



Human Subjects Training

v. 01/07



**Pregnancy Risk Assessment
Monitoring System**



January 11, 2007

Dear PRAMS Colleague,

The protection of human subjects is a critical part of the PRAMS project. In 2001 and 2002, PRAMS experienced different types of breaches in protocol in several PRAMS states that had implications for human subjects protections and research ethics. This series of events led the Institutional Review Board (IRB) at the Centers for Disease Control and Prevention (CDC) to recommend that we develop a training for all PRAMS staff. The purpose of the training is to emphasize the importance of protecting the rights of PRAMS participants.

Everyone on PRAMS who has contact with participants or access to identifiable information about participants is considered to be engaged in human subjects research. This is why you are required to complete this series of training modules.

The PRAMS Human Subjects Protections Training consists of 4 modules. Each module covers topics related to human subjects and the implications for PRAMS. CDC's IRB board requires that all new PRAMS staff:

- * Complete Module 1 (self-directed) as part of orientation and training. This should be done within the first 2 weeks of employment and prior to any contact with potential participants or identifiable data.
- * Complete Modules 2 and 3 (self-directed) within 2-3 months of completing Module 1.
- * Review Module 4 at least once per year as a group with all PRAMS staff in your state. Submit the sign-in sheet to your CDC Program Manager.

The training modules are designed to heighten awareness about the need to follow the PRAMS protocol as written and to protect PRAMS participants. I hope you will find the training both informative and enjoyable.

On behalf of the CDC PRAMS team, I want to take this opportunity to thank you for your contribution to PRAMS.

Sincerely yours,

Norma Harris

Norma Harris, Ph.D.

PRAMS Project Officer

Applied Sciences Branch

Division of Reproductive Health

National Center for Chronic Disease Prevention
and Health Promotion

PRAMS Human Subjects Training

MODULE 1

OVERVIEW OF HUMAN SUBJECTS PROTECTIONS

1a. Basic Principles in Conducting Human Subjects Research

Objectives for Module:

1. List the 3 basic ethical principles guiding human subjects research
2. Describe how these principles are addressed in PRAMS

OVERVIEW

There are three basic principles relevant to the ethics of conducting research with human subjects:

- Respect for Persons
- Beneficence
- Justice

Respect for Persons

The principle of respect for persons requires the researcher to acknowledge a person's ability to make his or her own decisions. This principle can be demonstrated in research by ensuring that subjects are fully aware that their participation is voluntary; the participant is free to choose to participate. The participant may also refuse to participate and should be able to recognize his or her right to withdraw from the research without penalty of any kind. Respect for persons can also be demonstrated by informing the participant about the length of the study, study procedures, outcomes, and any possible risks. Individuals must be provided enough information to allow them to determine if participating in the research is right for them.

To respect a person's ability to make decisions, you must give weight to their opinions and choices while not obstructing their actions (unless those actions are clearly harmful to others). In PRAMS, respect is accomplished by obtaining informed consent and recognizing individuals' right to privacy.

Beneficence

Beneficence (*ben-if-ih-sense*) means to do good and to avoid harm. It is your responsibility to protect participants from harm, as well as ensure that they experience the possible benefits of involvement. When do the benefits to society outweigh the possible risks to the individual participating in the research? This is an ethical question that researchers always face. Surveys like PRAMS generally have little risk and are aimed to benefit the respondents, groups, and society.

Balancing risks and benefits is very important. PRAMS involves no more than minimal risk. This means that the chance of or amount of harm from the research is not greater than the chance of or amount of harm ordinarily encountered in daily life. A PRAMS risk may include a mother feeling uncomfortable due to the sensitive nature of some of the questions (i.e. smoking, violence). However, PRAMS risks are balanced out by its benefits to society. These benefits include providing information to direct policy and programs. The "Data to Action" booklet has great examples of how PRAMS has informed policy and programs in areas such as unintended pregnancy, violence, folic acid, etc. (To view a copy of "Data to Action" go to: <http://www.cdc.gov/PRAMS/dataAct2002/index.htm>.)

Justice

The ethical considerations of risks and benefits raise the question of justice. Who should bear the risk of a study and who should receive its benefits? The concept of justice may be questioned when we decide who will be given an opportunity to participate and who will be excluded and for what reason.

Individuals and groups that benefit from the research should bear the risks and burdens of the research. Women have been underrepresented in certain research studies because of the risks associated with child-bearing. Now researchers must justify why women are not included in a study population. Failure to provide scientifically sound arguments for the exclusion of one gender is grounds for the denial of the research by funding agencies and research review boards.

Participants should not be selected due to class, socioeconomic status, race, or sex unless justified by study objectives. For example, PRAMS excludes men because men can not have babies. Excluding certain groups from participation often means excluding those same groups from the benefits of the research. PRAMS, for example, includes adolescents so that the findings from PRAMS can be used to improve the health of adolescent mothers and their babies.

Criteria for Review of Research

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of humans participating in research. PRAMS must go through the CDC's IRB review process and through local IRB review. The CDC IRB uses the following criteria to review research:

- Risks to the subjects are minimized
- Risks to the subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each prospective participant or his or her legally authorized representative
- Adequate preparation is taken to protect the privacy and confidentiality of subjects
- Adequate provisions are made for the ongoing monitoring of the subjects' welfare

REVIEW QUESTIONS

1. What is one example of how we show respect for participants in PRAMS?
2. What are the potential **benefits** of participating in PRAMS?
3. What are the potential **risks** of participating in PRAMS?
4. What can we do to minimize risks for PRAMS participants?
5. Are the risks involved in PRAMS fairly shared by women and groups who participate?
6. What are the 3 basic ethical principles that guide human subjects research?

Suggested answers are on Page 17. Some common terms used in human subjects research are listed on Page 18. Websites for additional information and training are listed on Page 19.

1b. Informed Consent

Objectives for Module:

1. Describe why informed consent is important in human subjects research
2. Identify the required elements of informed consent and how they relate to the 3 basic ethical principles guiding human subjects research

OVERVIEW

Research involving human subjects poses complex ethical issues. It requires careful thought and consideration on the part of both the researchers and research participants. Prospective participants must be given adequate information on both the possible risks and the potential benefits of their involvement to allow them to make informed decisions.

It is your responsibility to educate the participants about risks and benefits and obtain their consent before involving them in PRAMS. This is the **informed consent process**.

Informed consent is about people's understanding and willingness to participate in your study. Prospective participants in PRAMS must understand the purpose, the procedures, and the potential risks and benefits of their involvement in order to make a decision about their participation. In order for a participant to provide informed consent, they must be able to read (or listen to the interviewer read the information) and understand what is being conveyed to them about the study and what they are being asked to do as a participant.

Consent information for PRAMS is included in the "Mailed Informed Consent Document" and telephone script. While a consent document that gives information about the study is a vital part of the process, the opportunity to discuss any questions or concerns with a knowledgeable research team member is also necessary. This is why we include contact information for the PRAMS coordinator – for questions about PRAMS – and for the IRB contact – for questions concerning rights as a participant. Prospective participants may need time to think about their decision and to discuss it, if necessary, with family, friends, or religious advisors.

When speaking with a prospective PRAMS participant on the telephone, it is very important to realize that the phone conversation is the opportunity for the mother to become informed. Therefore, you need to allow her to ask for clarification. The script may seem long and unimportant to you because you see it all of the time. However, this is the first time the mother will hear the information and she needs to be fully informed and assured that her interests and rights are adequately protected.

Because in PRAMS we strive to achieve high response rates and completed questionnaires, the PRAMS staff may be uncomfortable with some of the consent language that tells women they don't have to participate or they don't have to answer any question that they don't want to answer. We must keep in mind the principle of respect and understand that despite our high response rate goals, participation in PRAMS is voluntary.

Failure to obtain informed consent or failure to fully inform a participant is considered a breach in protocol. Breaches can have serious consequences which are described in Module 2. Of

course we all want to avoid such problems, which is why we ask you to include all the elements of informed consent in the documents and scripts and why we stress the importance of reading the script exactly as it is written every time.

There are required elements for the mail packet and telephone script to ensure that informed consent is received. A yearly review by CDC of each state's cover letter and phone script is required to ensure that all required elements of consent are included in the letters and scripts. The elements to include in a PRAMS cover letter and telephone script are:

Required Elements	Why It's Important
9 A statement that PRAMS involves research and the CDC provides support for the research, its purpose and procedures, and expected duration	Respect
9 An explanation of how the mother was chosen and the reason for the identification number on the questionnaire	Respect
9 Notification that data may be linked to other sources	Respect
9 Any foreseeable risks or discomforts to the mother, including a statement that some of the questions may be sensitive	Beneficence Respect
9 Benefits to the participants and others (incentive or reward, improve the health of women and children)	Justice Beneficence
9 Protection of confidentiality to 'the extent of the law'	Beneficence Respect
9 Contact information for questions about the study and rights of participants	Respect Beneficence
9 Voluntary participation, may choose not to answer certain questions or to participate, no penalty or loss of benefits	Respect
9 If state child abuse reporting law requires that self reported abuse to teens be reported to the state, and the state does not have a separate questionnaire for teens, the requirement for reporting must be explicitly included in the letter	Respect Beneficence
9 Telephone scripts must include an explicit prompt for permission to continue with the interview.	Respect

The informed consent process is essential for protecting human subjects. Making an informed decision about participating in research includes having an understanding of the possible risks

and benefits of participation, knowing that participation is voluntary, and that the participant can withdraw at any time.

EXERCISE

The exercise for this module is to review a sample PRAMS mailed informed consent document and a sample telephone script to identify which elements of informed consent are missing. The following pages contain a copy of the exercise and a copy of the answers for your reference.

Instructions

- 1) Review the mailed informed consent document on Page 7
- 2) Using the checklist on Page 8, fill in the last column (“Is it there?”) indicating whether each element of informed consent is included in the mailed informed consent document.
- 3) Review your answers with the answer key on Page 11 and the corrected mailed consent document on page 13.
- 4) Review Phone script on Page 9.
- 5) Using the checklist on Page 10, fill in the last column (“Is it there?”) indicating whether each element of informed consent is included in the phone script.
- 6) Review your answers with the answer key on Page 14 and the corrected telephone script on page 16.

Mailed Informed Consent Document Exercise

Important Information About PRAMS

Please Read Before Starting the Survey

- The Pregnancy Risk Assessment Monitoring System (PRAMS) is a project sponsored by the Springfield Health Department.
- The purpose of the study is to find out why some babies are born healthy and others are not.
- We are asking 200 women in Springfield to answer the same questions.
- It takes about 20 minutes to answer all questions.
- You are free to do the survey or not. If you don't want to participate at all, or if you don't want to answer a particular question, that's okay.
- Your survey may be combined with information the health department has from other sources.
- If you choose to do the survey, your answers will be kept private and will be used only for research. If you are currently in jail, your participation in the study will have no effect on parole.
- Your name will not be on any reports from PRAMS. The booklet has a number so we will know when it is returned.
- Your answers will be grouped with those from other women.

If you have questions about PRAMS, or if you want to answer the questions by telephone, please call Susie Jones, Springfield PRAMS Project Coordinator, at 1-800-555-1234. This call is free.

Required Elements for Informed Consent

Mailed Informed Consent Document Exercise

Required Elements	Why It's Important	Is it there? Yes/No
9 A statement that PRAMS involves research and the CDC provides support for the research, its purpose and procedures, and expected duration	Respect	
9 An explanation of how the mother was chosen and the reason for the identification number on the questionnaire	Respect	
9 Notification that data may be linked to other sources	Respect	
9 Any foreseeable risks or discomforts to the mother, including a statement that some of the questions may be sensitive	Beneficence Respect	
9 Benefits to the participants and others (incentive or reward, improve the health of women and children)	Justice Beneficence	
9 Protection of confidentiality to 'the extent of the law'	Beneficence Respect	
9 Contact information for questions about the study and rights of participants	Respect Beneficence	
9 Voluntary participation, may choose not to answer certain questions or to participate, no penalty or loss of benefits	Respect	
9 If state child abuse reporting law requires that self reported abuse to teens be reported to the state, and the state does not have a separate questionnaire for teens, the requirement for reporting must be explicitly included in the letter	Respect Beneficence	
9 Telephone scripts must include an explicit prompt for permission to continue with the interview.	Respect	

Telephone Script Exercise

Introduction, Part 1.

Hello, I'm _____, and I'm calling from the <STATE> PRAMS project. PRAMS is a project to learn more about the health of women in <STATE>.

Recently we mailed you a questionnaire. <Did you receive it?> Since we have not received it yet, I'd like to go ahead and do the survey with you now. <In appreciation for your help, we will send you a special gift.>

First, I'd like to make sure that I am talking with the right person. You are <mother's name> and you were born in <mother's year of birth>. Is that correct?

Æ IF YES, CONTINUE WITH PART 2.

Introduction, Part 2.

PRAMS is short for the **P**regnancy **R**isk **A**ssessment **M**onitoring **S**ystem. PRAMS is sponsored by the Springfield Health Department. We want to find out why some babies are born healthy and others are not. We would like you to answer some questions about your recent pregnancy. The information you give us will be used to help us build programs to benefit mothers and babies in Springfield.

We are asking 200 women in Springfield to answer these same questions.

Your answers are very important, whether you and your baby have been healthy or sick. If you have lost your baby because of death, we are truly sorry about your loss and offer our sympathy to you and your family.

Most questions are about your health and life before, during, and after pregnancy. It takes about 15 - 20 minutes to answer all questions.

You are free to do the survey or not. If you don't want to participate at all, that's okay. If you want to stop in the middle, or quit, that's okay.

Your answers will be grouped with those from other women. Your name will not be on any reports from PRAMS.

If you choose to do the survey, your answers will be kept private and will be used only for research. What we learn from PRAMS will be used to plan programs to help mothers and babies in Springfield.

IF THE MOM IS IN JAIL, SAY: Your participation in the study will have no effect on parole.

Shall we begin?

Required Elements for Informed Consent Telephone Script Exercise

Required Elements	Why It's Important	Is it there? Yes/No
9 A statement that PRAMS involves research and the CDC provides support for the research, its purpose and procedures, and expected duration	Respect	
9 An explanation of how the mother was chosen and the reason for the identification number on the questionnaire	Respect	
9 Notification that data may be linked to other sources	Respect	
9 Any foreseeable risks or discomforts to the mother, including a statement that some of the questions may be sensitive	Beneficence Respect	
9 Benefits to the participants and others (incentive or reward, improve the health of women and children)	Justice Beneficence	
9 Protection of confidentiality to 'the extent of the law'	Beneficence Respect	
9 Contact information for questions about the study and rights of participants	Respect Beneficence	
9 Voluntary participation, may choose not to answer certain questions or to participate, no penalty or loss of benefits	Respect	
9 If state child abuse reporting law requires that self reported abuse to teens be reported to the state, and the state does not have a separate questionnaire for teens, the requirement for reporting must be explicitly included in the letter	Respect Beneficence	
9 Telephone scripts must include an explicit prompt for permission to continue with the interview.	Respect	

Answer Key

What's missing in the Mailed Informed Consent Document?

Required Elements	Why It's Important	Is it there? Yes/No	Comments
9 A statement that PRAMS involves research and the CDC provides support for the research, its purpose and procedures, and expected duration	Respect	NO	No mention that project is research. No mention of CDC providing support Purpose is mentioned – to understand why some babies are healthy and others are not. Procedures are mentioned – We are asking 200 women in the state to answer these same questions. Expected duration mentioned
9 An explanation of how the mother was chosen and the reason for the identification number on the questionnaire	Respect	NO	No mention that names were picked by computer from recent birth certificates. Explanation of ID number given – “...so we will know when the booklet is returned.”
9 Notification that data may be linked to other sources	Respect	YES	“Your survey may be combined with information that the health department has from other sources.”
9 Any foreseeable risks or discomforts to the mother, including a statement that some of the questions may be sensitive	Beneficence Respect	NO	No mention of sensitivity of some questions
9 Benefits to the participants and others (incentive or reward, improve the health of women and children)	Justice Beneficence	NO	No mention of benefit of improving the health of women and children
9 Protection of confidentiality to ‘the extent of the law’	Beneficence Respect	NO	No mention of protection to “extent of the law.”
9 Contact information for questions about the study	Respect Beneficence	NO	No mention of IRB contact information. PRAMS contact for additional information is mentioned.

Required Elements	Why It's Important	Is it there? Yes/No	Comments
and rights of participants			
9 Voluntary participation, may choose not to answer certain questions or to participate, no penalty or loss of benefits	Respect	NO	No mention of no penalty or loss of benefits if choosing to participate
9 If state child abuse reporting law requires that self reported abuse to teens be reported to the state, and the state does not have a separate questionnaire for teens, the requirement for reporting must be explicitly included in the letter	Respect Beneficence	NO	Not applicable
9 Telephone scripts must include an explicit prompt for permission to continue with the interview.	Respect	NO	Not applicable

Mailed Informed Consent Document (Corrected)

Important Information About PRAMS Please Read Before Starting the Survey

- The Pregnancy Risk Assessment Monitoring System (PRAMS) is a **research** project sponsored by **the Centers for Disease Control and Prevention** and the Springfield Health Department.
- The purpose of the study is to find out why some babies are born healthy and others are not.
- We are asking 200 women in Springfield to answer the same questions. **All of your names were picked by a computer from recent birth certificates.**
- It takes about 20 minutes to answer all questions. **Some questions may be sensitive, such as questions about smoking or drinking during pregnancy.**
- You are free to do the survey or not. If you don't want to participate at all, or if you don't want to answer a particular question, that's okay. **There is no penalty or loss of benefits for not participating or answering all questions.**
- Your survey may be combined with information the health department has from other sources.
- If you choose to do the survey, your answers will be kept private **to the extent allowed by law** and will be used only for research. If you are currently in jail, your participation in the study will have no effect on parole.
- Your name will not be on any reports from PRAMS. The booklet has a number so we will know when it is returned.
- Your answers will be grouped with those from other women. **What we learn from PRAMS will be used to plan programs to help mothers and babies in Springfield.**
- **If you have any questions about your rights in the project, please call Bob Harris at your local IRB Office at 1-800-555-6789.**

If you have questions about PRAMS, or if you want to answer the questions by telephone, please call Susie Jones, Springfield PRAMS Project Coordinator, at
1-800-555-1234.

This call is free.

Answer Key

What's missing in the telephone script?

Required Elements	Why It's Important	Is it there? Yes/No	Comments
9 A statement that PRAMS involves research and the CDC provides support for the research, its purpose and procedures, and expected duration	Respect	NO	No mention that project is research. No mention of CDC providing support Purpose is mentioned – to understand why some babies are healthy and others are not. Procedures are mentioned – We are asking 200 women in the state to answer these same questions. Expected duration mentioned
9 An explanation of how the mother was chosen and the reason for the identification number on the questionnaire	Respect	NO	No mention that the participant's name was picked by a computer from among recent birth certificates.
9 Notification that data may be linked to other sources	Respect	NO	No mention that information from the survey may be linked to other data that the health department may have.
9 Any foreseeable risks or discomforts to the mother, including a statement that some of the questions may be sensitive	Beneficence Respect	NO	No mention of sensitivity of some questions; however, do offer sympathy for mothers whose babies have died.
9 Benefits to the participants and others (incentive or reward, improve the health of women and children)	Justice Beneficence	YES	Benefit of using information from PRAMS to plan programs to help mothers and infants is mentioned. Benefit of a reward is mentioned.
9 Protection of confidentiality to 'the	Beneficence Respect	NO	No mention of protection to "extent of the law."

Required Elements	Why It's Important	Is it there? Yes/No	Comments
extent of the law'			
9 Contact information for questions about the study and rights of participants	Respect Beneficence	NO	No mention of IRB contact or PRAMS contact for additional information.
9 Voluntary participation, may choose not to answer certain questions or to participate, no penalty or loss of benefits	Respect	NO	Voluntary participation and right to stop in the middle or quit is mentioned. No mention of "if you don't want to answer a particular question". No mention of no penalty or loss of benefits if choosing to participate.
9 If state child abuse reporting law requires that self reported abuse to teens be reported to the state, and the state does not have a separate questionnaire for teens, the requirement for reporting must be explicitly included in the letter	Respect Beneficence	NO	Not applicable
9 Telephone scripts must include an explicit prompt for permission to continue with the interview.	Respect	YES	"Shall we begin?" is included as the end of the telephone introductory script.

Telephone Script (Corrected)

Introduction, Part 1.

Hello, I'm _____, and I'm calling from the <STATE> PRAMS project. PRAMS is a **research** project to learn more about the health of women in <STATE>.

Recently we mailed you a questionnaire. <Did you receive it?> Since we have not received it yet, I'd like to go ahead and do the survey with you now. <In appreciation for your help, we will send you a special gift.>

First, I'd like to make sure that I am talking with the right person. You are <mother's name> and you were born in <mother's year of birth>. Is that correct?

Æ IF YES, CONTINUE WITH PART 2.

Introduction, Part 2.

PRAMS is short for the **Pregnancy Risk Assessment Monitoring System**. PRAMS is sponsored by **the Centers for Disease Control and Prevention** and the Springfield Health Department. We want to find out why some babies are born healthy and others are not. We would like you to answer some questions about your recent pregnancy. The information you give us will be used to help us build programs to benefit mothers and babies in Springfield.

We are asking 200 women in Springfield to answer these same questions. **Your name was picked by a computer from recent birth certificates.**

Your answers are very important, whether you and your baby have been healthy or sick. If you have lost your baby because of death, we are truly sorry about your loss and offer our sympathy to you and your family. **We also ask that you do the interview because your answers are important, and could help other mothers and babies in the future.**

Most questions are about your health and life before, during, and after pregnancy. It takes about 15 - 20 minutes to answer all questions. **Some questions may be sensitive, such as questions about smoking or drinking during pregnancy.**

You are free to do the survey or not. If you don't want to participate at all, **or if you don't want to answer a particular question**, that's okay. If you want to stop in the middle, or quit, that's okay. **There is no penalty or loss of benefits for not participating or answering all questions.**

Your answers will be grouped with those from other women. Your name will not be on any reports from PRAMS. **Your survey may be combined with information the health department has from other sources.**

If you choose to do the survey, your answers will be kept private **to the extent allowed by law** and will be used only for research. What we learn from PRAMS will be used to plan programs to help mothers and babies in Springfield.

If you have questions about PRAMS, please call Susie Jones, Springfield PRAMS Project Coordinator, at 1-800-555-1234. If you have any questions about your rights in the project, please call Bob Harris at your local IRB Office at 1-800-555-6789.

IF THE MOM IS IN JAIL, SAY: Your participation in the study will have no effect on parole.

Shall we begin?

ANSWERS TO REVIEW QUESTIONS:

1. Some examples of how we show respect in PRAMS are:
 - Providing complete and accurate information to the potential participant to ensure informed consent
 - Recognizing individuals' right to privacy
 - Giving value to the potential participant's opinions and choices
 - Informing potential participants that they will not be penalized in any way if they choose not to participate in the survey

2. Individual benefits include:
 - Incentives/rewards
 - Sense of altruismBenefits to society include:
 - Informing maternal and child health policy and programs
 - The "Data to Action" booklet has examples of ways that broader groups of women and children benefited from women participating in PRAMS.

3. Risks are minimal in PRAMS. However, risks include:
 - A mother feeling upset or uncomfortable because some of the questions may be sensitive (i.e. if the baby has died or was put up for adoption, questions related to smoking, violence, etc.)
 - Breach in confidentiality

4. We can minimize risk by:
 - Informing women about sensitive questions in the survey
 - Continuous monitoring of project
 - Protecting confidentiality
 - Being respectful when interviewing mothers
 - Using the data to inform programs and policies
 - Always adhering to PRAMS Model Surveillance Protocol

5. In general, risks from PRAMS are shared by all participants.
 - However, women whose babies have died or who gave their babies up for adoption may be more upset than other mothers by some of the questions or the fact that we're asking them to participate in this survey.
 - It is difficult to predict who might be upset and why, but we need to understand that PRAMS questions may raise issues for some women and we need to be sympathetic.

6. The three principles are:
 - Respect for persons
 - Beneficence
 - Justice

Common Terms Used in Human Subjects Research

- 9 **Respect:** To acknowledge a person's ability to make his or her own decisions and to protect persons with a diminished capability to make informed decisions.
- 9 **Beneficence:** To do good, to avoid harm.
- 9 **Justice:** To treat persons fairly. To assume a fair sharing of burdens and benefits.
- 9 **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests. Both probability and magnitude must be considered when weighing risks and benefits.
- 9 **IRB:** Institutional Review Board. This is an administrative body established to protect the rights and welfare of humans participating in research. The PRAMS protocol must go through the CDC IRB and your state or local IRB.
- 9 **Informed Consent Process:** To educate the participants about risks and benefits and obtain their permission before involving them in your research.
- 9 **Researchers:** PRAMS staff involved in the decision of a research study, the development of methods/procedures for the study, or the collection, analysis or interpretation of data.
- 9 **Human Subjects:** Living individual about whom an investigator conducting research obtains data through interaction (i.e. interview/survey) or obtains identifiable private information.

Additional Human Subjects Information

Additional Human Subjects Research information and training are available at:

Centers for Diseases Control & Prevention (CDC), Human Subjects Research Homepage:

9 <http://www.cdc.gov/od/ads/hsr2.htm>

US Department of Health & Human Services (DHHS), Office for Human Subjects Protections (OHRP) Homepage:

9 <http://www.hhs.gov/ohrp/>

University of South Carolina, Office of Research Compliance Homepage:

9 <http://tutorial.orc.research.sc.edu/>

National Institute for Health (NIH), Office of Human Subjects Research Homepage:

9 <http://ohsr.od.nih.gov/cbt/>

The Belmont Report:

9 <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

The Nuremburg Code:

9 <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

Declaration of Helsinki:

9 <http://www.wma.net/e/policy/b3.htm>

PRAMS Human Subjects Training

MODULE 2

**PROBLEMS THAT ARISE DURING RESEARCH:
BREACHES AND ADVERSE EVENTS**

2a. Breaches and Adverse Events: What Gets Reported and How

Objectives for Module:

1. Recognize breaches and adverse events as they relate to human subjects
2. Know how soon a breach or adverse event must be reported and to whom it must be reported
3. Understand what an incident report should include
4. List corrective actions when a breach or adverse event has occurred

What is a breach?

Situations in which the protocol is not followed as specified are called breaches in protocol. Examples of breaches in protocol include deviating from approved procedures and violating confidentiality.

If a breach results in physical or psychological injury to a participant in a research study, it is then called an adverse event. Therefore, implementing the protocol as it is designed is very important, not only for scientific reasons, but also for the protection of participants.

What is an adverse event?

Adverse events include a physical or psychological injury to a participant in a research study. Adverse events can occur in any study. However, they are more common in clinical trials; a participant who has an unexpected reaction to a drug being tested in a placebo controlled drug trial is an example. An adverse event is usually discovered because a participant lets the researcher know that something has gone wrong.

Who to report a breach or adverse event to and when

Breaches and adverse events should be reported to the state PRAMS Project Coordinator **immediately**. The Project Coordinator should report these events to their CDC Program Manager or directly to the PRAMS Project Officer **immediately**.

The IRB (Institutional Review Board) is an ethics review committee that an institution appoints to ensure that research involving human participants adheres to the Code of Federal Regulations that protect human subjects involved in research (To view the codes go to: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). The PRAMS project is reviewed by both the CDC IRB and your local IRB. Breaches and adverse events should be reported to your local IRB. These incidents should also be reported to the CDC IRB through your CDC Program Manager or the PRAMS Project Officer.

What to Report

An incident report should include:

- A statement of the event describing what happened and when it happened
 - It is not necessary to use names but do include job titles of research staff
 - Do not use participant names

- A description of the impact on participants
- A description of what corrective actions have been or will be taken

Corrective Actions

In addition to reporting what happened, we need to try to fix the problem by taking corrective action. The Project Coordinator should discuss the steps that need to be taken with their CDC Program Manager. There may be situations when the Project Coordinator will need to take immediate actions to correct the situation.

Depending on the incident, some possible corrective actions are:

- Phone calls of apology
- Letters of apology
- Destruction of data
- Other actions determined by the IRB

Phone calls or letters to affected participants should state the problem, apologize for the adverse event and any distress it may have caused, and state what the PRAMS project is doing to rectify the situation. The contact information for the project coordinator should be provided in case the participants have any questions or concerns. Although the destruction of data is rarely done, it may be necessary in order to preserve the integrity of the PRAMS project. When the CDC IRB receives an incident report, they may suggest or require that other actions be taken.

All of the above corrective actions were taken for a PRAMS project when the informed consent document was not included in several batches of mailed surveys. The mistake was identified and the participants were contacted by mail and/or phone to state the problem, apologize for the adverse event and any distress it may have caused, and state the solution. In this example, the solution was to ask the participant whether or not they would consent to the use of their survey data. For those indicating a positive answer, the survey data were kept. For those indicating a negative answer, the survey data were destroyed. In addition, the CDC IRB suggested that CDC PRAMS conduct an additional site visit to the state to review project operations and ensure adherence to the study protocol.

CASE STUDY EXERCISE. PART 1

Please read the following five case studies. For case studies 1-4, answer the following questions:

1. Is this a breach or an adverse event? Why or why not?
2. Who would you report this incident to and when?
3. What information would you include in the incident report?

For case study 5, answer the following questions:

1. Is this a breach or an adverse event? Why or why not?
2. What was the purpose of obtaining an interim approval from the local IRB?

Case Study #1**Day 1**

It was a beautiful spring morning. The letters for the first mailing of batch #4 were being prepared by the data manager. Nothing unusual was noted by the staff about the mailing.

The letters were put in the mail at the end of the day.

Day 4

It was just after lunch that the phone began to ring at the PRAMS office. Over the course of the next few hours, the office received 9 calls from upset women whose babies were alive, but whose letters expressed sympathy for their babies' deaths. At the end of the day, the IRB chair called and said her office had received 2 calls.

Case Study #2

It was a cold and rainy afternoon when the CDC program manager, Jennifer, visited the state PRAMS project for a site visit. The PRAMS team and program manager had just finished lunch and were happy to return to a warm office. As Jennifer began her discussions with the state project coordinator, she began to look over the introductory and consent statements that are read to potential phone participants. She noticed that they were not the standard statements required by the PRAMS protocol and approved by the local and CDC IRB, but rather shorter versions of the statements.

The project coordinator and contractor supervising the telephone interviewing were given the correct phone introduction and consent statements and told to make the appropriate changes.

Two months later, CDC received a copy of the current state telephone scripts. The consent statements had not been corrected and were missing the following statements:

- That this is a research project
- That PRAMS is supported by CDC
- That data are kept confidential 'to the extent permitted by law'
- The PRAMS data might be combined with data the health department has from other sources

Case Study #3

The Springfield PRAMS staff was enjoying a festive lunch at the office. They had received data from CDC and were very excited to start some of their planned analysis activities!

The data manager heard the phone ring and rushed to get the call. The call was from an upset participant complaining about the PRAMS survey. The participant was angry because she had completed her survey and sent it in. Two weeks after she sent it, she received another PRAMS survey packet asking her to please complete the survey at her earliest convenience.

The participant felt it was unreasonable that she received a second survey since she had already completed the survey. She felt that the state PRAMS staff was irresponsible and harassing her.

The data manager apologized for any inconvenience the second survey may have caused the participant. She also attempted to explain the mailing procedures, but the angry woman kept yelling at her, telling her she was unprofessional and irresponsible. The data manager quickly thanked the caller for completing the PRAMS survey and hung up the phone.

Case study #4

Jane, a new mom, had not responded to the mailed surveys and therefore entered the phone phase. During her shift at the phone lab, one of the PRAMS telephone interviewers, Sara, reached an individual at Jane's listed telephone number. Sara identified herself and stated that she was calling for the Health Department and asked to speak to Jane.

The woman who answered the telephone said Jane was not there. She identified herself as Mona, Jane's mother-in-law, and asked what the phone call was regarding. Sara said the phone call was in reference to a health survey.

Mona continued to ask questions, requesting more details about the survey. Sara told Mona that the health survey was the Pregnancy Risk Assessment Monitoring System and she had questions for Jane about her new baby. Mona had no knowledge about a baby, but offered to ask Jane about a baby and have Jane return Sara's call.

The next morning, there was a message on the PRAMS answering machine from Jane. Jane was extremely upset. She had not told her in-laws about the pregnancy because she had given the baby up for adoption. Jane was very agitated and said her lawyer would be in touch.

Case study #5

Springfield PRAMS' annual IRB review was set to expire on June 18th. The Project Coordinator submitted the request for continuation to the local IRB 8 weeks prior to June 18th. The local IRB was delayed in reviewing the continuation due to a scheduling conflict with the prisoner representative.

On June 19th, the local IRB issued an interim approval for the continuation of data collection. The CDC Program Manager was notified of the interim approval. During the next scheduled IRB meeting on June 24th, the annual approval was issued to Springfield PRAMS.

2b. Severity and Consequences of Adverse Events

Objectives for Module:

1. Identify steps to prevent breaches and adverse events in the future
2. List 2 outcomes/consequences of breaches and adverse events as they relate to PRAMS

Prevent Breaches and Adverse Events in the Future

In addition to corrective actions, it is also necessary for the PRAMS staff to consider actions they can take that will help prevent breaches and adverse events from occurring in the future. Some steps that PRAMS staff can take to help prevent future breaches and adverse events are:

- Conduct additional training
- Identify and fix any software problems that may have contributed to the adverse event
- Change job duties for persons involved in the adverse event
- Review the protocol

In response to a series of breaches and adverse events, CDC PRAMS has taken steps to prevent incidents from occurring in the future. These include the following:

- Revising the protocol to require that PRAMS Project Coordinators or survey research laboratory supervisors monitor telephone interviewers at least 10% of the time that the interviewers are making calls
- Reminding state PRAMS staff to spot check 10% of all mail packets to verify that the correct letter is being sent (live vs. deceased infant) and that the name and address on the letter and the envelope match
- During the site visits, the CDC Program Managers will:
 - ③ Monitor at least one phone interview
 - ③ Conduct a review of the state protocol, letters, phone scripts, and mail packets
 - ③ Remind states of requirements for all PRAMS Staff to complete PRAMS Human Subjects Training Module 1 within the first 2 weeks of employment and/or prior to any contact with potential participants or identifiable data
 - ③ Remind states of requirement for all PRAMS staff to complete PRAMS Human Subjects Training Modules 2 & 3 within 2-3 months of employment
 - ③ Remind state coordinators to review PRAMS Human Subjects Training Module 4 once a year with all PRAMS staff

Consequences of Breaches

There are several consequences to *participants* that may result from breaches in the protocol. For example, the participants could complete the survey without being fully informed of their rights and/or participants' confidentiality could be violated without their knowledge.

Breaches can have consequences for the *PRAMS project*. These include:

- Loss of credibility
- Increased scrutiny by IRB

- Suspension of the PRAMS project by the IRB

Consequences of Adverse Events

There are several consequences to *participants* that may result from adverse events. For example, the participant and/or other family members may be upset or angry.

Adverse events can have consequences for the *PRAMS project*. These include:

- Loss of credibility
- The threat of legal action against the PRAMS project
- Suspension of the PRAMS project by the IRB
- Suspension or termination of PRAMS funding

These are all reasons that help to remind us all how important it is to follow the PRAMS protocol. The PRAMS protocol is written to ensure a strong research design as well as to protect the participants in the project.

CASE STUDY EXERCISE, PART 2

Review the case studies you determined to be breaches or adverse events in Part 1 of the exercise. For each one, answer the following questions:

1. What can be done to prevent this breach or adverse event from occurring again in the future?
2. What are some of the consequences of the breach or adverse event for the:
 - Participants
 - PRAMS project
3. How might these consequences affect your PRAMS project?

ANSWERS TO CASE STUDIES

Case Study #1**Day 1**

It was a beautiful spring morning. The letters for the first mailing of batch #4 were being prepared by the data manager. Nothing unusual was noted by the staff about the mailing.

The letters were put in the mail at the end of the day.

Day 4

It was just after lunch that the phone began to ring at the PRAMS office. Over the course of the next few hours, the office received 9 calls from upset women whose babies were alive, but whose letters expressed sympathy for their babies' deaths. At the end of the day, the IRB chair called and said her office had received 2 calls.

Part 1: Questions and Answers

1. Is this a breach or an adverse event? Why or why not?

Yes, this is a breach of protocol and an adverse event. It is a breach in protocol because the protocol was not correctly followed. The letters were not sent to the correct mothers (i.e. the deceased baby letters were sent to the wrong mothers). In addition, the spot check of 10% of the letters was not done. It is an adverse event because the participants let the researchers know something had gone wrong and because the women were upset as a result of the incorrect mailings.

2. Who would you report this incident to and when?

Adverse events should be reported to the project coordinator immediately. The project coordinator should then report it to the CDC and to the local IRB. In this case, even though the IRB received calls, an incident report describing the adverse event must still be filed with the local IRB. The CDC Program Manager will report the incident to the CDC IRB.

3. What information from the case study would you include in the incident report?

Describe the event. Describe the impact the adverse event had on the participant: the mothers were probably upset or angry. Possible corrective actions include phone calls or letters of apology sent immediately to all of the women in the batch explaining that the wrong letter was sent by mistake. It may also be necessary to halt the data collection and tell the mothers not to complete the survey. Other corrective actions may be recommended by the local or CDC IRB.

Part 2: Questions and Answers

1. What can be done to prevent this and other adverse events from occurring in the future?

Follow the protocol. Identify and fix any computer/software problems that may have caused the mix-up. Check at least 10% of the mail packets to make sure that the correct letters are going to the right people. Compare the number of mothers of living babies and number of mothers of deceased babies from PRAMTrac to the actual number of mail packets for each category prior to mailing the survey packets.

2. What are some of the possible consequences of the adverse events for the participants?
The mothers could be upset because they received a letter stating their baby had died, when in fact their babies were alive.
3. How could these consequences affect our PRAMS project?
 - *The mothers could refuse to participate thereby decreasing response rates*
 - *PRAMS credibility could decline*
 - *IRB could require that no further data be collected from this batch resulting in the loss of data*
 - *Increased scrutiny by IRB*

Case Study #2

It was a cold and rainy afternoon when the CDC program manager, Jennifer, visited the state PRAMS project for a site visit. The PRAMS team and program manager had just finished lunch and were happy to return to a warm office. As Jennifer began her discussions with the state project coordinator, she began to look over the introductory and consent statements that are read to potential phone participants. She noticed that they were not the standard statements required by the PRAMS protocol, but rather shorter versions of the statements.

The project coordinator and contractor supervising the telephone interviewing were given the correct phone introduction and consent statements and told to make the appropriate changes.

Two months later, CDC received a copy of the current state telephone scripts. The consent statements had not been corrected and were missing the following statements:

- That this is a research project
- That PRAMS is supported by CDC
- That data are kept confidential 'to the extent permitted by law'
- That PRAMS data might be combined with data the health department has from other sources

Part 1: Questions and Answers

1. Is this a breach or an adverse event? Why or why not?

This is a breach because the protocol was not correctly followed. The telephone script did not have all of the required elements of consent. In this case, the breach was discovered by the staff – it's not likely in this particular case that participants would notice that this is a deviation from the protocol.

2. Should the CDC Program Manager have advised the state to file an Incident Report after the site visit? Why or why not?

Yes, the Program Manager should have reported this because the state was not following the protocol. Two of the 3 ethical principles of human subjects research, respect and beneficence, were violated. If you recall from module 1, the principle of respect for persons requires the researcher to acknowledge a person's ability to make his or her own decisions. Adequately informing participants is out of respect for them as individuals. Without all of the elements, it is not possible that the participants were fully informed. Beneficence, the other principle, means to do good and to avoid harm which includes minimizing risk. Because the state's consent materials were lacking all of the required elements of informed consent, the risks were not minimized. The state PRAMS coordinator should also report this breach to the local IRB.

3. What information from the case study would you include in the incident report?

Describe the event. Describe the impact the breach had on the participants: the mothers were not fully informed.

Part 2: Questions and Answers

1. What can be done to prevent this and other breaches from occurring in the future?
Additional training, particularly in the area of human subjects protections will be beneficial. In particular, a review of the required elements of informed consent found in module 1 should be repeated. Additionally, a review of the state protocol including letters, phone scripts, and mail packets should be conducted.
2. What are some of the consequences of the adverse events for the participants?
The participants will not be fully informed and therefore will not be making a truly informed decision to participate or not to participate.
3. How might these consequences affect your PRAMS project?
 - *IRB could require that no further data be collected from this batch resulting in the loss of data*
 - *Increased scrutiny by IRB*
 - *IRB could halt the project*
 - *Possible problems with PRAMS' credibility*

Case Study #3

The Springfield PRAMS staff was enjoying a festive lunch at the office. They had received data from CDC and were very excited to start some of their planned analysis activities!

The data manager heard the phone ring and rushed to get the call. The call was from an upset participant complaining about the PRAMS survey. The participant was angry because she had completed her survey and sent it in. Two weeks after she sent it, she received another PRAMS survey packet asking her to please complete the survey at her earliest convenience.

The participant felt it was unreasonable that she received a second survey since she had already completed the survey. She felt that the state PRAMS staff was irresponsible and harassing her.

The data manager apologized for any inconvenience the second survey may have caused the participant. She also attempted to explain the mailing procedures, but the angry woman kept yelling at her, telling her she was unprofessional and irresponsible. The data manager quickly thanked the caller for completing the PRAMS survey and hung up the phone.

Part 1: Questions and Answers

1. Is this a breach or adverse event? Why or why not?

No, this is not a breach or adverse event. It's likely that when the second survey was mailed, the project had not yet received her completed survey. The data manager handled the situation correctly by apologizing for the inconvenience. Although the participant notified the project that she was upset, the protocol was followed correctly, so it's not an adverse event.

2. Who would you report this incident to and when?

N/A – not a breach or adverse event

3. What information from the case study would you include in the adverse event report?

N/A – not a breach or adverse event

Case study #4

Jane, a new mom, had not responded to the mailed surveys and therefore entered the phone phase. During her shift at the phone lab, one of the PRAMS telephone interviewers, Sara, reached an individual at Jane's listed telephone number. Sara identified herself and stated that she was calling for the Health Department and asked to speak to Jane.

The woman who answered the telephone said Jane was not there. She identified herself as Mona, Jane's mother-in-law, and asked what the phone call was regarding. Sara said the phone call was in reference to a health survey.

Mona continued to ask questions, requesting more details about the survey. Sara told Mona that the health survey was the Pregnancy Risk Assessment Monitoring System and she had questions for Jane about her new baby. Mona had no knowledge about a baby, but offered to ask Jane about a baby and have Jane return Sara's call.

The next morning, there was a message on the PRAMS answering machine from Jane. Jane was extremely upset. She had not told her in-laws about the pregnancy because she had given the baby up for adoption. Jane was very agitated and said her lawyer would be in touch.

Part 1: Questions and Answers

1. Is this a breach or an adverse event? Why or why not?

Yes, this is a breach and an adverse event because the telephone interviewer did not follow the protocol and broke the confidentiality of the mother by giving too much information. The disclosure of Jane's recent pregnancy to Mona, Jane's mother-in-law, was a breach in protocol because the interviewer gave information to someone other than the sampled mother. Not only did Jane's mother-in-law find out about Jane's recent pregnancy, she also found out about Jane's decision to give the baby up for adoption. As a result of the disclosure, Jane was upset and threatened legal action to the PRAMS staff; this made the situation an adverse event.

2. Who would you report this incident to and when?

Adverse events should be reported to the project coordinator immediately. The project coordinator should then report it to the CDC and to the local IRB.

3. What information from the case study would you include in the incident report?

Describe the event. Describe the impact the adverse event had on the participant: the mother was upset and angry; she threatened to take legal action. Possible corrective actions include a phone call or letter of apology sent immediately to the participant.

Part 2: Questions and Answers

1. What can be done to prevent this and other adverse events from occurring in the future?

Additional phone interviewer training is necessary. It may be beneficial to move that particular phone interviewer to a different area of the project. The protocol needs to be reviewed in order to identify other actions. Phone calls should also be monitored to

ensure that interviewers are following the phone script as outlined. The phone script has a verification component that would allow the interviewer to ask a few questions to verify the identity of the sampled mother.

2. What are some of the possible consequences of the adverse events for the participant?
The mother was very angry and upset. There could also be potential problems with her in-laws or other family members.
3. How could these consequences affect your PRAMS project?
Possible legal action could be taken against the PRAMS project. PRAMS could be suspended by the IRB or CDC could suspend/terminate funding.

Case study #5

Springfield PRAMS' annual IRB review was set to expire on June 18th. The Project Coordinator submitted the request for continuation to the local IRB 8 weeks prior to June 18th. The local IRB was delayed in reviewing the continuation due to a scheduling conflict with the prisoner representative.

On June 19th, the local IRB issued an interim approval for the continuation of data collection. The CDC Program Manager was notified of the interim approval. During the next scheduled IRB meeting on June 24th, the annual approval was issued to Springfield PRAMS.

Part 1: Questions and Answers

1. Is this a breach or an adverse event? Why or why not?
Yes, this is a breach in protocol. Although the Project Coordinator submitted the continuation request within the recommended timeframe, the scheduling conflict resulted in a lapse in protocol approval.
2. What was the purpose of obtaining an interim approval from the local IRB?
The interim approval from the local IRB provided the project with a temporary approval to continue data collection. Without an interim approval from the local IRB, the project would not have had the required authority to collect data for PRAMS as a research project.

Part 2: Questions and Answers

1. What can be done to prevent this and other incidents from occurring in the future?
Unfortunately, these circumstances were outside of the state PRAMS staff's control. However, it is recommended that projects submit their annual renewals 8-12 weeks prior to expiration. Most IRBs have established review schedules throughout the year. PRAMS project liaisons should obtain a copy of their local IRB review schedules and coordinate submission timelines according to their protocol expiration date. It is also recommended that state PRAMS staff maintain contact with local IRB staff to check the status of the protocol review throughout the local review process.
2. What are some of the consequences of this incident?
 - *Lapse in protocol review and approval by IRB*
 - *Halt in data collection*
 - *Multiple occurrences could result in extensive review of project operations by local and CDC IRBs*
3. How could these consequences affect your PRAMS project?
PRAMS could be suspended by the IRB and CDC could suspend/terminate project funding.

PRAMS Human Subjects Training

MODULE 3

CONFIDENTIALITY AND SECURITY OF PRAMS DATA

3a. Privacy and Confidentiality

Objectives for Module:

1. Understand why privacy and confidentiality are important for protecting human subjects
2. Identify possible causes of breaches in confidentiality

Privacy

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing information about yourself with others. Sensitive information should not be confused with privacy. Individuals may hold certain information to be sensitive, yet still choose to disclose the information.

Sensitive information may trigger a mental or emotional reaction, such as pain, annoyance, or irritation. Some examples of PRAMS information that may be sensitive to respondents include questions related to smoking during pregnancy, alcohol use during pregnancy, and physical abuse during pregnancy. Respondents may view these questions as sensitive but still answer them in order to contribute to the better understanding of maternal and child health issues.

Confidentiality

Confidentiality comes from professional-client relationships and applies to data or information. Confidentiality issues arise when personally identifiable information obtained in research is collected, maintained, or disclosed. In a general sense, confidentiality refers to the release of personal information in a relationship of trust and with the expectation that the information will not be given to others without permission. Assurances are given and methods are used to protect information about subjects from improper disclosure. You may be held responsible for data being inappropriately released to others, even if inadvertently.

PRAMS protects confidentiality in many ways. PRAMS requires staff to sign confidentiality statements agreeing to protect the confidentiality of the data and states require outside researchers to fill out a request for data and sign a confidentiality pledge before they have access to any PRAMS data. Another way that confidentiality is protected is by not allowing publication of data that permits identification of individuals. However, in some cases, the release of data is allowed in order to be combined with data from other sources. The consent information for PRAMS specifically states that “information from your survey may be combined with information the health department has from other sources.”

Why should I be concerned about keeping data confidential?

Protecting the confidentiality of data is a core public health value and is a key component of human subjects protections. PRAMS uses the informed consent process to explain data confidentiality to the participant. The informed consent letter states that the answers given will be kept private to the ‘extent permitted by law’. It also includes information about how data might be used – they may be “combined with information the health department has from other sources”. By agreeing to participate, respondents are agreeing to let their private information be used or shared, but with an assumption that it will be kept confidential.

Breach of Confidentiality

Confidentiality can be breached when confidential information is released while speaking on the phone or in writing, e.g. e-mail or letter. Although it's not very common, confidentiality can be breached if a participant's personal information is seen by someone else outside of the research group. For example, a survey or call worksheet with identifying information might be lying on your desk and a co-worker, not on the PRAMS team, could walk by and read confidential information about that participant.

There are many ways that confidentiality can be protected. The protocol describes specific measures that should be followed in order to protect confidentiality. For example:

- ③ When on the telephone, be certain you are speaking with the correct mother
- ③ Keep data secure
- ③ Release only de-identified data to outside researchers and CDC
- ③ Adhere to other procedures as outlined in your state's confidentiality agreement, if applicable

Most states have their staff sign a Confidentiality Agreement. The confidentiality agreement outlines the procedures that the State will follow in order to protect participants' privacy. These procedures are centered on protecting privacy; ensuring the integrity of the project; and complying with legislative or administrative rules. By signing the confidentiality agreement, you are agreeing to follow the procedures outlined in the agreement.

The informed consent process informs the participants that their data may be shared. It tells them that their data may be linked with other health department sources or that abuse will be reported as required by law. The informed consent process also tells the participants that their information will only be used for the purposes for which it was collected.

Telephone interviewers, like everyone else on the project, are expected to maintain high ethical project standards. The telephone interviews involve some extra confidentiality concerns. Any messages left with any persons or on answering machines/voicemail, etc. should only state the interviewer's name, telephone number, and that they are calling from the state PRAMS project or the state Department of Health. There should be no mention of a baby, pregnancy, etc. Also, calling participants for any reason other than the survey is unacceptable; it is a breach in protocol, and must be reported.

A breach of confidentiality is a breach in protocol. An incident report should be completed if there is a breach of confidentiality. In addition, the sharing of information about a mother or her baby with others may cause a host of other consequences for the mother and/or her baby (e.g. emotional distress, physical abuse). Remember, the benefits of PRAMS should outweigh the risks (principle of beneficence).

It is important to remember that we collect data for specified purposes; our data should be used only for those reasons. Data are released only for specified reasons and should be released, seen, or accessed by specified people. We will further discuss the security of data in the second half of this module.

EXERCISE

Review the confidentiality agreement in your state (If your state does not have a confidentiality agreement, skip to Part 3b on Page 5.)

Answer the following questions:

1. How will your state protect the confidentiality of your respondents?
2. Why are these provisions in the confidentiality agreement?

3b. Security

Objectives for Session:

1. Understand the difference between security and confidentiality
2. List 5 measures to make certain information is kept secure

Security

Security applies to physical, technical, and administrative safeguards that are put in place to protect information. Confidentiality is ensured, in part, by keeping information secure. No information about any participant should be revealed to anyone outside of the research staff. This includes people wandering in and out of your workspace and any other person contacted when trying to reach a participant, regardless of their relationship to the participant.

Maintaining Security

There are several measures that you can take to insure that all of the PRAMS information will be kept secure and confidential. These include:

- Limiting access to identifiable data
- Storing records in locked cabinet
- Storing questionnaires within the work area, in a locked cabinet
- Removing identifying call worksheets (face sheets) from completed surveys for situations where it is not practical to use WebCATI
- Securing identifying call worksheets generated by PRAMTrac when identifiers can not be uploaded to WebCATI
- Disposing of (shredding) computer sheets that have identifiers
- Limiting access to PRAMTrac to authorized users
- Password-protecting your computer screen
- Locking computer screen when stepping away from the desk (e.g. using Windows control+alt+delete buttons)
- Backing-up electronic files and store the back-up files in a secured location
- Encrypting data when sending electronically
- Training telephone interviewers to ensure confidentiality of participants' data
- Assuring outside researchers return or destroy data once the approved analyses are completed
- Assuring outside researchers comply with PRAMS security guidelines
- Sending data to CDC via the Secure Data network (SDN)

- Implementing monitoring procedures to ensure security protocol requirements are being met

The security of PRAMS data is essential to the project and can be easily managed.

REVIEW QUESTIONS

1. What do you do to keep data secure?
2. What are some other things you might do?

QUIZ**Security In Routine Practice Can
Be Accomplished By...**

- | | | |
|---|-------------|--------------|
| 1. Substituting codes for identifiers | True | False |
| 2. Removing identifying call worksheets from survey instruments | True | False |
| 3. Entering all information in one computer file | True | False |
| 4. Limiting access to identifiable data | True | False |
| 5. Stamping “confidential” on ALL paperwork | True | False |
| 6. Storing records in locked cabinets | True | False |
| 7. Shredding printed documents that have identifiers | True | False |
| 8. Archiving the original records in another location | True | False |
| 9. Educating research staff | True | False |
| 10. Sending data to CDC via the Secure Data network (SDN) | True | False |

Answers to Quiz

1. True
2. True
3. False
4. True
5. False
6. True
7. True
8. False
9. True
10. True

PRAMS Human Subjects Training

MODULE 4

REVIEW AND SUMMARY

4a. Review

Objectives for Module

1. Identify key points from the previous training modules
2. Understand the issues of ensuring quality and confidentiality for PRAMS

The PRAMS protocol ensures a scientifically sound surveillance system. When the protocol is correctly followed, PRAMS will run smoothly, efficiently, and appropriately protect human subjects.

This module will review the 3 main areas that we've covered in the past modules:

- Informed consent
- Breaches and adverse events
- Data confidentiality and security

The protection of human subjects is a critical part of the PRAMS project. Everyone who works on PRAMS or has contact with participants or identifiable information about participants is considered to be engaged in human subjects research.

The three basic principles -- respect for persons, beneficence, and justice -- guide human subjects research and should be incorporated into all aspects of the PRAMS project. Respect requires the researcher to acknowledge a person's ability to make his or her own decisions and to respect those decisions. Beneficence means to do good and to avoid harm. Justice means that those who bear the risk of a study will receive its benefits.

Informed consent is another vital element for protecting human subjects in research. It is about people's understanding and willingness to participate in a study. Consent information for PRAMS is included with the mail survey and is an essential part of the telephone introduction. Both the mailed information and the telephone introduction contain all of the required elements of informed consent. This ensures that the potential participants are fully informed about the purpose of the PRAMS survey, its risks, and its benefits. This will help women make decisions about their participation. The PRAMS staff has a responsibility to respect a person's decision, even if she chooses not to participate.

Situations in which the protocol is not followed as specified are called breaches in protocol. Examples of breaches in protocol include deviating from approved procedures and violating confidentiality. If a breach results in physical or psychological injury to a participant in a research study, it is then called an adverse event. Therefore, implementing the protocol as it is designed is very important not only for scientific reasons but also for the protection of participants.

An adverse event includes a physical or psychological injury to a participant in a research study. Adverse events can occur in any study and are usually discovered because a participant lets the researchers know that something has gone wrong.

When a breach or adverse event happens, it is important to report the incident immediately to the state project coordinator. The state project coordinator will inform the local IRB and CDC Program Manager. The CDC Program Manager will inform the CDC IRB. It may be necessary to either telephone or send a letter in the mail to the participants, apologizing for the event. There may be additional actions needed, depending on the event and IRB recommendations.

The prevention of breaches or adverse events is essential to PRAMS. There can be serious consequences, to both the participants and the project when breaches and adverse events occur. Several steps can be taken to prevent these incidents. These include:

- ③ Providing additional training to all PRAMS staff in Human Subjects Research
- ③ Identifying and fixing any software problems that may have contributed to the breach or adverse event
- ③ Moving staff involved in the incident to a different role in PRAMS
- ③ Reviewing the PRAMS protocol and identifying other actions or areas of concern
- ③ Checking the mail packets and monitoring telephone interviews

Confidentiality and data security are also critical elements to any public health activity, including PRAMS. Participants may hold certain information to be sensitive, yet choose to disclose the information. When they disclose private information, that information should be kept confidential. Generally, keeping information confidential entails not releasing it, whether intentionally or inadvertently, to anyone outside the PRAMS project.

There are instances when a participant's confidential information may be linked with other health department information, but the participant agrees to this when she chooses to participate in PRAMS. The consent information for PRAMS specifically states "*information from your survey may be combined with information the health department has from other sources.*" Releasing data to external researchers may require the researcher to sign a confidentiality agreement. In addition, the data may be stripped of any identifying information before being released (which is a way to protect confidentiality).

It is essential to keep confidential information secure. There are several ways to maintain the security of PRAMS data, including:

- ③ Storing records in a locked cabinet
- ③ Shredding computer printouts that have participants' identifying information
- ③ Limiting PRAMTrac to authorized users
- ③ Password protecting your computer monitor
- ③ Having well trained telephone interviewers who do not release information about a mother to other people who answer the phone

4b. Summary

Objectives for Module

1. Understand how the PRAMS Human Subjects Training relates to PRAMS operations

Case Study

Read through the following case study and complete each question.

Preparing for Phase 6

Sarah is the newest staff member of the state PRAMS project. She started her new position, just in time for Phase 6 implementation. As part of her orientation, she has completed Module 1 of the PRAMS Human Subjects Training and has read the model protocol (Version 4). Now she has to review the consent form and the phone scripts to ensure her state is complying with the protocol. As she reads through the informed consent document, which should be included in all of the PRAMS mailings, Sarah notices that the state project coordinator's contact information is missing.

1. What should Sarah do?

Preparing for Mailings

Sarah is preparing the first Phase 6 mailing. She is a little concerned about making sure that the correct letters go to the correct mothers. She asks your advice.

2. How do you ensure you are getting the right mailings to the right people?
3. What if the wrong letter was sent to a mother? For example, a deceased baby letter was sent to a potential participant whose baby is alive. Would this be a breach or an adverse event? What would you do?

It's been about 5 weeks since Sarah sent out her first questionnaire mailing. About half of her first batch has been completed by mail and the completed surveys are in the PRAMS office.

4. Does Sarah need to be concerned about confidentiality? Why?
5. What should Sarah do to ensure the security of the completed surveys?

Preparing for Phone Phase

Next, Sarah has entered the second half of the participants who have not completed the mailed survey into the phone phase. She is calling the mothers.

6. What recommendations would you give Sarah to ensure that she is speaking to the correct mother?

7. Sarah wants to know if it is okay to leave messages on answering machines or voicemails. Is this okay?

Sarah has called a mother in order to complete a survey and finds that she is not home. She leaves a message on the answering machine stating her name and that she is with the State PRAMS project and wants to ask the potential participant questions about her recent pregnancy.

8. Is this okay? Why or why not?

9. Should any of Sarah's telephone interviews be monitored? Why or why not?

10. How are phone interviews monitored in your state?

[This next question is only applicable if your state uses off-site contractors for phone interviews]

11. If your state uses off-site contractors for phone interviews, what do they do to protect the confidentiality and security of PRAMS data?

Completed Surveys

Sarah is now ready to enter data from the completed surveys. She goes to get the mail surveys.

12. Where and how should Sarah's mail surveys be stored?

One day, you stop by Sarah's cubicle and invite her to go out to lunch. She agrees and quickly grabs her wallet and coat. You notice that the mail surveys are still lying on her desk and the QDS file is open on her computer. You realize that you need to tell Sarah what to do with the mail surveys and the QDS file.

13. What do you tell her?

Sending data to CDC

Sarah has completed entering all of the data and is ready to send the batch to CDC.

14. What do you tell her in order to make sure that the data are kept secure and confidential when sending it to CDC?

Data requests

Sarah receives a request for a PRAMS dataset from a professor at her local University.

15. What is necessary for Sarah to do in order to maintain the confidentiality of the data when they are requested by anyone outside of the PRAMS staff?

Batch completed!

Congratulations! The protocol was correctly followed and your state had no breaches or adverse events for this batch. Remember, following the protocol helps PRAMS run smoothly, efficiently, and protect human subjects. Following the protocol is the most important way of ensuring high quality operations and protection of PRAMS participants.

ANSWERS TO CASE STUDY QUESTIONS:

1. Sarah should add the contact information to the document. Next she should make new copies of the informed consent document to use for the mailing.

[see section 5.6b,c and Appendix I of model protocol for further review]

2. Quality assurance while preparing mail packets is very important. There are several things that can be done to make sure the right letter goes to the right person. These include:

- Make sure the same name appears on both the letter and the envelope
- Make sure the proper letter is mailed with the proper activity (preletter, mail 1, tickler, mail 2, mail 3)
- Staff should spot check every 10th envelope to make sure the appropriate materials are being placed in that envelope
- Double check PRAMTrac for number of each type of letter being merged: live baby, deceased baby, teen, Spanish, etc

[see section 5.6e of model protocol for further review]

3. This would be a breach of protocol resulting in an adverse event. If the mistake was caught before the mailing was sent and the correct letters were put in the mailing, it would not be an adverse event. The way to catch these types of mistakes is to spot check 10% of the mailings.

If the mailing was sent, it would be a breach resulting in an adverse event. This should be immediately reported to the project coordinator. The project coordinator will then report it to the local IRB and CDC. CDC will inform the CDC IRB.

You would also need to take some sort of corrective action. This might include phone calls or letters of apology sent immediately to all of the women in the batch explaining that the wrong letter was sent by mistake. It may also be necessary to ask the mothers not to complete the survey.

[Adverse events were discussed in PRAMS Human Subjects Training Module 2]

4. Yes, because the survey may contain identifiable information, Sarah should be concerned about keeping the surveys secure and confidential. Although the survey by itself does not contain identifiable information, some women may write identifying information in their comments or other parts of the survey, etc.

5. There are several things that Sarah can do to ensure the security of the surveys. She should:
- Store the surveys in a locked cabinet
 - Shred any computer print outs that have participants' identifying information
 - Make sure PRAMTrac is limited to authorized users
 - Password protect her computer screen

[Confidentiality was discussed in PRAMS Human Subjects Training Module 3]

6. Sarah should use our State's telephone introduction when calling the household and follow the specified steps to introduce herself to the person who answers the telephone and to get the

mother to come to the telephone. The telephone script includes a verification process that will help the interviewer to verify that they are speaking to the sampled mother before proceeding with the interview.

[See section 5.7 and Appendix G of the model protocol and the Interviewer Training Manual for further review]

7. Yes, but see specifics described in #8.
8. It is acceptable for Sarah to leave her name and that she is with the State PRAMS project or state department of health. However, she should **not** mention that she wants to ask the potential participant questions about her recent pregnancy. The most important thing to remember is that the message should not contain any language about a pregnancy or baby.
[See Interviewer Training Manual and Appendix G of model protocol for further review]

9. Yes, this is required by the protocol.

The PRAMS Coordinator or other appropriate staff, such as the supervisor of a survey research laboratory, should regularly monitor the telephone interviewers to ensure that proper procedures are followed. Sarah should be monitored 10% of the time she is doing phone calls for PRAMS.

The monitor should determine whether the interviewer is appropriately consenting women, administering the interviews, protecting the mother's confidentiality, and keeping data collection forms secure.

[See section 5.8 of the PRAMS model protocol for further review]

10. **[NOTE:** Answers may vary from state to state]

Each interviewer should be monitored. Monitoring 10% of the time allows the supervisor to observe not only actual interviews, but also interactions with mothers that do not result in interviews (mother is busy, mother refuses, etc) and interactions with other household members.

The PRAMS Summary Monitoring Report should be completed for each batch and submitted to CDC with the batch files. This report should summarize the results of the monitoring efforts over the course of the batch. The PRAMS Summary Monitoring Report can be found in Appendix M of the model protocol.

In addition to monitoring phone calls using the Individual Monitoring Form, the monitor should periodically check to ensure that interviewers keep data forms with identifying information or completed copies of the interview secure (i.e. in a locked cabinet)

[See Sections 5.7, 5.8, and Appendix M of PRAMS model protocol for further review]

11. Answers will vary state by state, but it's important to remember that site visits to the contractor's office are important and enable the project coordinator to monitor telephone operations and security measures, even when the phone interviews are conducted off-site.

12. Mail surveys should be stored in a locked cabinet.

[See section 10.4 of the PRAMS model protocol for further review]

13. You will want to remind Sarah that the security of the surveys is important at all times, even when they are at the PRAMS office, surrounded by PRAMS staff. She should keep the surveys stored in a locked cabinet, even if she's just leaving her desk for a short while. Regarding the QDS file, Sarah should close the QDS window when she is leaving her desk. She should also make sure that the computer screen is password protected.

[See section 10.4 of the PRAMS model protocol for further review]

14. Survey data should be sent through the Secure Data Network (SDN). If sending a PRAMTrac database to CDC for technical assistance, it should be de-identified and e-mailed, or sent using a secure method approved by the state.

[See PRAMS Implementation Manual and section 6.6d of the PRAMS model protocol for further review]

15. Any person who works outside of the PRAMS project, including those that work within the same department, has to follow the data release policy for our state. Birth certificate numbers should be stripped before any data are released.

[Note: This is a good time to review your state's data release policy].

[Data confidentiality was discussed in PRAMS Human Subjects Training Module 3]

Additional Review Questions

1. Sarah receives a phone call on the 1-800 number from a caller who is asking questions about the PRAMS study. How should Sarah respond to the caller?
2. Since the "Springfield" PRAMS Project does not upload identifying information to WebCATI, call worksheets containing mothers' contact information are generated from PRAMTrac. The call worksheets were kept on the desk of the Survey Research Group's Supervisor during data collection for the month. The survey group's offices are accessible to the Survey Research Group interview staff who do not work on PRAMS, who have all signed the same confidentiality agreements required for PRAMS staff. These offices are also accessible to the custodial/janitorial staff. Is this an example of a breach or an adverse event? What steps can be taken to prevent this from recurring?
3. A set of PRAMS letters is collated incorrectly and the letters intended for delivery to sampled mothers whose babies have died are switched with the letters intended for sampled mothers whose babies are still alive. The PRAMS coordinator is out sick and a spot check is not performed. A support-staff member put the letters in the outbox for mailing.

The next day the PRAMS coordinator returns to the office and realizes that the letters were never checked, and luckily they are still in the outbox. She reviews the letters and notices the collation problem. This is a break in procedure - but does it really constitute a reportable breach in protocol? Should this incident be reported to the IRB?

N O T E S

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