

Attachment A: Informed Consent Documents

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An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

CONTINUING CAREGIVER QUANTITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: January 17, 2019 **Version #:** 3
Informed consent for: Home visiting caregiver
Enrolled in home visiting services BEFORE the MUSE study started

You and your child are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. Someone from your home visiting program will explain this study to you and answer your questions about it. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the children and families in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you and your child are in a tribal home visiting program. We want to know about your experiences with home visiting. We also want to know about you and about your child's development.

17 tribal home visiting programs are involved in the MUSE study.

Families receiving home visiting services and program staff will be asked to be in the study. Up to 1,606 people will be included.

What happens if I join this study?

If you join the study, you will be asked to:

1. Take a 5-minute survey after a few of your home visits.
2. Allow your home visiting program to share some information about you with the MUSE study. For example, they will share information about the services they provide to you. They will also share your responses to questions they ask you about financial needs [, substance use, and mental health].

We are also going to interview a few people about their experiences in home visiting. A MUSE researcher may contact you to ask if you would be willing to be interviewed.

What happens if I agree to let my child join this study?

If you agree to let your child join the study, you will allow your home visiting program to share the following information about your child with the MUSE study: birth month and year, sex, Ages and Stages Questionnaire scores.

How long will the MUSE study last?

The MUSE study will last for about 2 years. The length of time you are in the study will depend on how long you are enrolled in home visiting. The longest you will be in the study is 2 years.

What are the possible discomforts or risks?

The survey asks about your experiences with tribal home visiting and with your home visitor. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. The information we will collect about you from your home visiting program or on the surveys will not be connected to your name. Your home visiting program will assign you an ID number to keep your information private. Your name will not be shared with the MUSE study team. We do this to protect your sensitive information.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your tribal home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

You will not be paid for being in the study. It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, you can still receive home visiting services. If you decide to stop being in the study later, you can continue to receive home visiting services.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
Nighthorse Campbell Native Health Building
13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep potentially identifying information about research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Demographic Information (age, sex, ethnicity)
- Your record of participation in the home visiting program
- Your answers to survey questions about your experience with home visiting

What happens to data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Note: There is nothing in the survey that would require the study team to make a report to the authorities. Survey answers are kept private and do not have names linked with them.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. You may ask any questions you have now. If you have questions later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu. You may also ask your Home Visitor any questions you have or call your home visiting program office [On paper copy: LOCAL PROGRAM CONTACT INFO]. When you call, let them know you have a question about the MUSE research study.

You may have questions about your rights or your child's rights as people in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 [On paper copy only: or LOCAL IRB INFO].

Caregivers complete this section

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

Consent to use my child's data in the MUSE study

I agree to allow my home visiting program to share my child's birth month and year, sex, and Ages and Stages Questionnaire scores with the MUSE study. (Check one box)

- Yes
- No

Today's Date: _____

Staff member completes this section

Caregiver's program ID: _____

I explained the MUSE study to the caregiver and answered questions. I believe the caregiver understands what is expected during this study.

First name of staff member who explained the consent form:

Last name of staff member who explained the consent form:

Today's Date: _____

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

NEW CAREGIVER QUANTITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: January 17, 2019 **Version #:** 3
Informed consent for: Home visiting caregiver
18 years or older
Enrolled in home visiting services AFTER the MUSE study started

You and your child are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. Someone from your home visiting program will explain this study to you and answer your questions about it. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the children and families in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you and your child are in a tribal home visiting program. We want to know about your experiences with your home visiting program. We also want to know about you, your experiences as a parent, and your child's development.

17 tribal home visiting programs are involved in the MUSE study.

Families receiving home visiting services and program staff will be asked to be in the study. Up to 1,606 people will be included.

What happens if I join this study?

If you join the study, you will be asked to:

1. Take up to 3 surveys about you and your experiences with your tribal home visiting program. The survey questions ask about parenting, support you have as a parent, why you enrolled in home visiting, and other similar topics. The surveys will take approximately 15-30 minutes to complete.
2. Take a 5-minute survey after a few of your home visits.
3. Allow your home visiting program to share some information about you with the MUSE study. For example, they will share information about the services they provide to you. They will also share your responses to questions they ask you about financial needs [, substance use, and mental health].

We are also going to interview a few people about their experiences in home visiting. A MUSE researcher will contact you to ask if you would be willing to be interviewed.

What happens if I agree to let my child join this study?

If you agree to let your child join the study, you will allow your home visiting program to share the following information about your child with the MUSE study: birth month and year, sex, Ages and Stages Questionnaire scores.

How long will the MUSE study last?

The MUSE study will last for about 2 years. The length of time you are in the study will depend on when you enroll in home visiting. The longest you will be in the study is 2 years.

What are the possible discomforts or risks?

The survey asks about your experiences with your tribal home visiting program and as a parent. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. The information we will collect about you from your home visiting program or on the surveys will not be connected to your name. Your home visiting program will assign you an ID number to keep your information private. Your name will not be shared with the MUSE study team. We do this to protect your sensitive information.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your tribal home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

If you participate in the study, you will get:

- A \$10 gift card for taking a survey now.
- A \$15 gift card each time you take another survey. You will be asked to take up to 2 more surveys.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, you can still receive home visiting services. If you decide to stop being in the study later, you can continue to receive home visiting services.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
Nighthorse Campbell Native Health Building
13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Demographic Information (age, sex, ethnicity)
- Your record of participation in the home visiting program
- Your answers to survey questions about you, your family, and your experience with home visiting

What happens to data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Note: There is nothing in the survey that would require the study team to make a report to the authorities. Survey answers are kept private and do not have names linked with them.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. You may ask any questions you have now. If you have questions later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu. You may also ask your Home Visitor any questions you have or call your home visiting program office [On paper copy: LOCAL PROGRAM CONTACT INFO]. When you call, let them know you have a question about the MUSE research study.

You may have questions about your rights or your child's rights as people in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 [On paper copy only: or LOCAL IRB INFO].

Caregivers complete this section

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

Consent to use my child's data in the MUSE study

I agree to allow my home visiting program to share my child's birth month and year, sex, and Ages and Stages Questionnaire scores with the MUSE study. (Check one box)

- Yes
- No

Today's Date: _____

Staff member completes this section

Caregiver's program ID: _____

I explained the MUSE study to the caregiver and answered questions. I believe the caregiver understands what is expected during this study.

First name of staff member who explained the consent form:

Last name of staff member who explained the consent form:

Today's Date: _____

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HOME VISITOR QUANTITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: January 17, 2019 **Version #:** 3
Informed consent for: Home visiting professional (Home visitor)

You are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. If you have questions, you may contact a member of the MUSE study team and they will answer your questions. Their contact information is at the end of this form. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the staff in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you are a home visitor with your tribal home visiting program. We want to know about your experiences with your home visiting program. We also want to know about you and your experiences as a home visitor.

17 tribal home visiting programs are involved in the MUSE study.

Families receiving home visiting services and program staff will be asked to be in the study. Up to 1,606 people will be included.

What happens if I join this study?

If you join the study, you will be asked to take a survey about you and your experiences as a home visitor with your tribal home visiting program. The survey will take approximately 70 minutes to complete. Data you provide in your survey responses may be linked to data that your program sends to the MUSE research team about your work activities, including the supervision you receive, but your data will never be linked to your name or other directly identifiable information.

We are also going to interview a few home visitors about their experiences. A MUSE researcher may contact you to ask if you would be willing to be interviewed.

How long will the MUSE study last?

The MUSE study will last for about 2 years. The length of time you are in the study will depend on when you complete the survey and whether you participate in an interview. The longest you will be in the study is 2 years.

What are the possible discomforts or risks?

The survey asks about your experiences with your tribal home visiting program and as a home visitor. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. The information we will collect about you on the survey will not be connected to your name. We will assign you an ID number to keep your information private. We do this to protect your sensitive information.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your tribal home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

You will not receive anything for being in the study. It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, it will not affect your job as a home visitor with your tribal home visiting program. If you decide to stop being in the study later, it will not affect your job as a home visitor with your tribal home visiting program. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to be in the study or not. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to stop being in the study later.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
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Aurora, Colorado, 80045

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- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity)
- Your staff role with the home visiting program
- Your answers to survey questions about you and your experience with the home visiting program

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.

- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Note: There is nothing in the survey that would require the study team to make a report to the authorities. Survey answers are kept private and do not have names linked with them.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. If you have questions now or later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu.

You may have questions about your rights as a person in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 [On paper copy only: or LOCAL IRB INFO].

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will be given a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

PROFESSIONAL (NON HOME VISITOR) QUANTITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: January 17, 2019 **Version #:** 3
Informed consent for: Home visiting professional (Non-Home visitor)
18 years or older

You are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. If you have questions, you may contact a member of the MUSE study team and they will answer your questions. Their contact information is at the end of this form. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the staff in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you work with a tribal home visiting program. We want to know about your experiences with your home visiting program. We also want to know about you and your work experiences.

17 tribal home visiting programs are involved in the MUSE study.

Families receiving home visiting services and program staff will be asked to be in the study. Up to 1,606 people will be included.

What happens if I join this study?

If you join the study, you will be asked to take a survey about you and your experiences working with your home visiting program. The survey will take approximately [30/45/60] minutes to complete. The MUSE research team may link data you provide in your survey responses with data your program provides about your work activities, but your data will never be connected to your name or other directly identifiable information.

We are also going to interview a few people about their experiences. A MUSE researcher will contact you to ask if you would be willing to be interviewed.

How long will the MUSE study last?

The MUSE study will last for about 2 years. The length of time you are in the study will depend on when you complete the survey and whether you participate in an interview. The longest you will be in the study is 2 years.

What are the possible discomforts or risks?

The survey asks about you and your experiences with your tribal home visiting program. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. The information we will collect about you on the survey will not be connected to your name. We will assign you an ID number to keep your information private. We do this to protect your sensitive information.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your tribal home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

You will not receive anything for being in the study. It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, it will not affect your job with your tribal home visiting program. If you decide to stop being in the study later, it will not affect your job with your tribal home visiting program. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to be in the study or not. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to stop being in the study later.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
Nighthorse Campbell Native Health Building
13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity)
- Your staff role with the home visiting program
- Your answers to survey questions about you and your experience with the home visiting program

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Note: There is nothing in the survey that would require the study team to make a report to the authorities. Survey answers are kept private and do not have names linked with them.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. If you have questions now or later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu.

You may have questions about your rights as a person in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 [On paper copy only: or LOCAL IRB INFO].

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will be given a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

PROGRAM IMPLEMENTATION SURVEY CONSENT FORM

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: January 17, 2019 **Version #:** 3
Informed consent for: Home visiting program coordinator/manager and program director
18 years or older

You are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. If you have questions, you may contact a member of the MUSE study team and they will answer your questions. Their contact information is at the end of this form. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the staff in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you work with a tribal home visiting program. We want to know about your experiences with your home visiting program. We also want to know about you and your work experiences.

17 tribal home visiting programs are involved in the MUSE study.

Families receiving home visiting services and program staff will be asked to be in the study. Up to 1,606 people will be included.

What happens if I join this study?

If you join the study, you will be asked to take a survey about your tribal home visiting program and its operations. The survey will take approximately 15 minutes to complete.

We are also going to interview a few people about their experiences. A MUSE researcher will contact you to ask if you would be willing to be interviewed.

How long will the MUSE study last?

The MUSE study will last for about 2 years. The length of time you are in the study will depend on when you complete the survey and whether you participate in an interview. The longest you will be in the study is 2 years.

What are the possible discomforts or risks?

The survey asks about your tribal home visiting program operations. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. The information we will collect about you on the survey will not be connected to your name. We will assign you an ID number to keep your information private. We do this to protect your sensitive information.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your tribal home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

You will not receive anything for being in the study. It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, it will not affect your job with your tribal home visiting program. If you decide to stop being in the study later, it will not affect your job with your tribal home visiting program. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to be in the study or not. The MUSE study team will never tell anyone at your tribal home visiting program if you choose to stop being in the study later.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise. If you choose to complete this survey with another manager at your tribal home visiting program, they will see the answers you enter together. However, they will not have a link to access the survey on their own.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
Nighthorse Campbell Native Health Building
13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity)
- Your staff role with the home visiting program
- Your answers to survey questions about your home visiting program

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Note: There is nothing in the survey that would require the study team to make a report to the authorities. Survey answers are kept private and do not have names linked with them.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. If you have questions now or later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu.

You may have questions about your rights as a person in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 [On paper copy only: or LOCAL IRB INFO].

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will be given a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

CAREGIVER OVER 18 QUALITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: July 2, 2020 **Version #:** 4
Informed consent for: Home visiting caregiver
18 years or older

You are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. Someone from your home visiting program will explain this study to you and answer your questions about it. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We also want to learn about the children and families in these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you and your child are in a tribal home visiting program. We want to know about your experiences with your home visiting program. We also want to know about you, your experiences as a parent, and your child's development.

17 tribal home visiting programs are involved in the MUSE study.

We will ask families receiving home visiting services and program staff to be in the study. Up to 1,606 people will be included. Within this larger MUSE study, we will also interview up to 60 people who are receiving home visiting services.

What happens if I join this study?

You have been taking part in other parts of the MUSE study. We are now asking you to be interviewed about your experiences with home visiting.

If you agree to be interviewed, you will:

1. Talk with someone from the MUSE team about you, your family and your experience with your home visiting program.
2. You will be interviewed in a private office **or over a private telephone or video conference call**. Only you and the interviewer will be able to hear your conversation.
3. At the time of the interview, you will be asked to let us record the interview (audio only). If you agree, we will later transcribe the recording and remove any names you mention.
4. MUSE study team members will then share some of what they learn from these interviews in presentations, or written reports, or articles in professional journals. Anything shared from the interviews will be written or presented in a way that does not identify you, your family, your home visiting program or your community.

How long will the MUSE study last?

The full MUSE study will last for about 2 years. The interview you are being asked to participate in will happen one time and will take about one hour.

What are the possible discomforts or risks?

The interview will ask about your experiences with your home visiting program and as a parent. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. We will assign you an ID number and use this ID instead of your name on your interview transcript to keep your information private.

There are some times when we cannot keep your information private because we want to make sure people are safe. If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes. If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

If you participate in the study, you will get:

- A \$40 gift card for participating in the interview

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, you can still receive home visiting services. If you decide to stop being in the study later, you can continue to receive home visiting services.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Nancy Rumbaugh Whitesell
University of Colorado Anschutz Medical Campus
Mail Stop F800
Nighthorse Campbell Native Health Building
13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

If you consent to participate in the MUSE interview, your conversation with the MUSE study team member will be audio-recorded on a digital recording device. We will protect the audio-recordings by:

- Using only password protected portable audio-recording devices;
- Transferring and storing audio-recordings and interview transcripts using secure data platforms accessible to MUSE study team members only;
- De-identifying transcripts during the transcription process;
- Erasing audio-files stored on portable devices directly after successful transfer to secure data platform is confirmed;

Audio-recordings will be erased after the transcript is verified. Interview transcripts will be kept for 5 years after the MUSE study is complete and then erased.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Your answers to interview questions about you, your family, and your experience with home visiting

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. You may ask any questions you have now. If you have questions later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu. You may also ask your Home Visitor questions you have or call your home visiting program at [XXX-XXX-XXXX]. When you call, let them know you have a question about the MUSE research study.

You may have questions about your rights as a participant in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 or LOCAL IRB INFO.

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

Signature: _____ Today's Date: _____

I explained the MUSE study to the caregiver and answered questions. I believe the caregiver understands what is expected during this study.

Consent form explained by: _____ Today's Date: _____

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

PROFESSIONAL OVER 18 QUALITATIVE CONSENT

Study Title: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE)
Principal Investigator: Nancy Rumbaugh Whitesell, Ph.D.
COMIRB No: 18-0109
Version Date: July 7, 2020 **Version #:** 4
Informed consent for: Home visiting professional

You are being asked to be in a research study. This form provides you with information about the study. Your home visiting program is participating in this study with other tribal home visiting programs across the country. Please read the information below and ask questions about anything you don't understand before deciding whether or not you want to participate in this study.

Why is this study being done?

We are doing this study to learn about tribal home visiting programs. We want to learn about the children and families receiving services as well as the experiences of leadership and staff who work on these programs. This study may help programs by identifying what is working well and where services can be improved. It may also help programs to better understand the families they are serving.

We are asking you to be in this research study because you are currently employed by a tribal home visiting program. We want to know about your experience working with your home visiting program.

17 tribal home visiting programs are involved in the MUSE study.

We will ask families receiving home visiting services and program staff to be in the study. Up to 1,606 people will be included. Within this larger MUSE study, we will also interview up to 100 program staff.

What happens if I join this study?

You may have been taking part in other parts of the MUSE study. We are now asking you to be interviewed about your experiences with home visiting.

If you agree to be interviewed, you will:

1. Talk with someone from the MUSE team about you, the agency or organization where you work and your experience with your home visiting program.
2. You will be interviewed in a private office or over a private telephone or video conference call. Only you and the interviewer will be able to hear your conversation.
3. At the time of the interview, you will be asked to let us record the interview (audio only). If you agree, we will later transcribe the recording and remove any names you mention.
4. MUSE study team members will then share some of what they learn from these interviews in presentations, or written reports, or articles in professional journals. Anything shared from the interviews will be written or presented in a way that does not identify you, anyone you discuss in the interview, your home visiting program or your community.

How long will the MUSE study last?

The full MUSE study will last for about 2 years. The interview you are being asked to participate in will happen one time and will take between one and two hours.

What are the possible discomforts or risks?

The interview asks about your experiences at work with your home visiting program. Some of these questions may make you feel uncomfortable.

There is a small risk that your personal information will accidentally become known. We take steps to make this unlikely. We will assign you an ID number and use this ID instead of your name on your interview transcript to keep your information private.

There are sometimes when we cannot keep your information private because we want to make sure people are safe. If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes. If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

What are the possible benefits of the study?

This study is being done to learn more about home visiting services in Native communities. You will not benefit directly from being in this study.

Who is paying for this study?

This research is being paid for by the Administration for Children and Families Office of Planning, Research, and Evaluation, through a contract to James Bell Associates, Inc. and the University of Colorado. The Administration for Children and Families is one of the funders of your home visiting program.

Will I receive anything for being in the study? Will participating in the study cost me anything?

You will not be paid for being in the study.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study.

If you choose to be in the study, you have the right to stop at any time. If you choose not to be in the study, you will not be penalized.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Denver and James Bell Associates, Inc.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver, its affiliate hospitals, and James Bell Associates, Inc. may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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13055 E. 17th Place, Room 333
Aurora, Colorado, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study director and the rest of the study team at the University of Colorado and James Bell Associates, Inc.
- The Administration for Children and Families, who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

If you consent to participate in the MUSE interview, your conversation with the MUSE study team member will be audio-recorded on a digital recording device. We will protect the audio-recordings by:

- Using only password protected portable audio-recording devices;
- Transferring and storing audio-recordings and interview transcripts using secure data platforms accessible to MUSE study team members only;
- De-identifying transcripts during the transcription process;
- Erasing audio-files stored on portable devices directly after successful transfer to secure data platform is confirmed;

Audio-recordings will be erased after the transcript is verified. Interview transcripts will be kept for 5 years after the MUSE study is complete and then erased.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Your answers to interview questions about you and your experience working with your home visiting program

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Certificate of Confidentiality

We have applied for a Certificate of Confidentiality to protect your privacy. This means that Dr. Whitesell or the study team cannot be forced to give out information about you unless you request this.

However, this certificate will not prevent Dr. Whitesell or her research team from making a report in some special cases.

- If you tell us about child, spousal, or elder abuse or neglect, we have to report that to Social Services or the appropriate authority, as per tribal and state legal codes.
- If you tell us that you are going to physically hurt yourself or someone else, we have to report that to the police.

Who do I call if I have questions?

Dr. Nancy Rumbaugh Whitesell is the lead researcher for this study. You may ask any questions you have now. If you have questions later, you may call Dr. Whitesell at 303-724-1456 or email her at Nancy.Whitesell@ucdenver.edu.

You may have questions about your rights as a participant in this study. You can call Dr. Whitesell with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055 or [LOCAL IRB INFO].

Consent to be in this study and use my data

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a copy of this consent form.

Do you want to be in the study at this time? (Check one box)

- Yes
- No

Signature: _____ Today's Date: _____

I explained the MUSE study to the participant and answered questions. I believe the participant understands what is expected during this study.

Consent form explained by: _____ Today's Date: _____

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.