Protocol Detail Report

Printed By: Webber, Eliza
2/23/2023 10:26:31 AM

Report Comments

Protocol Information

Version # 2

Reference Number:	55		
Protocol Number:	2020-55-AA121820-EXPEDITED		
Protocol Title:	Protecting Our Community: A Pragmatic Randomized Trial of Home-Based COVID Testing with American Indian and Latino Communities		
Protocol Type:	Amendment		
Principal Investigator:	Adams, Alexandra	**Approval Date:**	8/24/2022
Submittal Date:	8/23/2022	**Effective Date:**	8/24/2022
Author:	Mee, Danielle	**Renewal Date:**	12/18/2025
Status:	Approved	**Next Review Date:**	12/18/2025
Inactive Date:		**Expiration Date:**	12/18/2025

Amendment Request 1

Summarize Amendment 1.1

*Amendments must be approved by the IRB prior to implementation.

Briefly state the reason for amendment and state the changes. Then edit the appropriate section/answer in the full form below to incorporate the changes.

We would like to add PhD student Anna Whiting Sorrell to the research personnel team to assist in data analysis, conduct interviews, and other tasks applicable to the completion of the RADx Aims 1, 2, and 3.

We would also like to calculate mileage from participants' home addresses to the test kit sample drop off site, to include as a variable in the analysis of Aim 2 results. The data needed to calculate mileage (participant addresses) has already received IRB approval to collect and has already been collected. The mileage data will be calculated by the Community Health Worker who has prior approval to access sensitive participant data. The mileage will matched to a unique identifier "participant ID", and the data analysis team will not see identifiable participant information.

Effect on Participants 1.2

How will the proposed amendment(s) affect study participants?

The proposed amendments should not affect study participants.

Human Subjects Research 2

Definition of Human Subjects Research 2.1

Only **human subjects research** studies require IRB review. If you have questions about whether your work qualifies as human subjects research, contact the IRB Office at 406-994-4706 or irb@montana.edu for determination assistance.

Full Committee and Expedited Review 2.2

Use this form for research studies that will be reviewed by the Full IRB Committee or by Expedited Review. Do not use this form for research that falls into an Exempt category. See Types of Review for guidance.

Cooperative or Multi-Site Research 2.3

For research collaborations, use this form to describe only MSU activities unless you are requesting that the MSU IRB provide the primary review for an entire project, including oversight for non-MSU collaborators.

Contact the IRB Office for assistance with collaboration questions about reliance, determination of reliance, SMART IRB, or Institutional Agreements.

Protocol Information 3

Created By 3.1

This is the author creating this research request (can be any personnel on the project, but PI must submit application).

Webber, Eliza	eliza.webber@montana.edu	

Reference Number 3.2

The reference number system tracking number assigned by TOPAZ.

55

Protocol Number 3.3

The protocol number will be assigned once the research request is approved.

2020-55-AA121820-EXPEDITED

Protocol Type 3.4

Protocol Type (Original, Amendment, Interim Review, or Renewal)

amendment

Principal Investigator 3.5

Identify the primary Principal Investigator who is responsible for all aspects of this research request. If the author is the primary PI, the question response will automatically fill; otherwise click the **silhouette (+)** button to change the PI.

Adams, Alexandra	alexandra.adams2@montana.edu	

Department 3.6

Choose the department for which this research is conducted by clicking the **green (+)**.

Center for American Indian and Rural Health Equity (CAIRHE)

Title 3.7

Research proposal title:

Protecting Our Community: A Pragmatic Randomized Trial of Home-Based COVID Testing with American Indian and Latino Communities

Personnel 4

Protocol Associates **4.1**

List all other MSU personnel who will participate in this research. MSU personnel means faculty, staff, and students or those who have been granted a non-employee appointment (i.e., anyone with an MSU NetID).

To add associates, click on the **green (+)** button to the right, find the associates in the staff selector grid, and click the OK button. Hint: The three dots are the easiest way to filter names.

Checkmark the appropriate role for each person:

- The **Co-Investigator** designation will allow the assigned individual the same permissions as the PI. This individual can work on the unsubmitted protocol, submit the protocol, and view the protocol after approval.
- The **Key Associate** role allows the individual to view the approved protocol and receive emails about the protocol only.
- Any individual listed here as personnel (no checkmark) has view only access following protocol approval.

You do not need to list the responsibilities or add comments for each person.

Review Personnel Training Information

After each person is selected, review the training credentials to ensure that required Human Subjects Training is up to date. Click the **blue (i) information** button adjacent to the full name. The "Staff Information" window will display. Click the "Staff Competency" tab to view training information.

Guidance and FAQs

- Who should be included as Protocol Personnel?
- What training is required?

- Cannot find personnel? Request to be added to Topaz

Ahmed, Selena		
Responsibilities		
Comments		
☐ Co-Investigator	☐ Key Associate	
Martin, Stephen		
Responsibilities		
Comments		
☐ Co-Investigator	☐ Key Associate	

Webber, Eliza	
Responsibilities	
Comments	
☑ Co-Investigator	☐ Key Associate
Warne, Teresa	
Responsibilities	
Comments	
☑ Co-Investigator	☐ Key Associate
Sorrell, Anna	
Responsibilities	Assist in data analysis, conduct interviews, and other tasks applicable to the completion of the RADx Aims 1, 2, and 3.
Comments	
☑ Co-Investigator	☐ Key Associate

Student Principal Investigator **4.2**

Are you a student PI?

☐ Yes

☑ No

Yes	**4.2.1**
No	**4.2.2**

External Protocol Personnel 4.3

Attachments: Wendy Westbroek CITI Certificate.pdf,Virgil Dupuis CITI Certificate.pdf,Victoria Lyon CITI Certificate.pdf,Victoria Lyon CITI Certificate 2.pdf,Sonia Bishop Certificate.pdf,Sonia Bishop Certificate 2.pdf,Paul Drain CITI Certificate.pdf,Paul Drain CITI Certificate 2.pdf,Nora Gonzalez CITI Certificate.pdf,Nora Gonzalez CITI Certificate 2.pdf,Nathan Marchello CITI Certificate.pdf,Monica Escareno CITI Certificate.pdf,Marissa Basler CITI Certificate.pdf,Linda Ko CITI Certificate.pdf,Laurie Hassell CITI Certificate.pdf,Laurie Hassell CITI Certificate 2.pdf,Genoveva Ibarra CITI Certificate.pdf,Charles Gregor CIT Certificate.pdf,Carleen Rowe CITI Certificate.pdf,Carleen Rowe CITI Certificate 2.pdf,Avigail Galvan CITI Certificate.pdf,Ashley Gervais CITI Certificate.pdf,Allison Lambert CITI Certificate.pdf,Allison Lambert CITI Certificate 2.pdf,Dillon van Rensburg.pdf,Lina Truong.pdf

Add external Protocol Personnel. Click the **green plus (+)** button to add a row.

Include the following information for each individual:

- First Name
- Last Name
- Institution (e.g., name of the university, business, nonprofit, etc.)
- Email Address

Attach external human subjects research training documentation for each individual with the **paper clip**.

First Name:	Last Name:	Institution:	Email Address:
Charlie	Gregor	University of Washington	cgregor2@uw.edu
Virgil	Dupuis	Salish-Kootenai College	virgil_dupuis@skc.edu
Laurie	Hassell	University of Washington	lhassell@uw.edu
Victoria	Lyon	University of Washington	vlyon@uw.edu
Nathan	Marchello	Fred Hutch Cancer Research Center	nmarchel@fredhutch.org
Genoveva	Ibarra	Fred Hutch Cancer Research Center	gibarra@fredhutch.org
Monica	Escareno	Fred Hutch Cancer Research Center	mescaren@fredhutch.org
Nora	Gonzalez	Fred Hutch Cancer Research Center	ngonzalez@fredhutch.org
Paul	Drain	University of Washington	pkdrain@uw.edu
Carly	Rowe	University of Washington	carowe6@uw.edu
Wendy	Westbroek	Salish-Kootenai College	wendy_westbroek@skc.edu
Linda	Ko	Fred Hutch Cancer Research Center	lko@fredhutch.org
Allison	Lambert	Providence Medical Research Center	allison.lambert@providence.org
Sonia	Bishop	Fred Hutch Cancer Research Center	sbishop@fredhutch.org
Avigail	Galvan	Fred Hutch Cancer Research Center	agalvan@fredhutch.org
Marissa	Basler	Salish-Kootenai College	marissa_basler@skc.edu
Ashley	Gervais	Salish-Kootenai College	ashley_gervais@skc.edu
Lina	Truong	University of Washington	
Dillon B.	van Rensburg	University of Washington	

Funding Information 5

Funding Sources 5.1

Select all applicable funding sources:

- [x] Funded Research
- [ ] Classroom Research
- [ ] Unfunded
- [ ] Thesis Project
- [ ] Other

Funded Research 5.1.1

Funding Source(s) 5.1.1.1

Provide a list of funding sources. Select the **green (+)** to add rows to the table.

Include the following details:

- Sponsor Agency Name
- Grant ID #
- MSU Fund # (W_____)
- Funding Start Date
- Grant PI (name of person who submitted the grant)

Sponsor Agency Name:	Grant ID#:	MSU Fund #:	Funding Start Date:	Grant PI:
National Institute of Health (NIH)	??	W_____		Alexandra Adams

Classroom Research 5.1.2

Unfunded 5.1.3

Thesis Project 5.1.4

Other 5.1.5

Other Funding Details 5.2

Provide additional information.

Please provide additional information upon first login.

Conflict of Interest 6

Conflict of Interest 6.1

Do the investigator(s) or other researchers (and their family members) involved in research design, conduct, or reporting have an outside interest related to this research?

An "interest" may include:

- *Compensation such as salary, a payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)*
- *Equity interest*
- *Management responsibilities*
- *Board membership*
- *Related non-University intellectual property rights and interests (e.g., patents, copyrights)*
- *Relationships*
- *Foreign influence*
- *(Conflict of) commitment*

☐ Yes
☑ No

Yes 6.1.1
No 6.1.2

Research Activities 7

Summary of Research Activity 7.1

In this section, **do not** refer to an accompanying grant or contract proposal.

Research Conduct Method 7.2

How will the research be conducted with human subject participants? Checkmark all that apply.

☑ In person (face-to-face)
☑ Remotely
☐ Not applicable

In person (face-to-face) 7.2.1

In-Person Research Locations 7.2.1.1

List all locations (on or off campus address) where the research and correlating procedures will be carried out.

As applicable: Cite MSU COVID-19 Guidance in your Research Procedures and Consent Forms.

Community Sites:
Flathead Reservation: Home to the Bitterroot Salish, Pend d'Oreille, and Kootenai Tribes, the Flathead Reservation is in northwestern Montana and includes over 1.2 million acres. The Reservation's population of approximately 26,700 (2018 data) includes roughly 26%, or 7,000 people, who identify as Native.

Yakima Community: The proposed intervention study will take place in the Lower Yakima Valley of Eastern Washington State, where much of the state's Hispanic population is concentrated. The Lower Yakima Valley includes many small agricultural communities, where apples, pears, peaches, cherries, and hops are the primary crops. Many Hispanics work in the agricultural industry. Yakima County, in southcentral Washington State, has a population of approximately 250,000, 45% of whom are of Hispanic or Latino origin.
Lab Testing Site: EverlyWell CLIA-certified lab will conduct all lab-based testing, and all samples have a 24- to 48-hour turnaround time. All home-based samples collected by participants will be returned to this lab for processing via biohazard bag inside a pre-addressed and pre-paid mailer distributed with sampling kits. After testing, samples are disposed of appropriately in accordance with biological specimen disposal standards (incinerated). Everlywell's COVID test is a commercially available product with FDAEUA approval for home-based sampling and kit shipment to commercial CLIA certified labs, with clinician support and reports, as well as connectivity to local public health systems.
Organizational/Administrative Site: The organizational/administrative site will be shared between the Center for American Indian and Rural Health Equity (CAIRHE) at Montana State University, assisted by clinical research coordination at the Institute of Translational Health Sciences (ITHS) at the University of Washington (UW).

Remotely 7.2.2

Remote Research Interaction 7.2.2.1

Select all planned methods of remote interaction with subjects.

- ☐ Web form survey
- ☐ Virtual Platform (e.g. WebEx, Zoom, Google Meet, Microsoft Teams)
- ☐ Email
- ☐ Telephone
- ☑ Mail
- ☐ Other

Web form survey 7.2.2.1.1

Virtual Platform (e.g. WebEx, Zoom, Google Meet, Microsoft Teams) 7.2.2.1.2

Email 7.2.2.1.3

Telephone 7.2.2.1.4

Mail 7.2.2.1.5

Other 7.2.2.1.6

Not applicable 7.2.3

Rationale and Purpose **7.3**

Explain in lay terms the rationale and purpose of the research. What research question is being asked?

Background Information: The COVID-19 pandemic has disproportionately infected people who identify as Native American and Hispanic/Latino,(1, 2) and these groups also have increased risk of poor prognosis due to high rates of chronic disease such as diabetes, cardiovascular disease, and cancer.(3-7) In the northwestern part of the U.S., Native American and Latino communities already face significant disparities in health care access,(8-13) which have been further exacerbated by the COVID-19 pandemic.(6, 7, 14-20) Our combined Montana State University/University of Washington team has established long-term community-based research partnerships for conducting clinical research in rural Latino and tribal communities. Prior to the COVID-19 pandemic, we have had extensive experience in conducting home-based testing for respiratory viruses and have conductedregional qualitative research to understand interest in use of point-of-care testing for respiratory tract infections. As part of the Seattle Flu Study, we evaluated home-based influenza testing, which allowed us to explore the challenges of electronic consent, rapid home delivery of self-testing materials, and instructions in self-testing. Our research indicated strong interest in home-based testing for respiratory viruses and potential impact on health behaviors. In our current work with tribal and rural communities, distance to testing sites, misinformation on SARS-CoV-2, and economic constraints are significant barriers to testing.
Our two long-term partner communities, the Flathead Indian Reservation of the Confederated Salish and Kootenai Tribes in Montana and the Yakima Valley of Washington, are underserved Native American and Latino communities with large populations of agricultural workers. In addition, these communities are uniquely connected across state lines, as migrant farmworkers regularly travel between the two sites to harvest a variety of crops throughout the growing season, increasing the potential for SARS-CoV-2 transmission. The Yakima Valley has been hard hit already by SARS-CoV-2, with the highest positivity rate of the entire state (28.3% positive rate in Yakima vs. 6.7% positive rate in WA state),(20) and the numbers are steadily increasing on the Flathead Reservation. Testing has been hard to access in both regions, and interest in home testing is high.
Study Objectives:
Aim 1: Determine the cultural, social, behavioral, and economic barriers and facilitators to SARSCoV-2 testing among underserved rural Native American and Latino communities in the Northwest, and culturally adapt SARS-CoV-2 home-based testing educational and outreach materials.
Using a combination of key informant interviews (n = 15) and focus groups (n = 3) in each community, we will jointly determine testing barriers and supports to SARS-CoV-2 home-based self-testing, and develop culturally appropriate training materials (including written, graphic, and YouTube videos) describing self-testing in Spanish and English that will be made widely available across the RADx-UP Consortium.
Aim 2: Test the effects of active (assistance from study team) vs. passive (assistance from EverlyWell standard customer service) on the completion rates of home-based self-testing in a pragmatic randomized trial.
Hypothesis: Active methods of community outreach will significantly enhance self-testing completion. Approach: Using an individually randomized trial design in two rural communities (AI and Latino), we will compare the impact, feasibility, and acceptability of each delivery method (n = 100 adults randomized to each study arm per community). The primary outcome measure will be the number of tests completed in each group. Secondary outcomes will include differences in sociodemographic characteristics of completers vs. non-completers in each arm and comparisons of active vs. passive rates across communities.
Aim 3: Evaluate the acceptability and feasibility of SARS-CoV-2 home self-testing and create model community-driven protocols that can be utilized within the RADx-UP Consortium to increase home-testing in Native American and Latino communities nationally. All trial participants will be surveyed on the acceptability and feasibility of home-based self-testing, with additional random phone interviews (n = 10 per arm) at 1 week after kit delivery. We will then finalize our educational materials and create culturally grounded home-testing protocols. Our community-academic team is uniquely positioned to fill evidence gaps in culturally relevant implementation strategies of home-based self-testing and to define optimal outreach strategies for dissemination in similar U.S. rural and tribal communities. In collaboration with the RADx-UP Consortium, this work will enable underserved Native American and Latino communities to take full advantage of the coming wave of rapid point-of-care home tests to decrease the significant impact of the COVID-19 pandemic in their communities.
Rationale: The rationale for the proposed study is that Native American and Hispanic/Latino are critical underserved populations. COVID-19 disproportionately affects people who identify as Native American or Hispanic/Latino, and testing has been hard to access for AIs and Latinos in both Montana and Washington. Home-based testing may be a key advance in SARS-CoV-2 testing, though limited data exists on factors impacting uptake, implementation, utility, acceptability, and follow-up in underserved communities. For rural Native American and Hispanic populations there are additional issues of mistrust; lack of health care providers and insurance; geographic distance between clinics or testing sites and frontline agricultural or tourism work; and crowded multigenerational living conditions that increase risk. Evidence-based, culturally relevant interventions are essential to improving health equity in rural Latino

and Native American populations. The study will harness our unique community and academic collaborations with both Native American and Latino communities in rural Montana and Washington, including the Flathead Indian Reservation. Our central goal will be creating culturally grounded solutions to increase SARS-CoV-2 testing in these communities.

References **7.4**

Optional: List pertinent recent references which support the protocol objectives and procedures. Select the **paper clip** to add links or documents.

Centers for Disease Control and Prevention. Covid-19 Hospitalization and Death by Race/Ethnicity 2020 [Available from: https://www.cdc.gov/coronavirus/2019-ncov/coviddata/ investigations-discovery/hospitalization-death-by-race-ethnicity.html.
Hatcher S, Agnew-Brune C, Anderson M, Zambrano L, Rose C, Jim M, et al. COVID-19 Among American Indian and Alaskan Native Persons- 23 States- January 31-July3, 2020. Centers for Disease Control and Prevention; 2020.

Clerkin KJ, Fried JA, Raikhelkar J, Sayer G, Griffin JM, Masoumi A, et al. COVID-19 and Cardiovascular Disease. Circulation. 2020;141(20):1648-55.

Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area. JAMA. 2020;323(20):2052-9.

Centers for Disease Control and Prevention. Chronic Diseases 2018 [December 21, 2018]. Available from: https://www.cdc.gov/tribal/data-resources/information/chronic-diseases.html.

Calo WA, Murray A, Francis E, Bermudez M, Kraschnewski J. Peer Reviewed: Reaching the Hispanic Community About COVID-19 Through Existing Chronic Disease Prevention Programs. Preventing Chronic Disease. 2020;17.

Artiga S, Orgera K. COVID-19 Presents Significant Risks for American Indian and Alaska Native People. Henry J Kaiser Family Foundation; 2020.

Perez-Escamilla R. Health care access among Latinos: implications for social and health care reforms. Journal of Hispanic Higher Education. 2010;9(1):43-60.

Pérez-Escamilla R, Garcia J, Song D. Health care access among Hispanic immigrants:¿ Alguien está escuchando?[Is anybody listening?]. NAPA bulletin. 2010;34(1):47-67.

Cromer KJ, Wofford L, Wyant DK. Barriers to Healthcare Access Facing American Indian and Alaska Natives in Rural America. Journal of Community Health Nursing. 2019;36(4):165-87.
Call KT, McAlpine DD, Johnson PJ, Beebe TJ, McRae JA, Song Y. Barriers to care among American Indians in public health care programs. Medical care. 2006:595-600.

Montana Department of Health and Human Services. Montana State Health Assessment. 2018.

Yen W, Mounts T. Washington State's Uninsured Rate Increased Significantly in 2018 for the First Time Since 2014. Washington State Office of Financial Management; 2019.

Tai DBG, Shah A, Doubeni CA, Sia IG, Wieland ML. The Disproportionate Impact of COVID-19 on Racial and Ethnic Minorities in the United States. Clinical Infectious Diseases. 2020.

United States Census Bureau. Quick Facts Montana 2019 [Available from: https://www.census.gov/quickfacts/MT.
Montana Department of Public Health and Human Services. Coronavirus Disease 2019 (COVID-19) 2020 [Available from: https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt/demographics.

Washington State Department of Health. COVID-19 Morbidity and Mortality by Race, Ethnicity and Language in Washington State. 2020.
United State Census Bureau. Quick Facts Washington 2019 [Available from: https://www.census.gov/quickfacts/WA.

The New York Times. Montana Coronavirus Map and Case Count 2020 [Available from: https://www.nytimes.com/interactive/2020/us/montana-coronavirus-cases.html.

Washington State Department of Health. Covid-19 Data Dashboard 2020 2020 [Available from: https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard.

Research Procedures **7.5**

Describe research procedures and include:

- Sequence and methods of procedures that will be performed with human subjects
- Details of painful or uncomfortable procedures
- Frequency of procedures
- Duration
- Names of psychological tests
- Restrictions on usual life patterns
- Follow-up procedures

Select the **picture icon** to attach photos or pictorial diagrams as needed.

Below are the research procedures involved for each specific aim of this project.
Aim 1. Determine the cultural, social, behavioral, and economic barriers and facilitators to SARS CoV-2 testing among underserved rural Native American and Hispanic communities in the Northwest, and culturally adapt SARS CoV-2 home-based testing educational and outreach materials.
Demographic survey: A brief demographic survey will be proctored on the phone upon receiving informed consent from key informant interview and focus group participants (see key informant and focus group recruitment/enrollment script, attached).
Interviews with Key Informants: Interviews will be held with 30 key informants in each community (15 interviews on the Flathead Reservation and 15 interviews in Yakima) including with clinic and public health officials, tribal council members, local incident commanders, and other community leaders (e.g., elders) to understand barriers and opportunities for SARS CoV-2 home-based testing (See key informant interview guide, attached). Purposive sampling will be used to identify informants including members of our existing community advisory boards in each community.
Focus Groups with Community Members: We will convene six focus groups with 10 community members each (3 focus groups in each community) via a HIPAA-approved video conferencing platform with community members to document knowledge, beliefs, and practices with regards to COVID-19 / SARS CoV-2. Specifically, the interviews will focus on: (1) knowledge of COVID-19, transmission, severity, and preventive measures; (2) beliefs about COVID-19 / SARS CoV-2 testing (including barriers and opportunities); and (3) socio-cultural factors that affect decisions to participate in testing. Drs. Linda Ko, Alexandra Adams, and Matthew Thompson will develop the focus group moderator guide. (See focus group interview guide, attached). We will use purposive sampling to recruit 10 community members per focus group, aiming for up to 3 migrants and farmworkers per group to gather their perspectives. Potential participants will be contacted by the community health workers through flyers, outreach phone calls, or face-to-face.
Prior Informed Consent: We will obtain informed consent from each participant using the attached consent forms for the interviews and focus groups.
Incentives: Informants who will be surveyed and informants who participate in the focus groups will receive an incentive of $25.
Aim 2. Test the effects of active (assistance from study team) vs. passive (assistance from EverlyWell standard customer service) delivery on the completion rates of home-based SARS CoV-2 self-testing in a pragmatic randomized trial.
Randomized Trial on SARS CoV-2 Home-Based Self-Testing: Working with the Yakima and Flathead community teams, we will implement a two-arm pragmatic randomized trial with 200 adult community members in each of the two communities (n = 400 total) to evaluate the effectiveness of active (assistance from the study team with online registration, self-testing, and accessing test results) vs. passive (participants directed to EverlyWell’s standard customer service team for assistance with all aspects of testing except shipping) delivery on the completion rates of home-based SARS CoV-2 self-sampling via anterior nasal swab. Participants will each receive an EverlyWell testing kit containing a nasal swab, home sample collection instructions, follow-up resources and a pre-paid, pre-addressed return-mailing envelope, and be asked to submit one anterior nasal sample to EverlyWell’s testing lab for analysis. We will recruit participants between March–July 2021 and implement the randomized trial between March–September 2021. Our hypothesis is that underserved communities will have increased testing rates when testing is made available with active assistance provided via trusted lay community health workers vs. a passively received or picked-up home-testing kit. The trial will enable us to determine best practices for home-based testing in the Native American and Latino communities, as well as create community-driven protocols for future testing and vaccine delivery strategies.
Recruitment: 200 adult community members will be recruited in each of the two communities (n = 400 total) Recruitment will be done by the local community coordinator using word of mouth, community flyers, and Facebook/social media postings (see recruitment script, attached).
Informed Consent: We will obtain informed consent from each participant using the attached consent form. The study coordinator at each site will introduce the study via phone to each participant and email them the attached consent form. The participant will complete the consent form by verbal consent, or sign electronically. Many participants are low literacy or have little computer access. The study coordinator will speak English or Spanish to the participants depending on their preference. The consent form will be available in both Spanish and English.
Incentives: Participants will each receive one home-based COVID-19 testing kit free of charge and a monetary incentive upon completion of a telephone survey on participant demographics and beliefs.
Pre-Trial Survey: After obtaining informed consent, the research assistants will ask several demographic, social, and health questions related to age, birthdate, income, employment history, living conditions, prior SARS COV-2 testing, medical conditions, and current symptoms. The research coordinators will also obtain a phone number, address, and other relevant contact information from each participant. The information will be recorded and entered into REDCap, a secure online database platform designed for research trials. Once eligibility screening and informed consent have been completed,

participants will be randomized by age to active vs. passive assistance with home-based SARSCoV-2 testing kits (see demographic questionnaires, attached).
Self-Collection of Biological Sample for SARS COV-2 Testing: The proposed research project involves the collection of biological samples from each participant. Active participants will receive assistance creating an EverlyWell account and registering their EverlyWell testing kit. Active participants will also have the option of receiving assistance from the study team to complete their self-sample using a nasal swab. Passive participants will not receive assistance with the creation of their EverlyWell online account and will not receive additional support beyond what is provided by EverlyWell. Both active and passive group participants will receive the same options for delivery and pick-up of the testing kits. All participants will receive identical study materials from Everlywell including an overview video and paper-based instructions for home testing, sample mail back, and information about how to interpret their test result in either Spanish or English. Participants in the Active and Passive study arms will receive differing supplemental printed materials, directing them to contact either the study team (active arm) or Everlywell (passive arm) for additional support.
Processing of Samples for SARS COV-2: Samples will be shipped to an EverlyWell affiliated CLIAcertified lab for testing using a biohazard bag and pre-paid, pre-addressed mailer. Participants will be provided with an alcohol prep pad to disinfect the mailer before shipping. Samples must be shipped within 24 hours of collection to ensure they are within the stability window when they arrive at the lab. Site staff will calculate distance in miles from each participant's home address to nearest shipping location, as this may be a factor influencing test completion rates. Results will be available on EverlyWell's online results portal for participants and designated study team members to view within 24-48 hours of samples arriving at the lab.
Returning Results to Participants: All participants, regardless of study arm, will receive a notification from EverlyWell, directing them to access their Everlywell account to view their test results. Those who test positive for COVID-19 will also receive a phone call from an EverlyWell-contracted clinician. Everlywell's contracted clinicians will report positive test results to appropriate public health authorities, per local public health reporting regulations. Site staff will contact participants in both study arms to confirm they have received their test results and will provide guidance to obtain results from the participant's Everlywell account, If necessary. Site staff will be trained to provide test results in the event a participant is not able to access their results from Everlywell account. Participants will be referred to local healthcare resources in the event of distress or other hams which may arise from positive test results or study participation (see return of results script, attached). Project staff may help implement a safety plan to ensure that participants are adequately supported.
Aim 3. Evaluate the acceptability and feasibility of SARS CoV-2 home self-testing and create community-driven protocols to increase self-testing in Native American and Hispanic communities nationally.
Post-Trial Surveys: We will conduct a post-trial participant feedback survey to understand barriers and opportunities for SARS CoV-2 home-testing towards creating culturally grounded home-testing protocols. All trial participants (n = 200/community), will be asked to participate in a post-trial survey regardless of test completion, one week after test kits were received to ask opinions on testing barriers and supports, interest and barriers to self-testing before and after the study, usefulness of training materials, and active or passive distribution mechanisms. The survey will be brief (estimated completion time = 10 minutes) and will contain a mix of multiple choice and open-ended questions, developed based on the themes identified in key informant interview and focus group responses. Surveys will be available in both Spanish and English and administered by phone (see post-testing feedback survey, attached). A more in-depth random follow-up phone survey (n = 10 participants within each arm at each site) will be administered at the end of the trial, enabling us to follow up with completers and non-completers of home testing. Participants will receive a $25 gift card upon completion of the more in-depth phone survey. Working with our Community Advisory Board (CAB)/study teams, we will utilize study and survey results to refine testing educational materials and create culturally grounded home-testing protocols.

Questionnaires and Measures **7.6**

Attachments: Everlywell Test Results.pdf,Eligibility Screener.pdf,Aim 1 Focus Group Demographic Survey.pdf,Aim 1 Key Informant Demographic Survey.pdf,COVID 19 Survey.pdf,Demographic Questionnaire Part 1 and 2.pdf,Aim 3 Post-Testing Feedback Survey.pdf,Post-Testing Feedback Survey.pdf

Select the **paper clip** to attach or link all questionnaires, eligibility screeners, survey instruments, interviews, measures, and scales that will be used under this proposal - OR - include below. Select the **picture icon** to attach photos or pictorial diagrams as needed.

Additional Materials **7.7**

Attachments: In-Depth Aim 3 Interview Guide.pdf,Return of Results by Site Staff Phone Script and Mailed Letter Template.pdf,Material Provided.pdf,Welcome Box Page.pdf,Script for Clinical Trial Welcome Video.pdf,Welcome Email communication with Participants 7/13/21,English- Interview Guide.pdf,Focus Group Moderator and Key Informant Inverview Guide.pdf,Focus Group Moderator Guide,In-depth Aim 2 Interview Guide.pdf,Aim 2 Clinical Trial Test Kit Replacement Call Script

Describe, attach, or link to any additional materials to be utilized in the study.

Subjects 8

Target Subject Populations 8.1

My research will target or specifically involve the following subject populations: (Select all that apply)

- ☐ This research does not require a specific population.
- ☐ Minors
- ☐ Gender Specific
- ☐ Pregnant Women
- ☐ Prisoners
- ☑ Ethnic Minority
- ☐ Non-English Speaking
- ☑ American Indian or Alaskan Native Tribe
- ☐ College Students
- ☐ Military Veterans or Active Service Members
- ☐ Members of a particular religious group or sect
- ☐ Crime or Trauma Victims
- ☐ Substance Abusers
- ☐ Terminally Ill
- ☐ Decisionally Impaired
- ☐ Other population not listed

This research does not require a specific population.	8.1.1
Minors	8.1.2
Gender Specific	8.1.3
Pregnant Women	8.1.4
Prisoners	8.1.5
Ethnic Minority	8.1.6
Non-English Speaking	8.1.7
American Indian or Alaskan Native Tribe	8.1.8
College Students	8.1.9
Military Veterans or Active Service Members	8.1.10
Members of a particular religious group or sect	8.1.11
Crime or Trauma Victims	8.1.12
Substance Abusers	8.1.13
Terminally Ill	8.1.14
Decisionally Impaired	8.1.15
Other population not listed	8.1.16

Research Subjects 8.2

Fill out the Research Subjects table below. Select the **green (+)**to add rows to the table.

- (Optional) Subject Group Name
- Approximate Total Number of Subjects
- Age Range of Subjects
- (Optional) Additional Comments

(Optional) Subject Group Name:	Approximate Total Number of Subjects:	Age Range of Subjects:	Comments:
Key Informants for Interviews	30	18 or older	
Focus Groups	60	18 or older	
Post-Trial In-Depth Phone Survey	40	18 or older	
For Trial	400	18 or older	

Normal/Control Subjects 8.3

If you are using Normal/Control subjects in your study, fill out the table below. Select the **green (+)**to add rows to the table.

- (Optional) Normal/Control Subject Group Name
- Approximate Total Number of Subjects
- Age Range of Subjects

- (Optional) Additional Comments

(Optional) Normal/Control Subject Group Name:	Approximate Total Number of Subjects:	Age Range of Subjects:	Comments:

Selection Criteria **8.4**

Explain the criteria for subject selection. How will subjects be identified?

If applicable, address equitability in the inclusion of subjects or alternatives available to those not selected.

Inclusion criteria for the clinical trial of the active vs. passive self-testing for COVID-19 intervention include: 1) being a Native American (including close family members e.g., non-Native) living on the Flathead Reservation in Montana or individuals who are Hispanic/Latino and living in Eastern Washington sate of Yakima Valley; 2) aged 18 or older. Subjects for key informants for interviews and focus groups will be community members identified through purposive sampling that are 18 or older.

Exclusion Criteria **8.5**

Explain the criteria for subject exclusion.

1) severe current symptoms of respiratory tract infection consistent with COVID-19, such as shortness of breath or high fever

Source of Subjects **8.6**

What is the source of research subjects (including patients)?

Flathead Reservation in Montana and Yakama Valley region of Washington

Recruitment Methods **8.7**

How will you advertise for and recruit subjects? Select all that apply.

- [x] Poster or Flyer
- [ ] In-Class Instructional Document
- [x] Email
- [ ] Website
- [x] Social Media (Facebook, Instagram, etc.)
- [ ] Subject or Recruitment Pool
- [ ] Person-to-person solicitation or word of mouth
- [x] Phone
- [ ] Postal Mail
- [x] Media (TV, newspaper, radio)
- [x] Other

Poster or Flyer	**8.7.1**
In-Class Instructional Document	**8.7.2**
Email	**8.7.3**
Website	**8.7.4**
Social Media (Facebook, Instagram, etc.)	**8.7.5**
Subject or Recruitment Pool	**8.7.6**
Person-to-person solicitation or word of mouth	**8.7.7**
Phone	**8.7.8**
Postal Mail	**8.7.9**
Media (TV, newspaper, radio)	**8.7.10**
Other	**8.7.11**

Other Recruitment Method **8.7.11.1**

Describe.
Text messaging

Recruitment Procedure **8.8**

Describe the procedures for approaching and recruiting subjects, and explain how coercion will be avoided.
Announcements and recruitment materials will specify these inclusion criteria and will list the telephone number and email address of the local Flathead Reservation and Yakima Valley project managers, Virgil Dupuis, and Wendy Westbroek, respectively, with instructions provided to contact them if interested in learning more about or enrolling in the study. Once contacted by prospective participants, the project managers and their teams, including research coordinators, will screen the participants to confirm that they meet the study eligibility criteria. After prospective participants provide verbal assent for the eligibility screening, those who are ineligible will be thanked for their interest in the study and their contact information will be destroyed by the project manager.
For eligible participants who confirm that they wish to be enrolled in the clinical trial, the study research coordinators will discuss the study and obtain informed consent. Study coordinators will provide prospective participants with an explanation of the purpose, goals, and procedures for the clinical trial and the purpose, goals, and procedures for the active vs. passive testing intervention, highlighting anticipated risks and benefits to participants. The study coordinators will answer any questions that arise. Following this thorough informed consent discussion, the study coordinators will obtain verbal or electronic informed consent from each participant using consent forms approved by the University of Washington, Salish Kootenai College, and Montana State University Institutional Review Boards.
Consent forms will be written in plain language to facilitate comprehension of study requirements. Forms will be offered in both Spanish and English. The informed consent process will involve an in-depth conversation about the study procedures in which the site project managers will verify that the participant understands the scope, goals, and procedures of the study. No one will be coerced or pressured to complete the proposed study, and if any member of the research team suspects that a participant does not fully comprehend what participating in the project entails, steps will be taken to further explain the study until the participant demonstrates understanding by explaining in their own words what they are being asked to do in the study.

Recruitment Materials **8.9**

Attachments: Aim 1 Focus Group Recruitment Script,Aim 2 Clinical Trial Recruitment Call Script 6/21/21,Testing Poster 10.06.2021,Aim 1 Focus Group Twitter and Text Recruitment Text,Radio, TV and Print Recruitment Flyer- FOCUS GROUP,Aim 1 Key Informant Recruitment Call Script,Facebook Recruitment Script,Aim 1 Key Informant Recruitment Email,Aim 2 Clinical Trial Recruitment Email 7/13/21

Select the **paper clip** to attach or link to all recruitment materials or paste text below.

See Subject Recruitment best practices.
Attached

Deception Required **8.10**

Is deception (withholding of complete information from research participants) a required element of the research?

- ☐ Yes
- ☑ No

Yes **8.10.1**

No **8.10.2**

Compensation **9**

Compensation **9.1**

Will subjects receive payments, service without charge, or extra course credit?

- ☑ Yes
- ☐ No

Yes **9.1.1**

Compensation Type **9.1.1.1**

Choose all that are applicable.

- ☑ Monetary (US dollars or other currency)
- ☐ Non-Monetary Equivalency
- ☐ Services
- ☐ Gift Cards
- ☐ Course Credits
- ☐ Other

Monetary (US dollars or other currency) **9.1.1.1.1**

Monetary Compensation **9.1.1.1.1.1**

How much money will be offered? How will payments be made?

Participants will receive home-based COVID-19 testing kits free of charge and a $50 incentive for completing an initial brief survey on participant demographics, and the post-kit survey. Randomly selected participants will have an opportunity to receive a $25 gift card upon completion of a longer post-intervention interview on perceived barriers and supports to home-based testing.

Non-Monetary Equivalency **9.1.1.1.2**

Services **9.1.1.1.3**

Gift Cards **9.1.1.1.4**

Course Credits **9.1.1.1.5**

Other **9.1.1.1.6**

No **9.1.2**

Risks, Benefits, and Adverse Effects **10**

Risk Details 10.1

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

Risks to participants (for Aims 1 and 3) mainly involve the privacy of their personal data from surveys or interviews and the potential violation of confidentiality resulting from others in the focus group sessions sharing personal information with people outside of the group. These risks will be minimized by ensuring that electronic data are properly stored on secure, password protected, and encrypted servers and that hardcopies of data are stored in securely locked drawers only accessible by approved study team members. Also, all video or audio tapes will be kept within each community. Survey data will be deidentified and kept within the REDCap system.
During the clinical trial (Aim 2), answering demographic and health-related questions will present minimal risk to consenting participants. Other possible risks include becoming distressed from the notification of a positive COVID-19 test result. Everlywell has a commercial system that has been FDA-EUA approved for home-based sampling and email/web results reporting with telephone follow-up for positive cases, as well as direct connectivity to public health in each region for follow-up. To ensure that all of our participants have received their results, our local site coordinators will contact each participant and ensure they have accessed their results. Dr. Allison Lambert, assistant professor of medicine at the University of Washington and critical care physician will follow up with participants, as necessary to concerns or issues that cannot be resolved by the local coordinator, and ensure clinical follow-up if necessary. If necessary, project staff will implement a safety plan to ensure that the participants are adequately supported in cases of extreme distress.

Restriction of Standard Procedures 10.2

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

- ☐ Yes
- ☑ No

Yes 10.2.1

No 10.2.2

Benefits 10.3

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

DO NOT LIST COMPENSATION AS A BENEFIT.

**Very few studies have direct or immediate benefit to participants other than services that they otherwise would not receive. It is acceptable to state that there are no direct benefits.*

The goal of this project is to determine the cultural, social, behavioral and economic barriers to homebased SARS-CoV-2 testing, enhance home test kit educational materials, conduct a pragmatic randomized trial of active (tailored assistance from a community worker) vs. passive (delivery without assistance) of home-based testing kits, and create community-driven protocols and materials that can be used to increase testing among Native American and Hispanic communities nationally. While no direct benefit of participation in the study can be promised, we anticipate that participating will be helpful in increasing access to healthcare resources and reducing the burden of disease in these communities. Individual benefits are knowing SARS CoV-2 status at the time of testing, which if positive can reduce individual spread to family and community. Education and experience with home-based testing may be valuable to participants and communities in the future as it becomes more commercially available.

Adverse Effects 10.4

How will possible adverse effects be handled? Select all that apply.

- ☑ By the PI (and/or Co-Investigators)
- ☑ Referred by PI and/or Co-Investigators to appropriate care
- ☑ Other

By the PI (and/or Co-Investigators) **10.4.1**

Managing Adverse Effects: PI/Co-Investigators **10.4.1.1**

Describe (how, where).

Dr. Lambert is an expert in COVID as she helps run the COVID ward at Providence Hospital and will provide oversight of the testing.

Referred by PI and/or Co-Investigators to appropriate care **10.4.2**

Managing Adverse Effects: Referrals **10.4.2.1**

Describe referrals to appropriate care (how, where, to whom).

Dr. Lambert and the study nurse will refer individuals testing positive to appropriate follow-up care as necessary.

Other **10.4.3**

Managing Adverse Effects: Other **10.4.3.1**

Describe (how, where).

All research team members will be trained in techniques to help resolve participant distress in the unlikely occurrence of an adverse event (AE). Project staff will refer participants to appropriate services and resources in the community when needed. The local project manager will be available to assist participants in contacting services and resources if needed.

Adequate Facilities/Equipment **10.5**

Are facilities/equipment adequate to handle possible adverse effects?

- [x] Yes
- [ ] No

Yes **10.5.1**

Describe Adequacy of Facilities **10.5.1.1**

Optional: Provide details.

No **10.5.2**

Financial Responsibility **10.6**

Describe the arrangements for financial responsibility for any possible adverse effects. Select all that apply.

- [x] Subject is responsible.
- [ ] MSU is responsible.
- [ ] Sponsoring agency is responsible.
- [ ] Other

Subject is responsible. **10.6.1**

Subject Responsibility **10.6.1.1**

Optional: Provide subject responsibility details.

MSU is responsible. **10.6.2**

Sponsoring agency is responsible. **10.6.3**

Other **10.6.4**

Data Confidentiality 11

Data Confidentiality/Management Plan 11.1

Attachments: Data Confidentiality Plan.docx

Fill out a Data Confidentiality Plan (template link below) and attach using the **paperclip**. Alternately, attach an existing Data Management Plan or enter in text box below.

***PI, please answer upon first activity.

Personal Identifiable Information (PII) 11.2

Are you collecting, accessing, or creating Personal Identifiable Information (PII) under this study?

PII is defined as:

Any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means. Further, PII is defined as ***information (i) that directly identifies an individual*** *(e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or (ii) by which an agency intends to identify specific individuals in conjunction with other data elements, i.e., indirect identification. These data elements may include a combination of gender, race, birth date, geographic indicator, and other descriptors. Digital files such as photographs, videos, or audio recordings that reveal an individual's identity are considered PII. Additionally, information permitting the physical or online contacting of a specific individual is the same as PII.*

- [x] Yes
- [ ] No

Yes 11.2.1

Encoded Data 11.2.1.1

Will data be coded?

- [x] Yes
- [ ] No

Yes 11.2.1.1.1

Master Code 11.2.1.1.1

Will the master code be kept separate from identifiable data?

- [x] Yes
- [ ] No

Yes 11.2.1.1.1.1.1

No 11.2.1.1.1.1.2

No 11.2.1.1.2

No 11.2.2

Protected Health information (PHI) **11.3**

Are you collecting or accessing Protected Health Information (PHI) under this study?

PHI is defined as:

- Information that is a subset of health information, including demographic information, collected from an individual, relates to the past, present, or future physical or mental health or condition of an individual;

  AND

- Either (i) identifies the individual (see PHI identifiers below); or (ii) where there is a reasonable basis to believe the information can be used to identify the individual.

  AND

- Used within or disclosed from a covered entity: 1) health plans; 2) health care providers that conduct certain financial and administrative transactions electronically (i.e., billing, funds transfer); and 3) health care clearinghouses, which process or facilitate the processing of health information in a non-standard format to standard format or vice versa. *Most healthcare and mental healthcare providers, hospitals, insurance companies, and clinics are considered covered entities under HIPAA.*

PHI Identifiers:

1. **Names** (individual, employer, relatives, etc.)
2. **Address** (street, city, county, precinct, zip code − initial 3 digits if geographic unit contains >20,000 people, or any other geographical codes)
3. **Telephone number**
4. **Fax number**
5. **Social Security numbers**
6. **Medical record numbers**
7. **Dates** (except for years) connected to subjects, including date(s) of birth, admission, discharge, death, ages >89, and all elements of dates indicative of such age (except that such age and elements may be aggregated as "Age <90")
8. **E-mail addresses**
9. **Health Plan Beneficiary numbers**
10. **Account numbers**
11. **Certificate/license numbers**
12. **Vehicle Identifiers** and **Serial numbers** (e.g., VINs, License Plate #, etc.)
13. **Device Identifiers** and **Serial Numbers**
14. **Universal Resource Locator** (URLs)
15. **Internet Protocol (IP) address numbers**

16. **Biometric Identifiers** (e.g., finger or voice prints)
17. **Full face photographic images** (and any comparable images)
18. Any other unique identifying number, characteristic, or code

- ☐ Yes
- ☑ No

Yes	11.3.1
No	11.3.2

External Access to Data 11.4

Will any other group, agency, or organization have access to any MSU data?

- ☐ Yes
- ☑ No

Yes	11.4.1
No	11.4.2

Document and Data Storage 11.5

How will data be stored and protected? Checkmark all that apply.

- ☑ Documents and supporting material physically locked
- ☑ Electronic files stored on secure/password-protected hardware (e.g., PC, Local Access Network Drive, external hard drive, USB, etc.)
- ☐ Electronic files stored on secure/password-protected software (e.g., Qualtrics, REDCap, OneDrive, cloud based storage, etc.)
- ☐ Other

Documents and supporting material physically locked	11.5.1
Electronic files stored on secure/password-protected hardware (e.g., PC, Local Access Network Drive, external hard drive, USB, etc.)	11.5.2
Electronic files stored on secure/password-protected software (e.g., Qualtrics, REDCap, OneDrive, cloud based storage, etc.)	11.5.3
Other	11.5.4

Student Education Records 11.6

Do you plan to use student education records?

34 CFR 99: The term "education records" is defined as *records that contain information directly related to a student and which are maintained by an educational agency or institution or by a party acting for the agency or institution.*

- ☐ Yes
- ☑ No

Yes	11.6.1
No	11.6.2

Additional Protocol Details 12

Reliance on MSU IRB **12.1**

Do you wish for MSU to serve as the IRB of record/single IRB for one or more external entities to follow this protocol? Will this project involve joint IRB review?

Reliance on MSU IRB can be achieved via SMART IRB or Institutional Authorization Agreement (IAA).

See MSU Reliance Agreements for more information.

- [x] Yes
- [ ] No

Yes **12.1.1**

Reliance Agreement **12.1.1.1**

Attachments: Reliance Structure Clarification 5.3.21.pdf,SmartIRB #4893.pdf

After protocol approval, the IRB Administrator will add your IAA or Smart IRB Reference number here.

University of Washington and Fred Hutch rely on MSU via SmartIRB #4893

No **12.1.2**

Other Entity Involvement **12.2**

Will any other group, agency, organization, or tribal partner be involved in the research (e.g., supplying data or subjects, sharing in design, conduct, research, or reporting)? "Other" may include external entities or MSU internal entities outside of your immediate research group.

- [x] Yes
- [ ] No

Yes **12.2.1**

Permissions from Other Entities **12.2.1.1**

Attachments: SKC Tribal IRB # 2021_4_Adams Amendment Approval 10.01.2021,SKC Amendment Approval 04.06.2021.pdf

Provide written letter of cooperation (MOU, letter, email, etc.) from the group, agency, organization, or tribal partner providing permission or demonstrating willingness to participate in the research. Select the **paper clip** to attach this documentation.

Salish Kootenai College Tribal IRB Approvals attached

No **12.2.2**

Related Research **12.3**

Does this research relate to any other submitted or approved research requests involving any of the following?

- Other IRB/human subjects protocols
- Other compliance areas: IBC, IACUC, RSC, LSC
- Potential biosafety risks, radiation, x-ray equipment, lasers, or the use of animals

☐ Yes

☑ No

Yes **12.3.1**

No **12.3.2**

Clinical Trial **12.4**

Is this study considered a clinical trial?

See Clinical Trials for guidance.

☑ Yes

Personnel must take a relevant Good Clinical Practices training course in CITI and may also need to register the trial federally or convene a DSMB depending on funding requirements.

☐ No

Yes **12.4.1**

No **12.4.2**

Human Biospecimens **12.5**

Will this research involve the use of human biospecimens?

Biospecimens include, but are not limited to:

- Blood and other bodily fluids (including saliva)
- Cells or tissues from any part of the human body
- Molecules derived from tissues (DNA, RNA, proteins, etc.)
- Gametes (ova and sperm)
- Stem cells
- Bodily products such as teeth, hair, urine, feces

☑ Yes

☐ No

Yes **12.5.1**

Biospecimen Collection and Transfer 12.5.1.1

Will you be collecting, receiving, storing, transporting, or shipping biospecimens?

- [x] Yes
- [ ] No

Yes 12.5.1.1.1

MSU Collection of Human Biological Specimens Policy 12.5.1.1.1.1

If the research team is only collecting, receiving, storing, transporting, or shipping specimens, an IBC protocol is not required. However, all project personnel must complete OSHA Bloodborne Pathogens training (regardless of who will be conducting the specimen activities.) Training may be completed via CITI online training or in-person training provided by the Biosafety Officer. See the MSU Collection of Human Biological Specimens Policy for more information.

Contact MSU Occupational Health for information on required Hepatitis vaccinations, titration, safety issues, accident reporting, and research injuries (needle stick, exposure to bodily fluids, etc.).

Sharing of biospecimens should take place under an appropriate agreement. See the MSU Agreements with Industry Grid for guidance.

Future Use of Biospecimens 12.5.1.1.1.2

Do you plan to keep unused material or extra material for future research?

- [ ] Yes
- [x] No, all biospecimens will be consumed or destroyed at the end of the study.

Yes 12.5.1.1.1.2.1

No, all biospecimens will be consumed or destroyed at the end of the study. 12.5.1.1.1.2.2

Biospecimen Source **12.5.1.1.1.3**

Do the materials come from any of the following sources?

- Minors
- Prisoners
- Pregnant women
- American Indian or Alaskan Native peoples
- Vulnerable population
- Other patient population that for religious or other reasons would prohibit its use in biomedical research

- [x] Yes
- [ ] No
- [ ] Unknown (no identifiers or impossible to know source type)
- [ ] Other/Explain

Yes	**12.5.1.1.1.3.1**
No	**12.5.1.1.1.3.2**
Unknown (no identifiers or impossible to know source type)	**12.5.1.1.1.3.3**
Other/Explain	**12.5.1.1.1.3.4**
No	**12.5.1.1.2**

Biospecimen Analysis **12.5.1.2**

Will you be handling, manipulating, or performing analysis on biospecimens in any MSU laboratory?

- [ ] Yes
- [x] No

Yes	**12.5.1.2.1**
No	**12.5.1.2.2**

Biospecimen Link to Subjects **12.5.1.3**

Are these materials linked in any way to the subject after collection (by code, identifier, or other link to subject identity)?

- [x] Yes
- [ ] No

Yes	**12.5.1.3.1**
No	**12.5.1.3.2**

Use of Blood 12.5.1.4

Will human blood be utilized in this work?

- ☐ Yes
- ☑ No

Yes 12.5.1.4.1

No 12.5.1.4.2

No 12.5.2

Drugs, Substances, or Devices 12.6

Will drugs, substances, or devices be used in the research?

- ☐ Yes
- ☑ No

Yes 12.6.1

No 12.6.2

Consent Forms 13

Multimedia Records 13.1

Will audio, audio-visual, recordings, images, graphics, photographs, or other multimedia records of the subject be used or created?

- ☑ Yes
- ☐ No

Yes 13.1.1

Multimedia Authorization 13.1.1.1

Be sure to include multimedia details in your Consent Form and include language that seeks specific permission for use of personal multimedia in research data or results.

See media/photo/recording release for guidance.

No 13.1.2

Informed Consent 13.2

Will informed consent be obtained?

Informed Consent may be written (tangible medium, e.g., paper form or electronic format) or oral and serves to obtain the legally effective permission of the subject.

- ☑ Yes
- ☐ No

Yes 13.2.1

Documentation of Consent 13.2.1.1

Will Consent be documented in writing and/or electronically?

- ☐ Yes
- ☑ No, oral consent only or no documentation

Yes	13.2.1.1.1
No, oral consent only or no documentation	13.2.1.1.2

Request Waiver of Documentation of Consent 13.2.1.1.2.1

A Waiver of Documentation of Consent must be approved by the IRB. One of the following criteria must be met:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Provide justification for one of the above reasons to request this waiver.

*Provide info on verbal consent scenarios.

Alteration of Consent 13.2.1.2

Do you plan to alter or omit elements of a standard informed consent? See all required elements of informed consent.

An Alteration of Consent must be approved by the IRB.

- ☐ Yes
- ☑ No

Yes	13.2.1.2.1
No	13.2.1.2.2

Consent/Assent Forms 13.2.1.3

Attachments: 5) Yakima- Aim 1 Key Informant Interview Consent Approved 03.22.2021,3) Flathead- Aim 1 Key Informant Interview Consent Approved 03.22.2021,4) Yakima- Aim 1 Focus Group Consent Approved 03.22.2021,2) Flathead- Aim 1 Focus Group Consent Approved 03.22.2021,1) Flathead Aims 1 & 2 Swab Samples Consent Form Approved 10.6.2021,6) Yakima- Aim 2 and Aim 3 Consent Approved 03.22.2021

Enter Consent/Assent Form(s) text below - AND - use the **paper clip** to attach all clean Consent/Assent forms with your preferred formatting (content must match text provided below). You will be provided with the IRB-stamped document(s) upon protocol approval.

Tips:

- Utilize an accepted Montana State University Consent Form template and include the required elements of consent.
- Within your Consent Form, be sure to state that ***participation is voluntary, and the participant may stop at any time.***
- Ensure that all information in the Consent Form corresponds with the Research Procedures and includes relevant subject information as previously described in this application.

1) Flathead Aims 1 & 2 Swab Samples Consent Form APPROVED MSU 10/06/2021
IRB #AA121820
Informed Consent Form:
Protecting Our Community: A Pragmatic Randomized Trial of Home-Based COVID Testing with Native American and Latino Communities
You are being asked to take part in a research study. This consent form will give you information about the study to help you decide whether to be in the study or not. You will be given a copy of this form for your records. This form has information, including important names and telephone numbers, which you may wish to refer in the future.
PURPOSE OF THE STUDY
The goal of this study is to examine what strategies are needed to support individuals to complete a home-based testing for COVID-19. Participation will involve you taking a self-nasal swab sample from inside your nose and sending it back to a lab for analysis of COVID-19.
Why am I being asked?
You have been asked to participate in this research because you:
1) Are part of the Native community on the Flathead Reservation in Montana.
2) Are 18 years of age or older
3) Haven't experienced any of the following symptoms within the past week: fever over 102F or a high fever lasting more than 48 hours, inability to speak in full sentences or do simple activities without shortness of breath, severe coughing spells or coughing up blood, blue face or lips, severe and constant pain or pressure in your chest, extreme lethargy, dizziness, lightheadedness or being too weak to stand, slurred speech or seizures, or being hospitalized and due to being too sick and unable to stay at home.
4) Have no other household members participating in any activities related to Protecting Our Communities. (Household members are defined as individuals who live under the same roof or share same housing unit).
Taking part in this study is voluntary. You can stop at any time. You may refuse to participate, and you are free to leave the study at any time.
What procedures are involved? The study procedures include the completion of a brief demographic survey, home-based testing including taking a nasopharyngeal sample (nasal swab), and post-testing feedback survey. A small subset of participants will also be invited to complete a post-testing follow-up interview.
For the survey, we will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.
For the home-based testing, you will receive a testing kit, which will include a nasal swab, home-based testing instructions, follow-up resources and a pre-paid, pre-addressed return-mailing envelope. Participants will be asked to send their completed nasal swab samples to a commercial company (Everlywell) testing laboratory for analysis.
When you get the testing kit (within 1-2 days), you will follow instructions and take a swab sample from inside your nose. The nasal swab is collected by gently putting a swab (like a Q-tip) about ½ inch inside your nose and gently turning it around.
You will be asked to provide a valid email address to create a free user account with Everlywell in order to receive results to your home-based self-sample. You will also be asked to complete a short follow-up survey 1-week after receiving the home-based testing kits. Surveys will be brief (estimated completion time = 10-15 minutes) and will help us understand your experience with home testing.
At the end of the survey, you will be asked if you would like to participate in a 40 to 60-minute follow-up phone interview. We will randomly select 20 participants among those who answered yes and follow-up with a call.
What are the potential risks and discomforts?
To the best of our knowledge there are no risks associated with the collection of nasopharyngeal samples. Participants may experience mild, brief discomfort while taking a swab test from their nose. Rarely this might cause a small nosebleed.
Are there benefits to participating in the research?
You will receive the results of your test by a trained health professional. Such knowledge and resources may help
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IRB #AA121820
reduce the spread of COVID-19 and overall burden of disease in your family and community.
Are there costs for participating in the research?
There are no costs for participating in this research.

What other options are there?
You have the option to not participate in this study.
Who is paying for this study? The NIH, which stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services.
Will my study-related information be kept confidential?
Your record will be kept confidential. You will not be identified in any report or publication about this study. Identifiable information such as your name, address, email, and phone number will be collected and used to mail you a test kit, contact you with your testing results and send you a survey at 1 week follow-up.
We will assign a study code to you. Your identifiable information and study code will be kept in a secure database where the researchers do not have access. Only the study's physician and your local Community Health Worker will be able to match study codes with identifying information, such as your name, address, and phone number. The nurse will use this information to contact you about your COVID-19 testing results, if you have questions. Participants who test positive will receive a call from an Everlywell physician with their results and have their contact information given to local public health officials for contact tracing and follow-up as per usual clinical protocol. All other researchers will have access to deidentified coded data only.
Your Everlywell account information and test results may be shared with Everlywell affiliated health consultants and labs for the purposes of processing samples, delivering testing results, providing treatment information and conducting research. Everlywell will only have access to your Everlywell account information, nasal sample and COVID-19 testing result. No further information collected in this study will be shared with Everlywell. The information you provide to Everlywell may be stored in a repository and used for validation, educational, and/or research purposes.
Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your responses in the interview may be examined.
All research personnel have taken the required training on research Privacy and Confidentiality. Records on all participants will be kept confidential by maintaining consent forms in a file cabinet in a locked office at MSU.
When this research is discussed or published, no one will know that you were in the study. But, when required by law, identifying information (including your signed consent form) may be seen or copied by Federal regulatory agencies such as the Office of Human Research Protections in the Department of Health and Human Services.
Will I be reimbursed for any expenses or paid for my participation in this research?
You will receive a $35$50 gift card upon completing the post-testing feedback survey. If you are interested in participating in the follow-up phone interview and are among the 20 individuals randomly selected to participate in a longer phone interview, then you will receive an additional $25 gift card as compensation for your time and effort.
Can I withdraw or be removed from the study?
You are free to withdraw your consent and stop your participation at any time during the study.
Will data collected from me be used for any other research?
Our study is funded by NIH under the initiative called RADx-UP. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. The goal of RADx-UP is to understand factors that drive health disparities related to COVID-19 among underserved communities and use the data to reduce the disparities. If you join this study, some information we gather will be shared with RADx-UP the Coordination and Data Collection Center (CDCC). The CDCC's activity includes collecting the similar data from everyone taking part in RADx-UP studies and combining them to understand the problem at the population level.
No identifying information will be shared about you. The CDCC will keep your data securely (which means with extra protection), along with the data from all other people who take part in the RADx-UP studies. It will not contain your name or any other information that could easily identify you. The CDCC will transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form. When using the data from this database, researchers will only have access to your non-identifiable data and cannot link the data back to you. Because the data cannot be linked back to you, the CDCC will not contact you to inform you or ask your permission before sharing the data with researchers.

Who should I contact if I have questions?
If you have any questions or comments about the study, we encourage you to contact the principal investigator, Dr. Alexandra Adams at 406-994-6077 or Alexandra.adams2@montana.edu.
If you have questions about the project locally, contact the Salish Kootenai College Extension site study coordinator

at (406) 209-8201
What are my rights as a research subject?
If you have any questions about your rights as a participant in this study, please contact the Salish Kootenai College Institutional Review Board (406-275-4931 or irb@skc.edu).
I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. If desired, I will be given a copy of this form. Yes No
Reason(s) for opting out of the study (if provided by participant):
_____
You have the option of allowing your contact and survey information to be kept at MSU for future COVID-19 research studies. This information will also be stored at Fred Hutch (for Yakima Valley participants) and at Salish-Kootenai College (for Flathead participants). Your information will remain in a locked cabinet at all times. Otherwise, this information will not be saved for future research use. Yes No
Do you agree to allow your information to be saved?
First name:_____ Last name:_____
Signature:_____ Date:_____

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2) Flathead- Aim 1 Focus Group Consent Approved 03.22.2021
Focus Group Verbal Consent Script
Site Principal -Investigator:
Virgil Dupuis
Extension Director
Salish Kootenai College
Phone: 406-275-4899
Virgil_dupuis@skc.edu
Dr. Wendy Westbroek
Life Sciences Faculty
Life Sciences Department
Salish Kootenai College
Phone: 406-275-
wendy_westbroek@skc.edu
Principal Investigator:
Dr. Alexandra Adams
Professor
Center for American Indian and Rural Health Equity at Montana State University
Phone: 406-994-2901
Email: Alexandra.adams2@montana.edu
FRED HUTCH OR SALISH KOOTENAI STAFF READS THE FOLLOWING SCRIPT TO POTENTIAL STUDY PARTICIPANT PRIOR TO SCHEDULING THE ZOOM OR PHONE FOCUS GROUP
READ VERBATIM
This purpose of this study is to understand barriers and opportunities for SARS CoV-2 (COVID-19) homebased testing. Researchers at Montana State University, The University of Washington Fred Hutchinson Cancer Research Center (Fred Hutch), and Salish Kootenai Extension program to increase COVID-19 testing in the community.

If you decide to take part in this focus group, we will ask you questions about your knowledge and experiences with COVID-19 testing and what makes it difficult or easy for community members to get tested for COVID-19. A focus group is a 60 to 90-minute conversation between a group of 6-10 participants and a moderator. This focus group will be audio-recorded to maintain a good record of the discussion. Prior to the focus group we will ask a short series of questions, called a demographic survey. The survey covers questions about you, so we have a better understanding of the participants who have participated in the focus groups.
With the exception of your time there are no costs to you for participating in this focus group. At the end, you will receive a $25 gift card for participating.
Your participation will help us develop a better understanding about people's experiences with COVID-19 testing and improve the current public health practice for COVID-19 prevention and future vaccination.
We do not anticipate any risks to you for taking part in the interview. However, answering questions on your experience with COVID-19 testing may make you feel uncomfortable.
Your participation in this interview is voluntary. You may choose not to answer specific questions or stop your participation at any time. There are no right or wrong answers to the questions; we just want to know your opinions. There is no penalty or loss of benefits to you if you choose not to respond to certain questions or stop your participation.
APPROVED MSU IRB 03/22/2021
Everything you say in this focus group is private and will not be shared with anyone outside the research team. Reported or published data will not identify anyone by name or other personal information. De-identified quotes might be used in reports or publications. Demographic data is presented as combined participant data as a whole, and not individual.
To protect your privacy, project staff will give each participant an identification (ID) number. Information linking the participant name and study ID number is kept in a password-protected computer file. Project staff will destroy all study materials with personal information three years after the study has been completed. This includes permanently deleting the audio recording of the interview and shredding the signed consent forms. All shredded paper will be placed in a private recycling bin.
The following organizations may ask to review participant data during the study: the National Institutes of Health), the Office for Human Protections (OHRP), and the Institutional Review Board (IRB) at Salish Kootenai College.
By law, the Institutional Review Board (IRB) at Salish Kootenai College may ask to look at participant data.
This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.
We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or another person.
This protection has some limits. We would voluntarily provide the information:
· To a member of the federal government who needs it in order to audit or evaluate the research.
· To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
· To the federal Food and Drug Administration (FDA), if required by the FDA.
· To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
· To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.
If you have any questions or comments about the study, I can clarify questions with you now, or I can provide you with the phone numbers of the Principal Investigator, Dr. Alexandra Adams, or if Spanish is needed. If you have any questions about the interviews today and the overall research, or your rights as a research participant, you may contact the SKC Institutional Review Office. I can provide you with that number.
Do you have any questions regarding the Focus Group or the research project?
IF YES – ANSWER QUESTIONS AND PROVIDE APPROPRIATE PHONE NUMBERS:
PI: Dr. Alexandra Adams 406-994-6077
IRB: SKC Institutional Review Office # 406-275-4931; irb@skc.edu
SKC Extension Office # 406-275-4899; virgil_dupuis@skc.edu
IF NO – PROCEED TO NEXT STATEMENT
Are you in agreement with the consent that I read?

IF YES – PROCEED TO NEXT STATEMENT
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Since you agree with the consent that I have read, can we proceed with scheduling the focus group?
APPROVED MSU IRB 03/22/2021
Since you agree with the consent that I have read, can we proceed with obtaining your signature on this consent using DocuSign. Next, we can proceed with scheduling the focus group?
IF YES – PROVIDE POTENTIAL DATES AND TIMES FOR FOCUS GROUP DISCUSSIONS
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Signature of Participant Date
Signature of Research Staff Date
APPROVED MSU IRB 03/22/2021
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3) Flathead- Aim 1 Key Informant Interview Consent Approved 03.22.2021
Key Informant Interview Verbal Consent Script
Site Principal Investigator:
Virgil Dupuis
Extension Director
Salish Kootenai College
Phone: 406-275-4899
Virgil_dupuis@skc.edu
Dr. Wendy Westbroek
Life Science Faculty
Life Sciences Department
Salish Kootenai College
Phone: 406-275-
wendy_westbroek@skc.edu
Principal Investigator:
Dr. Alexandra Adams
Professor
Center for American Indian and Rural Health Equity at
Montana State University
Phone: 406-994-2901
Email: Alexandra.adams2@montana.edu
SALISH KOOTENAI STAFF READS THE FOLLOWING SCRIPT TO POTENTIAL STUDY PARTICIPANT PRIOR TO SCHEDULING THE ZOOM OR PHONE FOCUS GROUP
READ VERBATIM
The purpose of this study is to understand barriers and opportunities for SARS CoV-2 (COVID-19) homebased testing. Researchers at Montana State University, The University of Washington Fred Hutchinson Cancer Research Center (Fred Hutch), and Salish Kootenai Extension program to increase COVID-19 testing in the community.
You have been invited to take part in a 40 to 60-minute interview. We want to learn more about your knowledge and experiences with COVID-19 testing and what makes it difficult or easy for community members to get tested for COVID-19. If you decide to take part in this interview, we will ask you general questions on people's feelings about COVID-19 and COVID-19 testing, social, cultural, behavioral and economic barriers to getting a COVID-19 testing, and support and resources that make it easy to obtain a COVID-19 test. The interview is expected to last about an hour and is a conversation between you and a member of our research staff. This interview will be audio-recorded to maintain a good record of your answers. Prior to the interview we will ask a short series of questions, called a demographic survey. The survey covers questions about you, so we have a better understanding of the participants who have participated in the interviews.
There are no costs to you for participating in this interview. At the end of the interview, you will receive a $25 gift card as a thank you for your time.
Your participation will help us develop a better understanding about people's experiences with COVID-19 testing and improve the current public health practice for COVID-19 prevention and future vaccination.
We do not anticipate any risks to you for taking part in the interview. However, answering questions on your

experience with COVID-19 testing may make you feel uncomfortable.
APPROVED MSU IRB 03/22/2021
Your participation in this interview is voluntary. You may choose not to answer specific questions or stop your participation at any time. There are no right or wrong answer to the questions; we just want to know your opinions. There is no penalty or loss of benefits to you if you choose not to respond to certain questions or stop your participation.
Everything you say in this interview is private and will not be shared with anyone outside the research team. Reported or published data will not identify anyone by name or other personal information. De-identified quotes might be used in reports or publications. Demographic data is presented as combined participant data as a whole, and not individual.
To protect your privacy, project staff will give each participant an identification (ID) number. Information linking the participant's name and study ID number is kept in a password protected computer file. Project staff will destroy all study materials with personal information three years after the study has been completed. This includes permanently deleting the audio recording of the interview and shredding the signed consent forms. All shredded paper will be placed in a private recycling bin.
The following organizations may ask to review participant data during the study: the National Institutes of Health, the Office for Human Protections (OHRP), and the Institutional Review Board (IRB) at Salish Kootenai College. By law, the Institutional Review Board (IRB) at Salish Kootenai College may ask to look at participant data. An IRB is a group that reviews the study to protect your rights as a research participant.
This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.
We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or another person.
This protection has some limits. We would voluntarily provide the information:
· To a member of the federal government who needs it in order to audit or evaluate the research.
· To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
· To the federal Food and Drug Administration (FDA), if required by the FDA.
· To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
· To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.
If you have any questions or comments about the study, I can clarify questions with you now, or I can provide you with the phone numbers of the Principal Investigator, Dr. Alexandra Adams. If you have any questions about the interviews today and the overall research, or your rights as a research participant, you may contact the SKC Institutional Review Office. I can provide you with that number.
Do you have any questions regarding the Key Informant Interview or the research project?
IF YES – ANSWER QUESTIONS AND PROVIDE APPROPRIATE PHONE NUMBERS:
PI: Dr. Alexandra Adams 406-994-6077
IRB: SKC Institutional Review Office # 406-275-4931; irb@skc.edu
SKC Extension Office # 406-275-4899; virgil_dupuis@skc.edu
IF NO – PROCEED TO NEXT STATEMENT
Are you in agreement with the consent that I read?
APPROVED MSU IRB 03/22/2021
IF YES – PROCEED TO NEXT STATEMENT
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Since you agree with the consent that I have read, can we proceed with obtaining your signature on this consent form using DocuSign. Next, we can conduct the interview or schedule a more appropriate time for you?
IF YES – PROCEED TO INTERVIEW QUESTIONS
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Signature of Participant Date
Signature of Research Staff Date

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4) Yakima- Aim 1 Focus Group Consent Approved 03.22.2021
Focus Group Verbal Consent Script
Site Principal -Investigator:
Dr. Linda K. Ko
Associate Professor
Fred Hutchinson Cancer Research Center
Phone: (206) 667-7182
Email: lko@fredhutch.org
Principal Investigator:
Dr. Alexandra Adams
Professor
Center for American Indian and Rural Health Equity at
Montana State University
Phone: 406-994-2901
Email: Alexandra.adams2@montana.edu
FRED HUTCH STAFF READS THE FOLLOWING SCRIPT TO POTENTIAL STUDY PARTICIPANT
PRIOR TO SCHEDULING THE ZOOM OR PHONE FOCUS GROUP
READ VERBATIM
This purpose of this study is to understand barriers and opportunities for SARS CoV-2 (COVID-19) homebased testing. Researchers at Fred Hutchinson Cancer Research Center (Fred Hutch) are collaborating with Montana State University and University of Washington to increase COVID-19 testing in the community.
If you decide to take part in this focus group, we will ask you questions about your knowledge and experiences with COVID-19 testing and what makes it difficult or easy for community members to get tested for COVID-19. A focus group is a 60 to 90-minute conversation between a group of 6-10 participants and a moderator. This focus group will be audio-recorded to maintain a good record of the discussion. Prior to the focus group we will ask a short series of questions, called a demographic survey. The survey covers questions about you, so we have a better understanding of the participants who have participated in the focus groups.
With the exception of your time there are no costs to you for participating in this focus group. At the end, you will receive a $25 gift card for participating.
Your participation will help us develop a better understanding about people's experiences with COVID-19 testing and improve the current public health practice for COVID-19 prevention and future vaccination.
We do not anticipate any risks to you for taking part in the interview. However, answering questions on your experience with COVID-19 testing may make you feel uncomfortable.
Your participation in this interview is voluntary. You may choose not to answer specific questions or stop your participation at any time. There are no right or wrong answers to the questions; we just want to know your opinions. There is no penalty or loss of benefits to you if you choose not to respond to certain questions or stop your participation.
Everything you say in this focus group is private and will not be shared with anyone outside the research team. Reported or published data will not identify anyone by name or other personal information. De-identified quotes might be used in reports or publications. Demographic data is presented as combined participant data as a whole, and not individual.
To protect your privacy, project staff will give each participant an identification (ID) number. Information linking the participant name and study ID number is kept in a password-protected computer file. Project staff will destroy all study materials with personal information three years after the study has been completed. This includes permanently deleting the audio recording of the interview and shredding the signed consent forms. All shredded paper will be placed in a private recycling bin.
APPROVED MSU IRB 03/22/2021
The following organizations may ask to review participant data during the study: the National Institutes of Health), the Office for Human Protections (OHRP), and the Institutional Review Board (IRB) at the Fred Hutchinson Cancer Research Center. By law, the Institutional Review Board (IRB) at Fred Hutchinson Cancer Research Center may ask to look at participant data.
This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate

means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.
We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or another person.
This protection has some limits. We would voluntarily provide the information:
· To a member of the federal government who needs it in order to audit or evaluate the research.
· To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
· To the federal Food and Drug Administration (FDA), if required by the FDA.
· To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
· To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.
If you have any questions or comments about the study, I can clarify questions with you now, or I can provide you with the phone numbers of the Principal Investigator, Dr. Alexandra Adams, or if Spanish is needed, Dr. Linda Ko.
If you have any questions about the interviews today and the overall research, or your rights as a research participant, you may contact the MSU Institutional Review Office. I can provide you with that number.
Do you have any questions regarding the Key Informant Interview or the research project?
IF YES – ANSWER QUESTIONS AND PROVIDE APPROPRIATE PHONE NUMBERS:
PI: Dr. Alexandra Adams 406-994-6077
Spanish: Dr. Linda Ko 206-667-7182
IRB: MSU Institutional Review Office # 406-994-4706
Salish Kootenai Tribal Office # 406-275-4931
IF NO – PROCEED TO NEXT STATEMENT
Are you in agreement with the consent that I read?
IF YES – PROCEED TO NEXT STATEMENT
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Since you agree with the consent that I have read, can we proceed with scheduling the focus group?
IF YES – PROVIDE POTENTIAL DATES AND TIMES FOR FOCUS GROUP DISCUSSIONS
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Signature of Research Staff Date

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5) Yakima- Aim 1 Key Informant Interview Consent Approved 03.22.2021
Key Informant Interview Verbal Consent Script
Site Principal Investigator:
Dr. Linda K. Ko
Associate Professor
Fred Hutchinson Cancer Research Center
Phone: (206) 667-7182
Email: lko@fredhutch.org
Principal Investigator:
Dr. Alexandra Adams
Professor
Center for American Indian and Rural Health Equity at
Montana State University
Phone: 406-994-2901
Email: Alexandra.adams2@montana.edu
FRED HUTCH STAFF READS THE FOLLOWING SCRIPT TO POTENTIAL STUDY PARTICIPANT PRIOR TO SCHEDULING THE ZOOM OR PHONE FOCUS GROUP
READ VERBATIM
The purpose of this study is to understand barriers and opportunities for SARS CoV-2 (COVID-19) homebased testing. Researchers at Fred Hutchinson Cancer Research Center (Fred Hutch) are collaborating with Montana State University and University of Washington to increase COVID-19 testing in the community.
You have been invited to take part in a 40 to 60-minute interview. We want to learn more about your knowledge

and experiences with COVID-19 testing and what makes it difficult or easy for community members to get tested for COVID-19. If you decide to take part in this interview, we will ask you general questions on people's feelings about COVID-19 and COVID-19 testing, social, cultural, behavioral and economic barriers to getting a COVID-19 testing, and support and resources that make it easy to obtain a COVID-19 test. The interview is expected to last about an hour and is a conversation between you and a member of our research staff. This interview will be audio-recorded to maintain a good record of your answers. Prior to the interview we will ask a short series of questions, called a demographic survey. The survey covers questions about you, so we have a better understanding of the participants who have participated in the interviews.
There are no costs to you for participating in this interview. At the end of the interview, you will receive a $25 gift card as a thank you for your time.
Your participation will help us develop a better understanding about people's experiences with COVID-19 testing and improve the current public health practice for COVID-19 prevention and future vaccination.
We do not anticipate any risks to you for taking part in the interview. However, answering questions on your experience with COVID-19 testing may make you feel uncomfortable.
Your participation in this interview is voluntary. You may choose not to answer specific questions or stop your participation at any time. There are no right or wrong answer to the questions; we just want to know your opinions. There is no penalty or loss of benefits to you if you choose not to respond to certain questions or stop your participation.
Everything you say in this interview is private and will not be shared with anyone outside the research team. Reported or published data will not identify anyone by name or other personal information. De-identified quotes might be used in reports or publications. Demographic data is presented as combined participant data as a whole, and not individual.
APPROVED MSU IRB 03/22/2021
To protect your privacy, project staff will give each participant an identification (ID) number. Information linking the participant name and study ID number is kept in a password protected computer file. Project staff will destroy all study materials with personal information three years after the study has been completed. This includes permanently deleting the audio recording of the interview and shredding the signed consent forms. All shredded paper will be placed in a private recycling bin.
The following organizations may ask to review participant data during the study: the National Institutes of Health, the Office for Human Protections (OHRP), and the Institutional Review Board (IRB) at the Fred Hutchinson Cancer Research Center. By law, the Institutional Review Board (IRB) at Fred Hutchinson Cancer Research Center may ask to look at participant data. An IRB is a group that reviews the study to protect your rights as a research participant.
This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.
We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or another person.
This protection has some limits. We would voluntarily provide the information:
· To a member of the federal government who needs it in order to audit or evaluate the research.
· To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
· To the federal Food and Drug Administration (FDA), if required by the FDA.
· To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
· To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.
If you have any questions or comments about the study, I can clarify questions with you now, or I can provide you with the phone numbers of the Principal Investigator, Dr. Alexandra Adams, or if Spanish is needed, Dr. Linda Ko. If you have any questions about the interviews today and the overall research, or your rights as a research participant, you may contact the MSU Institutional Review Office. I can provide you with that number.
Do you have any questions regarding the Key Informant Interview or the research project?
IF YES – ANSWER QUESTIONS AND PROVIDE APPROPRIATE PHONE NUMBERS:
PI: Dr. Alexandra Adams 406-994-6077

Spanish: Dr. Linda Ko 206-667-7182
IRB: MSU Institutional Review Office # 406-994-4706
Salish Kootenai Tribal Office # 406-275-4931
IF NO – PROCEED TO NEXT STATEMENT
Are you in agreement with the consent that I read?
IF YES – PROCEED TO NEXT STATEMENT
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
Since you agree with the consent that I have read, can we proceed with scheduling or conducting the interview?
IF YES – PROCEED TO INTERVIEW QUESTIONS
IF NO – THANK PARTICIPANT FOR THEIR TIME AND END CALL
APPROVED MSU IRB 03/22/2021

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6) Yakima- Aim 2 and Aim 3 Consent Approved 03.22.2021
Informed Consent Form
Protecting Our Community: A Pragmatic Randomized Trial of Home-Based COVID Testing with Native American and Latino Communities
You are being asked to take part in a research study. This consent form will give you information about the study to help you decide whether to be in the study or not. You will be given a copy of this form for your records. This form has information, including important names and telephone numbers, which you may wish to refer in the future.
PURPOSE OF THE STUDY
The goal of this study is to examine what strategies are needed to support individuals to complete a home-based testing for COVID-19. Participation will involve you taking a swab sample from inside your own nose and sending it back to a lab for analysis of COVID-19.
Why am I being asked?
You have been asked to participate in this research because you:
1) Are part of the Latino community living in the Yakima Valley region of Washington state.
2) Are 18 years of age or older
3) Haven't experienced any of the following symptoms within the past week: fever over 102F or a high fever lasting more than 48 hours, inability to speak in full sentences or do simple activities without shortness of breath, severe coughing spells or coughing up blood, blue face or lips, severe and constant pain or pressure in your chest, extreme lethargy, dizziness, lightheadedness or being too weak to stand, slurred speech or seizures, or being unable to stay at home due to being too sick.
4) Have no other household members participating in any activities related to Protecting Our Communities. (Household members are defined as individuals who live under the same roof or share same housing unit).
Taking part in this study is voluntary. You can stop at any time. You may refuse to participate, and you are free to leave the study at any time.
What procedures are involved?
The study procedures include the completion of a brief demographic survey, home-based testing including taking a nasopharyngeal sample (nasal swab), and post-testing feedback survey. A small subset of participants will also be invited to complete a post-testing follow-up interview.
For the survey, we will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.
For the home-based testing, you will receive a testing kit, which will include a nasal swab, home-based testing instructions, follow-up resources and a pre-paid, pre-addressed returnmailing envelope. Participants will be asked to send their completed nasal swab samples to a commercial company (Everlywell) testing laboratory for analysis. When you get the testing kit (within 1-2 days), you will follow instructions and take a swab sample from inside your nose.
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The nasal swab is collected by gently putting a swab (like a Q-tip) about ½ inch inside your nose and gently turning it around.
You will be asked to provide a valid email address to create a free user account with Everlywell in order to receive results to your home-based self-sample.
You will also be asked to complete a short follow-up survey 1-week after receiving the homebased testing kits. Surveys will be brief (estimated completion time = 10-15 minutes) and will help us understand your experience with home testing.
At the end of the survey, you will be asked if you would like to participate in a 40 to 60-minute follow-up phone interview. We will randomly select 40 participants among those who answered yes and follow-up with a call.
What are the potential risks and discomforts?
To the best of our knowledge there are no risks associated with the collection of nasopharyngeal samples. Participants may experience mild, brief discomfort while taking a swab test from their nose. Rarely this might cause a small nosebleed.
Are there benefits to participating in the research?
You will receive the results of your test by a trained health professional. Such knowledge and resources may help reduce the spread of COVID-19 and overall burden of disease in your family and community.
Are there costs for participating in the research?
There are no costs for participating in this research.
What other options are there?
You have the option to not participate in this study.
Who is paying for this study?
The NIH, which stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services.
Will my study-related information be kept confidential?
Your record will be kept confidential. You will not be identified in any report or publication about this study. Identifiable information such as your name, address and phone number will be collected and used to mail you a test kit, contact you with your testing results and send you a survey at 1 week follow-up.
We will assign a study code to you. Your identifiable information and study code will be kept in a secure database where the researchers do not have access. Only the study's physician and your local site coordinator will be able to match study codes with identifying information, such as your name, address, and phone number. The nurse will use this information to contact you about your COVID-19 testing results, if you have questions. Participants who test positive will receive a call from an Everlywell physician with their results and have their contact information given to local public health officials for contact tracing and follow-up as per usual clinical protocol. All other researchers will have access to deidentified coded data only.
Your Everlywell account information and test results may be shared with Everlywell affiliated health consultants and labs for the purposes of processing samples, delivering testing results, providing treatment information and conducting research. Everlywell will only have access to your Everlywell account information, nasal sample and COVID-19 testing result. No further information
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collected in this study will be shared with Everlywell. The information you provide to Everlywell may be stored in a repository and used for validation, educational, and/or research purposes.
Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your responses in the interview may be examined.
All research personnel have taken the required training on research Privacy and Confidentiality.
Records on all participants will be kept confidential by maintaining consent forms in a file cabinet in a locked office at MSU.
When this research is discussed or published, no one will know that you were in the study. But,

when required by law, identifying information (including your signed consent form) may be seen or copied by Federal regulatory agencies such as the Office of Human Research Protections in the Department of Health and Human Services.
Will I be reimbursed for any expenses or paid for my participation in this research?
You will receive a $35 gift card upon completing the post-testing feedback survey. If you are interested in participating in the follow-up phone interview and are among the 40 individuals randomly selected to participate in a longer phone interview, then you will receive an additional $25 gift card as compensation for your time and effort.
Can I withdraw or be removed from the study?
You are free to withdraw your consent and stop your participation at any time during the study.
Will data collected from me be used for any other research?
Our study is funded by NIH under the initiative called RADx-UP. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. The goal of RADx-UP is to understand factors that drive health disparities related to COVID-19 among underserved communities and use the data to reduce the disparities. If you join this study, some information we gather will be shared with RADx-UP the Coordination and Data Collection Center (CDCC). The CDCC's activity includes collecting the similar data from everyone taking part in RADx-UP studies and combining them to understand the problem at the population level.
No identifying information will be shared about you. The CCDC will keep your data securely (which means with extra protection), along with the data from all other people who take part in the RADx-UP studies.
· It will not contain your name or any other information that could easily identify you.
· The CDCC will transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
· When using the data from this database, researchers will only have access to your nonidentifiable data and cannot link the data back to you.
· Because the data cannot be linked back to you, the CDCC will not contact you to inform you or ask your permission before sharing the data with researchers.
Who should I contact if I have questions?
If you have any questions or comments about the study, we encourage you to contact the principal investigator, Dr. Alexandra Adams at 406-994-6077 or Alexandra.adams2@montana.edu
What are my rights as a research subject?
If you have any questions about your rights as a participant in this study, please contact the Montana State University Institutional Review Board (406-994-4707).
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I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. If desired, I will be given a copy of this form.
Data banking
You have the option of allowing your contact and survey information to be kept at MSU for future COVID-19 research studies. This information will also be stored at Fred Hutch (for Yakima Valley participants) and at Salish-Kootenai College (for Flathead participants). Your information will remain in a locked cabinet at all times.
Otherwise, this information will not be saved for future research use.
Do you agree to allow your information to be saved?
Yes_____
No_____
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No **13.2.2**

Assurances **14**

Assurance Statements 14.1

Acknowledge each of the following assurances. All boxes must be checked and confirmed, or the protocol will be returned.

- [x] I will submit any future changes to the research affecting human subjects, protocol, consent form, recruitment materials, survey instrument, interv questions, or personnel via Amendment prior to implementation (except for changes to eliminate apparent immediate hazards to subjects, which enact and then inform the IRB).
- [x] It is my responsibility to facilitate subject understanding by informing subjects of all aspects of the project, providing an opportunity to ask questio and describing risks and benefits of participation.
- [x] I acknowledge that the Consent Form documents that consent has been obtained. Subjects should receive a copy of the Consent Form, and I wil signed copies for my records for at least three years after completion of the research.
- [x] I will keep track of the number of subjects who participate in the study.
- [x] I will report any adverse events or unanticipated problems to the IRB within 3 days of occurrence. If there are serious adverse consequences, I w

Your Protocol Application is now complete and ready to SUBMIT.

I will submit any future changes to the research affecting human subjects, protocol, consent form, recruitment materials, survey instrument, interview questions, or personnel via Amendment prior to implementation (except for changes to eliminate apparent immediate hazards to subjects, which I will enact and then inform the IRB).	14.1.1
It is my responsibility to facilitate subject understanding by informing subjects of all aspects of the project, providing an opportunity to ask questions, and describing risks and benefits of participation.	14.1.2
I acknowledge that the Consent Form documents that consent has been obtained. Subjects should receive a copy of the Consent Form, and I will keep signed copies for my records for at least three years after completion of the research.	14.1.3
I will keep track of the number of subjects who participate in the study.	14.1.4
I will report any adverse events or unanticipated problems to the IRB within 3 days of occurrence. If there are serious adverse consequences, I will suspend the research until the situation has been reviewed by the Institutional Review Board.	14.1.5

Review Category - No Response Required 15

Review Category 15.1

IRB Program Manager will complete this section. NO RESPONSE REQUIRED

Category of Review per Office of Human Research Protections (See full definitions from Health& Human Services):

- [ ] 1. Clinical studies of drugs and medical devices
- [ ] 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- [x] 3. Prospective collection of biological specimens for research purposes by noninvasive means
- [ ] 4. Collection of data through noninvasive procedures
- [ ] 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
- [ ] 6. Collection of data from voice, video, digital, or image recordings made for research purposes
- [x] 7. Research on individual or group characteristics or behavior (e.g., perception, cognition, motivation, identity, language, communication, cultural beliefs/practices, and social behavior) or employing survey, interview, oral history, focus group, program or human factors evaluation, or quality assurance methodologies
- [ ] 8. - 9. Continuing Review
- [ ] Full Committee Review

1. Clinical studies of drugs and medical devices	15.1.1
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture	15.1.2
3. Prospective collection of biological specimens for research purposes by noninvasive means	15.1.3
4. Collection of data through noninvasive procedures	15.1.4

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)	**15.1.5**
6. Collection of data from voice, video, digital, or image recordings made for research purposes	**15.1.6**
7. Research on individual or group characteristics or behavior (e.g., perception, cognition, motivation, identity, language, communication, cultural beliefs/practices, and social behavior) or employing survey, interview, oral history, focus group, program or human factors evaluation, or quality assurance methodologies	**15.1.7**
8. - 9. Continuing Review	**15.1.8**
Full Committee Review	**15.1.9**