Community-Based Intergenerational Oral Health Study

Baby Smiles

Protecting Your Child’s Teeth Begins In Pregnancy

Manual of Operations

NIDCR Protocol Number: 09-016E

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Day Month Year 19/4/2010
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Significant Changes to the Revised (version Jan 4, 2011) Manual of Operations:

**Part I**
Descriptions of the postpartum materials (both HE and MI) were revised.

Assignment of the postpartum intervention was revised.

**Part II**
Screening information and form was revised to reflect reduced minimum age.

Consent section and forms were revised to reflect the reduced minimum age and change in postpartum intervention delivery timing.

**Part III**
Prenatal steps were revised to include the amount of the gift card incentive and sending the baby gift.

Dropout and withdrawal section was slightly revised.

**Part IV**
Study forms section was revised to reflect the new study forms added (See Tables 4.1 and 4.2)

**Appendix**
Sections added to the appendix include:
- How to send the baby gift
- Revised postpartum steps
- Contents of the study packets
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Part I. Overview

This section will briefly go over the purpose of this research project, what we would like to find out from the research, and how the research will be done.

Study Objectives (Specific Aims)
The aim of this study is to test a community-based intervention trial using brief motivational interviewing provided to low-income women during the prenatal and/or postpartum period(s) to; (1) increase utilization of dental care during pregnancy or the postpartum period, and (2) increase utilization of preventive dental care by their young children.

Figure 1 shows the study model for the intervention. Recent articles point to promising treatment variables that may account for behavior change (MI spirit and variables related to change talk). MI theory does not lend itself to a model that focuses on subject variables. Therefore, we will employ the Stages of Change model under the rubric of MI to develop our model. There are two life stages addressed in this study: pregnancy and motherhood. Each is represented in the model. The study begins in pregnancy when the focus of the study is the pregnant woman. Two interventions are delivered at this stage – women receive either 1) pregnancy-focused (prenatal) traditional health education materials or 2) brief motivational interviewing (MI). The study then continues into motherhood where the focus of the study is both mother and child. Similarly to the pregnancy stage, there are two groups – women receive either 1) child-focused (postpartum) traditional health education materials or 2) brief MI.

The primary outcome measure for the pregnant woman is dental utilization during pregnancy and up to two months postpartum. The outcome will be mediated by readiness to change which will result from the MI intervention. Mediating variables or intervening factors may be an underlying mechanism for achieving the outcome or behavior. The moderating variables are oral health quality of life, dental anxiety, perinatal depression, and perceived stress which are individual characteristics that may modify the relationship
among the variable readiness to change. The primary outcome measure for the child is preventive dental utilization by 18 months of age. Similar to the first stage, this second stage's outcome is mediated by readiness which can be moderated by several variables including mother's self-efficacy for providing children's oral hygiene, fatalism, knowledge, and dental anxiety.

Figure 1  Study Model

The study will utilize a four-group, multi-site, single-blind, randomized trial design. Figure 2 describes the four groups and the sample size of each group. The intervention will be a mother-child focused (prenatal-postpartum) brief Motivational Interviewing (MI) counseling intervention provided to low-income women in four rural Oregon counties. The first part will be focused on pregnant women (prenatal MI); the second part will be aimed at their live born children (postpartum MI). Figure 2 shows a 2 x 2 design where each
participant is randomized at enrollment to one of four groups - MI or traditional health education in pregnancy and MI or traditional education postpartum.

<table>
<thead>
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<th>Child (Postpartum) MI</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Group 1</td>
</tr>
<tr>
<td></td>
<td>(Prenatal MI - Postpartum MI)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Group 2</td>
</tr>
<tr>
<td></td>
<td>(Prenatal MI - Postpartum Traditional Health Ed)</td>
</tr>
<tr>
<td></td>
<td>N=52</td>
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<tr>
<td></td>
<td>Group 3</td>
</tr>
<tr>
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<td>(Prenatal Traditional Health Ed - Postpartum MI)</td>
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<td>N=148</td>
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<td>Group 4</td>
</tr>
<tr>
<td></td>
<td>(Prenatal Traditional Health Ed - Postpartum Traditional Health Ed)</td>
</tr>
<tr>
<td></td>
<td>N=52</td>
</tr>
</tbody>
</table>

Description of Traditional Health Education Group

Traditional Health Education: The control group will receive modified prenatal education materials ((published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles“)) supplemented with a brief video (~10-15 minutes) that covers the information in the written pamphlet. Women will also receive information about using their dental care coverage, guidelines to being a successful dental patient, and a “prescription” for good oral health care. Within six weeks of the in-person session, the **Counselor** will provide two follow-up telephone sessions.

The postpartum materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”, “A Healthy Smile For Your Baby”, and “A Healthy Smile For Your Young Child) and also from NMCOHRC (“Topical fluoride recommendations for high risk children”). A supplemental video will also be provided (~10-15 minutes) on preventing early childhood dental decay. We will also include the “prescription” for good oral health care again. It will be followed by one telephone session within six weeks of the first session.
Description of the Motivational Interviewing Group

Brief Motivational Interviewing (BMI) Intervention: The MI intervention will involve brief counseling and follow-up with the use of materials that motivate and provide choices among community-recommended strategies to utilize preventive dental services and engage in home care activities to prevent tooth decay provided by local trained women in a Women, Infants, and Children (WIC) or public health (PH) setting. Participants will also receive the written traditional health education materials as described above for each stage.

The prenatal MI participants will receive one-to-one in-person counseling during pregnancy (after enrollment). The Counselor will identify their dental needs, their dental risks, reinforce their dental needs, and navigate barriers to care. During the first MI visit, the Counselor will utilize both a written and electronic protocol (~30 minutes) to deliver the intervention. Within six weeks of the in-person session, the Counselor will provide two follow-up telephone sessions. Additionally, participants will receive a phone call 1 month prior to birth. Its purpose is to inquire about their pregnancy as well as dental issues.

The postpartum MI participants will receive their first child-centered MI session at 9 months post-partum. The content will focus on the child and include preventive strategies such as oral hygiene and dietary practices, and the 12 month dental visit. The in-person MI session will be approximately 30 minutes. It will be followed by one telephone session within six weeks of the first counseling session.

Timeline

Figure 3 shows the timeline of the study including the anticipated time to complete recruitment and enrollment (~ 14 months), time to complete data collection (Year 5, 6th month), and time to complete the study (end of Year 5). The duration for participation for each subject will be approximately 24 months (up to 6 months during pregnancy; 18 months after birth).
Randomization Process and Blinding

This section covers the assignment of participants to either the traditional health education or motivational interviewing group. “Blinding” refers to the process of not revealing the group assignment to the mother.

Participants will be randomly assigned to a study group using computer-generated permuted blocks of varying block sizes and stratification on county to ensure that the study groups will be proportionally balanced across study period and within each county. (In addition, randomization will be stratified on the two Counselors for Lincoln County.) Study group assignments for the prenatal period will be recorded on slips of paper numbered consecutively within each county and study personnel, not involved in the enrollment and randomization of subjects, will put the randomization assignments in sealed envelopes sequentially numbered for each county. The randomization envelopes will be placed inside the baseline questionnaire packets for use by the Counselor.

The Counselor must not inform the participant of the study group assignment, and the Counselor must remain blinded to the group assignment prior to enrolling the participant.
Assignment of Prenatal Intervention
After the subject has been screened for eligibility, given informed consent and has been enrolled in the study, the Counselor will open the sealed envelope with the study group assignment for the prenatal period and record the subject’s study group assignment for the prenatal period on the Screening Form. The Counselor will record the information on the Screening Form in the study tracking (ACCESS) database.
DO NOT inform the study participant of the study intervention assignment.

Assignment of Postpartum Intervention
After the Counselor schedules a participant’s 9 month postpartum visit, the Data Manager will send an email to the Counselor with the postpartum period study group assignment. The Counselor will record the participant’s postpartum group assignment in the study tracking database.
DO NOT inform the study participant of the study intervention assignment.

Blinding and Unblinding
All study participants will be blinded to the study groups but not the local study team (i.e., Counselor), the Data Manager and the Co-Principal Investigators. The Data Manager will assign codes to the groups to mask all study personnel, including the Biostatistician, from the study group for reports on study enrollment and follow-up aggregated by study group or county, as well as other aggregated data summaries.

The study groups in the aggregate summaries may be unmasked for the following reasons:

1) At the request of an Institutional Review Board (IRB), Clinical Studies Oversight Committee (CSOC), or Medical Monitor (Dr. Holli Hamilton) to investigate an imbalance in the number of unanticipated problems between the study groups.

2) The study has two parts, prenatal (pregnancy) phase and postpartum (child) phase. The study groups may be unmasked after all the data is collected for the prenatal phase in order to report on these results before the postpartum phase is completed.
Part II. Getting Started – Recruitment, Eligibility, Consent, and Enrollment

This section describes the recruitment, eligibility screening, consenting, and enrollment procedures for this study.

Recruitment

All subjects will be recruited in Oregon State within each of the four study counties (Douglas, Jefferson, Josephine, and Lincoln) and will be volunteers. Recruitment will be a multi-pronged approach.

Primary recruitment will come through posted Recruitment Flyers/leave behind Cards in the four counties’ public health departments/WIC settings (Women, Infant, Child) as well as at prenatal care providers in the community and other community agencies whose clientele are pregnant women. Recruitment will also be done in-person through the health department staff mentioning the study to their clients using a Recruitment Script within the WIC setting and pregnancy test department within the county health departments.

The Counselor will work with the public health department staff to identify and refer potentially eligible pregnant women. The recruitment flyers/cards could be handed out at the “all staff” meetings for the health department. Health department staff (most likely WIC staff) as well as other prenatal care providers will refer potentially interested women to the Counselor for a more thorough explanation of the study, eligibility screening, and consenting (if eligible and interested).

There will be a variety of recruiting methods to inform the community and potential enrollees about the study. We will advertise the study with recruitment flyers/cards in prenatal care providers’ offices, community service organizations, in the WIC offices, and other offices of each County’s public health department.

See Appendix 1 for copies of the Recruitment Flyer/Card and Recruitment Script.
Screening the Participant for Eligibility

To be eligible for the study, women must meet all of the inclusion criteria described below.

Inclusion Criteria

- Pregnant (week 26 or earlier)
- At least 15 years of age
- OHP eligible: OHP # _______
- Speaks English
- Willing and able to comply with study instructions
- Mother AND child available for length of the study (~ 24 months)

The Counselor will contact each referred woman (by phone or in person) to speak with her about the study. The Counselor will answer any general questions the woman might have about the study and collect general information about her using the Baby Smiles Screening Form to record the information. To determine eligibility, the Counselor will use the same form to record if the woman meets all of the inclusion criteria. If the woman meets all of the inclusion criteria she is eligible to be consented and enrolled in the study.

See Appendix 2 for a copy of the revised Baby Smiles Screening Form.

Consenting Process

Informed consent is a process that begins prior to the woman agreeing to be in the study and continues for the entire time she is in the study. The Counselor will fully inform the potential participant about the study procedures by going over the consent documents. Written informed consent must be obtained from all study participants using only the stamped approved forms. Consent from the participant will be obtained by the Counselor prior to enrollment and the participant can withdraw consent at any time during the study.

The Counselor will read through the consent documents with the pregnant woman to explain the research study, and to answer any of her questions. The Counselor will discuss any risks and possible benefits related to taking part in this study. The rights and welfare of the women will be protected by emphasizing to them that the quality of their care will
not be adversely affected if they do not wish to participate in the study. If the pregnant woman is unsure about participating she may take the study information home to discuss with her family or to think about it prior to agreeing.

**Consent Forms**

There are two documents involved in the consent process: The University of Washington (UW) stamped approved Consent Form which describes the study procedures, benefits, and risks in detail (stamped approved on December 21, 2010). The HIPAA form, which describes how health information about the woman and her newborn will be used.

The woman's signature on both of the UW and HIPAA forms is required before she begins or continues the study. *This is the only time the participant will be asked to sign the consent form; this form includes consent for both study stages (prenatal and postpartum).*

*UW stamped approved Consent Addendum:*

This form is to be completed by the women who have already consented to participating. It will be completed at the 3 month postpartum visit. All participants enrolled before January 1, 2011 need to sign and date the addendum to the consent form (See list of ID#s in Appendix 2)

Once the consent form is reviewed with the pregnant woman, the Counselor will print and sign her name (under study staff obtaining consent) and write the current date. If after reviewing the consent form the woman agrees to take part in the study, she will also print and sign her name (under subject) and write the current date. Two copies of either of the consent forms need to be signed and dated by both the Counselor and the pregnant woman. The same process is followed for the HIPAA form. One signed original of each form goes to the participant; the Counselor retains the other signed original forms. Once consent is obtained, the Counselor will record this information on the Baby Smiles Screening Form.
The Counselor's originals of the consent documents are to be treated as confidential. The documents must be put it in a secure location (locked filing cabinet) upon return to the office. Consent documents MUST NOT be stored with study data (questionnaires). Copies of the consent documents will be mailed to the University of Washington (see Section "Data Management and Forms").

See Appendix 2 for a copy of the University of Washington stamped approved consent forms and the HIPAA form.

**Enrollment**

A woman is enrolled in the study after the consent documents are reviewed and signed by both the Counselor and the pregnant woman. The Counselor will take the first sequentially numbered packet from the box of packets sent by the University of Washington. The Counselor will record the number from the front-side of the packet on the Baby Smiles Screening Form's **Study ID#** section. For enrolling participants the packets must be used in their sequential order. Once the **Study ID#** is recorded, the Counselor will open the packet; the packet will contain the study group protocol (traditional health education (ED); motivational interviewing (MI)) for the specific stage of the study (prenatal; postpartum), and a questionnaire (Baby Smiles Prenatal Baseline Questionnaire). The Counselor will record which of the two prenatal study groups (ED or MI) the participant is assigned to on the screening form.

See Appendix 3 for a copy of the Baby Smiles Prenatal Baseline Questionnaire.
Part III. Procedures: How to do the study

This section describes the specific contacts that the Counselors will have with the participants and what will occur during those contacts.

How to Schedule the Initial Visit Using TWIST
TWIST is the scheduling, education, and data collection system used by the Oregon State Department of Health Services, and specifically the WIC (Women, Infant, and Child) program.


Counselors can use TWIST to make the initial and follow-up appointments (both prenatal and postpartum) with study participants using the F2 slot. The F2 slot is available in the TWIST system for appointment scheduling and can include the Counselors' schedules of availability. This can be helpful if the Counselor is unavailable and a participant needs her appointment rescheduled.

Procedures for Each of the Four Study Groups
In this section, the procedures involved in delivering interventions to the two groups (MI; HE) within the two phases (prenatal and postpartum) of the study are described.
Prenatal Period

Steps for the **Prenatal MI Group**
This section describes Counselor responsibilities for events after the pregnant woman has been enrolled in the study and group assignment is known (See Appendix 3 for Steps for the Prenatal MI Group).

**Initial Baseline Visit - Prenatal Period**
- **Counselor** has the participant fill out (or assists her in filling out) the Baby Smiles Prenatal Baseline Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participants with the questionnaire (See Appendix 3 for Baby Smiles Prenatal Baseline Questionnaire and Response Cards).
- **Counselor** records the baseline session with study participants using the UW-provided digital audio recorder (See Appendix 5 How to Use the Audio Recorder).
- **Counselor** goes through the Baby Smiles Prenatal MI Protocol (Appendix 3).
- **Counselor** schedules two follow-ups (telephone contacts) with the participant:
  - 4 weeks after the baseline session
  - 6 weeks after the baseline session
- At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment. If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- **Counselor** provides the participant with a folder containing:
  - their copy of the consent documents (University of Washington stamped approved consent form and the HIPAA form),
  - health educational materials (Two Healthy Smiles, Understanding Your Dental Care Coverage, Tips for a Successful Prenatal Dental Care Visit, and Prescription for Good Oral Health - See Appendix 3),
  - their written plan,
- Counselor’s business card,
- Gift card ($15 amount), and
- Toothbrush and toothpaste.

- Counselor enters all necessary information in the tracking database (See Appendix 5).
- Counselor mails all necessary forms to the UW (See Appendix 5).
- Counselor uploads audio recording (See Appendix 5).
- If desired, Counselor sends follow-up phone call postcard 1 week before the follow-up call (See Appendix 3).

**Follow-up Telephone Call (4 weeks after baseline)**

- Counselor follows the 4 week follow-up section of the Baby Smiles Prenatal MI Protocol (See Appendix 3).
- Counselor records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- At the end of the call, Counselor asks the participant if she is ready to make a dental appointment (if she hasn’t had an appointment made). If ready, the Counselor helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- Counselor confirms the 6 week telephone contact with the participant.
- Counselor enters all necessary information in the tracking database (See Appendix 5).
- If desired, Counselor sends follow-up phone call postcard 1 week before the follow-up call (See Appendix 3).

**Follow-up Telephone Call (6 weeks after baseline)**

- Counselor follows the 6 week follow-up section of the Baby Smiles Prenatal MI Protocol (See Appendix 3).
- Counselor records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
• At the end of the call, Counselor asks the participant if she is ready to make a dental appointment (if she hasn’t had an appointment made). If ready, the Counselor helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).

• Counselor enters all necessary information in the tracking database (See Appendix 5).

Follow-up Visit (1 month prior to due date)
• Counselor sends a postcard 1 month prior to due date (See Appendix 3).
• Counselor enters all necessary information in the tracking database (See Appendix 5).

Follow-up Visit (1 week after due date)
• Counselor calls the participant 1 week after due date to check in.
• Counselor records the birth outcomes (See Appendix 3 Prenatal Phone Contact 3) and any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
• If possible, Counselor schedules the postpartum baseline visit.
• Counselor enters all necessary information in the tracking database (See Appendix 5).
• Counselor sends the participant a baby gift via US Priority Mail, containing:
  o a small baby gift provided by the University of Washington (a teething rattle or similar), and
  o a “congratulations!” gift enclosure card (provided by the University of Washington).
Steps for the Prenatal Traditional Health Education (ED) Group
This section describes Counselor responsibilities for events after the pregnant woman has been enrolled in the study and group assignment is known (See Appendix 3 for Steps for the Prenatal ED Group).

Initial Baseline Visit - Prenatal Period

- **Counselor** has participant fill out (or assists her in filling out) the Baby Smiles Prenatal Baseline Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participants with the questionnaire (See Appendix 3 for Baby Smiles Prenatal Baseline Questionnaire and Response Cards).

- **Counselor** records the baseline session with study participants using the UW-provided digital audio recorder (See Appendix 5 How to Use the Audio Recorder).

- **Counselor** goes through the Baby Smiles Prenatal ED Protocol (Appendix 3).

- **Counselor** schedules two follow-ups (telephone contacts) with the participant:
  - 4 weeks after the baseline session
  - 6 weeks after the baseline session

- At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment. If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).

- **Counselor** provides the participant with a folder containing:
  - their copy of the consent documents (University of Washington stamped approved consent form and the HIPAA form),
  - health educational materials (Two Healthy Smiles, Understanding Your Dental Care Coverage, Tips for a Successful Prenatal Dental Care Visit, and Prescription for Good Oral Health - See Appendix 3), and
  - **Counselor**'s business card,
  - Gift card ($15 amount), and
  - Toothbrush and toothpaste.
• **Counselor** enters all necessary information in the tracking database (See Appendix 5).

• **Counselor** mails all necessary forms to the UW (See Appendix 5)

• **Counselor** uploads audio recording (See Appendix 5).

• If desired, **Counselor** sends follow-up phone call postcard 1 week before the follow-up call (See Appendix 3).

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**Follow-up Telephone Call (4 weeks after baseline)**

- **Counselor** follows the 4 week follow-up section of the *Baby Smiles Prenatal ED Protocol* (See Appendix 3).

- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 *Unanticipated Problems Form*).

- At the end of the call, **Counselor** asks the participant if she is ready to make a dental appointment (if she hasn’t had an appointment made). If ready, the **Counselor** helps make the dental appointment (See Appendix 5 *How to Make a Dental Appointment*).

- **Counselor** confirms the 6 week telephone contact with the participant.

- **Counselor** enters all necessary information in the tracking database (See Appendix 5).

- If desired, **Counselor** sends follow-up phone call postcard 1 week before the follow-up call (See Appendix 3).

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**Follow-up Telephone Call (6 weeks after baseline)**

- **Counselor** follows the 6 week follow-up section of the *Baby Smiles Prenatal ED Protocol* (See Appendix 3).

- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 *Unanticipated Problems Form*).

- At the end of the call, **Counselor** asks the participant if she is ready to make a dental appointment (if she hasn’t had an appointment made). If ready, the
Counselor helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).

- Counselor enters all necessary information in the tracking database (See Appendix 5).

**Follow-up Visit (1 month prior to due date)**
- Counselor sends a postcard 1 month prior to due date (See Appendix 3).
- Counselor enters all necessary information in the tracking database (See Appendix 5).

**Follow-up Visit (1 week after due date)**
- Counselor calls the participant 1 week after due date to check in.
- Counselor records the birth outcomes (See Appendix 3 Prenatal Phone Contact 3) and any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- If possible, Counselor schedules the postpartum baseline visit.
- Counselor enters all necessary information in the tracking database (See Appendix 5).
- Counselor sends the participant a baby gift via US Priority Mail, containing:
  - a small baby gift provided by the University of Washington (a teething rattle or similar), and
  - a “congratulations!” gift enclosure card (provided by the University of Washington).
Postpartum Period

Steps for the Postpartum MI Group
This section describes events 3 months after the baby is born. It is considered the 3 month postpartum visit (See Appendix 4 for Steps for the Postpartum MI Group).

3 Month Visit - Postpartum Period
- **Counselor** contacts participant to schedule appointment if not already scheduled.
- **Counselor** has participant fill out (or assists her in filling out) the UW Consent Addendum (if enrolled before January 1, 2011) and the Baby Smiles Postpartum 3 Month Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participants with the questionnaire (See Appendix 4 for Baby Smiles Postpartum 3 Month Questionnaire and Response Cards).
- **Counselor** debriefs the participant about the prenatal intervention using the following:
  - **Counselor** gives the participant the form, Baby Smiles Prenatal Phase Feedback Form, to complete privately, place, and seal in the stamped, UW addressed envelope.
  - **Counselor** asks the participant whether she visited the dentist prior to the 3 month visit. Depending on the response, the Counselor asks the participant the debrief questions using one of the two Prenatal Debrief Questionnaires (Women who went to the dentist; Women who did not go to the dentist). Counselor briefly records the participant’s responses on the questionnaire (See Appendix 7 for Baby Smiles Prenatal Phase Feedback Form and Prenatal Debrief Questionnaires).
- **Counselor** provides the participant with the following:
  - health educational materials (Two Healthy Smiles (2009 version) and A Healthy Smile For Your Baby- See Appendix 4),
  - Counselor’s business card,
- gift card ($20 amount), and toothbrush and toothpaste.

- **Counselor** enters all necessary information in tracking database (See Appendix 5).
- **Counselor** mails all necessary forms to the UW (See Appendix 5)
- **Counselor** calls 1 week before the follow-up call as a reminder (See Appendix 3).

**6 month Telephone Call - Postpartum Period**

- **Counselor** checks in with the participant regarding any upcoming changes in address, phone number.
- **Counselor** asks participant about child’s teething and any newly erupting teeth.
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 **Unanticipated Problems Form**).
- **Counselor** enters all necessary information in tracking database (See Appendix 5).

**9 Month Visit - Postpartum Period**

- **Counselor** has participant fill out (or assists her in filling out) the **Baby Smiles Postpartum 9 Month Questionnaire** and ensures that all items are completed. The laminated **Response Cards** can be used when assisting the participant with the questionnaire (See Appendix 4 for **Baby Smiles Postpartum 9 Month Questionnaire** and **Response Cards**).
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 **Unanticipated Problems Form**).
- **Counselor** records the postpartum session with study participants using the UW-provided digital audio recorder (See Appendix 5 **How to Use the Audio Recorder**).
- **Counselor** goes through the **Baby Smiles Postpartum MI Protocol** (Appendix 4).
- **Counselor** schedules one telephone follow-up with the participant:
  - 6 weeks after the session
- At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment **for her child**. If ready, the **Counselor** helps make the dental appointment (See Appendix 5 **How to Make a Dental Appointment**).
- **Counselor** provides the participant with a folder containing:
o health educational materials (A Healthy Smile For Your Child, Topical Fluoride Recommendations For High Risk Children, First Dental Visit Card, and Prescription for Good Oral Health - See Appendix 4),
  o her written plan,
  o Counselor's business card,
  o Gift card ($20 amount), and
  o Toothbrushes and toothpaste (for mother and child).

- Counselor uploads audio recording (See Appendix 5). Counselor enters all necessary information in tracking database (See Appendix 5).
- Counselor mails all necessary forms to the UW (See Appendix 5).

Follow-up Telephone Call (6 weeks after the 9 month visit)
- Counselor follows the 6 week follow-up section of the Baby Smiles Postpartum MI Protocol (See Appendix 4).
- Counselor records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- At the end of the call, Counselor asks the participant if she is ready to make a dental appointment for her child (if she hasn’t had an appointment made). If ready, the Counselor helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- Counselor enters all necessary information in tracking database (See Appendix 5).

18 Month Visit - Final Study Visit
- Counselor has participant fill out (or assists her in filling out) the Baby Smiles Postpartum 18 Month Questionnaire and ensures that all items are completed.
  The laminated Response Cards can be used when assisting the participant with the questionnaire (See Appendix 4 for Baby Smiles Postpartum 18 Month Questionnaire and Response Cards).
- Counselor records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
• At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment for her child (if she hasn’t had an appointment made). If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).

• **Counselor** debriefs the participant about the postpartum intervention using the following:
  
  o **Counselor** gives the participant the form, Baby Smiles Postpartum Phase Feedback Form, to complete privately, place, and seal in the stamped, UW addressed envelope.

• **Counselor** asks the participant whether her child visited the dentist prior to the 18 month visit. Depending on the response, the **Counselor** asks the participant the debrief questions using one of the two Postpartum Debrief Questionnaires (Child who went to the dentist; Child who did not go to the dentist). **Counselor** briefly records the participant’s responses on the questionnaire (See Appendix 7 for Baby Smiles Postpartum Phase Feedback Form and Postpartum Debrief Questionnaires).

• **Counselor** gives gift card ($25 amount).

• **Counselor** gives toothbrushes and toothpaste (for mother and child).

• **Counselor** enters all necessary information in tracking database (See Appendix 5).

• **Counselor** mails all necessary forms to the UW (See Appendix 5).

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**Steps for the Postpartum Traditional Health Education (ED) Group**

This section describes events 3 months after the baby is born. It is considered the 3 month postpartum visit (See Appendix 4 for **Steps for the Postpartum ED Group**).
3 month Visit - Postpartum Period

- **Counselor** contacts participant to schedule appointment if not already scheduled.
- **Counselor** has participant fill out (or assists her in filling out) the UW Consent Addendum (if enrolled before January 1, 2011) and the Baby Smiles Postpartum 3 Month Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participants with the questionnaire (See Appendix 4 for Baby Smiles Postpartum 3 Month Questionnaire and Response Cards).
- **Counselor** debriefs the participant about the prenatal intervention using the following:
  - **Counselor** gives the participant the form, Baby Smiles Prenatal Phase Feedback Form, to complete privately, place, and seal in the stamped, UW addressed envelope.
  - **Counselor** asks the participant whether she visited the dentist prior to the 3 month visit. Depending on the response, the **Counselor** asks the participant the debrief questions using one of the two Prenatal Debrief Questionnaires (Women who went to the dentist; Women who did not go to the dentist). **Counselor** briefly records the participant’s responses on the questionnaire (See Appendix 4 for Baby Smiles Prenatal Phase Feedback Form and Prenatal Debrief Questionnaires).
- **Counselor** provides the participant with the following:
  - health educational materials (Two Healthy Smiles (2009 version) and A Healthy Smile For Your Baby- See Appendix 4),
  - gift card ($20 amount),
  - **Counselor**’s business card, and
  - Toothbrush and toothpaste.
- **Counselor** enters all necessary information in tracking database (See Appendix 5).
- **Counselor** mails all necessary forms to the UW (See Appendix 5).
- **Counselor** calls 1 week before the follow-up call as a reminder (See Appendix 3).
6 month Telephone Call – Postpartum Period

- **Counselor** checks in with the participant regarding any upcoming changes in address, phone number.
- **Counselor** asks participant about child’s teething and any newly erupting teeth.
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- **Counselor** enters all necessary information in tracking database (See Appendix 5).

9 Month Visit - Postpartum Period

- **Counselor** has participant fill out (or assists her in filling out) the Baby Smiles Postpartum 9 Month Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participant with the questionnaire (See Appendix 5 for Baby Smiles Postpartum 9 Month Questionnaire and Response Cards).
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- **Counselor** records the postpartum session with study participants using the UW-provided digital audio recorder (See Appendix 5 How to Use the Audio Recorder).
- **Counselor** goes through the Baby Smiles Postpartum ED Protocol (Appendix 4).
- **Counselor** schedules one telephone follow-up with the participant:
  - 6 weeks after the session
- At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment for her child. If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- **Counselor** provides the participant with a folder containing:
  - health educational materials (A Healthy Smile For Your Child, Topical Fluoride Recommendations For High Risk Children, First Dental Visit Card, and Prescription for Good Oral Health - See Appendix 4),
  - Counselor’s business card,
  - Gift card ($20 amount), and
- Toothbrushes and toothpaste (for mother and child).
- **Counselor** uploads audio recording (See Appendix 5).
- **Counselor** enters all necessary information in tracking database (See Appendix 5).
- **Counselor** mails all necessary forms to the UW (See Appendix 5).

**Follow-up Telephone Call (6 weeks after the 9 month visit)**
- **Counselor** follows the 6 week follow-up section of the Baby Smiles Postpartum ED Protocol (See Appendix 4).
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- At the end of the call, **Counselor** asks the participant if she is ready to make a dental appointment for her child (if she hasn’t had an appointment made). If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- **Counselor** enters all necessary information in tracking database (See Appendix 5).

**18 Month Visit - Final Study Visit**
- **Counselor** has participant fill out (or assists her in filling out) the Baby Smiles Postpartum 18 Month Questionnaire and ensures that all items are completed. The laminated Response Cards can be used when assisting the participant with the questionnaire (See Appendix 4 for Baby Smiles Postpartum 18 Month Questionnaire and Response Cards).
- **Counselor** records any unanticipated problems as reported by participant (See Appendix 6 Unanticipated Problems Form).
- At the end of the visit, **Counselor** asks the participant if she is ready to make a dental appointment for her child (if she hasn’t had an appointment made). If ready, the **Counselor** helps make the dental appointment (See Appendix 5 How to Make a Dental Appointment).
- **Counselor** debriefs the participant about the postpartum intervention using the following:
- **Counselor** gives the participant the form, **Baby Smiles Postpartum Phase Feedback Form**, to complete privately, place, and seal in the stamped, UW addressed envelope.

- **Counselor** asks the participant whether her child visited the dentist prior to the 18 month visit. Depending on the response, the **Counselor** asks the participant the debrief questions using one of the two **Postpartum Debrief Questionnaires** (*Child who went to the dentist; Child who did not go to the dentist*). **Counselor** briefly records the participant's responses on the questionnaire (See Appendix 4 for **Baby Smiles Postpartum Phase Feedback Form** and **Postpartum Debrief Questionnaires**).

  - **Counselor** gives gift card ($25 amount).
  - **Counselor** gives toothbrushes and toothpaste (for mother and child).
  - **Counselor** enters all necessary information in tracking database (See Appendix 5).
  - **Counselor** mails all necessary forms to the UW (See Appendix 5).
What to Do If a Participant Misses a Follow-up, Drops Out or Is Discontinued

A participant may stop taking part in this study at any time or be discontinued by study personnel. Even though the participant may not follow the study all the way through to the end, the researchers may still find her experience important.

Missed Follow-up

Participants not completing or refusing a follow-up during the required time frame (within two weeks of the scheduled date) are considered to have a missed follow-up. Careful documentation and monitoring of missed follow-ups is important. If a study follow-up is missed the Counselor should enter the reason(s) for the missed the follow-up in the appropriate study follow-up Notes box in the tracking database and enter a disposition for the follow-up as either Refusal (if subject explicitly refuses the follow-up) or Missed.

Drop Out/Withdrawal by Participant

Participants who drop out (or withdraw) from the study by their own choice will be considered dropouts/withdraws. In the event of a participant telling the Counselor that she is dropping out of the study, the Counselor should gather the following information as much as the participant allows.

- Record the reason for dropping out of the study.
- Record any unanticipated problems as reported by participant.
- Debrief about the prenatal or postpartum intervention.
- Complete the appropriate questionnaire nearest the drop out time point.

The Counselor should notify the Data Manager and Principal Investigators as soon as they learn that a participant drops out.

If a participant refuses all further study participation, the Counselor should use the Discontinuation tab of the tracking database to record the date that the participant refused further participation and record the reason(s) for dropping out.
If the participates refuses all further study participation when contacted for a study follow-up, the Counselor should enter the disposition for the study follow-up as Discontinued.

If the participant refuses further participation only in the study intervention, the Counselor should not enter the participant information as a discontinuation but continue follow-up on the participant without the intervention.

**Discontinuation by Study Personnel**
Participants may also be withdrawn from the study by study personnel if the subject becomes ineligible or for other reasons (e.g., miscarriage or loss of child custody). The date of discontinuation and reasons for discontinuation should be entered to the tracking database by the Counselor.

If it is determined by study personnel that a participant should be withdrawn from the study, the decision to withdraw a participant must be discussed and confirmed by both the Counselor and study Co-PI's. If both the Counselor and study Co-PI’s agree that a participant should be withdrawn from the study, the date of withdrawal and reason(s) for withdrawal should be recorded in the tracking database by the Counselor. For gathering information on discontinuation, Counselors will be contacting participants regarding birth outcomes as miscarriages will not be on the birth record.

**Reporting A Missed Visit, Dropout or Withdrawal**
All reasons for missed visits/follow-ups and study discontinuations will be documented in the tracking database. Summary reports will be generated regularly by the S&DCC and reviewed by the study Co-PI’s. Summary reports on missed visits and study discontinuation will be also included in regular reports to the CSOC and NIDCR as part of Data and Safety Monitoring.
Part IV. Data Management and Forms

The primary goal of data collection and management activities in the Baby Smiles study is to ensure the integrity and safety of participants' data. Accurate, reliable data will provide the study team with the best opportunity to assess differences between groups in the study, and ultimately determine whether or not the intervention is successful. Along with the primary outcome measure of dental care utilization, the study team will examine subject scores on multiple instruments administered during the study. Therefore, it is imperative that data is collected and managed with close attention to detail and adherence to the guidelines described in this section.

Types of Data
Four different sources of data will be generated for the study: paper forms and questionnaires, tracking data, counseling sessions, and Medicaid claims data. Paper forms will be used at different time points throughout the study. A list of all paper forms is shown in Tables 4.1 and 4.2. Tracking data is used to manage subject progression through the study and summarize recruitment and enrollment. Counselors will record MI and Traditional Health Education sessions with study participants on a digital audio recorder. Recordings will be used to monitor fidelity to the intervention. Medicaid claims data will be provided by Oregon Division of Medical Assistance Programs (DMAP) to the Statistical and Data Coordinating Core (S&DCC) at the University of Washington. This data will be used to determine dental care utilization by participants and their children.

Table 4.1 List of Study Forms

- Screening Form (Appendix 2)
- University of Washington Consent/Assent Form* (Appendix 2)
- University of Washington Consent Addendum Form* (Appendix 2)
- HIPAA form* (Appendix 2)
• Unanticipated Problems Form** (Appendix 6)

• Prenatal MI Protocol* (Appendix 3)

• Prenatal ED Protocol* (Appendix 3)

• Postpartum MI Protocol* (Appendix 4)

• Postpartum ED Protocol* (Appendix 4)

• Counselor Self Assessment Form* (Appendix 7)

• Fidelity Monitoring Coder Worksheet (Appendix 7)

• UW Mailing Cover Sheet* (Appendix 5)

• Baby Smiles Prenatal Phase Feedback Form *** (Appendix 7)

Table 4.2  List of Study Questionnaires

• Prenatal Baseline Questionnaire (Appendix 3)

• Postpartum 3 Month Questionnaire (Appendix 4)

• Postpartum 9 Month Questionnaire (Appendix 4)

• Postpartum 18 Month Questionnaire (Appendix 4)

• Prenatal and Postpartum Debrief Questionnaires (Appendix 7)

*Copy of completed form will be mailed by Counselor to UW.

**Copy of completed form will be faxed to UW.

***Completed form will be mailed by participant to UW in UW-provided mailer.
Data Collection

Paper questionnaires and forms
Copies of questionnaires and forms will be provided to Counselors by the University of Washington. Questionnaires will have study ID numbers preprinted on them, although blank versions will be available on the Baby Smiles web portal. Versions downloaded must have study ID numbers written in by the Counselors.

The Counselors have overall responsibility of ensuring the accuracy, completeness and legibility of the forms and questionnaires used in the study. All forms and questionnaires should be completed in pen. Counselors will complete paper questionnaires with study participants, or allow participants to complete the questionnaires independently. If a participant chooses to complete the form by herself, Counselors, will review the questionnaire before the appointment ends.

General questionnaire and form review

- Blank questions
  Counselors will ensure that participant intended to leave items blank and that missing items were not an oversight.

- Ambiguous marks/checks
  Counselors will ask for clarification.

- Open-ended responses
  Counselors will ensure that the participant’s writing is readable.

- Corrections
  To make corrections or modifications to any items on a questionnaire or form, draw a single line through the incorrect item and indicate the correct response in close proximity to the original item. Do not use white out or
correction tape, make all corrections in ink. Please initial and date any changes made.

Consent documents
Stamped, paper versions of the consent documents will be mailed to Counselors by the UW and should be the only versions to be used in the study. A PDF of the stamped consent documents will be available on the Baby Smiles web portal for download, if needed.

DO NOT consent a participant without a stamped consent form.

Tracking data
Counselors will enter data into the tracking database as instructed in the tracking database documentation (See Appendix 5).

Counseling session data
Counselors will record MI and ED sessions with study participants on the UW-provided digital audio recorder. See Appendix 5 - How to Use the Audio Recorder.

Data Transmission

Paper Questionnaires and Forms
Copies of completed paper questionnaires and forms will be sent to the University of Washington via U.S. mail. Prior to mailing, Counselors will complete a UW Mailing Cover Sheet to indicate the type/quantity of forms and/or questionnaires being included in the envelope and include the UW Mailing Cover Sheet in the mailing.

For the University of Washington consent documents, the Counselors will:

1. Review the consent form as described the section “Consenting process”.
2. Ensure that the study ID number does not appear anywhere on the consent form.

3. Give one signed and dated set of consent documents to the subject.

4. Make a copy of the consent documents (HIPAA and UW consent forms); file the original documents separate from the questionnaire data (Prenatal Baseline Questionnaire, Postpartum Baseline Questionnaire (3 months postpartum), Postpartum Visit Questionnaire (9 months postpartum), and Final Study Visit Questionnaire (18 months postpartum)).

5. Send the other copy of the consent documents (HIPAA and UW consent forms) to the UW in a postage paid mailer (provided by the UW) with no other study documents.

Questionnaires, Protocols, and Phone Call Follow-up Forms

Counselors will:

1. Review the questionnaires/forms.

2. Ensure that no identifiable information other than the participant's study ID number appears on the questionnaire/form. Any identifiable information on copies must be completely erased or blacked out.

3. Make a copy of the questionnaire/form.

4. Within one week of questionnaire/form completion, send the copy version of the questionnaire to the UW in a pre-addressed postage paid mailer (provided by the UW). Multiple questionnaires/forms (e.g. from more than one subject) can be mailed in the same mailer with the UW Mailing Cover Sheet.

5. Record the mailing date in the tracking database as described in the tracking database documentation (Appendix 5).

The S&DCC will:

1. Review packets received to ensure contents match the UW Mailing Cover Sheet.
2. Request clarification/resubmission for any contents that are missing or are not identified on the mailing form.

3. Log receipt of forms in the tracking database.

Tracking data
Counselors will upload a copy of their tracking database to the UW Baby Smiles secure web portal at least once every 2 weeks. (See Appendix 5)

1. Go to http://depts.washington.edu/nacrohd/babysmiles/[username], substituting Counselor’s username for [username] in the URL.

2. Log in with user name and password.

3. Click on “edit” and upload the tracking database.

Counseling session data
Counselors will upload the audio files of counseling sessions within the same day of completing the session (See Appendix 5 – How to Send Audio Files to the UW).

1. Go to http://depts.washington.edu/nacrohd/babysmiles/[username], substituting Counselor’s username for [username] in the URL.

2. Log in with user name and password.

3. Click on “edit” and upload the audio file.

4. Rename the audio file as described in Appendix 5 – How to Send Audio Files to the UW.

Data Storage and Access

Storage at the County Sites
County Sites will be responsible for storing data as described below.
Paper Forms

- All paper documents will be kept in locked cabinets at all times when not being used or reviewed.

- Only Counselors or study personnel with defined needs to access the information will have access to the file cabinets.

- Paper forms with identifiable subject information (i.e., Consent Form, Screening Form, Unanticipated Problems Form) will be stored separately from study questionnaires/data (Prenatal Baseline Questionnaire, Postpartum Baseline Questionnaire (3 months postpartum), Postpartum Visit Questionnaire (9 months postpartum), and Final Study Visit Questionnaire (18 months postpartum)).

Electronic data

- The tracking database will be maintained in a secured, encrypted MS Access file. Only the Counselor or study personnel with defined needs to access the information will have the database password.

- Audio files of counseling sessions will be kept on secured computers. Counselors will upload the audio files of counseling sessions within the same day of completing the session. After the Counselors receive confirmation from the Data Manager that the uploaded file was received, she will delete it from her computer AND the MS recycle bin located on the computer's desktop.

Storage at the S&DCC
The S&DCC will be responsible for storing data as described below.

Paper forms

- All paper documents will be kept in locked cabinets at all times when not being used, reviewed, or entered into an electronic database.
• Only the **Data Manager** or study personnel with defined needs to access the information will have access to the file cabinets.

• Paper forms with identifiable subject information (i.e., Consent Form, Screening Form) will be stored separately from questionnaire data.

**Electronic data**

• The tracking database copies, audio files of counseling sessions, and the electronic database of questionnaire data will be kept on a secure password protected server and secure password protected computers at the University of Washington.

• Only the **Data Manager** will have access to personal identifiable information. The Clinical Study Oversight Committee (CSOC), NIDCR Program Official (PO), University of Washington Institutional Review Board (UW IRB), Oregon State IRB, and Co-PI’s may request access to identifiable information when necessary, such as cases of unanticipated problems, death, or other circumstances. These requests must be approved by the CSOC and the NIDCR PO. Other UW study team members will only have access to personal identifiable information if it is deemed necessary by the CSOC and NIDCR PO for specific reasons.

**Quality Control of the Study Forms and Data**

**Counselor Responsibilities**

**Counselors** will be responsible for ensuring the quality of data collected on paper forms as described above. In addition, **Counselors** will be responsible for accurately entering data into the tracking database.

**S&DCC Responsibilities**

The **S&DCC** staff will be responsible for managing the double-data entry of paper questionnaires received from the **Counselors** into an electronic database and for validating...
the information entered. The **Data Manager** will run diagnostic checks on the electronic database and check for errors, missing data, and outliers. Anomalies will be verified with **Counselors**, and any corrections will be documented by the **S&DC C** for **CSOC** reporting.
Part V. Monitoring and Reporting

This section describes the monitoring and reporting of participant safety, protocol violations and deviations, and intervention fidelity.

Clinical Study Oversight Committee (CSOC)
Per the NIDCR guidelines this study’s oversight structure will be a Clinical Study Oversight Committee (CSOC) appointed by NIDCR. Members of the CSOC (individuals not directly involved in the study) will be responsible for:

- Periodically reviewing accumulated data for evidence of adverse or beneficial intervention effects
- Initiating recommendations for modification of study protocols, including termination of the intervention protocol when appropriate
- Assessing data quality and study performance

The CSOC will operate in a manner consistent with the NIDCR guidelines for Data and Safety Monitoring of Clinical Trials. The CSOC will meet regularly to review the protocol, data collection and data completeness. Data and safety monitoring will occur in the following domains: 1) identification of unanticipated problems; 2) identification of protocol violations; 3) review of data completeness; and 4) review of aggregate data.

Monitoring and Reporting of Participant Safety
This section explains the procedures and organizations in place for identifying and reporting safety concerns, unanticipated problems and serious adverse events that arise during the study.

The MI and ED interventions/questionnaires present no physical or medical safety risks to the participants. However, there is the possibility that some questions asked may be perceived by the participants as personal and may elicit some embarrassment or
discomfort in answering the items. The outcome measures and survey tools to be used are as follow: assessment of perinatal depression (Center for Epidemiologic Studies Depression Scale (CES-D)); perceived stress (Perceived Stress Scale (PSS)) by pregnant women; oral health impact (Oral Health Impact Profile short form (OHIP)); child oral health impact (Early Childhood Oral Health Impact Scale (ECOHIS)); and dental anxiety questions (M-DAS).

Counselors should let the participants know prior to the interview to not answer any questions that they feel uncomfortable with. Also, Counselors should tell them that their response or non-response to the questionnaire items does not affect their eligibility for health and support services, such as medical, dental, WIC, for which they are entitled.

Another safety concern is associated with information that is disclosed during the intervention (e.g., depression, domestic violence). Counselors should follow their county specific County Mandatory Reporting Guidelines (Insert in Appendix 6 your County Mandatory Reporting Guidelines) if participants disclose information that is a safety concern for themselves or others.

Unanticipated Problems and Serious Adverse Events
Given there is minimal risk to study subjects for participating in the study, unanticipated and serious adverse events should be rare, and hence, only unanticipated problems need to be documented and reported. Procedures are described below to ensure all unanticipated events, including serious adverse events, are documented and promptly reported.

Unanticipated Problems
Unanticipated problems, in general, include any incident, experience, or outcome that meets all of the following criteria:
(1) **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the study protocol and informed consent form; and (b) the characteristics of the subject population being studied;

(2) **related or possibly related to participation in the research** (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

(3) suggests that the research places participants or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

An incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the approved study **protocol** or informed consent process or other corrective actions in order to protect the safety, welfare, or rights of participants or others. Only a small subset of adverse events occurring in study participants will meet these three criteria for an unanticipated problem.

Other types of incidents, experiences, and outcomes that occur during the conduct of research represent unanticipated problems but may not be considered adverse events. For example, some unanticipated problems involve social or economic harm instead of physical or psychological harm associated with adverse events. In other cases, unanticipated problems place participants or others at increased **risk** of harm, but no harm occurs.

**Serious Adverse Events**
Adverse events that are unexpected related or possibly related to participation in the study and serious are the most important subset of adverse events representing unanticipated problems and must be **promptly** reported. A serious adverse event is any event that

(1) results in death;

(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);

(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;

(5) results in a congenital anomaly/birth defect; or

(6) based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

All events that meet the definition of an unanticipated problem or serious adverse event must be documented and reported according to procedures described below.

Reporting Unanticipated Problems and Serious Adverse Events

Counselor Reporting
The Counselor will function as the first level of safety oversight by observation, contact, and inquiries into the health of the participant, and ascertaining and reporting unanticipated problems.

When the Counselor (or other any study personnel) becomes aware of an unanticipated event she should immediately contact and inform the study Co-PI's (Dr. Riedy or Dr. Weinstein) by phone, and also send by email or fax an Unanticipated Problem Report Form to the study Co-PI's as soon as possible.

The Counselor should record the unanticipated problem in the tracking database within 1 week of becoming aware of the problem.

Unanticipated problems that are not resolved by the time the event is reported to the study Co-PI's will be followed by the Counselor until satisfactory resolution or until the Co-PI's deem the event to be chronic or the participant to be stable. After becoming aware of an unanticipated problem, the Counselor will contact the participant within 1 week to ask about the status of the unanticipated problem and will continue to contact the participant periodically depending on the nature of the unanticipated problem until the event resolves.
or is determined to be a chronic condition. The Counselor should record in the tracking
database all follow-up contacts with participants in relation to an unanticipated problem
and the date the event is resolved.

Unanticipated Problem Report Form
The Unanticipated Problem Report Form will include:

- Description of the unanticipated problem
- Date of event or onset
- Severity of the event
  - Mild: Events that require no treatment and do not interfere with the participant's daily activities.
  - Moderate: Events that resolve with minor intervention.
  - Severe: Events that require therapeutic intervention (including interrupts daily activities, hospitalization).
  - Life-threatening: Events that endanger life such as a life-threatening illness.
  - Fatal: Events resulting in death.
- Relatedness of the event to the study
  - Definitely
  - Probably related
  - Possibly related (cannot be certain or determine relationship)
  - Unlikely to be related
  - Unrelated
- Whether the event was unexpected or expected.
- Whether the event is or is not considered a serious adverse event.
- Description of action taken, if any.
• If the event is resolved, the date resolved. Otherwise, whether the participant is still in the study or has completed the study.

See Appendix 6 for a copy of the Unanticipated Problem Report Form.

Co-PI Reporting
The study Co-PI’s are responsible for reviewing all unanticipated problems, confirming the information with the Counselor or participants, as needed, and promptly reporting all unanticipated problems to the UW-IRB, Oregon State IRB and the NIDCR Medical Monitor. The Co-PI’s will notify the UW-IRB and the NIDCR Medical Monitor via telephone, email, or fax of an unanticipated problem within 24 hours of becoming aware of the event, and by written report as promptly as possible, but no later than 7 days after becoming aware of the event for serious adverse events and no later than 30 days for other unanticipated problems. The Co-PI’s will also send the written reports for all unanticipated problems to the NIDCR Program Official and CSOC Chair.

In addition to the immediate reporting of all unanticipated problems to the IRBs, NIDCR and CSOC, the S&DCC will create summary reports of all unanticipated problems that will be included in regular reports to NIDCR and the CSOC.

Protocol Violations and Deviations
A protocol violation is an event or incident that occurs off protocol (i.e., Manual of Operations), without the permission of the sponsor (UW-IRB, Oregon State IRB, and NIDCR), which has a significant or potential significant impact on participants. A protocol deviation is an event or incident that occurs off protocol, with or without the permission of the sponsor, but has minor or no impact on participants. Protocol violations and/or deviations may be either on the part of the participant, the investigator, or the Counselor. As a result of deviations or violations, corrective actions may be implemented promptly by the Co-PI’s and the CSOC.
It is the responsibility of the Counselors to use continuous vigilance to identify and report violations within 24 hours, and deviations within 5 working days of identification of the protocol deviation. All violations and deviations must be promptly reported to the Co-PI’s (Dr. Riedy or Dr. Weinstein) who will investigate the event and will inform the NIDCR PO and CSOC. The Co-PI’s will also complete the standardized UW-IRB, Oregon State IRB, and NIDCR Protocol Deviation Forms for the event.

Site Monitoring

Compliance with the Study Protocol (Manual of Operations)
To reduce the possibility of protocol deviations, study staff (Baby Smiles Program Manager) will be responsible for conducting bi-annual “assistance and monitoring” visits to county sites. During these visits the Program Manager will review the items outlined below in the checklist Monitoring Site Visit Checklist.

Table 5.1 Monitoring Site Visit Checklist
- All paper forms are kept in a locked file cabinet, accessible only to study personnel.
- Identifiable information (Screening Form; Consent Form) is stored separately from questionnaire data.
- A signed, stamped consent form and a HIPAA form are on file for all enrolled subjects.
- All electronic data (tracking database) is stored on a secured computer.
- All audio files were deleted from a secured computer after transmission confirmation was obtained.

See Appendix 7 for a copy of the Monitoring Site Visit Checklist.
Fidelity of the Intervention
Our approach to monitoring the fidelity of the intervention is based on the framework by Bellg et al., (2004), Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (BCC). Fidelity monitoring is a strategy used to monitor and enhance the reliability and validity of the delivered interventions. The BCC treatment fidelity approach includes five areas within which fidelity can be addressed prior to the study (study design, training interventionists) and during the study (delivery, receipt, and enactment of treatment skills). A series of activities will be undertaken in the Baby Smiles study within these five areas to enhance and monitor the fidelity of the intervention.

The Fidelity Monitoring Plan and Coding Manual in Appendix 7 describes the five activities (study design, counselor training, delivery, receipt, and enactment of treatment skills). This section will focus on the select activities that the Counselor will perform to ensure the fidelity of the intervention.

Counselor Responsibilities
- **Counselors will be trained to defined performance criteria and be “certified”**.
- **Counselors will take notes of each encounter within the standardized protocol as well as noting the length of the encounter in the tracking database.**
- **Counselors will record each session (ED and MI) using the digital audio recorder (See Appendix #5 How To Use the Audio Recorder) to ensure fidelity of the delivery of the interventions. The first five sessions will be audio taped and reviewed by the Co-PI’s so that immediate feedback can be given. Twenty percent of the subsequent session audio files will be reviewed and coded for fidelity purposes (Coding Manual). The audio tapes will be coded by trained fidelity coders. Coders will complete the Fidelity Coders Motivational Interviewing Adherence and Competence Worksheet and the Fidelity Coders Motivational Interviewing Adherence and Competence Feedback Form based on specified scales as each audio tape is reviewed.**
• **Counselors** will complete the *Motivational Interviewing Counselor Self-Assessment Report Form* after each contact with a MI participant. The form lists the critical unique elements of the intervention.

• **Counselors** will have participants complete a brief questionnaire about their perceptions of the provider's warmth and credibility to assess interpersonal differences. The questionnaire will be mailed directly by the study participant to the UW in a stamped, addressed envelope.

• **Counselors** will meet weekly for study staff meetings to discuss their self-assessments of their delivery of the interventions as well as other study concerns.

• **Counselors** will attend regular booster sessions via video conference (1x per month for first 3 months; every other month for the 4th-6th month; every 4 months for the remainder of the study).

See Appendix 7 for a copy of the *Fidelity Monitoring Plan and Coding Manual*, the *Fidelity Coders Motivational Interviewing Adherence and Competence Worksheet*, the *Fidelity Coders Motivational Interviewing Adherence and Competence Feedback Form*, and the *Motivational Interviewing Counselor Self-Assessment Report Form*. 