

Vermont Oxford Network

ELBW Infant Follow-up Project

Parental Interview and Reporting Questionnaire (PIRQ)

Manual of Operations

Version 3

SEPTEMBER, 2010

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Vermont Oxford Network
 Extremely Low Birth Weight Follow-Up Project
 Parental Interview and Reporting Questionnaire Version 3

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I. Overview

The purpose of the Parental Interview and Reporting Questionnaire (PIRQ) is to establish a simple and reliable interview tool to record the 2 year corrected age health and neuro-developmental outcome of extremely low birth weight infants enrolled in the Vermont Oxford Network.

Infants enrolled and consented for the ELBW Infant Follow-up Project are eligible to have the PIRQ completed at the two year corrected age follow-up visit. For infants and families completing the 2 year corrected age follow-up visit, the PIRQ is completed at the time of the follow-up visit but independently of the follow-up evaluation. For infants and families NOT completing the follow-up visit, the PIRQ is completed by phone.

Data collected for the PIRQ at the follow-up visit supplements data collected for the ELBW Infant Follow-up Project Health Status Report and the Developmental Status Report. The PIRQ **does not** replace the Health Status Report or the Developmental Status Report.

Data collected for the PIRQ by phone does NOT substitute for the follow-up visit evaluation, and is not to be considered medical care.

IRB Requirement

Before the PIRQ is used to collect data, each participating Network Center must obtain local Institutional Review Board (IRB) approval. Most commonly, approval will be obtained by submitting **an addendum** to the IRB approval received for participating in the ELBW Infant Follow-up Project. Each participating Network Center should submit a copy of the addendum to their current IRB approval for the ELBW Infant Follow-up Project. The VON Clinical Trials & Follow-up Data Coordinating Center must have a copy of this addendum before any data may be collected.

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Version 3 Changes

The overall format of the Parental Interview and Reporting Questionnaire is unchanged. In Version 3 there are twenty (20) questions. For families of infants completing the PIRQ by phone there are two (2) additional questions. The first question asks why a follow-up clinic visit was not completed. Parents may choose one or all of several possible reasons. The second question asks if the parent would like to re-schedule the follow-up visit.

Table 1. Questions added when the PIRQ is completed by phone.

21	Were you unable to come to a follow-up clinic visit with (name of child) because
<u>[obtain answers for all of the following questions]</u>	
21A	You did not know that (<u>name of child</u>) had an appointment?
21B	You had transportation or parking issues?
21C	You had cost or insurance issues?
21D	Your family relocated to a different geographical area?
21E	Your child was well and you believed there was no reason to come?
21F	Your child was already receiving support services?
21G	Because of another reason? [Describe the reason in the box provided below]
22	Would you like to re-schedule a follow-up clinic visit for (<u>name of child</u>) at (<u>name of hospital</u>)?

II. Using the Parental Interview and Reporting Questionnaire (Version 3)

The PIRQ is used to interview the child’s parent or guardian and record data during this interview. Before conducting the interview, the Vermont Oxford Network (VON) identification information must be recorded. The VON identification information is recorded in the Top Section of each page of the PIRQ. Information about the interview is also collected before conducting the interview. This information is reported in Section A on the first page of the PIRQ.

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If the PIRQ is completed at the follow-up clinic visit, Sections B and C of the PIRQ are used to interview the parent and record data during this interview. The interview should be completed at the Network Center Follow-up Clinic, at the time of the two year corrected age visit, **before** the actual follow-up evaluation.

If the PIRQ is completed by phone, Sections B, C and D of the PIRQ are used to interview the parent and record data during this interview. The interview should ONLY be completed by phone with families unable to complete the visit at the Follow-up Clinic. In Section D, the parent is offered the opportunity to re-schedule the follow-up visit.

Interviewing the Parent (or Guardian)

The PIRQ is a scripted interview dialogue designed to be completed by Follow-up Clinic support staff. The PIRQ **does not** require a physician or nurse or health care provider to be completed. Once completed, either at the Follow-up Clinic or by phone, the PIRQ **should not** be shared or discussed with the physician, nurse or health care provider responsible for the follow-up evaluation.

To use the PIRQ, the interviewer reads a scripted dialogue to the child's parent and obtains answers to twenty (20) questions (if the interview is conducted at the clinic) or twenty-three (23) questions (if the interview is conducted by phone). Beginning with a simple purpose statement, the scripted introduction of the PIRQ confirms the parent's willingness to be interviewed as a part of the ELBW Infant Follow-up Project at the Network Center's Follow-up Clinic. After reading the introduction to the parent, the interviewer turns to Sections B and C (and D, if appropriate) to read the questions to the parent.

Reading the introduction and questions to the parent requires the interviewer to know the first name of the child, and the gender of the child. The name of the child, or "he", "she", "his" or "her" **should not** be written on the Parental Interview and Reporting Questionnaire. This information is confidential and protected and not part of the data collected or transmitted to the Vermont Oxford Network.

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Sections B, C and D of the PIRQ are formatted to allow the interviewer to record answers given by the child's parent as the interview is conducted. Most questions require a Yes / No answer.

To record the answers to these questions, a box for "Yes", "No", or "Unsure" can be marked () on the form. Two (2) questions are open-ended. To record the answers to these questions, words used by the parent or guardian should be written using the space provided. Please be sure to record an answer for every item on the PIRQ.

Recording Data

As a data record, the PIRQ will be scanned as it is received. For recording the answers, use a No.2 pencil or blue or black ink pen **only**; do not use felt-tip pens. When recording text or numbers, enter only one character in each box. When recording the answers to "Yes", "No", or "Unsure" questions, mark the "X" **inside** the appropriate box (). Erase completely any answer which needs to be changed. When recording the answers to the open-ended questions, write clearly within the boxed spaces provided. Proofread each PIRQ form for completeness and be sure that the correct VON ID number is used. Please **do not** make stray marks or write any comments on the Questionnaire.

Submitting Data

Please mail or fax a completed PIRQ to the **ELBW Infant Follow-up Project** at the Vermont Oxford Network.

ELBW Follow-up Project
Vermont Oxford Network
33 Kilburn Street
Burlington, VT 05401

FAX: 802-865-9613
FAX: 802-865-0359

Please keep the original PIRQ on file. **Send copies only.** Changes/updates made on a PIRQ previously submitted should be highlighted or noted as being "corrected" when sent to the Vermont Oxford Network.

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Publications

The Vermont Oxford Network will author all publications, which are based on data collected at all centers during the conduct of this follow-up project. An appendix listing each participating center, up to two investigators from each of the centers, and the study coordinator from each center will be included. The centers will be listed in alphabetical order. The appendix will also list the members of ELBW Infant Follow-up Project Steering Committee and the VON Clinical Trials & Follow-up Data Coordinating Center. All investigators listed in the appendix will be considered co-authors of the manuscript and entitled to include the publication in their curricula vitae.

Publications based on follow-up data collected at individual centers or a subgroup of centers which address ancillary research questions may be authored by the individual investigators responsible, but will not be submitted for publication until after the primary follow-up manuscript has been submitted. All ancillary studies must have prior approval of the Steering Committee to ensure that these studies will not interfere with the main study

III. Data Items of the Parental Interview and Reporting Questionnaire (Version 3)

TOP SECTION (COMPLETE BEFORE PARENTAL INTERVIEW)

The top section of each page of the PIRQ records the Vermont Oxford Network identification information: the Center Name, Center Number, Infant Network ID Number and Infant Year of Birth. The Center Name is the name of your medical center. When recording the Center Name, use only the first twenty (20) characters of the name; do not use punctuation symbols. The Center Number is the number assigned to your center for the VON Database. These fields will be the same for all infants enrolled in the ELBW Infant Follow-up Project at your center. The Infant Network ID Number is the number assigned to the infant for the VON Database according to the VON Database Manual of Operations. The Infant Year of Birth is recorded using four digits. For example, an infant born in 2009 will have the Infant Year of Birth recorded as “2009”.

SECTION A: Parent Interview (COMPLETE BEFORE INTERVIEW)

Section A of the Data Collection Form records information about the parent interview at the time of the two year corrected age follow-up visit.

1. Setting of the parental interview:

Record the setting in which the parental interview was conducted.

Mark () “**At Clinic Visit**” if the interview was conducted at the Follow-up Clinic .

Mark () “**By Phone**” if the interview was conducted by phone. Note that an interview is conducted by phone **ONLY** when a family is unable to complete the visit at the Follow-up Clinic.

2. Corrected age of infant at interview:

Record the child’s corrected age in months and days at the time of the interview using the boxes provided. For example if the child was 23 months and 18 days corrected age when evaluated for the 2-year follow-up visit, record “23” months and “18” days.

SECTION B: Health Status (complete as scripted parental interview)

Completing the following questions requires the interviewer to know the first name of the child and the gender of the child. The first name of the child should be used in the interview whenever the script reads (**name of child**). The gender of the child should be used in the interview whenever the script reads (**he / she**) or (**his / her**).

3. Did (name of child) need any oxygen after coming home from the Neonatal Intensive Care Unit?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

4. Did (he/she) need special feedings like a tube feeding or extra calories added to feedings to promote growth or weight gain?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

5. Did (he / she) need any medicines to help (his / her) breathing? These medicines can be breathed in, or taken as pills or liquids.

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

6. Since coming home from the Neonatal Intensive Care Unit, has (name of child) been back in the hospital overnight?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

If Item 6 is answered “Yes”, then ask and obtain answers for all of the following

6A. Was it for surgery?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

6B. Was it because of a breathing problem?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

6C. Was there another problem?

Mark () “Yes”, “No”, or “Unsure” based on the parent’s answer.

If Item 6C is answered “Yes”, then ask

6D. What was the problem?

Describe the problem using the words of the parent or guardian, within the boxed space provided.

SECTION C: Developmental Status (complete as a scripted parental interview)

Completing the following questions requires the interviewer to know the first name of the child, and the gender of the child. The first name of the child should be used in the interview whenever the script reads (**name of child**). The gender of the child should be used in the interview whenever the script reads (**he / she**) or (**his / her**).

7. Can (name of child) walk ten (10) steps alone without holding on to anyone or anything?

Mark () “Yes” or “No” based on the parent’s answer.

8. Have you ever been told by a doctor or a nurse or other health care provider that (name of child) has increased muscle tone?

Mark () “Yes” or “No” based on the parent’s answer.

9. Has (he / she) been evaluated by a physical or occupational therapist?

Mark () “Yes” or “No” based on the parent’s answer.

10. Does (he / she) child have a program of physical therapy or exercise (he / she) currently does at home?

Mark () “Yes” or “No” based on the parent’s answer.

11. Have you ever been told by a health care provider that (he / she) has cerebral palsy?

Mark () “Yes” or “No” based on the parent’s answer.

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12. Have you ever been told by a health care provider that (name of child) has a loss of vision or is blind in one or both eyes?

Mark () "Yes" or "No" based on the parent's answer.

13. Does (he / she) wear glasses now?

Mark () "Yes" or "No" based on the parent's answer.

14. Have you ever been told by a health care provider that (name of child) has a hearing loss or is deaf in one or both ears?

Mark () "Yes" or "No" based on the parent's answer.

15. Does (he / she) wear hearing aids now?

Mark () "Yes" or "No" based on the parent's answer.

16. Does (name of child) say single words like "mama" or "dada"?

Mark () "Yes" or "No" based on the parent's answer.

17. Does (he / she) use simple gestures such as waving or shaking (his / her) head for "no"?

Mark () "Yes" or "No" based on the parent's answer.

18. Does (he / she) search for toys that are hidden while (he / she) watches?

Mark () "Yes" or "No" based on the parent's answer.

19. Does (he / she) explore objects by shaking, banging or dropping?

Mark () "Yes" or "No" based on the parent's answer.

20. Does (he / she) point to pictures or objects?

Mark () "Yes" or "No" based on the parent's answer.

IF the parental interview was conducted at the Follow-up Clinic visit, STOP HERE

SECTION D: Follow-up Status (complete if the interview is conducted BY PHONE)

Completing the following questions requires the interviewer to know the first name of the child, and the gender of the child. The first name of the child should be used in the interview whenever the script reads (**name of child**). The gender of the child should be used in the interview whenever the script reads (**he / she**) or (**his / her**).

21. Were you unable to come to a follow-up clinic visit with (name of child) because

Ask and obtain answers for all of the following

21A. You did not know that (name of child) had an appointment?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21B. You had transportation or parking issues?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21C. You had cost or insurance issues?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21D. Your family relocated to a different geographical area?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21E. Your child was well and you believed there was no reason to come?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21F. Your child was already receiving support services?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

21G. Because of another reason?

Describe the reason using the words of the parent or guardian, within the boxed space provided.

22. Would you like to re-schedule a follow-up clinic visit for (name of child) at (name of hospital)?

Mark () "Yes", "No", or "Unsure" based on the parent's answer.

Vermont Oxford Network

Parental Interview and Reporting Questionnaire (PIRQ) Booklet

2 Year Corrected Age Follow-up

Release 3

SEPTEMBER, 2010

PATIENT IDENTIFICATION DATA

Patient Name: _____
Date of Birth: _____
Medical Record Number: _____
VON ID Number: _____
Parental Interview Date: _____

FAX copies of all completed forms to the Vermont Oxford Network at:

FAX: 802 865 9613
Attn: Clinical Trials Division

OR

Mail copies of all completed forms to:

Clinical Trials Division
Vermont Oxford Network
33 Kilburn Street
Burlington, VT 05401

DO NOT FAX or MAIL THIS COVER PAGE WITH YOUR FORMS

General Instructions to complete the Parental Interview and Questionnaire (PIRQ) booklet

- Verify Parental Consent has been obtained before the interview.
- Complete the Patient Identification Data on the Cover page before the interview.
- Complete the Top Section and Section A of the PIRQ forms before the interview.
- Complete the five steps of the PIRQ. Use a blue or black ball point pen or a felt tip pen to record answers by making a mark inside the appropriate box.
- Make a copy of the completed PIRQ forms on white paper: FAX or mail copies to VON.
- Keep the original PIRQ booklet for your records.

Steps to the PIRQ Script

STEP 1: Introduce yourself.

Hello, my name is (give your name). I am the (give job role) for the Follow-up clinic at (name of hospital). Before going home from the hospital, a staff person in the Neonatal Intensive Care Unit discussed a follow-up project with you. You agreed to be interviewed about the physical health and mental development of (name of child) as a part of (his / her) Follow-up Clinic visit when (he / she) is two years old.

STEP 2: Choose the setting in which the interview was done.

For a child who WAS SEEN in the Follow-up Clinic. (complete sections B and C).

This follow-up will happen at today's clinic visit with the doctors and nurses. Before the doctors and nurses see (name of child), I would like to ask you a few questions about (him / her).

For a child who WAS NOT SEEN in the Follow-up Clinic. (complete sections B, C and D).

I am calling because we have been unable to complete a follow-up visit with (name of child). I hope (name of child) is well. I would like to ask you a few questions about (him / her). If you wish, we can also re-schedule a Follow-up Clinic visit.

STEP 3: Explain the PIRQ.

The reason I am asking these questions is to learn about (name of child), and to see if general questions like these can tell about a child's health and development. These questions do not take the place of a clinic follow-up assessment, and will not be a part of (name of child)'s medical record. The doctors and nurses at the Follow-up Clinic visit will not hear or see your answers to these questions. Some of the questions ask about problems with health and development. The questions do not mean that I think or know that (name of child) has these problems. The questions shouldn't take very long. If any of the questions are confusing, please stop me, and I will explain.

STEP 4: Read the Questions and Record the Answers to the PIRQ.

STEP 5: Finish the PIRQ.

Thank you for answering these questions. This information is helpful to anticipate and plan for the health and developmental needs of children who are born premature.

PARENTAL INTERVIEW SCRIPT *Version 3*

CENTER NUMBER: _____	CENTER NAME: _____
VON ID NUMBER: _____	YEAR OF BIRTH: _____

SECTION A: Parental Interview

1	Setting of parental interview	<input type="checkbox"/> At Clinic Visit	<input type="checkbox"/> By Phone		
2	Corrected age of infant at interview	<input type="checkbox"/> <input type="checkbox"/> (Months)	<input type="checkbox"/> <input type="checkbox"/> (days)		

SECTION B: Health Status (complete as a scripted parental interview)

These first questions ask about (**name of child**)’s health. If what I am asking is not clear, please stop me, and I will explain.

3	Did (name of child) need any oxygen after coming home from the Neonatal Intensive Care Unit?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
4	Did (he / she) need special feedings like a tube feeding or extra calories added to feedings to promote growth or weight gain?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
5	Did (he / she) need any medicines to help (his / her) breathing? These medicines can be breathed in, or taken as pills or liquids.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
6	Since coming home from the Neonatal Intensive Care Unit, has (name of child) been back in the hospital overnight?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure

[If # 6 is YES, then ask and obtain answers for all of the following questions]

6A	Was it for a surgery?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
6B	Was it because of a breathing problem?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
6C	Was there another problem?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
6D	What was the problem? [Describe the problem in the box provided below]			

SECTION C: Developmental Status (complete as a scripted parental interview)

These next questions ask about (**name of child**)’s development. Again, if what I am asking is not clear, please stop me, and I will explain.

7	Can (name of child) walk <u>ten</u> (10) steps without holding on to anyone or anything?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8	Have you ever been told by a doctor or a nurse or other health care provider that (name of child) has increased muscle tone?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9	Has (he / she) been evaluated by a physical or occupational therapist?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10	Does (he / she) have a program of physical therapy or exercise (he / she) currently does at home?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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11	Have you ever been told by a health care provider that (<u>he / she</u>) has cerebral palsy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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PARENTAL INTERVIEW SCRIPT Version 3

CENTER NUMBER: _____	CENTER NAME: _____
VON ID NUMBER: _____	YEAR OF BIRTH: _____

12	Have you ever been told by a health care provider that (name of child) has a loss of vision or is blind in one or both eyes?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13	Does (he / she) wear glasses now?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14	Have you ever been told by a health care provider that (name of child) has a hearing loss or is deaf in one or both ears?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
15	Does (he / she) wear hearing aids now?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
16	Does (name of child) say single words like “mama” or “dada”?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
17	Does (he / she) use simple gestures such as waving or shaking (his/her) head for “no”?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
18	Does (he / she) search for toys that are hidden while (he / she) watches?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
19	Does (he / she) explore objects by shaking, banging or dropping?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
20	Does (he / she) point to pictures or objects?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

IF the parental interview was conducted at the Follow-up Clinic visit, STOP HERE.

SECTION D: Follow-up Status (complete if the parental interview is conducted BY PHONE)

These last questions ask about why we were not able to complete a follow-up clinic visit with (**name of child**).

21	Were you unable to come to a follow-up clinic visit with (name of child) because
----	--

[obtain answers for all of the following questions]

21A	You did not know that (name of child) had an appointment?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21B	You had transportation or parking issues?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21C	You had cost or insurance issues?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21D	Your family relocated to a different geographical area?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21E	Your child was well and you believed there was no reason to come?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21F	Your child was already receiving support services?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
21G	Because of another reason? [Describe the reason in the box provided below]			

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22	Would you like to re-schedule a follow-up clinic visit for (<u>name of child</u>) at (<u>name of hospital</u>)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
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**APPENDIX A: SAMPLE IRB ADDENDUM LETTER
FOR CENTERS CONTINUING WITH VERSION 3**

[your University or Hospital]
Committees on Human Research

September 1, 2010

Dear **[your IRB Chair]**:

I am writing to request an approval of an addendum to the "The Vermont Oxford Network (VON) Extremely Low Birth Weight Infant Follow-up Project" (**your ELBW Infant Follow-up Project IRB reference number**).

The addendum consists a protocol change to the scripted parental interview during which the answers to questions are recorded on a standardized data collection form. The addendum allows for the interview will be conducted in by phone if a family is a "no show" at the time of the scheduled follow-up clinic visit, as a part of the Extremely Low Birth Weight Infant Follow-up Project.

If the interview is conducted by phone there are of two (2) new questions supplemental to the normal interview conducted in the clinic setting. The new questions ask about why the parent/family was unable to attend the follow-up clinic visit and whether the parent/family would like to re-schedule the visit.

It is anticipated the interview will continue to take no longer than 20 minutes to administer. The interview questions continue to maintain HIPAA compliance; there is a modification to the consent to participate form. No additional examination or testing of the child will be performed. A sample of the scripted interview, data collection form, and consent to participate form are attached.

I would like to request an expedited review of this addendum.

Sincerely,

[your ELBW Infant Follow-up Project Principal Investigator]

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**APPENDIX B: SAMPLE IRB ADDENDUM LETTER
FOR CENTERS STARTING WITH VERSION 3**

[your University or Hospital]
Committees on Human Research

September 1, 2010

Dear **[your IRB Chair]**:

I am writing to request a approval of an addendum to the “The Vermont Oxford Network (VON) Extremely Low Birth Weight Infant Follow-up Project” (**your ELBW Infant Follow-up Project IRB reference number**). The addendum consists of a scripted parental interview during which the answers to questions will be recorded on a standardized data collection form. The interview will be conducted in person at the time of the clinic visit, or by phone at the time of the clinic visit if the parent/family was a “no show” for the visit. Both interviews will be conducted as a part of the Extremely Low Birth Weight Infant Follow-up Project. It is anticipated the interview will take no longer than 20 minutes to administer. The interview questions maintain HIPAA compliance. There is a modification of the consent to participate form. No additional examination or testing of the child will be performed. A sample of the scripted interview, data collection form, and consent to participate form are attached.

I would like to request an expedited review of this addendum.

Sincerely,

[your ELBW Infant Follow-up Project Principal Investigator]

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APPENDIX C: SAMPLE CONSENT FORM

THE EXTREMELY LOW BIRTH WEIGHT INFANT FOLLOW-UP PROJECT

VERMONT OXFORD NETWORK

PATIENT NAME: _____

I understand that my child was born prematurely and with extremely low birth weight (birth weight less than 2 pounds 3 ounces). I understand that because my child was born so prematurely and at such a low birth weight, he/she is at risk for problems in physical and mental development (developmental delay).

I understand that periodic assessment of my child's physical health and mental development is recommended as a routine of follow-up care after discharge from the Neonatal Intensive Care Unit of (*Name of Institution*). I understand that one assessment is to be scheduled between 18 and 24 months of age (corrected for prematurity) at the Neonatal Intensive Care Unit Follow-up Clinic of (*Name of Institution*). I understand that I may be telephoned by the Neonatal Intensive Care Unit Follow-up Clinic of (*Name of Institution*) to schedule this assessment.

If I am able to schedule or attend this assessment, I understand I will be interviewed in person at the clinic and asked about the progress of my child's physical health and mental development since his/her hospital discharge from the Neonatal Intensive Care Unit. On the other hand, if I am unable to schedule or attend this assessment, I understand I will be interviewed by phone about the progress of my child's physical health and mental development since his/her hospital discharge from the Neonatal Intensive Care Unit

If my child is able to attend the follow-up assessment, I understand that my child will have a physical examination, a neurological examination and a developmental test. I understand that the Revised Bayley Scales of Infant Development is the standard developmental test which will be given to my child. The Revised Bayley Scales of Infant Development assesses an infant's developmental performance and compare it to other infants of his/her age. The Revised Bayley Scales use three "tests" for this assessment. The first test is called the Neonatal Development Scale. It tests skills relating to social skills, language and problem solving. The second test is called the Psychomotor Development Scale. It tests skills relating to physical activity. The third test is called the Infant Behavior scale. It looks at an infant's temperament and behavior.

I understand the developmental test may take about one and one half-hours, is easy to understand and administer, and will be stopped if my child does not want to cooperate. I understand that the results of the test will be shared with my child's primary care provider and me, and that I will be counseled about the meaning of the test result. Should the test

APPENDIX C: SAMPLE CONSENT FORM (continued)

THE EXTREMELY LOW BIRTH WEIGHT INFANT FOLLOW-UP PROJECT
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indicate that my child could benefit from special help, that help will be explained to me and coordinated by the developmental pediatrician seeing my child at the clinic visit, as well as my child's primary care provider.

I understand that my answers to interview questions and information about my child's physical health and mental development, including and the results of the developmental test, will be reported to the Extremely Low Birth Weight Infant Follow-up Project of the Vermont Oxford Network. The Extremely Low Birth Weight Infant Follow-up Project is a registry of infants born weighing less than 1001 grams organized by the Vermont Oxford Network.

I understand neither I, as the parent, nor my child, as a patient, will be identified by name or medical record number. I understand that the collection and submission of all medical information from the Follow-up Clinic visit will be accomplished with strict adherence to professional standards of confidentiality. I understand that information of the Extremely Low Birth Weight Infant Follow-up Project may eventually be published, and that information may be exchanged between medical investigators, but that patient confidentiality will be maintained.

I understand that I am giving permission to be interviewed as a part of routine follow-up care at the Neonatal Intensive Care Unit Follow-up Clinic of (*Name of Institution*). I understand that I am giving permission for my answers to interview questions and information about my child's physical health and mental development, including and the results of the developmental test, to be reported to the Extremely Low Birth Weight Infant Follow-up Project of the Vermont Oxford Network, I understand that there will be no cost to me for participating in this interview. I also understand that there is no financial compensation for participating in the interview, or for allowing my child to participate in the Follow-up Clinic.

I understand that I may contact (*Name of Person Contact*) at (*phone number*), the administrator of the Committee on Human Research at (*Name of Institution*) for more information should I believe my child has been physically injured by the testing procedure.

I have been given an opportunity to discuss this study with the physicians conducting it and I understand that I may ask further questions and I may withdraw my child from the testing at any time without prejudice to my child's present and/or future medical or developmental care.

Vermont Oxford Network
Extremely Low Birth Weight Follow-Up Project
Parental Interview and Reporting Questionnaire Version 3

APPENDIX C: SAMPLE CONSENT FORM (continued)

THE EXTREMELY LOW BIRTH WEIGHT INFANT FOLLOW-UP PROJECT
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I agree to be interviewed and to have my child participate in the Neonatal Intensive Care Unit Follow-up Clinic. I agree to have my answers to interview questions and information about my child's physical health and mental development, including and the results of the developmental test, reported to the Extremely Low Birth Weight Infant Follow-up Project of the Vermont Oxford Network. I understand that I will receive a signed copy of this form.

Parent/Guardian

Date

Witness

Date

Physician

Date

Principal Investigator
(Name and Name of Institution)