Crow community members. They are each leading 7 gatherings/meetings in the community. We are taking a random sample of one of the 10 facilitators for each of the 7 gatherings to complete an additional fidelity evaluation. The data will be gathered by co-PI Alma McCormick, a member of the Crow Nation. The evaluation instrument is below.

In addition, for process evaluation and fidelity tracking, we are keeping field notes of texts and phone call communications with the intervention facilitators. This information will provide context and a deeper understanding of the delivery of the intervention. An example of this information is when a gathering is postponed due to weather or because participants are out of town at a basketball tournament.

6. **Have these requested changes been initiated?**
   X No – for #1, participants of intervention
   X Yes – for #3, intervention facilitators

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

The only affect is that the survey (#1 above) will take approximately 5 minutes longer for participants.

		Not Completed	Partially Completed	Fully Completed	Did the Mentor add new components not in the original protocol?
Welcoming, prayer, meal	30 min				
Story	10 min				
Mentor provides information: introduction/purpose of gathering	30 min				
Sharing circle	50 min				
Supportive partnerships activity	50 min				
Closing	10 min				
Mentor Responsibility (Communication with participants, bringing all necessary materials, being on-time, etc.)					
Mentor Interactional Style (Ex. Speaking Crow, facilitation style, food choices, humor, empathy, etc.)					
Comments:					
Participant & Environmental Factors (Ex. Health condition, weather, deaths, presence of people not in the program, etc.)					
Comments					

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3. **Principal Investigator: Suzanne Held**
   Contact information (phone/e-mail): 994-6321/suzanne@montana.edu

4. **Requesting modification/amendment to:**

   x Research protocol
   □ Consent form
   □ Recruitment materials
   x Survey instrument, interview questions
   □ Research personnel
   □ Other, please explain:

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.)

We would like to make amendments to our IRB application that was approved last fall. In the application, we have three different groups of people from whom data will be gathered.

1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

1. Participants of intervention: all participants. There are three additions we would like to make to our data collection.

First addition: To gather accurate data for adverse reporting, we would like to add these questions to the computer tablets:

- Since you last took this survey have you been in a hospital overnight because of your health?

Yes/no

- Since you last took this survey have you been to the emergency room because of your health?

Yes/no

<u>Second addition:</u> The first question below was on our original protocol to gathering information on contamination from the wait-list control group. We would like to add the second and third question.

1. The Messengers for Health Baa nnilah program consists of 7 gatherings in the local Crow communities and Hardin that are led by a community member mentor. Have you taken action for your health because of something you have heard or learned from a friend or family member who has attended the gatherings?

Yes (if they choose this, go to the next two)

No

2. To what extent have you taken action from what you learned? Please choose the number that best describes your action taken:

(not at all) 0 1 2 3 4 5 6 7 8 9 10 (A lot)

3. Please share what actions you have taken or changes you have made in your life because of what you heard or learned from a friend or family member who has attended the gatherings (open ended-question):

<u>Third addition:</u> We are proposing to add a data collection element for the intervention participants. All participants attend 7 gatherings as a part of the intervention. The intervention is led by facilitators who are members of the Crow community. During the intervention, participants receive incentives related to health. We want to know if these incentives are being used. At the data gathering meeting, we will put the incentive on a table with a sheet of paper asking: "How often did you use this?" Participants who attended the intervention will put a check mark by the response that represents their behavior. There will also be space where they can write comments. Below is a table that shows the incentives and scale.

	Not at all	Rarely	Sometimes	Often	All the time
Medication tracking sheet					
Preparing for your doctor visit					
Business card doctor visit					
Exercise bands					
Walking a good path					
Ground, breathe, settle bracelet					
Living a healthy life book					
Wrist activity tracker (fit bit)					
Journal					

2. Participants of intervention: subgroup – no changes at this time

3. Intervention facilitators. – no changes at this time

6. **Have these requested changes been initiated?**
   x No
   Yes

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

   The only affect is that the data collection time will take approximately 5 minutes longer for participants.

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3. **Principal Investigator:** Suzanne Held
   Contact information (phone/e-mail): 994-6321/suzanne@montana.edu

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   □ Research personnel
   □ Other, please explain:

   _____

   _____

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.)

We would like to make amendments to our IRB application that was approved August 2017. In the application, we have three different groups of people from whom data will be gathered.

1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

We would like to make amendments to #2 and #3.

2. Participants of intervention: subgroup. This is a random sample of #1. The participants will complete an interview with project staff. The interview protocol was approved in August 2017. We would like to make minor modifications to some of the questions. The protocol showing track changes is below.

3. Intervention facilitators. We would like to add an interview to be conducted by project staff with the intervention facilitators. The interview protocol is below.

6. **Have these requested changes been initiated?**
   x No
   Yes

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

   This will not affect study participants except the minor changes to the interview protocol for a subsample of participants (#2) and an additional interview for #3, which will take approximately 1 hour of their time.

2. Participants of intervention: subgroup

Báa nnilah program qualitative interview questions

Hello. I am Alma McCormick. Thank you for agreeing to talk about your experiences with the Báa nnilah program. We plan to use the information shared in the interviews to improve the program for the future. We hope you will share with us your true feelings, for there are no right or wrong answers to these questions. We will be tape-recording our conversation so that we make sure to receive everything that you have to share. Participation in this interview is voluntary and you can choose to either share your name or have the information you share be anonymous, meaning that your name will not appear anywhere. You can stop the interview at anytime or not answer any question. The interview will take about one hour of your time and you will be paid a $30 gift card to thank you for your help. Let's begin.

- How did participating in the Báa nnilah program influence your life?
    - Probe if needed: Can you tell me more about that?
    - Probe if needed: Can you give me an example?
- How did your Báa nnilah program mentor influence your life?
    - What did you learn from your mentor?
    - How did the mentor's teaching style influence your learning?
- What have you shared about the program with family members, community members and others?
    - Could you give me some of examples of how you have shared about this program?
- What have you changed about your self-care after participating in the Báa nnilah program?
    - What information/tips/techniques from the Báa nnilah program did you apply or are you applying to your own life?
- In what ways, if at all, has attending the Báa nnilah program changed how you share about your health with others?
- What has changed in your relationships with your family and friends since being in the Báa nnilah program?
- Have you seen your doctor since participating in the program?
    - If no, go to "How has this program…"
    - If yes, continue to the next question.
- What has changed in your relationship with your doctor since being in the Báa nnilah program?
    - How has the communication between you and your doctor changed?
    - How has your doctor's attitude changed since being in Báa nnilah?
        - Probe if they don't mention these: how about their concern and thoroughness?
    - How has the doctor's behavior and treatment toward you changed?
- How has this program influenced your feelings of hope toward your health?

Give participant the list of gathering topics for the next set of questions.

- Which parts of the program (which gathering) were most helpful?
- Which parts of the program (which gathering) was least helpful?
- What would you change to make the program better for the future?
    - What would you add?
    - What would you get rid of?
- Since starting with the Báa nnilah program, what other support in addition to being in the program has made a difference for your health?
- What changes have you noticed in the community as a result of this program?
- What do you see for your health for the future?
- What information/tips/techniques from the program will you use in the future?

- What ideas do you have for the future of the Báa nnilah program in the Crow community?

Aho. Thank you for your time today. You are helping us to make the Báa nnilah program most effective.

3. Intervention facilitators interview protocol.

Mentor Qualitative Interview Questions

Mentor: _____

Date: _____ Time: _____

Location: _____

Hello, I am Shannen Keene. Thank you for taking the time to visit with me today. We would like to learn about your experience as a Mentor in the Báa nnilah program. This will help us understand how to improve the program in the future. If it's ok with you, I would like to record our conversation so I don't miss anything that you're sharing. Do you have any questions before we get started?

1. What does being a Mentor mean to you?
2. What experiences did you have before your involvement in the Báa nnilah program that helped prepare you for being a Mentor?
3. How did you prepare for your gatherings?
4. How did you feel leading the first gathering of your first group compared to leading the first gathering of your second group?
5. Think back to a time when you were feeling the most <u>comfortable</u> leading your gathering. What made you feel that way?
6. Think back to a time when you were feeling the most <u>confident</u> leading your gathering. What made you feel that way?
7. How did you personalize your gatherings to make them your own?
8. How did you know that participants understood or didn't understand the gathering material?
9. Can you tell me about the support that you received from program staff (i.e, Alma, Lucille, Jerik, Shauna, and the Bozeman team)?
    a. What worked well for you?
    b. What didn't work well for you?
10. How was it for you when program staff attended your gathering(s)?
    a. How did that support you or not support you as a Mentor?
11. What other ways can program staff support you as a Mentor?
12. What does successful mentorship look like to you?

Aho. Thank you for your time today. You are helping us make the Báa nnilah program better.

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3. **Principal Investigator:** Suzanne Held
   Contact information (phone/e-mail): 994-6321 / suzanne@montana.edu
   Address (where you want approval letter sent):

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   _____

   _____

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   We have made slight wording changes to reflect a less stringent timeline of follow-up.

6. **Have these requested changes been initiated?**
   □ No
   X Yes

7. **How will the proposed modification(s) affect study participants?**
   Study participants indicating higher levels of depression symptoms and/or more frequent suicidal thinking during study assessments will still be followed-up by community project leaders (Alma and Lucille) but with a less stringent timeline than previously indicated.

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1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

We would like to make amendments to #1 and to introduce a new group:

4. Participants of modified intervention

1. Participants of intervention: all participants. We have completed data collection 3 times for this group, which consists of our intervention group and our wait-list control group completing the survey approved by the IRB. We would like approval to:

- Make slight modifications to some of the demographic questions to ask if the response changed since the last survey and if it did not, to skip the question. This will hopefully make the survey quicker for participants to complete.
- Remove 2 questions that should not vary over time: 1) gender and 2) year of birth.
- Add a checklist of questions to assess changes in participants since they began the program.

The original questions and changes and the checklist of questions are below.

4. Participants of modified intervention. We have run both the intervention and wait-list control group through our 7-session intervention. We would like to explore the idea of an implementation study and are also committed to sustaining the intervention, as we shared in our grant application to NIH. We have made small changes to our intervention to improve the experience for participants. For example, wording changes for clarity, adding a new handout on whole grains, switching the order of 2 of the gatherings for clarity, and changing a few of the exercises in the handouts to make it easier for all community members to engage in the exercises. This spring, we will run 2 groups of approximately 10 participants through the 7 gatherings of the intervention. We will not have them complete the survey and exercises that the intervention and wait-list control group completed. We would like permission to gather information in two areas:

1) Have them complete the PHQ-9 survey, which gathers information on depression. This will be given to each participant at the first gathering. We are having them complete this survey as we saw many community members with concerning scores and we have implemented a follow-up protocol with our intervention and wait-list control that we will follow with these participants.
2) We will have participants complete the checklist of questions that is below at the bottom of the document at the end of their participation.

6. **Have these requested changes been initiated?**
   x No
   Yes

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

   This will not affect study participants except the minor changes to the interview protocol.

1. Participants of intervention: all participants.

"From" is the existing format of the question. **"To"** is the revised format.

From: Which community do you live in?

To: Since the last time you took this survey, have you moved to a different community?
No: go to next question
Yes: go to choices of community

From: What is your current marital status?

To: Since the last time you took this survey, has your marital status changed?
No: go to next question
Yes: go to choices, with this difference: combine "separated" and "divorced" into one choice ("separated or divorced"); delete "single, never married" and "other" categories

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From: What was the highest grade or year of school that you completed?

To: Since the last time you took this survey, have you gone back to or graduated from school?
No: go to next question
Yes: go to choices of education with these differences:

- combine: "some technical/vocational school" and "some college" into one choice "some education after high school"
- change "high school graduate or diploma" to "high school graduate or GED"

From: Employment status: select the statement that fits your situation best

To: Since the last time you took this survey, has your employment status changed?
No: go to next question
Yes: go to choices of employment status

From: Please select the number that shows how much your total household income was for the past 12 months [Household means all of the people who live with you and share income and expenses]

From: About how many miles do you travel to get to the clinic where you receive your health care?
To: About how many miles do you travel to get to the clinic where you receive most of your health care? (one way)

From: Please select the type of health insurance or health coverage that pays for your health care? (select all that apply)

To: Since the last time you took this survey, has your health insurance or health coverage changed?

No: go to next question
Yes: go to question and choices of health insurance

From: Please select the ongoing illness(es) that a doctor has told you that you have.

To: Since the last time you took this survey, has your doctor told you that you have a new ongoing illness?
No: go to next question
Yes: Please type in the new ongoing illness that you now have (include an open box)

And: Since the last time you took this survey, has your doctor told you that you that you no longer have an illness that you were diagnosed with before?
No: go to next question
Yes: Please type in the ongoing illness that you no longer have (include an open box)

From: do you have any additional comments you would like to add? (tap the white box below)

To: Please share what you gained or learned from the program and what changes in your health or behavior you made because of the program? (tap the white box below)

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1. Participants of intervention: all participants.
4. Participants of modified intervention.

We will add this checklist: Check off all of the changes you have noticed since you started in the Báa nnilah program:

Eating healthier
Drinking more water
Drinking less pop or other sugary drinks
Taking more walks or exercising more
Taking my medication more regularly
Having better communication with my doctor
Having better relationships with my spouse or other family members
Feeling less alone
Lost weight
Shared information from the Báa nnilah program with others
Feeling more hopeful
Feeling less stressed
Having more support
Having more understanding that there are others going through what I am going through
Feeling more connected to my community

Montana State University
Institutional Review Board
Request for Minor Modifications/Amendments

Instructions: E-mail completed form and all revised and/or new study documents to: cherylj@montana.edu

Note: The project's IRB-approved Research Protocol must be kept current and followed throughout the life of the project with yearly renewals. Protocols approved in the Exempt category do not require yearly renewals. All study documents are subject to review.

1. **IRB approval number:** SH082017

2. **Project Title:** Improving chronic illness management with the Apsaalooke Nation: The báa nnilah project

3. **Principal Investigator:** Suzanne Held
   Contact information (phone/e-mail): 994-6321/suzanne@montana.edu

4. **Requesting modification/amendment to:**

   Research protocol
   Consent form
   Recruitment materials
   x Survey instrument, interview questions
   Research personnel
   Other, please explain:

   _____

   _____

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.)

We would like to make amendments to our IRB application that was approved August 2017. In the application, we had three different groups of people from whom data was to be gathered.

1. Participants of intervention: all participants
2. Participants of intervention: subgroup
3. Intervention facilitators

We would like to make amendments to #1:

1. Participants of intervention: all participants. We have completed data collection 4 times for this group, which consists of our intervention group and our wait-list control

group completing the survey approved by the IRB. We have one more data collection event and this event is only with the wait-list control group. We would like approval to add this question:

- What do you think is the best way to for us to learn what the Báa nnilah program did for its participants, family members, and for the Crow community as a whole?
    - If they say, "a survey" or "asking people who took part" say, "please explain" or "what questions would you ask?"

6. **Have these requested changes been initiated?**
   x No
   Yes

7. **How will the proposed modification(s) affect study participants?**
   Note: Federal regulations require IRB approval prior to changing a research procedure or deviating from IRB approved documents unless it is in the best interest of or for the safety of study participants.

   This will not affect study participants except the minor changes to the interview protocol.