TRIBAL
HOME
VISITING

Data Collection in the Home

A TEI Toolkit

Module 3: Collecting High-Quality Data

TRIBAL
EVALUATION
INSTITUTE
Supporting Community Decision Making by
Strengthening Data Collection and Use

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This toolkit was developed in response to needs and questions related to data collection that emerged through TEI's work with Tribal MIECHV grantees. TEI members from two institutions collaborated to create this toolkit: **James Bell Associates, Inc. (JBA)**, and **Johns Hopkins Center for American Indian Health**.

Please contact us with any questions related to this toolkit and its use.

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MODULE 3: COLLECTING HIGH-QUALITY DATA

This module discusses what high-quality data are and how program managers, data coordinators, and evaluators can support and maintain the collection of high-quality data. You get high-quality data when you ask the right questions and use the right data collection techniques. For example, you might get data by asking families questions, or you may observe interactions to collect data. In home visiting, we need to make sure we collect high-quality information from families so we can make solid decisions about our programs. In addition, if we get good data collected from the start, we will not have to go back and ask for more information later. Training staff, establishing data quality checks, and using technology are some strategies covered in this module to support high-quality data collection.

LEARNING OBJECTIVES:

By the end of this module, you will be able to:

- Understand what it means to collect high-quality data.
- Understand the purpose of, and how to prepare for, the informed consent process.
- Use strategies to support and maintain high-quality data collection.
- Answer questions about real-world challenges to quality data collection.
- Utilize strategies for developing inter-rater agreement in data collection.
- Use tools to identify the best data system for your needs.

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WHAT DOES COLLECTING HIGH-QUALITY DATA MEAN?

High-quality data are:

- **Consistent:** You collect data the same way each time. All staff members use the same data collection procedures across all participants.
- **Accurate:** Each time you collect data you follow the data collection protocol. All staff collecting data administer the measures and carefully document the data.
- **Complete:** You ask each participant every question and record each answer. The staff try to avoid missing data.

HOW DO YOU MAINTAIN HIGH-QUALITY DATA COLLECTION?

Okay, so program staff have been trained and are out in the field collecting data (see Module 2 for training ideas). What's next? Now you need to make sure you and any staff collecting data continue to collect high-quality data over time. Two processes that can help the team maintain high-quality data collection are ongoing refresher training and quality assurance checks. Over time, it is easy to drift away from what was planned, especially in the early stages of establishing practices when a protocol may seem overwhelming.

Similar to implementation fidelity, *data collection fidelity* is the extent to which data collection follows the protocol. The natural tendency to gradually deviate from a protocol over time is called *drift*.

Ongoing Data Collection Supervision

Data collection strategies aren't learned overnight. You should plan for ongoing data collection supervision. Supervision of data collection typically includes specific checks for relearning and correction. These checks should happen at least quarterly throughout the year and more often if a data collector needs extra support and guidance. You can incorporate data collection supervision into weekly staff meetings to address data collection issues that may arise (see **Agenda for Weekly Staff Meetings** for an example of how to integrate these issues into a regular staff meeting). You can identify specific topics based on the work you are doing at that time. For example, you might focus on data collection protocol development and training in the first few months of your program. Later, you might shift to continuous quality improvement topics, such as ensuring data collection visits are happening on schedule and all home visitors are collecting data as indicated in the data collection protocol. You can use interactive quizzes or games to confirm the home visitors' knowledge of the data collection policies and procedures.

TOOLS:

3.1: Agenda for Weekly Staff Meetings

Below are a few key supervision processes to think about as you plan to collect high-quality data in your program.

Supervision Processes To Support High-Quality Data Collection: Led by Program Manager, Data Coordinator, and/or Evaluator

Process	Timing	Activity
Observe data collection visits	Quarterly	Attend and observe a data collection home visit conducted by a home visitor or data collector, review data collection procedures, ensure the protocol is being followed, and problem solve together with the home visitor or data collector if necessary.
Review data collection tracking log(s)	Twice weekly	Frequently review electronic tracking log(s) to make sure data collection visits are completed as scheduled.
Review database(s)	Weekly	Review electronic database(s). Check whether data are being entered on time and accurately.
Manage paper and electronic files	Twice weekly	Observe and review file management systems in person. Check that all consent forms and data collection forms are accounted for and are filed correctly.
Check forms to make sure they are current	Monthly	Check to make sure you are using the most up-to-date versions of consent and data collection forms. Throw out, file, or recycle outdated forms.

INFORMED CONSENT PROCESS: PROTECTING YOUR FAMILIES' RIGHTS AND INFORMATION

Informed consent means that families are given information and can choose whether or not to participate in a set of activities. Frequently in home visiting programs, families engage in an informed consent process for enrolling in services, known as *consent for services*, and for participating in evaluation, known as *consent for evaluation*. Evaluation studies are sometimes referred to as *research* by Institutional Review Boards (IRBs), and your IRB may ask you to use research consent forms. Informed consent processes ensure that participants have the opportunity to understand:

In this toolkit, *consent for evaluation* refers to consent to participate in evaluation studies. *Consent for services* refers to consent to participate in the home visiting program. Both types of consent processes are likely to include descriptions of data collection.

- The purpose of data collection
- When participation in data collection is voluntary and when it is required
- The potential risks and benefits of participating

- The type of information they will be asked to provide
- The ways in which data will be used, shared, and protected
- The limits of confidentiality
- Any incentives for participation
- Whom to contact with questions about the data collection and participants' rights

Developing the Informed Consent Process

There is no "one size fits all" process for obtaining consent for all Tribal MIECHV programs. Tribal MIECHV programs collect data for many purposes, including performance measurement, evaluation studies, program improvement to meet model developer guidelines, and sometimes reporting to meet the grant recipient's own agency requirements. Further, the home visiting programs use these data in many ways; they keep some data internally for their own use and disseminate other data for reporting purposes or to inform the broader field. It is critically important that families participating in Tribal MIECHV be informed about the particular data collection activities in their program, what data will be collected, how they will be collected, and how they will be used. You will need to consider many community factors when determining the best approach for consent in your program. Given the multiple purposes of data collection in Tribal MIECHV programs, making decisions about your program's consent process can be very complicated. We have included a tool called **Informed Consent Decision-Making Guidance** to walk you through some of the decisions you need to make and some options for how to set up your program's consent process in a way that fits your community. The requirements involved in obtaining informed consent for evaluation vary and tend to be specific to the requirements of an IRB, so make sure you contact the board directly to get additional guidance on obtaining informed consent for your evaluation.

TOOLS:

3.2: Informed Consent Decision-Making Guidance

Consent Forms

You will likely develop your program's own consent forms for both services and evaluation. Both of your consent forms will probably include information about your program and the specific home visiting model you are using. For Tribal MIECHV grantees, any demographic and benchmark data collection that is required as part of the program should be clearly explained and included in the consent for services form because individuals cannot participate in the program without providing this information. The evaluation consent form will help participants distinguish this mandatory programmatic data collection from voluntary evaluation data collection. An evaluation consent form will also explain if mandatory programmatic data are going to be used in the evaluation. If you are collecting data from a comparison group of individuals not participating in services, they will need to consent to the evaluation but won't need to consent to services.

Voluntary means done by choice or free will. An individual has been fully informed about any risks and benefits of participation and has had the chance to decide to participate based on free will and not because of a sense of obligation to participate for any reason.

TOOLS:

3.3: Program Consent Form Template

3.4: Evaluation Consent Form Template

3.5: Evaluation Assent Form Template

3.6: Parental Evaluation Consent Form Template

If you plan to collect data from youth (under age 18), you will need special forms. Youth sign assent forms, which are generally shorter than consent forms and are written at a reading level more appropriate for the age of the youngest potential enrollees. Under most circumstances, a parent or guardian will sign consent forms to allow his or her child (or the child in his or her custody) to participate in the program and data collection. The following tools will help you develop your program's consent forms: **Program Consent Form Template**, **Evaluation Consent Form Template**, **Evaluation Assent Form Template**, and **Parental Evaluation Consent Form Template**.

Training Staff To Obtain Informed Consent

Whenever you plan to collect data, whether for performance measurement or evaluation purposes, it is essential that every person collecting data engages in thorough training on informed consent procedures and the protection of human subjects before he or she participates in any data collection activities.

The National Institutes of Health (NIH) offers a free public training on informed consent you can easily integrate into your training for home visitors: http://www.nimh.nih.gov/funding/grant-writing-and-application-process/elements-of-a-successful-informed-consent-video.shtml

Following any required human subjects protection training, home visitors can follow these steps to ensure they are properly trained in administering informed consent to participants:

1. Review the informed consent documents with a supervisor.
2. Observe at least two home visits in which the informed consent process is carried out by a senior home visitor.
3. Practice the consent process with co-workers.
4. Conduct a mock consent visit with the supervisor. Supervisors can use a **Consent Certification Checklist** to rate the thoroughness of the home visitor's consent process.
5. Conduct a consent visit with a prospective family while being observed/supported by a supervisor or a senior home visitor.
6. Begin conducting consent visits independently.
7. Discuss the informed consent process regularly in individual or group supervision.

A *consent visit* is a visit in which the consent form is introduced to and reviewed with the prospective participant.

TOOLS:

3.7: Consent Certification Checklist

Now that your team knows how to obtain family members' informed consent, it's time to learn more about collecting data.

DATA COLLECTION IN THE HOME

No matter where you collect data, you need to make sure the space is appropriate for data collection activities. If you are collecting data in someone's home, you may want to consider:

- How will you handle it if members of the family are suspicious about data collection?
- Will there be adequate privacy for data collection?
- Is there Internet connectivity for web-based data collection tools?
- Will noise or other activity in the home be distracting?

ACTIVITIES:

3.1: Common Questions About Data Collection in the Home

TOOLS:

3.8: Common Questions About Data Collection in the Home

As a team, you can address these issues during data collectors' training and supervision. Using an activity that appears at the end of this module, **Common Questions About Data Collection in the Home**, you can come up with strategies for dealing with various situations that may arise in the home. You can also use the tool by the same name—**Common Questions About Data Collection in the Home**—to supplement the discussion.

Even after training, data collectors may not follow the data collection protocol exactly as trained for a variety of reasons. How do you know when a data collector might need some additional training? Supervisors can observe home visits where data collection takes place and check in about the data collection process during supervision meetings with staff. We have provided a sample standardized **Data Collection Quality Assurance Form** for supervisors and home visitors to use during supervision visits. You can use this form to see if a home visitor needs to improve his or her data collection practices. If you find there are frequent lapses in the data collection protocol, you may need to provide the home visitor or data collector with more frequent observation and refresher training. You can provide feedback on use of the protocol on a regular basis, such as during a weekly staff meeting when you or a supervisor highlights any missing forms or pending data collection visits based on the continuous review of files, logs, and databases. Don't forget to celebrate when your staff are doing a great job!

Frequent data check-ins with staff provide a consistent way to ensure that data collectors are given the opportunity to do their best work and that problems are identified and resolved quickly before becoming overwhelming.

TOOLS:

3.9: Data Collection Quality Assurance Form

MEASURES USED IN HOME VISITING DATA COLLECTION

How you maintain high-quality data may depend on the type of data collected. As discussed in Module 1, home visiting programs generally use three data sources: administrative data or data from third-party agencies, client self-report, and observations. **Administrative data** or data from third-party agencies are often abstracted from databases outside of the home visiting program, such as medical or birth certificate records. **Self-report** forms or tools collect information from individuals about themselves. Self-report is a good method for collecting basic information and for asking questions that are private or potentially stigmatizing in nature. One way to collect self-reported data is to use a survey, a set of questions that can collect consistent data across participants. Surveys can be administered through various methods, such as electronically or with a paper and pencil. An interview is a method of collecting self-reported data that is administered verbally by the home visitor with the participant about his or her experiences, feelings, or opinions. The home visitor asks the participant questions and then records the responses.

Observational measures are completed by the home visitor and capture the home visitor's views or ratings of what he or she observes in the parent, child, relationship, and/or home environment. To collect high-quality observational data, you will need to make sure all your staff are collecting the data consistently or using the same pattern to score the observations. One way to confirm consistency (also called *reliability*) for observational measures is to have two staff members complete a data collection visit together. During the visit, each staff member independently completes the data collection form. After the visit, the responses can be compared to see the rate of agreement between the two staff members' data (also called *inter-rater reliability*). The goal is to have greater than 90% agreement between raters. We have provided an **Inter-Rater Agreement Tool** to calculate this agreement.

TOOLS:

3.10: Inter-Rater Agreement Tool

No matter what type of measure you use in your program, ensuring that the data collected are high quality requires a well-prepared data plan, training and supervision for home visitors, and many check-ins to ensure timely and accurate use of the measures.

USING TECHNOLOGY FOR HOME-BASED DATA COLLECTION

Increasingly, people are using technology to improve the quality and efficiency of data collection in home visiting programs. Technology can help manage visit schedules, administer data collection measures, and store outcome data. Electronic data collection can improve the accuracy and consistency of data and reduce the risk of human error during data entry. However, home visitors need to be carefully trained to use the technology for it to work correctly.

Choosing Software for Data Collection

You may need to consider many factors when choosing data collection software:

- How easy is it to use? Does it allow family members to enter data themselves or will home visitors need to enter responses?
- What do you get out of the software? What types of reports can be run, and can these reports be customized for use by home visitors and parents?
- Do you want to be able to enter data from the home? One critical consideration with software options is whether you have to be connected to the Internet to enter data. If you are working in rural communities with limited connectivity, you may want to consider software the can be used without consistent Internet access.

ACASI: Audio Computer-Assisted Self-Interview (ACASI) software is one example of software that allows you to collect data without an Internet connection. ACASI technologies can be used in two ways: (1) Home visiting participants complete self-report assessments confidentially on a laptop. Participants wear headphones during the assessment, and questions and response options appear on the screen and are read aloud over the headphones. This tool is helpful for participants who may have literacy issues and also maintains confidentiality of participants' responses by minimizing the role of an interviewer. (2) Staff-administered interviews are implemented using ACASI. In this scenario, the home visiting staff member sits across from the participant, reads questions aloud to the participant from the computer screen, and then records the participant's response into the computer in real time, thereby eliminating the need for later data entry.

In either scenario, ACASI technologies can provide real-time screening of risk assessment and reporting of screening results. In the self-report assessment completed by home visiting participants, there may be standardized questions that screen for elevated risk in areas such as mental health and substance use.

Although using ACASI technology generally takes a significant investment up front, it can save time and money in the long run by reducing data entry and improving data quality. Your program can hire an experienced developer to create ACASI software to fit your program needs, and/or you can have a program staff member trained in ACASI software development build your ACASI system.

Choosing a Data System

TOOLS:

3.11: Choosing a Data System

In addition to selecting a software program for collecting data, you may also need to choose a data system for managing your data. It is crucial to consider how the software will connect to your program's data system. It is also important to consider whether the system has easy-to-use reporting features that will enable you to run frequent data quality checks. The **Choosing a Data System** tool offers some considerations for selecting a data system.

MODULE SUMMARY

Collecting high-quality data is important, because they provide you with essential information on what your families need. Developing processes for data quality checks, supervising and training staff to collect data in the home, and determining which database will fit your program's needs are all essential approaches to successfully support high-quality data collection within your program.

APPENDIX

DEFINITIONS OF KEY TERMS

Key Term	Definition
ACASI	Audio Computer-Assisted Self-Interview, techniques for collecting data using a computer or software that allows data collection without an Internet connection.
Administrative Data	Information collected primarily for administrative (not evaluation) purposes. This type of data is collected by government departments and other organizations for the purposes of registration, transaction, and record keeping, usually during the delivery of a service. They can be data from third-party agencies and are often abstracted from databases outside of the home visiting program, such as medical or birth certificate records.
Assent	The process of involving children in the decision to take part in the evaluation or data collection. To take part in the assent process, children must be mature enough to understand the data collection and what they are expected to do. Like informed consent, assent is an ongoing conversation between the child, parents or guardian, and data collector that ensures the child is volunteering to participate. Parental or guardian consent may also be required for participation.
Consent for Evaluation	A process for ensuring participants understand the purpose of the evaluation, the voluntary nature of participation, any potential risks or benefits of participating, the type of information that will be collected, how the data will be protected, the limits of confidentiality, any incentives for participation, and whom to contact with questions about the evaluation activities and participants' rights.
Consent for Services	A process through which a program explains and gets permission from families to participate in program activities.
Consent Visit	A home visit in which the home visitor or data collector introduces and reviews the consent form with the prospective participant.
CQI	Continuous quality improvement, a strategy for thoughtfully using data to improve services by testing small, measurable changes. CQI often relies on a framework, such as the Plan-Do-Study-Act (PDSA) cycle, for understanding a problem and testing a solution.
Drift	The natural tendency to gradually deviate from a protocol over time.

Key Term	Definition
Fidelity	The extent to which delivery of an intervention adheres to the protocol or program model originally developed or the extent to which the data collector follows the data collection protocol.
High-Quality Data	Data that are consistent, accurate, and complete.
Informed Consent Process	A process for fully explaining a program or set of activities and getting permission from a person to participate. Informed consent ensures that participants understand all associated risks and benefits of participation, the activities that are required and those that are voluntary, the purpose of the program, and the ways their individual information will be used.
Inter-Rater Reliability	The degree of agreement between data collected or observed by two staff members.
Interview	A method of collecting qualitative data that is generally used to gather information verbally on a person's experience, perspectives, feelings, or opinions.
Observational Measures	Measures used to collect data that involve a data collector directly watching or observing participants' behaviors or setting. These measures capture the home visitor's views or ratings of what he or she observes in the parent, child, relationship, and/or home environment. Examples include the HOME observational tool.
Protection of Human Subjects	Protection of the rights, welfare, and well-being of people involved in research. The protection of human subjects includes using Institutional Review Boards (IRBs) to review research protocols and designs and ensuring the informed consent of research participants.
Quality Assurance	A process for ensuring that data collectors comply with required standards and protocols. For example, supervisors may examine a data collector's screener form to make sure all information was completed correctly.
Refresher Training	Training that takes place after the initial training to provide updates and reminders about how to complete the required tasks. Refresher training may be provided if a data collector has routinely forgotten to administer a part of the data collection tools or has not consistently followed the protocol.
Reliability	The degree to which a measurement tool produces stable and consistent results.

Key Term	**Definition**
Self-Report	A type of data collection that requires individuals to report data about themselves.
Survey	A tool to collect data using a set of questions for a participant to answer. Surveys can be administered through various methods: with paper and pencil, verbally, electronically, and with audio.
Voluntary	Done by choice or free will. An individual has been fully informed about any risks of participation and has had the chance to decide to participate based on his or her own free will and not because of a sense of obligation to participate for any reason.

ACTIVITY INDEX

Activity	Purpose of Activity
3.1: Common Questions About Data Collection in the Home	Explore strategies for dealing with various situations that may arise in the home.

ACTIVITY 3.1: COMMON QUESTIONS ABOUT DATA COLLECTION IN THE HOME

Once data collection begins in the "real world," your staff may run into some situations they didn't encounter during training. Below are some common questions home visitors have when collecting data in homes.

Instructions: Read each question aloud. Allow staff to brainstorm and jot down what they would do in each situation. Discuss as a group using the FAQ sheet in **Tool 3.8: Common Questions About Data Collection in the Home** at the end of the module to help guide the discussion.

Question	Response
What do I tell a family that is suspicious about data collection?	
How can I possibly collect data in a home with multiple distractions, including noise and a lot of children running around?	
How can I protect the participant's privacy when many family members are present?	

What should I do if members of the family cannot read well or do not understand English well?	
How do I handle a participant who is not paying attention to the questions or is rushing through the data collection?	
What do I do if I think the participant is not being honest in her responses to the questions?	
What do I do if a family is actively in crisis?	

TOOL INDEX

Tool	Type of Tool	Purpose of Tool
3.1: Agenda for Weekly Staff Meetings	Sample	Provides an example for how data collection can be included in a weekly team meeting and a format for meeting agendas more generally.
3.2: Informed Consent Decision-Making Guidance	Description	Explains some of the primary issues in the informed consent decision-making process. For use by program directors and evaluators making decisions about the local process for informed consent and development of necessary forms. Provides general guidance on the development of consent/assent forms.
3.3: Program Consent Form Template	Template	Provides a template for a home visiting consent form that is programmatic in nature and addresses non-evaluation-related data collection.
3.4: Evaluation Consent Form Template	Template	Provides a template for a consent form used for evaluation.
3.5: Evaluation Assent Form Template	Template	Provides a template for a child assent form for use when evaluation participants are under 18 years old.
3.6: Parental Evaluation Consent Form Template	Template	Provides a template for a parental consent form for use when evaluation participants are under 18 years old.
3.7: Consent Certification Checklist	Sample Checklist	Provides supervisors a system for tracking home visitor's training activities related to attaining informed consent.
3.8: Common Questions About Data Collection in the Home	FAQ Sheet	Provides frequently asked questions and answers for home visitors collecting data in the home.

3.9: Data Collection Quality Assurance Form	Sample	Provides an example of a tool used by supervisors and home visitors to rate data collection quality and assess training/supervision needs.
3.10: Inter-Rater Agreement Tool	Excel Template	Provides a template for calculating and reviewing agreement between raters for observational tools.
3.11: Choosing a Data System	Description	Provides an explanation of things to consider when selecting a data system (software) for your program.

TOOL 3.1: AGENDA FOR WEEKLY STAFF MEETINGS

Home Visiting Project
Weekly Team Meeting
Standing Agenda

- Welcome, Check-In, and New Items for Agenda

- Recruitment and Status of Referrals
    - Number of referrals and enrollment in the past week
    - Progress toward recruitment goal

- Participant Update From Each Home Visitor
    - Review of visits completed in the past week
    - Review of missed visits and plan to connect with participants
    - Other participant concerns, challenges, or successes home visitors would like to share

- Evaluation/Data Reminders
    - Participant tracking log review
    - Upcoming data collection visits
    - Missing data in database
    - Other evaluation/data issues

- Community Meetings and Community Partnerships

- Media
    - Facebook
    - Photos
    - Newsletter

- Other Items

TOOL 3.2: INFORMED CONSENT DECISION-MAKING GUIDANCE

Context 1: Data for Program Use Only

- Program data are used for program purposes only, not for evaluation.
- Identify the body that has authority to review/authorize your program consent process.
- Describe demographic and benchmark data collection activities in the **program consent form**.

Context 2: Data for Combined Program and Study Use

- Program enrollees can participate in a voluntary evaluation study. Enrollees can still participate in the program without participating in the evaluation.
- Identify both the IRB with authority to review and authorize your consent plan for evaluation studies and the body that has authority to review and authorize your program consent process.
- Use guidelines from both authorities to develop your informed consent procedures and forms. **Use separate or combined program and evaluation consent forms**.

Context 3: Data for Evaluation or Research Study Only

- Data are collected as part of an evaluation or research study independent of program implementation.
- Identify the IRB with authority over your agency or partner agency (university) and develop informed consent processes and forms using that IRB's guidelines.
- Include all language about data collection activities in the **research consent forms**.

The first step to developing your informed consent process is understanding the context within which data will be collected. There are three primary possible contexts presented below that have different implications for the informed consent process.

Context 1: Data for Program Use Only

CONTEXT 1: DATA FOR PROGRAM USE ONLY: In the first context, there are home visiting programs that collect required data for program performance measurement only and not any additional data. These programs require a *consent for services* process that meets the requirements for the agency hosting the program. Generally, this will look like what you sign at the doctor's office and will explain that participation in the program also requires participation in required data collection.

Developing a Program Consent Form: For this context, you will likely develop a consent for services form. If your home visiting program does not have any associated studies, you will have a *program consent form* only. It is likely that the agency sponsoring your project has other projects that use consent forms and you can use these forms to model your program's materials. Just because data are not being collected for an evaluation or research study, it is still important for you to clearly explain data collection procedures. By explaining required data collection in a consent for services process, families will be less likely to react negatively when they are asked to provide information during home visits.

Context 2: Data for Combined Program and Evaluation Use

CONTEXT 2: DATA FOR COMBINED PROGRAM AND EVALUATION USE: In the second context, home visiting programs (such as the ones funded by Tribal MIECHV) collect required program data (demographic and performance measurement data) and evaluation data.

Developing Consent Forms for Both Program and Evaluation Data: If your home visiting program offers participation in an optional *rigorous evaluation* (participants can receive home visiting services and chose not to participate in the evaluation), you will likely need a separate *consent for services form* and *evaluation consent form*. You can also generate one combined consent form that meets the criteria for all relevant authoritative bodies (i.e., agency and IRBs) and includes a check box for individual participants to opt in or out of optional activities (e.g., the evaluation component). **Most Tribal MIECHV grantees fall into this context and are conducting rigorous evaluations that have data collection goals and procedures distinct from their program services.** These programs are likely to administer separate consent forms or use the check box method for providing families an opportunity to consent to service and evaluation activities separately. All Tribal MIECHV grantees must receive IRB approval to conduct their rigorous evaluation. IRB approval includes careful review of the program's consenting procedures.

Context 3: Data for Evaluation or Research Study Only

CONTEXT 3: DATA FOR EVALUATION OR RESEARCH STUDY ONLY: In the third context, data collection happens as part of a larger evaluation or research study rather than a particular community's home visitation program. This context means that participants *cannot* receive home visiting services without consenting to participate in the research or evaluation study. For example, the Family Spirit model was developed with a series of research studies that were overseen by the Johns Hopkins Institutional Review Board. All home visiting services were provided as part of the research study, and all data collection activities were done as part of a systematic investigation with the goal of contributing information to general knowledge (definition of research) with human subjects (individuals receiving home visiting services).

Developing a Study Consent Form: A *study consent form* will need to be developed and submitted for review by an IRB when information on individuals participating in your home visiting program will be used in a research study. It is likely that if your home visiting services are provided in this context, you will be working in partnership with a university. This partner will play a big role in the development of informed consent processes and materials and should offer significant support in this area. If home visiting services are being provided as part of the study, your program can use a single *study consent form*. In this case, if a person declines participation in the study, he or she will not be able to receive home visiting services because those services are tied to the research study rather than to community programs. The IRB must review and approve all data collection protocols and consenting materials.

GUIDANCE FOR WRITING CONSENT MATERIALS: It is generally recommended that consent forms for adult participants (at least 18 years old) be written at an 8th-grade reading level and assent forms for minor participants (under 18 years old) be written at a 4th-grade reading level. Microsoft Word will display information about the reading level of a document after it checks the spelling or grammar (to adjust this setting in Word, go to File, Options, Proofing, and select "Show readability statistics"). It is important to consider the needs of the community, as well as its members' literacy, oral tradition, and interpretation/translation, in the development of the informed consent process and consent forms. Local universities and national tribal research groups can be good resources for additional guidance on preparing a consent or assent form.

Informed Consent Must:

- Ensure the potential participant can reach a truly informed decision about whether or not to participate.
- Be given freely and voluntarily, without coercion or influence by the person or organization administering the consent.
- Establish a clear understanding of what participation involves.

- Be an ongoing process and not just a form a potential participant must sign.
- Ensure a clear understanding that consent can be withdrawn anytime by the participant.
- Clearly state the situations in which program staff can no longer maintain the participant's privacy/confidentiality.

In home visiting, it is particularly important for the person developing the informed consent process and materials to understand any relevant mandatory reporting laws. The obligation to report abuse, neglect, or other issues must be clearly understood by all staff and explained in the consent forms that are provided to potential participants.

Special Considerations for Participants Under 18: If potential participants are under 18 years old, their legal guardian must consent for them to participate and the minor must also assent. Assent is a process that allows minors to indicate that they have chosen to participate voluntarily. In the Tool Index for this module, you will see an Evaluation Assent Form Template and a Parental Evaluation Consent Form Template, which are necessary for individuals under 18 to engage in data collection. In some situations in which obtaining written parental consent for the minor would actually increase the minor's risk, the requirement to obtain consent can be waived. For example, a "waiver" is sometimes used when teenage mothers are not supported by their families or are at risk within their families. In such a case, a program might apply for a waiver of documentation of consent for the parents of the teenage mother and allow her to assent independently to receive the services she needs.

Program Logo

TOOL 3.3: PROGRAM CONSENT FORM TEMPLATE
[Program Name]
Consent To Participate in Home Visiting Services

Program Introduction

Sample text: [Program Name] supports pregnant women and families with children from [catchment area of program]. In this program, parents will learn...
If you choose to take part in this program, [Home Visitor] will come to your home to support you and your family in [brief statement about overall program goals and/or outcomes].

Program Activities

- [Add program participation requirements as bullets here].
  Some suggestions include:
    - Timeline for participation (*Sample text:* Visits will begin once you enter the program and continue until…).
    - Description of the commitment for participation (*Sample text:* Your Home Visitor will visit you on a weekly or biweekly basis until your child is age 2).
    - Description of the policy for withdrawing from the program (*Sample text:* You can stop receiving services at any time by calling the program office at…).
    - Introduction of data collection (*Sample text:* You will be asked to provide information about yourself and your family…).
    - Use of information from other agencies (*Sample text:* We will access information about your family from other organizations you might be working with including WIC and Social Services…).
    - Provision of feedback (*Sample text:* You will be asked to provide feedback about the program to help us improve).
    - Introduction to the related voluntary evaluation (*Sample text:* You may be asked to participate in a voluntary evaluation of the program…).

Introduce Relevant Staff

Sample text: A [Home Visitor] is a professional who will meet with you to….
You may also meet with other program staff including (e.g., directors, evaluators)….

Participant Rights

Sample text: Enrolling in this program is voluntary and you can stop any time. (State other rights as they apply.)

Program Funding

Sample text: [Program Name] is funded by a grant from the Administration for Children and Families to the [name of tribal organization administering the program].

Program Staff Contact Information

Sample text: You can speak with your [Home Visitor] anytime if you have questions. You may also contact the [Title and Name of Individual responsible for the program] at [appropriate contact information] anytime if you have questions. Calls will be returned within 24 business hours.

<u>How Information Collected on Families Will Be Shared</u>

Sample text: You will be asked to share personal information as you take part in this program. We need to collect this information to make sure you receive the best possible home visiting services and to make sure these services work for you, your family, and the [tribal community/organization].

[Program Name] staff will make sure information that identifies you will not be shared for any purposes other than:

- To help you receive **best possible services**
- To ensure your family's **safety**

Best Possible Services: *Sample text:* Information that identifies you and/or your family may be shared with other service providers to help you receive the best services possible. One example would be a [Home Visitor] sharing information in order to make a referral for yourself or your child.

Safety: *Sample text:* It is important that you know that the program staff may disclose your protected health information to [agency responsible for mandatory reporting in your community] to avoid a serious threat to your health and safety or the health and safety of others. We want to make sure you and your family feel safe at home and in your community.

Sample text: Because this program is funded by an organization outside of [name of tribal organization], staff must report certain information about everyone who participates in the program. This information is de-identified. *De-identified* means that your name and any other information that can identify you (such as address and phone number) will not be shared. An example might be that we would report that 15 families took part in home visits in year 1. In this example, we do not share any information about which families participated, just that 15 families did participate in that year. De-identified information about you, your family, and the home visiting services you receive will be shared for tribal and federal reporting and for program evaluation.

Tribal and Federal Reporting: *Sample text:* De-identified information about you and your family will be shared with the federal entity that funded this program, Administration for Children and Families and with [tribal organization administering the program].

Evaluation: *Sample text:* The information gathered by your [Home Visitor] during your participation in the program will be shared with an Evaluator. This information will be used to see how well [Program Name] is achieving its goals and how we can improve the program. We will not use names or any other identifiers with your information, and the answers you provide will be combined with answers from all the other program participants.

If your program videotapes home visits for any reason:

Videotaping:

Sample Text: At some point your Home Visitor may want to videotape parts of the home visit. These videotapes would be used during your [Home Visitor's] supervision to make sure your family is receiving the best possible care. Also, the videotapes would be used by your [Home Visitor] to observe your child and family in order to see if there are changes in the way you and your child communicate. The tapes will not be shared with anyone other than program staff and will be destroyed after the program ends. If you have any concerns about videotaping, please feel free to talk to your [Home Visitor]. Being videotaped is voluntary and does not have an effect on your home visiting services.

Please check below to consent to be videotaped during your participation in this project:

_____ Yes, I agree to be taped during my participation in this project.
_____ No, I do not agree to be taped during my participation in this project.

Consent Documentation

Sample text: This consent will be valid until you have finished taking part in the [Program Name]. You can end your consent at any time by contacting [Name of Program Contact, Contact Information]. If you choose to do so, your authorization will be terminated after a written request has been received and logged by program staff. Any information provided prior to termination will not be affected.

Sample text: My signature below indicates I was given the opportunity to ask any questions I have about participating in [Program Name] and my questions were answered. By signing this consent form, I agree to take part (or let my child take part) in this program and in the evaluation of the program. A copy of this consent form will be provided to me.

______________________	______________________	________________
Participant's Signature	Participant's Printed Name	Date
______________________	______________________	________________
Parent/Legal Guardian's Signature	Parent/Legal Guardian's Printed Name	Date
______________________	______________________	________________
[Program Name] Representative's Signature	[Program Name] Representative's Printed Name	Date

Program Logo

TOOL 3.4: EVALUATION CONSENT FORM TEMPLATE
[Program Name]
Consent To Participate in the Evaluation Study

Introduction

Sample text: You and your child are part of the [Program Name] home visiting program, which supports pregnant women and families with children from [catchment area of the program]. In this program, a Home Visitor will meet with families in their home and support them in [brief statement about overall program goals and/or outcomes].

Purpose of the Evaluation

Sample text: As part of the grant that pays for these services, [Program Name] is required to do an evaluation to learn more about the kinds of services that work well for families in tribal communities. We are asking for your help in this process. This consent form will tell you more about the study so you can decide if you want to participate.

Participation

Sample text: If you agree to participate in the evaluation study, we will set up an initial appointment with a member of the [Program Name] staff to review the consent for the study and answer any questions you may have. You will then be asked to participate in [type and number of assessments required]. You will be asked questions about [brief description of the topics]. Some of the questions may be very personal to you. Your answers will help [Program Name] learn the best ways to provide services to families in the community.

- **If you agree** to be part of the evaluation study, your answers will be given to the Local Project Evaluator without your name. Your answers will be combined with answers from other study participants.
- **If you do not agree** to be part of the evaluation study, you will still receive services through the [Program Name] home visiting program. Your answers will NOT be given to the Local Project Evaluator and they will NOT be included in the study.

Information You Share

Sample text: The only groups of people who will see the information about you and your family are:

- **[Program Name] home visiting team:** This team includes [list of positions on the program team]. This team will use the information you share to make sure you get services that meet your individual and family goals. Your information will be kept strictly confidential.
- **Local Project Evaluator:** The Local Project Evaluator is required to keep all information private and confidential. Study forms provided to the Evaluator will use a code, instead of your name, so the Evaluator will NOT know your name. The Evaluator will not be in any staff discussion or see the notes Home Visitors keep about their work with you.

- **Federal funding agency:** [Program Name] and the Local Project Evaluator will develop reports to meet the federal grant requirements. These reports will combine information from all study participants. They will not report on individuals, so your name will not be part of these reports.

Privacy Protection

Sample text: Strict precautions will be taken to protect information you share with us about you and your family. Typical procedures to protect your privacy include:

- Removing identifying information (such as your name, your child's name, your address, and your social security number) from your records. For example, instead of using your name on your records, we will use a random number code.
- Keeping records on a password-protected computer in a locked office.
- Allowing only authorized members of the evaluation team to have access to your records.
- Making sure the authorized members of the evaluation team, including your Home Visitor, will never disclose your information unless required by a court of law, which is highly unlikely.
- Confirming that your specific data will never be singled out or identified on reports for this program.

Possible Risks

Sample text: This evaluation study has little risk associated with participation. Your consent or dissent to participate in the evaluation will not affect your eligibility to continue receiving any services, including [Program Name] home visiting services. Risks could include breaks in privacy of information about you; however, [Program Name] has taken many steps to make sure this does not happen. You might become emotionally upset in answering some of the questions. If you say you may harm yourself or others, we will report it to a clinician or the police. If we become aware of child abuse or neglect, we will report it to Child Protection Services.

Possible Benefits

Sample text: There may not be any immediate benefits to you and your family. The information collected for this evaluation study will help families like yours continue to receive high-quality home visiting services. It can improve programs that support better parenting for families.

Incentive To Participate

Sample text: You do not have to pay anything to be in the study. You will be provided with [brief description of incentive] to complete each assessment. You could receive a total of [incentive total] if you participate in all the assessments required for the study.

Participation Is Voluntary

Sample text: You do not have to participate in the evaluation study if you do not want to. You will continue to get all the services you are currently getting whether or not you participate or continue to participate in the study. You do not have to answer every question, and you may choose to end your participation in the evaluation at any time. If you choose to stop participating in the evaluation study, you will not be penalized in any way. If you decide to leave the study, we will no longer collect data from you for evaluation purposes and the information that was already collected will not be included in the study of the program.

If you wish to stop participating in the evaluation study, please call the [Program Name] Director at [phone number].

If you agree to participate, please read and sign below. *Sample text:* This study has been explained to me. The [Program Name] staff told me that some questions may be very personal. I was told that if I plan to hurt others or myself, it will be reported to a clinician or the police. If staff are concerned about child abuse or neglect, they will report it to Child Protection Services. The project will provide me [brief description of incentive] to complete the assessments. I freely agree to be in this study. I know I do not have to answer every question, and I can leave the study at any time without penalty. I have had a chance to ask questions. If I have further questions or want to leave the study, I can call the [Program Name] Director at [phone number].	
PARTICIPANT SIGNATURE:	**DATE:**
PRINT NAME:	
SIGNATURE OF [PROGAM NAME] STAFF:	**DATE:**

Program Logo

TOOL 3.5: EVALUATION ASSENT FORM TEMPLATE
[Program Name]
Assent To Participate in the Evaluation Study
FOR YOUTH PARTICIPANTS UNDER 18 YEARS OLD

Sample text: You are part of the [Program Name] home visiting program, which supports pregnant women and families with children from [catchment area of the program]. In this program, a Home Visitor meets with families in their home and supports them in [brief statement about overall program goals and/or outcomes].

We want to tell you about an evaluation study we are doing. An evaluation study is a way to learn about how well a program is working. The [Program Name] evaluation study will be used to learn more about the kinds of services that work well for families in tribal communities. We are asking for your help in this process. This consent form will tell you more about the study so you and your parent(s) can decide if you want to participate.

If you agree to participate in the evaluation study, we will set up an initial appointment with a member of the [Program Name] staff to answer any questions you and your parent(s) may have about the study. You will then be asked to participate in [type and number of assessments required]. You will be asked questions about [brief description of the topics]. Some of the questions may be very personal to you. Your answers will help [Program Name] learn the best ways to provide services to families in the community.

- **If you agree** to be part of the evaluation study, your answers will be combined with answers from other study participants and no one will know which answers you gave.
- **If you do not agree** to be part of the evaluation study, your answers will NOT be included in the study, but you will still be able to receive services through the [Program Name] home visiting program.

Only certain people will see the information you share:

- **The [Program Name] home visiting team:** This team will use the information you share to make sure you get the best services. They will not tell anyone what you shared.
- **Local Project Evaluator:** The Local Project Evaluator will be provided with the information you share but not your name. The Evaluator will not talk with your Home Visitor about you or see any notes about his or her work with you.
- **Federal funding agency:** [Program Name] and the Local Project Evaluator will develop reports. These reports will combine information from all study participants, and your name will not be part of these reports.

We will protect what you share with us by keeping your personal information anonymous, only allowing authorized evaluation team members to see your information, and making sure no one from the evaluation team shares your information with anyone else.

This evaluation study has little risk. Whether you agree or disagree to participate in the evaluation study, you will still be able to continue receiving any services, including [Program Name] home visiting services. Risks could include breaks in privacy of information about you; however, [Program Name] has taken many steps to make sure this does not happen. You might become emotionally upset in answering some of the questions. If you say you may harm yourself or others, we will report it to a clinician or the police. If we become aware of child abuse or neglect, we will report it to Child Protection Services.

There may not be any immediate benefits to participating in the evaluation study. The information collected for this evaluation will help families like yours continue to receive high-quality home visiting services. It can improve programs that support better parenting for families.

You do not have to pay anything to be in the study. You will be provided with [brief description of incentive] to complete each assessment. You could receive a total of [incentive total] if you participate in all the assessments required for the study.

Please talk this over with your parent(s) before you decide whether or not to participate. We will also ask your parent(s) to give their permission for you to take part in this study. Even if your parent(s) says "yes," you can still decide not to be in this study. If you do not want to be in the study, you do not have to. Being in this study is up to you, and no one will be upset if you do not want to participate or even if you change your mind later and want to stop. Remember, you will continue to get all the services you are currently getting whether or not you participate, or continue to participate, in this study.

You can ask questions you have about this study. If you have a question later or you wish to stop participating in the evaluation study, please call the [Program Name] Director at [phone number] or talk to your Home Visitor the next time you see him or her.

Signing your name below means that you agree to be in this study. You and your parent(s) will be given a copy of this form after you sign it.	
PARTICIPANT SIGNATURE:	**DATE:**
PRINT NAME:	
SIGNATURE OF [PROGRAM NAME] STAFF:	**DATE:**

Program Logo

TOOL 3.6: PARENTAL EVALUATION CONSENT FORM TEMPLATE

[Program Name]
Parental Consent To Participate in the Evaluation
FOR PARENTS/GUARDIANS OF YOUTH PARTICIPANTS UNDER 18 YEARS OLD

Introduction

Sample text: Your child is part of the [Program Name] home visiting program, which supports pregnant women and families with children from [catchment area of the program]. In this program, a Home Visitor will meet with families in their home and support them in [brief statement about overall program goals and/or outcomes].

Purpose of the Evaluation

Sample text: As part of the grant that pays for these services, [Program Name] is required to do an evaluation to learn more about the kinds of services that work well for families in tribal communities. We are asking for your child's help in this process. This consent form will tell you more about the study so you and your child can decide if he or she will participate.

Participation

Sample text: If you and your child agree that he or she will participate in the evaluation study, we will set up an initial appointment with a member of the [Program Name] staff to review the consent for the study and answer any questions you or your child may have. Your child will then be asked to participate in [type and number of assessments required]. He or she will be asked questions about [brief description of the topics]. Some of the questions may be very personal to your child. Your child's answers will help [Program Name] learn the best ways to provide services to families in the community.

- **If you and your child agree** that your child will be part of the evaluation study, his or her answers will be given to the Local Project Evaluator without your child's name. Your child's answers will be combined with answers from other study participants.
- **If you and your child do not agree** that your child will be part of the evaluation study, your child will still receive services through the [Program Name] home visiting program. Your child's answers will NOT be given to the Local Project Evaluator and they will NOT be included in the study.

Information Your Child Shares

Sample text: The only groups of people who will see the information about your child are:

- **[Program Name] home visiting team:** This team includes [list of positions on the program team]. This team will use the information your child shares to make sure your child gets services that meet his or her individual and family goals. Your child's information will be kept strictly confidential.
- **Local Project Evaluator:** The Local Project Evaluator is required to keep all information private and confidential. Study forms provided to the Evaluator will use a code, instead of your child's name, so the Evaluator will NOT know your child's name. The Evaluator

will not be in any staff discussion or see the notes Home Visitors keep about their work with your child.

- **Federal funding agency:** [Program Name] and the Local Project Evaluator will develop reports to meet the federal grant requirements. These reports will combine information from all study participants. They will not report on individuals, so your child's name will not be part of these reports.

<u>Privacy Protection</u>

Sample text: Strict precautions will be taken to protect the information your child shares with us about your child and his or her family. Typical procedures to protect your child's privacy include:

- Removing identifying information (such as your child's name, address, social security number, and family members' names) from your child's records. For example, instead of using your child's name on his or her records, we will use a random number code.
- Keeping records on a password-protected computer in a locked office.
- Allowing only authorized members of the evaluation team to have access to your child's records.
- Making sure the authorized members of the evaluation team, including your child's Home Visitor, will never disclose your child's information unless required by a court of law, which is highly unlikely.
- Confirming that your child's specific data will never be singled out or identified on reports for this program.

<u>Possible Risks</u>

Sample text: This evaluation study has little risk associated with participation. You and your child's consent or dissent for your child to participate in the evaluation will not affect his or her eligibility to continue receiving any services, including [Program Name] home visiting services. Risks could include breaks in privacy of information about your child; however, [Program Name] has taken many steps to make sure this does not happen. Your child may become emotionally upset in answering some of the questions. If your child says he or she may harm him- or herself or others, we will report it to a clinician or the police. If we become aware of child abuse or neglect, we will report it to Child Protection Services.

<u>Possible Benefits</u>

Sample text: There may not be any immediate benefits to your child. The information collected for this evaluation study will help families like your child's continue to receive high-quality home visiting services. It can improve programs that support better parenting for families.

<u>Incentive To Participate</u>

Sample text: You do not have to pay anything for your child to be in the study. Your child will be provided with [brief description of incentive] to complete each assessment. Your child could receive a total of [incentive total] if he or she participates in all the assessments required for the study.

Participation Is Voluntary

Sample text: Your child does not have to participate in the evaluation study if he or she does not want to. Your child will continue to get all the services he or she is currently getting whether or not he or she participates or continues to participate in the study. Your child does not have to answer every question and may choose to end his or her participation in the evaluation at any time. If your child chooses to stop participating in the evaluation study, your child will not be penalized in any way. If your child decides to leave the study, we will no longer collect data from your child for evaluation purposes and the information that was already collected will not be included in the study of the program.

If your child wishes to stop participating in the evaluation study, please call the [Program Name] Director at [phone number].

If you agree to participate, please read and sign below. *Sample text:* This study has been explained to me. The [Program Name] staff told me that some questions may be very personal to my child. I was told that if my child plans to hurt him- or herself or others, it will be reported to the police or a clinician. If the [Program Name] staff are concerned about child abuse or neglect, they will report it to Child Protection Services. The project will provide my child [brief description of incentive] to complete the assessments. I freely agree to allow my child to be in this study. I know my child does not have to answer every question and my child can leave the study at any time without penalty. My child and I have had a chance to ask questions. If we have further questions or my child wants to leave the study, I can call the [Program Name] Director at [phone number].	
PARENT/GUARDIAN SIGNATURE:	**DATE:**
PRINT NAME:	
SIGNATURE OF [PROGRAM NAME] STAFF:	**DATE:**

TOOL 3.7: CONSENT CERTIFICATION CHECKLIST

Supervisors: Observe the home visitor in a role play providing informed consent to a new participant. Check off each item as it is addressed, and in the comments section, note any impressions and any follow-up training needed.

Date of role play: _______________

ELEMENT	Completed	Comments
Describes criteria for program enrollment (e.g., first-time mom, age of mother, risk factors)		
Describes when to get informed consent from participants		
Shows ability to introduce program in a positive way		
Verifies participant's identity and age (if obtaining permission from a parent or legal guardian, confirm identity and relationship to participant)		
Briefly describes project history		
Describes what it means to give informed consent		
Explains that the participant does not have to take part in the program		
Explains the purpose of the home visiting program		
Explains program participation in detail, including duration and content (e.g., how many home visits, how long the program goes)		
Explains data collection activities (e.g., when and by whom data will be collected, what type of information will be collected, how data will be used and stored, when data will be destroyed)		
Explains confidentiality, including use of ID numbers, Certificate of Confidentiality, and situations in which information cannot be kept private (i.e., mandatory reporting)		
Introduces the evaluation study if appropriate		
Explains there is no penalty if the participant stops receiving home visiting services		
Explains who to call with questions		
Gives participant/parent/legal guardian time to read consent		
Invites questions and checks for understanding		
Describes documentation required on consent/parent permission forms		

Print name of home visitor being certified____

Signature of home visitor _______________________ Date___________________

Signature of supervisor _________________________ Date___________________

Modified from Consent Certification Checklist with permission from Johns Hopkins Center for American Indian Health,

TOOL 3.8: COMMON QUESTIONS ABOUT DATA COLLECTION IN THE HOME

FAQ Sheet

What do I tell a family that is suspicious about data collection? It is actually a good sign that the family members can communicate to you that they are suspicious of data collection. Some people have had negative experiences or have negative associations with evaluation, research and data. There are a couple of things that might alleviate their concerns:

- During the informed consent process, tell the family all of the steps the program staff take to ensure confidentiality (e.g., data will be presented in a way that does not identify individual participants).
- Reassure the family that the data will be used only for the specific purpose of this program and not for any other purpose.
- Talk with the family members about the potential for their participation in the evaluation to help many other families in similar communities around the country and around the world.
- Create a safe space with enough time to talk through this important issue.

How can I possibly collect data in a home with multiple distractions, including noise and a lot of children running around? For a noisy or potentially distracting home environment, bring a second staff member to help entertain children or talk with adults who are not part of the data collection. Bring paper and crayons, toys, books, and/or a portable electronic device (iPad) for children. Consider doing some parts of the visit in the vehicle where it is quiet, or if allowed by your organization, drive the participant to a quieter location such as the program office. This scenario can also be used as a teaching moment for the parents. Get the parents to help set up the child with a pleasant distraction and reward the child with non-material reinforcements (e.g., hug, positive words, time to play at the end with the home visitor and mom) for being contented and attentive to her/his toy or task.

How can I protect the participant's privacy when many family members are present? Consider doing the visit in the vehicle or bringing the participant back to the project office. Also consider technology such as ACASI (discussed in Module 3), which enables the participant to complete the assessment on a laptop while wearing headphones to hear the questions.

What should I do if members of the family cannot read well or do not understand English well? It is important that you handle this situation the same way for all families. Once you decide the best way to handle this type of situation, share the decision with any staff who collect data. A simple memo or perhaps a more in-depth training may be appropriate for conveying the decision to staff. Some possible solutions could include a longer visit for data collection. For participants who do not read well, you could read the questions aloud to them. For participants who do not understand English, you could bring a staff member who speaks the same language and have that staff member translate questions and responses when appropriate.

How do I handle a participant who is not paying attention to the questions or is rushing through the data collection? At times we all get impatient, bored, or distracted. When you are collecting data, you may find that participants feel this way while you are asking questions. We have included some general strategies to help you if you run across a participant who appears to be distracted or rushing.

- Take a break with the participant. Answering questions, especially when they are personal, can be exhausting.
- Bring healthy snacks and water to offer to the participant during data collection.
- Check in with *you*! Ask yourself how you are feeling and what impression you are giving. Are you hot, tired, or hungry? If you are, your participant may be feeling the same way. Are you giving off the impression that you are tired or bored? Your participant might be picking up that you are feeling tired or are thinking of something else. If you think this might be the case, take a moment to regroup yourself. Take a few deep breaths, smile, or do something small to help you get refocused or energized. Can you open a window or change the environment in some way? See what you can control in the situation and act accordingly.

What do I do if I think the participant is not being honest in her responses to the questions? Sometimes you may need to ask participants sensitive or difficult questions. Remember that we all have a desire to "look good" to others. Because of the phenomenon psychologists call "social desirability," people answering questions will sometimes give answers they think the data collector wants to hear. For example, if a person is asked how much he or she smokes, he or she may say "a few cigarettes a day," when in reality the person smokes half a pack a day. Although this is a normal response, we want our participants to feel comfortable being honest when answering our questions. Throughout the visit you can:

- Remind the participant that there are no right or wrong answers to the questions.
- Assure her that her responses are confidential.
- Do not challenge the participant during the data collection.

If there are reasons to believe the participant is not reporting truthful responses, document your thoughts and discuss the case with a supervisor and/or an evaluator. In some cases, it may make sense for a different home visitor to re-do the data collection visit.

What do I do if a family is actively in crisis? It is important to know your boundaries and the limits of your role as a home visitor. Unless you have training (e.g., in nursing or mental health) that specifically qualifies you to respond to a family in crisis, you will need to contact the person in your agency/community who is identified to respond to crises. Have a plan among the project team for addressing acute mental health or domestic issues. Be sure you have emergency contacts (e.g., police, fire, EMT, program supervisor, co-workers) programmed in your phone. Bring a list of resources in the community so you can call other resources as needed, or give the contact information to the family. If necessary, remind the family of any mandated reporting that might be required. Be prepared to stop the assessment and reschedule for another time.

TOOL 3.9: DATA COLLECTION QUALITY ASSURANCE FORM

Home Visiting Program

Observation of Home Visitor Data Collection

Date of Review ___ ___ / ___ ___ / ___ ___
Reviewer Initials ___ ___ ___
Home Visitor Initials ___ ___ ___
Participant ID #____ ____ ____ ____

Length of Visit: ____hr ___min

Type of Assessment (check all that apply):	Time Point:
☐ Demographic Interview ☐ Participant Self-Report	☐ Baseline ☐ 3 months ☐ 6 months ☐ 12 months

OVERALL

1. Brings all necessary equipment/materials.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
2. Introduces purpose of interview/assessment.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
3. Attempts to establish rapport with participant.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
4. Uses time efficiently.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
5. Maintains neutral judgment.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
6. Maintains professionalism and appropriate boundaries.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
7. Follows proper order indicated on the data collection flowchart.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
8. Distributes gift card and enters it correctly on gift card log.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**

DEMOGRAPHIC INTERVIEW

1. Reviews Demographic Interview purpose and directions.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
2. Asks interview questions clearly and gives ample time for participant to respond.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
3. Clearly and thoroughly answers participant's questions.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**

PARTICIPANT SELF-REPORT				
1. Completes the first portion of the ACASI including participant ID.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
2. Describes procedure for completing the self-administered ACASI. Gives the participant headphones to wear.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
3. Administers PAR as an interview and asks detailed follow-up questions on activities reported.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
4. Reviews the PHQ-9 Summary Report and discusses with participant if total score is >11 or the participant answered "yes" to questions 12 or 13.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**
5. Addresses the participant's questions.	**EXCELLENT**	**GOOD**	**FAIR**	**POOR**

Recommendations:

☐ No action needed

☐ Action needed: ____

____

____

Reviewer Signature ________________________________ Date ___ ___ / ___ ___ /___ ___

Home Visitor Signature ______________________________ Date ___ ___ / ___ ___ /___ ___

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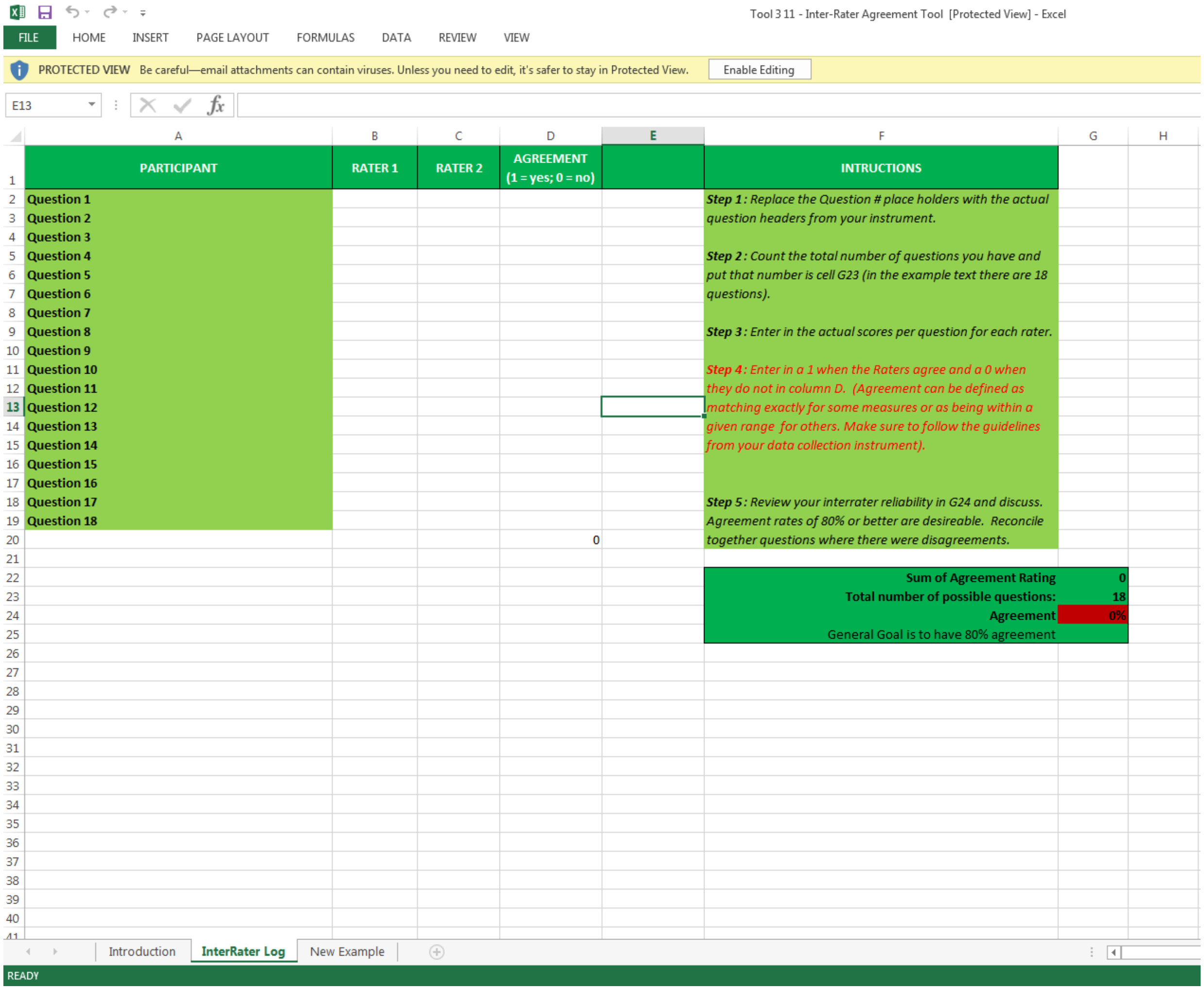
TOOL 3.10: INTER-RATER AGREEMENT TOOL
EXCEL FILE

This Excel file provides a template you can use for calculating and reviewing the level of agreement between raters using observational tools.



PARTICIPANT	RATER 1	RATER 2	AGREEMENT (1 = yes; 0 = no)
Question 1			
Question 2			
Question 3			
Question 4			
Question 5			
Question 6			
Question 7			
Question 8			
Question 9			
Question 10			
Question 11			
Question 12			
Question 13			
Question 14			
Question 15			
Question 16			
Question 17			
Question 18			
			0

INTRUCTIONS

***Step 1**: Replace the Question # place holders with the actual question headers from your instrument.*

***Step 2**: Count the total number of questions you have and put that number is cell G23 (in the example text there are 18 questions).*

***Step 3**: Enter in the actual scores per question for each rater.*

***Step 4**: Enter in a 1 when the Raters agree and a 0 when they do not in column D. (Agreement can be defined as matching exactly for some measures or as being within a given range for others. Make sure to follow the guidelines from your data collection instrument).*

***Step 5**: Review your interrater reliability in G24 and discuss. Agreement rates of 80% or better are desireable. Reconcile together questions where there were disagreements.*

Sum of Agreement Rating	0
Total number of possible questions:	18
Agreement	0%
General Goal is to have 80% agreement	

TOOL 3.11: CHOOSING A DATA SYSTEM

Issue	Considerations	Notes
Platform	• Is it a web-based system or installed ("stand alone")? • Does your tribe/community have the needed infrastructure if data are housed on site? • Do the platform needs of the system (e.g., bandwidth, server space, wireless access) match the infrastructure realities of your community?	
Security	• If you have off-site home visitors or evaluators, will it be possible to provide secure remote access to the data? • Do you have the ability to change user access rights? • How are data backed up? • Is information encrypted and HIPAA compliant?	
Access	• Will you have access to raw data or only aggregated reports? • How will data be accessible? ○ For CQI? ○ For performance measurement? ○ For the rigorous program evaluation? ○ For dissemination efforts? • Will the evaluation team have needed access to these data?	
Flexibility/ Customizability	• Will the system allow for use of tribal language(s) or other languages spoken by your participants? • Does the system have a pre-populated list of measures or interventions? Can this be adapted for your program? • Can you change questions on forms or items on reports? • Does the system allow for qualitative data fields? • How long will changes take to design and test?	

Issue	Considerations	Notes
Reporting	• Can the database handle the data collection and reporting needs of your performance measurement plan? ○ Be sure to share your plan with vendors so they can assess this appropriately. • Will the system be able to generate real-time reports for use in CQI processes? • Who builds reports? If the developer, what is cost of developing each report?	
Analysis	• Will the system have analysis capabilities? • Will your data be exported into another program for analysis purposes? What software package will you use to conduct this analysis (e.g., Excel, SPSS, R)? • Do you have the ability to import data not originally held in the system for analysis?	
Integration	• Can the database system be linked with existing electronic datasets from other programs in your community, or do data from other datasets need to be entered manually? • Will the system be able to integrate with IHS, social services, tribal enrollment, Head Start/early childhood, or other programs?	
Ownership	• Will your community retain ownership of the data being collected and stored? • Will the data system developer be able to see your raw data? • Will your community be able to use the data system for other programs in your tribe/community? • Will you have access to the data after the end of the grant?	
Training/ Maintenance	• Is there ongoing user support and maintenance? • Have you identified a staff person to provide “in-house” training on an ongoing basis?	

Issue	Considerations	Notes
Cost	• Is the cost one time or ongoing? • Is the cost per user or a set fee? • For tribal consortia or multisite communities, is there a licensing agreement based on number of sites? • Is there a cost for training? • What are the charges for maintenance? • Are updates an additional cost?	

This document was adapted for Tribal MIECHV grantees from:

- Comparing Data Collection Tools for US Virgin Islands MIECHV (Technical Assistance Coordinating Center, Draft)
- Guidelines for Selecting Data Management Systems Brief (Design Options for Home Visiting Effectiveness, Draft)