

CONSENT FOR CDC RESEARCH

**A Reference for Developing Consent Forms
and Oral Scripts**

November 1998

About the Development of this Guide

One of the more difficult tasks in developing a research study is to write a consent form that describes all the information about the study in such a way that the participants can understand it and make an informed choice about whether to volunteer to participate in the study. For years, CDC investigators have been asking for guidance in writing consent forms and oral scripts.

In 1997, I asked Mr. Russ Havlak, one of the Institutional Review Board (IRB) chairs, to develop a document for investigators to use in writing consents. Unselfishly, Russ gave his time to produce the guide while continuing his regular job responsibilities. After much thought about the best approach and what would be most useful to investigators, Russ embarked upon a long, tedious process of reviewing CDC IRB approved consent forms. He then wrote a document that explains the information, element by element, that should be contained in a consent form and used examples from existing approved consents as illustrations. The document he produced is, perhaps, one of the best documents available on writing consent documents and oral scripts.

We are greatly indebted to Russ for developing this reference guide for investigators. Russ began serving on a CDC IRB in 1980 and became a chair in 1994. During that time, he has been deeply committed to the ethical principle that potential participants should freely chose whether to participate in research. That voluntary choice can only be made when investigators use a consent process that fully informs participants about the research in a way that participants can understand the information. Russ has spent countless hours reading and editing consent forms for all of us, in each case trying to make the consent more understandable, informative and non-coercive. This document reflects his vast knowledge and great skill in writing consent forms.

Thank you, Russ.

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Foreword

The Centers for Disease Control and Prevention (CDC) has had an Institutional Review Board (IRB) for almost 30 years. The IRB's role is to review proposed studies and approve those which comply with 45 Code of Federal Regulations, Part 46 (45 CFR Part 46), the federal regulations that govern research involving human participants. However, the guiding vision of the IRB has less to do with review and approval than with the idea of helping all of CDC to carry out ethical research.

The CDC IRBs have reviewed a couple of thousand study protocols over the years, giving them insight into the strengths of CDC research and weaknesses common to the process. Top among the problem areas are consent documents—both written forms and oral consent scripts. Consent in human participant research should be a process that continues from the time participants sign up for a study to the time they complete the study or withdraw from it. The consent form or oral consent script is but one piece of that process, but a piece which the IRB is obligated to take very seriously.

This is a reference to help CDC investigators write research consent forms and scripts that conform to the Federal Regulations. It draws on the wisdom gained by the IRB and offers suggested wording similar to that found in CDC consent forms the IRB has approved. No attributions are cited, but this does not lessen the appreciation to the many CDC investigators who contributed to this reference.

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Introduction

The research we conduct at the Centers for Disease Control and Prevention (CDC) provides information that is vital to our mission. An integral part of this research is obtaining informed consent of all participants, as required by 45 CFR 46, the federal regulations that govern research involving human participants. Throughout this reference, 45 CFR 46 is referred to as “the federal regulations.”

This reference will provide:

- A general overview of the principles and requirements of informed consent
- Tips on writing and formatting consent forms that are easy to read and understand
- A section-by-section guide for crafting an effective consent form

We recognize that consent can be obtained using oral consent scripts, as well as consent forms. We have chosen to focus on consent forms because they are the format required by the Federal Regulations and the most common form of consent in CDC studies. Most of the guidance provided in this reference will apply both to consent forms and to oral consent scripts. However, we will discuss the differences between the two when they arise.

Principles and Requirements of Informed Consent

Research involving human participants is explained in the federal regulations. The combination of two definitions there defines research involving human participants to be a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, and which involves a living individual about whom an investigator conducting research obtains (1) data through interventions or interactions with the individual or (2) identifiable private information. Perhaps the most basic ethical requirement of this kind of research is informed consent.

Basic Principles of Informed Consent

The federal regulations set out four overriding principles which are meant to apply to all consents, unless there are specific exceptions made or allowed elsewhere in the regulations. These principles are:

1. Human research can proceed only with informed consent unless waived under the Federal Regulations - No investigator may involve a human being as a participant in research covered by the federal regulations without legally effective informed consent of the participant or his/her legally authorized representative.
2. Minimize coercion in obtaining consent - An investigator shall seek consent under conditions that provide the prospective participant or his/her representative sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence.
3. Consent must involve understandable language - The information that is given to the prospective participant or his/her representative shall be in language the participant or the representative can understand.
4. Waiver of rights is prohibited in the consent process - No informed consent, whether oral or written, may include any exculpatory language through which the prospective participant or his/her representative is made to waive or appear to waive any of the prospective participant's legal rights, or made to release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Required Elements of Informed Consent

The federal regulations list eight required elements of informed consent. These are:

1. Purpose and Procedures - You must tell a prospective participant that the study involves research, explain the purpose of the study and the length of time you expect the person to participate, describe the procedures to be followed, and identify any experimental procedures.
2. Risks - You must describe any reasonably foreseeable risks or discomforts to the prospective participant.
3. Benefits - You must describe any benefits to the prospective participant or to others which may reasonably be expected from the research.
4. Alternatives - You must disclose any appropriate alternative procedures or courses of treatment that might benefit the prospective participant.
5. Confidentiality - You must tell prospective participants whether their records will be kept confidential and, if so, explain the level of confidentiality.
6. When There is Greater than Minimal Risk¹ - You must tell prospective participants whether they will receive any compensation and/or medical treatments if injury occurs and, if so, what compensation or treatment will consist of, or where to obtain further information.
7. Persons to Contact - You must tell prospective participants whom to contact if they have questions about the research and their rights as a study participant, and whom to contact if they have an injury that may be related to the research.
8. Voluntary Participation, Refusal, and Withdrawal - You must state that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the person is otherwise entitled, and that the person may discontinue participation at any time without penalty.

¹ Minimal risk means that 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 or psychological examinations or tests. Both factors must be considered in weighing whether a risk is greater than “minimal risk.” In deciding if research involves minimal risk, the IRB is expected to consider risk from study procedures in relation to all persons eligible to participate--not just from the perspective of a person in good health or of someone with health problems matching circumstances of the research.

Additional Elements of Consent

When appropriate, the following six additional elements of consent should be included:

1. Unforeseeable Risk - You should state that the study treatment or procedures may have risks for the prospective participant (or to the embryo or fetus, if the participant is or may become pregnant) that you cannot currently foresee.
2. Termination of Participation Without Consent - You should explain anticipated circumstances under which the investigator may terminate the participant's further involvement without regard to the person's consent.
3. Additional Costs - You should describe any additional costs to prospective participants that may result from participation in the study.
4. Consequences and Process of Withdrawal - You should explain how participants can leave the study and what may happen if they choose to withdraw.
5. Impact of Significant New Findings - You should state that participants will be told of any significant new findings developed during the research which may relate to their willingness to continue in the study.
6. Number of Participants - You should tell prospective participants the approximate number of persons involved in the study.

Alteration or Waiver of Consent

In some cases, the federal regulations allow an IRB to approve a consent procedure which excludes or alters some of the 14 required and situational elements discussed previously or calls for a waiver of consent entirely. These situations fall into two categories.

1. Research Involving Public Service or Benefit Programs

- a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (1) Public benefit or service programs;
 - (2) Procedures for obtaining benefits or services under those programs;
 - (3) Possible changes in or alternatives to those programs or procedures; **or**
 - (4) Possible changes in methods or levels of payment for benefits or services under those programs, **AND**

b. The research could not practicably be carried out without the waiver or alteration.

2. Other Research (not involving public service or benefit programs)

To approve an alteration or waiver of consent for research involving other than public benefit or service programs, an IRB must find and document the following:

- a. Minimal risk - The research involves no more than minimal risk to the participants;
- b. No adverse affects - The waiver or alteration will not adversely affect the rights and welfare of the participants;
- c. Research not practicable otherwise - The research could not practicably be carried out without the waiver or alteration; **and**
- d. Follow-up information available - Whenever appropriate, the participants will be given additional pertinent information after their role in the study is over.

Waiver of the Need for Signed Informed Consent

As a rule, consent forms and oral consent statements must be signed to be legally valid. However, the federal regulations recognize that, in some situations, having a signature on record is not in the best interest of the participant. The regulations state that an IRB may waive the requirement for a signed consent form for some or all of the prospective participants in a study if one of the following applies:

1. Consent is the only link - The only record linking the participant to the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Prospective participants must decide if they want documentation linking them with the research and their wish is to govern; **or**
2. Minimal risk and a common nonconsent procedure are involved - The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

When the requirement for signed consent is waived, the IRB may require the investigator to provide prospective participants with a written statement about the research.

How to Make Consent Forms Easy to Read and Understand

Only if participants understand what you're telling them about the study and their participation can they give "true informed consent." The tips that follow will help you write consent forms that are easy for prospective participants to read and understand.

Write at a level that matches the reading ability of your prospective participants.

We tend to assume that if our colleagues can understand what we've written, others can too. This assumption too often proves false. Most CDC studies target persons from economically and educationally disadvantaged populations whose reading skills tend to be at or below the 8th grade level. However, most consent forms for these studies are written at or above the 12th grade reading level.

To increase the likelihood that your consent form will be understood, you should:

- decide at which reading level to write your consent form
- follow the rules for writing easy-to-read materials
- test the reading level of your consent form and, if too high, make any changes needed to lower the reading level

This section will help you complete these steps.

A. At which reading level should you write your consent form?

The National Adult Literacy Survey (NALS), conducted in 1993, found that nearly half of all American adults read at very basic levels. This percentage was much higher among welfare recipients, older adults, racial and ethnic minorities, and disadvantaged and inner-city populations. In addition:

- ✧ Only 21% of responders performed in the highest levels.
- ✧ Most people at the lowest levels did not perceive their problem; they described themselves as being able to read "well" or "very well."
- ✧ Adults with relatively few years of education were most likely to perform in the lower levels than those who completed high school or received some postsecondary education.
- ✧ Older adults were more likely than middle-aged or younger adults to demonstrate limited literacy skills.

The NALS is the source of the estimate that the “average” American reads at or below the 8th grade reading level. Also, the NALS found that a significant proportion of persons from disadvantaged, inner city, racial/ethnic minority populations read even below that level. In addition, the NALS found that perhaps for reasons of either self-deception or embarrassment, those with profound reading difficulties are unlikely to admit it. Thus, an investigator cannot necessarily rely on a prospective participant’s reaction to a consent form as signifying the achievement of “true informed consent.” It argues for making any form as readable (hence, understandable) as possible, but always making it the centerpiece of a consent “process” involving enough dialogue to ensure that the person truly understood the words in the consent document.

B. What tools are available to grade the readability of a consent form?

Several tools are available to help a CDC investigator determine if a consent form will be readable by a study population. One is an electronic readability formula through Grammatik in WordPerfect versions 6.1 and above. First, if the consent form is part of the protocol, rather than in a separate document, copy the consent to a new blank document. Go into Tools and select Grammatik. From the dialogue box, select View, and under that, Statistics. Then select Readability, which is presented using the Flesch-Kincaid Readability Test. In WordPerfect 7.0, this is found under Analysis. The resulting grade is based on the number of words per sentence and the average number of syllables per word. For persons (such as IRB members) who often do not have electronic versions of consents to test using Grammatik, two convenient manual options are available:

1. SMOG - which bases grade level on a scale that counts the number of ≥ 3 syllable (or polysyllabic) words in 30 sentences, 10 each from the beginning, the middle, and the end of the document. Readability of a piece with less than 30 sentences is judged on the scale by taking the average number of polysyllabic words from the sentences and multiplying that average by 30. SMOG is quick and easy to use. It equates well with other formulas at the high end of the readability scale. It only drops to the 5th grade level, and really does less well when measuring a document written ≤ 8 th grade level. It tends to overrate readability level at these lower levels. The SMOG scale appears in Appendix A, along with references to formulas for testing the readability of materials written in Spanish.
2. Fry Graph Reading Level Index - which bases the grade level on a two-way graph with average sentences/100 words on one axis and average number of syllables/100 words on the other. Derive the averages by counting 100 words (including proper nouns, initials/acronyms, and number sets) at the front, middle, and end of the document. Then calculate the means of the three sentence and syllable counts. The Fry Graph Reading Level Index involves more work than SMOG, but gets easier with practice. It is probably more sensitive than SMOG at all reading levels, but is much more sensitive on the lower end of the readability scale. A copy of the Fry Graph, with more tips on its use, also appears in Appendix A. Jane Root, Ph.D., reading expert and Fry Graph advocate has a rule to only

count once a medical/technical term with which there can be no doubt that the reader is already familiar, e.g., “diabetes” in a study consent for diabetics. The CDC IRB has also adopted this rule.

C. How do you write (or rewrite) a consent so that it achieves an ≤ 8 th grade reading level?

You can get to a ≤ 8 th grade reading level, and maximize comprehension in your consent forms by following some rules described below, combined with some creative writing and use Appendix B, a job aid that cites alternatives to complex terms that the IRB has found common to CDC consent forms.

Rule 1 Assume that your study participants will not recognize any ≥ 3 syllable words you use.

Rule 2 Accept that some ≥ 3 syllable words (e.g., proper nouns such as organizations, places, diseases/organisms, and persons’ names) may be abbreviated (e.g., CDC, in this state/city, HIV, AIDS, STDs), truncated (e.g., Emory University Transfusion Services Unit [Blood Center]) or reduced in their number of usages; but most cannot be replaced or deleted entirely, so use the minimum you need to and move on.

Rule 3 Assume that nearly every other ≥ 3 syllable word, other than proper nouns, CAN be replaced, and that doing so will improve readability (since at the 12th grade reading level the ratio of these “replaceable” words to ≥ 3 syllable proper nouns is about 8 to 1) in the usual CDC consent form. For example, the following actual wording in a CDC consent: “Your name and other information which could be used to identify you will be kept as confidential as legally possible,” upon revision was replaced with: “Your name and what you say to us for this study will be kept private to the extent allowed by law.” The

Tips for eliminating polysyllabic words

1. Find a synonym. For example, replace “compensate” with “pay” or “re pay.”
2. Use active voice. You can change “It is recommended” to “We recommend.”
3. Try a combination of less complex words. Instead of “researchers,” try “people doing the study.”
4. Start over. If replacing words and finding synonyms is too much trouble, try rewriting the sentence. You may find an easier way to say what you need to say.
5. Ask if the term can be deleted. In some cases, you may even be able to delete a whole sentence, if the information is not essential to informed consent.
6. Live with it. Accept that some terms just can’t be fixed. For example, you can’t replace or delete terms like “bandages,” “reaction,” “positive,” and “negative.” However, relatively few polysyllabic words will fall into this category.

5 replaced ≥ 3 syllable words proved expendable as the sentence, now more readable, sends the same basic message.

Rule 5 Be less concerned with the length of the consent than its ability to be read and understood. Replacing single complex terms with a series of less complex ones often will lengthen what might otherwise have been a short consent. Balance is important. Brevity is desired in that it encourages one to read a document that they might not if it was longer. However, the esthetics of achieving that brevity is sometimes purchased at the cost of informed consent.

Rule 6 In addition to minimizing the number of ≥ 3 syllable words in a consent form, its readability and comprehension can be improved by:

- Using the active voice - Concentrating on using the active voice can prevent readability problems from the outset;
- Limiting use of medical/technical terms - At times their use is unavoidable, but repetition can be limited by using abbreviations and some creative alternatives.
- Keeping your sentences short - Short sentences are more readable than long ones. Whenever possible, break up sentences over **20** words; and
- Limiting ideas to one per sentence - Persons with weak reading skills will have more trouble understanding complex sentences than ones which transmit only a single idea. If you need to keep two ideas closely connected, consider using a semicolon to break them apart in a single longer sentence.

Write to prospective participants--don't put words in their mouths.

We've all seen (and probably written) consent forms written in the first person singular, the "I" construct. These consent forms result in sentences that start out like this: "I understand that I will be asked..." "I realize that I will be given..." and "I recognize that I may be at some risk for..." These sentences almost always contain words with three or more syllables and tend to be hard to read. This sentence structure also seems to place the onus on the participants to understand rather than on the investigators to explain.

Writing to your prospective participants—rather than putting words in their mouths—sounds much more natural and results in language that is easier to read and understand. The sentences in the previous paragraph, for example, are much easier to understand when written as follows: "We will ask you..." "We will give you..." and "You may be at risk for..." These sentences mimic natural conversation and may more readily facilitate conversation between participants and investigators, a critical step in the consent process.

You should avoid first person singular construction for other important reasons. It is a legalistic form and, therefore, can be intimidating to prospective participants. For this reason, IRB experts and the Office for Protection from Research Risks (OPRR) view this construction as coercive, which is not allowed under the federal regulations.

Organize your consent form in sections.

The format of a consent form, as much as its content and phrasing, influences how well prospective participants understand it. The best way to organize your consent form, according to the IRB, is to use headings to separate subject matter. In addition to increasing comprehension, this format can lessen the risk of omissions and redundancies.

Below is one suggested format, which allows you to cover all of the required and situational elements of informed consent.

- ▶ Introduction
- ▶ Purpose of the Research
- ▶ Procedures
- ▶ Risks or Discomforts
- ▶ Benefits
- ▶ Confidentiality
- ▶ Cost/Payment
- ▶ Compensation (if appropriate)
- ▶ Right to Refuse or Withdraw
- ▶ Storage of Specimens for Future Testing (if appropriate)
- ▶ Alternative Treatment (if appropriate)
- ▶ Persons to Contact
- ▶ Your Consent(s)
- ▶ Signature Lines, Approval Boxes, Witness Signature Lines, and Designations

Three Problem Elements to Avoid

Before using your consent form, edit it carefully. Or, better yet, have someone else edit it for you. A thorough review can help you avoid three problem elements.

1. Proselytizing words and phrases

It's tempting to try to "sell" your study to prospective participants by focusing on how great the benefits can be both to the individuals in the study and to society at large. But a consent form must present all information, good and bad, if true informed consent is to be obtained. Reread your consent form to make sure that it does not understate the risks or overstate the benefits. You may want someone who is not involved in the study to read your consent form to make sure it presents an honest and objective picture of the study.

2. Adverbs and Adjectives

Minimize the use of adverbs and adjectives in consent forms. These modifiers can result in unintended influence on prospective participants. One might be more willing to participate in a study with risks involved if it will lead to "vital" information about a disease or "substantially" improve understanding of a health issue.

3. Spelling Errors

Errors reflect poorly on the author of a document of any type. Do not rely on your word processor's spell check. You still need to reread your consent form carefully to eliminate spelling errors. For example, your word processor won't know that "you" is supposed to be "your" or that "them" should be "then." Manually proofread your consent form after having applied an electronic spell check. Also, an editor can proofread your consent form quickly to find errors like these.

Note: The principles and rules discussed in this section also apply to writing an oral consent script.

A Section-by-Section Guide to Writing Consent Forms

This guide will walk you through the process of writing a consent form, section-by-section. It addresses the common situations you will face in conducting research at CDC, as well as some less common situations. Throughout the guide, you will see examples of wording similar to that which the IRB has approved in CDC consent forms. These examples appear in ***“bolded italics in quotation marks.”***

**INTRODUCTION
Common Situations**

INTRODUCTION - Common Consent Situations

Each consent form should begin with a clearly labeled introduction that does the following:

**INTRODUCTION
Research Purpose**

1. Clarify the Research Purpose - You want prospective participants to know that they are giving their consent to take part in research and not agreeing to let you perform a medical procedure, get medical records, or some other routine purposes. If the project name you cite in the Introduction section does not convey this idea, use a simple declarative sentence. For example,

“This project we want you join is a research study.”

**INTRODUCTION
Identify Sponsors**

2. Identify the Study Sponsors - Identify all of the agencies, organizations, and institutions that are asking the prospective participant to take part in this research so that the participant knows who is responsible for what the participant is being asked to do. This will likely require the use of several polysyllabic words—mainly proper nouns and medical/technical terms. To improve the readability of your consent form, you want to give abbreviations and simplified terms now so participants will recognize them later in the form. For example,

“The Tropical Disease Research Centre and the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, USA, are doing a study on malaria.”

**INTRODUCTION
Summarize the Problem**

3. Summarize the Problem - Summarize the (actual or potential) illness-producing problem which is important enough to justify both the study and the person’s participation. For example,

“Doctors have learned a lot about what affects the health of mothers and babies. But there is still much that we do not know. Through this study, we hope to learn more about what causes babies to be born premature.”

4. Explain the Disease - Most CDC studies involving human

INTRODUCTION

Explain the Disease

participants are focused on a specific disease, syndrome, medical condition, or environmental risk. Prospective participants, in general, may know something about the study focus. However, an investigator cannot assume that they know enough to give their informed consent. The challenge is to provide an explanation in which the words are readable and the content can be understood. The following language, approved by the IRB, is a good example:

“Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). Acute hepatitis sometimes begins with mild feelings of illness. These may include loss of wanting to eat, a feeling of illness coming on, and being very tired. A person also could have an upset stomach, vomiting, stomach pain, dark urine, and jaundice (yellow eyes and skin). At times, a skin rash and joint pain can occur.”

INTRODUCTION

Explain Complex Concepts

5. Explain Complex Concepts - CDC studies often require that prospective participants understand rather complex concepts if they are to give fully informed consent. Some of these concepts include multi-drug resistance, disease diagnosis, and complicated testing procedures. The examples below are from CDC IRB-approved consent forms and do well in explaining complex issues in fairly simple language.

“TB germs are strong and take powerful drugs to kill them. Some TB patients have mutant germs which are “resistant” to the TB drugs. This means that the germs are so strong that they are not killed by some of the drugs. TB germs can become resistant if TB patients do not swallow their pills every day. TB patients who do not take the pills can spread these resistant germs to others. Those other people can become sick with resistant TB. Patients who have these resistant germs must be treated with special drugs to be cured.”

“The long-term storage place of lead in the body is

in the bones. We will measure the amount of lead in your bones and the density of your bones. This is to assess the amount of lead in the bones and if that lead has had any effect on them. We measure bone density based on X-rays with low radiation doses. We will measure the minerals in the bones in a person's hip and spine. These measures will take us 30-60 minutes of your time. We will measure the amount of lead in the bone by using a technique called X-ray fluorescence. For this test, we will ask you to sit still for between 15-30 minutes."

INTRODUCTION
Answer "Why me?"

6. Answer the Implicit "Why Me?" Question - Explain why prospective participants have been chosen. This reason may differ for study participants and control participants. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

"We are asking you to be in this study because you are a resident of Goodwin House. We are asking people who got flu vaccine there during the past 5 years and also some who did not get the vaccine."

"We are asking you to be in the study because you live in the farming area which may have exposed you to this chemical."

INTRODUCTION
Less Common Situations

INTRODUCTION - Less Common Situations

The Introduction section almost always addresses common research situations. However, two other circumstances occasionally arise within this section which bear mentioning.

INTRODUCTION
CDC Not Cited

1. CDC's Participation Should Not be Cited in the Consent - On rare occasions, usually in studies conducted outside of the United States, circumstances arise where it is strategically necessary not to cite the role of CDC as a sponsor or active participant in the research. The IRB understands that such situations can occur. However, the process requires the investigator to explain the background and ramifications in detail as part of justifying any such deletion of a reference to CDC's role.

INTRODUCTION Blinding

2. Participants Must be Blinded to Some Aspect of the Study

On rare occasions, full knowledge of the study aspects usually addressed in the Introduction section might produce either a selection bias among prospective participants or a response bias among actual participants. The IRB understands that certain types of CDC epidemiologic studies may face this potential problem. However, the IRB may alter the consent process if it can do so according to the criteria in the federal regulations (see page 7 of this reference). Therefore, if either the problem summarization and/or “Why me?” explanation segments of the Introduction section are points in the form which require blinding, the informing language should be inserted in its place. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“We do not want to influence your (enrollment/ answers) so there are some details of the study (about why we asked you to enter the study) that we cannot tell you about until the study is over. But at the end of the study, we will send you a report of our findings and answer any questions you may have.”

PURPOSE OF THE RESEARCH

Common Situations

PURPOSE OF THE RESEARCH - Common Situations

Use the Purpose section to explain the research question to be answered by the study. While this information could be included in the Introduction section, it is helpful to discuss it separately.

We have not included any specific examples in this section because each consent form calls for unique phrasing based on the research question associated with its protocol. However, remember that the wording in this section should be easy to read and understand; do not simply restate the research protocol

**PURPOSE OF THE RESEARCH
Less Common Situations**

PURPOSE OF THE RESEARCH - Less Common Situations

The Purpose of the Research section almost always is a straightforward explanation of the research question. On rare occasions, however, the circumstances of the research dictate otherwise.

**PURPOSE
Blinding**

Participants Must be Blinded to Some Aspect of the Study -

As in the Introduction section, on rare occasions, full knowledge of the study aspects usually addressed in the Purpose of Research section might produce either a selection bias among prospective participants or a response bias among actual participants. (Procedures for requesting an alteration of informed consent begin on page 4 of this reference.) The wording used here is roughly identical to what is suggested for the Introduction section on the previous page.

“Because we do not want to influence your (enrollment/ answers), there are some details of the purpose of the study that we cannot tell you about until the study is over. But at the end of the study, we will send you a report of our findings and answer any questions you may have.”

**PROCEDURES
Common Situations**

PROCEDURES - Common Situations

Use the Procedures section to explain the study design. While this will vary from one study to another, certain procedures are common to CDC consent forms, and all forms should include a statement that participation is voluntary.

**PROCEDURES
Voluntary Participation**

1. Participation is Entirely Voluntary - Tell prospective participants early in the consent form that being part of the study is completely their decision. This message can be introduced here, in the Refusal/Withdrawal section, or in both places. The last choice results in some redundancy, but it is advised due to the importance of the message. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“You are free to join the study or not. If you do not join, you will not lose any health care service that you expect to get apart from this study.”

**PROCEDURES
Randomization**

2. Randomization - Randomization is common to CDC research protocols. If your study design employs randomization, you must explain it in the consent form. Some CDC investigators have devised simplified wording to explain this procedure. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“The decision of who receives calcium and who receives starch is random, like the lottery. Nobody, neither you nor us, will know who is receiving which. This will be kept secret until the end of the study, when we all will know who received which supplement.”

“If you agree to be in this study, you will be in one of the two groups by chance.”

“You have a fifty-fifty (50%) chance of being in one of two groups.”

**PROCEDURES
Blood to be Taken and How**

3. Blood to be Taken and How - Taking blood is a procedure common to many CDC studies. The consent form needs to explain the amount of blood to be taken, in equivalent teaspoons, tablespoons, or other measures with which most participants would be instantly familiar. Also, the consent should specify how and from where the blood will be taken. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“If you choose to be in this study, we will draw about 30 ccs (2 to 2 ½ tablespoons) of blood from the vein in your arm.”

“If you allow your child to be part of this study, we will take about 1 cc (about 2 or 3 drops) of blood by using a finger stick.”

“We will collect the blood in a tube the size of a man’s finger. It holds 5 ml, or the same amount as one teaspoonful.”

PROCEDURES

Taking Other Samples

4. Taking Other Samples - While taking blood is common in CDC studies, it is not the only type of specimen which is needed for research. Examples of readable working akin to what the CDC has approved in CDC consent forms for a number of these situations include:

[Saliva Specimens]

“To collect a saliva sample, we will ask you to hold a small cotton pad between your cheek and lower gum for 2 minutes. This pad will have a salty taste, but does not present a risk to you.”

[Nasal Specimens]

“We will obtain this sample by placing a cotton-tipped swab inside your nose. We will twirl it gently, and leave it in place for a few minutes before we remove it.”

[Nasopharyngeal Specimens]

“We will collect the nose sample by very briefly placing a small cotton swab into your nose. We will quickly wipe a second swab across the back of your throat. We will test these samples to see if your illness was caused by the flu virus.”

[Vaginal Secretion Specimens]

“While you are lying down, you will place a syringe filled with a mild salt water solution in your vagina, as you would a tampon or douching syringe. You will squeeze out solution, and then draw it back into the syringe. Then you will put the solution that is in the syringe into a test tube.”

[Genital Ulcer Specimens]

“If you are a man or a woman with ulcers or sores in the genital area (on, in, or near your penis or vagina) - We will take a sample of fluid after cleaning the base of the ulcer. As a rule, this is

painless but it may cause some slight burning. We will send this sample out of the country for testing. Thus, it will not be available for deciding on the treatment of your ulcer or sore.”

PROCEDURES
Procedures Not to be Done

5. Procedures Not to be Done - In some cases, it is as important to cite the procedures which are not involved as to cite those which are important. An example of readable wording addressing such an issue akin to that which the IRB has approved includes:

“Your doctor or nurse practitioner will take a sample from your cervix (the opening of your womb). They will take two swabs (like a Q-tip) for this study during your routine scheduled internal exam. No internal exams will be performed just for this study. We are asking you to be in this study because you are going to have an internal exam anyway.”

PROCEDURES
Questionnaires/Interviews

6. Questionnaires/Interviews - Administering questionnaires and conducting structured interviews have always been common components of CDC research. In your consent form, find a more readable synonym for the words questionnaire and interview (e.g., “survey”), if possible. Then explain how much time is required, the nature of the questions (noting any sensitive areas of questioning), and the fact that the participant is not required to answer any of them, for any reason. A common error to avoid is combining the statement that some questions may be sensitive with the fact that participants may choose not to answer any question. This can seem to put a condition on declining to answer (e.g., feeling embarrassed, feeling it is too sensitive, etc.). You want participants to know that they can decline to answer any question, for any reason, without feeling a need to justify their reason. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“We will ask you to take part in a survey in which we will ask you a number of questions. This survey will take about ½ hour. During this survey, we will ask you questions about the health care you got when you were last pregnant and about having HIV.

Some of these questions ask about your sex life and may concern you. You may choose not to answer any question and for any reason. Say that you want to pass on the question and we will just move on to the next one.”

“...It’s all right to skip any question you don’t want to answer. You may end the questions any time you want. This won’t affect any care that you or your child expect to get at the clinic or from your doctor.”

7. Time Commitments - It is important to tell prospective participants how much time their enrollment will entail. This can be done procedure by procedure, as above, or in summary fashion. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“We will need less than 5 minutes to take the blood sample. The interview will take about 30 minutes, and the other tests should be over in 1½ hours.”

8. Consent for Review of Medical Records - Often the study design of a CDC protocol will call for a review and abstraction of a participant’s medical records. The Procedures section is where this is explained. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“We need to check with doctors who have given your child health care. They need to confirm that your shot record shows all of the vaccines s/he has gotten and that we haven’t missed any. To let us do this, we ask you to sign a form to let those doctors share your records with us.”

9. Storage Without Identifiers - The Procedures section should be used to announce plans to store leftovers of blood or other specimens for future testing when the specimens will be stored WITHOUT identifiers. (A separate section is needed when specimens are to be stored WITH identifiers—see page 44 of this reference

PROCEDURES
Time Commitments

PROCEDURES
Review of Medical Records

PROCEDURES

Storage Without Identifiers

document.) Meanwhile, suggested readable wording akin to that which the IRB has approved in CDC consent forms for announcing the intent to store specimens without identifiers includes:

“We would like to store any blood that is left over after we do your test. We plan to use this sample for studies we will do in the future. We will store your sample with some data about you, such as your age, race, sex, and about your health problem. But we will not put your name on the sample, and there will be no way to know it is yours. Thus, we will not be able to report back any test results to you. You can decline to let us store your blood and still be in this study.”

Note: The last sentence of this example is very important. You must let prospective participants know that they do not have to let you store their blood or other specimens—it’s their choice.

PROCEDURES Less Common Situations

PROCEDURES - Less Common Situations

Occasionally, CDC protocols involve the use of mail and telephone questionnaires, focus groups, placebos, or situations in which it may be necessary to break the study code. Because these situations can be inherently more sensitive than some of the common situations, you must explain them in words prospective participants can understand.

PROCEDURES Mail/Telephone Questionnaires

1. Mail and Telephone Questionnaires - Interviews and questionnaires are common procedures in CDC studies, and sometimes they are administered by mail or over the phone. These involve the same elements of informed consent that apply when such instruments are administered in person, plus some special elements: assertive implied consent (through the return of a questionnaire), a reminder of the right of refusal to answer questions, and an explanation of the procedure to account for responses. Examples of readable wording akin to that which the IRB has approved for CDC consents include:

[Assertive Implied Consent]
“We will take your return of the completed survey as your consent to be part of this study.”

*[Right of Refusal to Answer Questions]
“It would be helpful to have a complete response. But, you are free to choose not to respond to any part of the survey. We will not contact you further about any questions which you decline to answer.”*

*[Explaining Response Accounting]
“You will see that your survey does not ask your name or for any other way to identify you. But, you will see that it is stamped with a number. That number matches to your identity on a list. We will keep that list only to track who has and has not responded. We expect to follow up with those who have not sent us a response. After we have performed our follow-up, we will destroy the list. This will break any link to the names of persons who completed the survey.”*

2. Genetic Testing - While genetic testing has not been common in studies thus far, genetic testing technology and its potential applications are growing. The process spans a wide spectrum of biomedical applications, including testing the DNA of infecting organisms; identifying the genetic predisposition of participants and their families to life-threatening, untreatable, hereditary conditions; and pinpointing potential cures for diseases and illnesses. If your study will involve genetic testing, you must thoroughly explain it in your consent form. Examples of readable wording describing genetic testing akin to that which the IRB has approved in CDC consents include:

“The only genetic testing we will do on your blood is to help us learn more about the disease. It may help us develop better tests for schistosomiasis.”

“We will test part of this blood sample to study your child’s DNA and the folic acid and homocysteine content of his/her blood. Tests will be done on samples with names removed. There will be no way to link a sample to your child. This means that for this study, we cannot give you back any test results.”

PROCEDURES Genetic Testing

“We would like to test your blood to learn your human leukocyte antigen, or HLA type. Your HLA type is a basic genetic marker that helps the body recognize itself. For instance, HLA markers help your body detect and fight cells that are infected or abnormal (such as cells infected with a virus). And these markers avoid other healthy cells in the body. We will use this to learn if a certain HLA type is associated with certain immune responses to measles.”

3. Focus group taping and related issues - The use of focus groups is becoming much more common. The procedural requirements to carry out an effective focus group session (e.g., to transcribe responses and/or to video/audio tape the interaction) raise some special concerns. These include how participants are identified in the focus group session, how the session will be observed and recorded, and confidentiality issues related to any recordings. These concerns need to be addressed in the protocol, but should also be explained in the consent form. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“For the focus group, we will ask you to pick a name other than your own to call you by. We will give you a tag with that name on it. You can expect that some study staff will sit in and take notes during your focus group session. Also, we plan to record the session on audio tape. Only study staff will be able to use the tapes. The tapes are to help learn more about what is said by all of you as you discuss the topics. At the end of the study, we will erase the tapes and throw them away.”

4. Avoidance Requirements - On occasion, participation in a CDC research project may mean suspending certain functions required for study testing procedures, avoiding certain drugs which could confound research results, or discontinuing certain lifestyle practices. Prospective participants need to know about these requirements in order to give their informed consent. Suggested readable wording akin to that which the IRB has approved to

PROCEDURES
Focus Group Taping, etc.

PROCEDURES
Avoidance Requirements

address this contingency in CDC consent forms include:

“During this study, we ask that you not take any antimalarials other than what the team gives you.”

“Rifampin may interfere with other drugs you may be taking. We will discuss your list of drugs, then tell you of possible problems with any of them.”

“We ask people in the study not to receive any other vaccine. This applies to the 2 weeks before and the 2 weeks after each meningococcal serogroup B immunization. If you need to receive any other immunization during the study period, please tell a member of the study staff listed above.”

“Between the visit today and the one next week, we ask that you not have sex. If you feel that you cannot do this, we ask that you use a condom when you do have sex.”

“You must not eat or drink anything (other than water) from after dinner until the morning of the test. At that time, we will give you a sweet cola drink. One test will be done before you drink the cola and the other one 2 hours after drinking the cola.”

“If you join the study, we will ask that you not eat anything for 4 hours before the test. In the test, you will drink a can of orange juice, and then breathe down a straw into a tube. This provides a baseline breath sample. You will then drink a test solution; 30 minutes later you will again breathe down a straw into a tube. This is the test sample.”

PROCEDURES

Refusal of HIV Test Results

5. Refusal of HIV Test Results - CDC studies involving serologic testing for HIV antibody remain fairly common. However, the issue of whether participants should be able to refuse to get their test results is fading into obscurity. This is true at least in developing countries where antiviral therapies are making the knowledge of one's HIV antibody status a life preserving necessity. However, in some domestic research situations, and in developing countries, this issue remains alive. Policy of the Department of Health and Human Services (HHS) developed in 1988 remains in effect on this issue. In summary, it says that, in domestic research, individuals whose HIV test results are associated with personal identifiers MUST be informed of their results and provided with the opportunity to receive appropriate counseling; they may not be given the option not to know, either at the time they consent to the test or thereafter, unless an exception is granted.

An exception to the HHS policy may be considered for studies in foreign sites. However, allowing a right to refuse must be consistent with host country cultural norms and the resources, capabilities, and official health policy there. Also, the IRB must determine that the modification of policy to allow refusal is significantly justified by the risk/benefit evaluation of the research project itself. Since the default is to not allow a "right to refuse HIV tests", suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

"If you choose to be in this study, we will take your blood and test it for HIV antibody at CDC. We will give you the results of that test. We will also explain the results. We will counsel you about what you might do next and services open to you."

6. The Use of Placebo Controls - When you conduct a placebo controlled trial, your consent form must explain what this is, why it is used, and how it will work. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

"In this study your child will be put in one of two

PROCEDURES
Use of Placebo Controls

groups as a matter of chance. Children in one group will get the drug we want to test. The other group will get pills which look the same, but they will have no drug in them. They are harmless and are meant to hide who has the drug. This is so our study doctors will give each child the same exam and not look harder at one group over the other. This will give the drug the fairest test and allow us to tell if it works.”

“We are doing this study to see if giving this drug late in pregnancy will also lower the chance of a mother passing the virus to her baby. To do this, we will give some women the drug and give other women a placebo. A placebo is like a “sugar pill” which has no benefit or risk to your baby’s health.”

7. Conditions for Breaking the Study Code - In blinded randomized clinical trials, and occasionally in other types of CDC studies, there is a real prospect of breaking the code before the study ends. Prospective participants need to hear about this possibility so that they understand the operating rules, and are not surprised if it occurs. Sample wording might pick up from the example cited just above and add:

“...to tell if it works. Before the study ends, our exams may tell that many children are getting ill while others are staying well. In that case, we may look at the code that tells us which children are in each group. If this tells us that the drug is working, we will end the study early and give the drug to every child.”

PROCEDURES
Breaking the Code

RISKS OR DISCOMFORTS

Naturally, risks or discomforts are going to vary in type and degree from one study to another. The charge is to neither understate nor overstate risks so that a prospective participant will be able to make an informed choice about entering the study. The challenge is to explain those risks in a way that prospective participants can understand. The more common risk situations that find their way into CDC consent forms are

addressed below. These begin with a common situation where the risk is minimal.

RISKS/DISCOMFORTS

1. Rare or Nominal Risks - Even when risks or discomforts are rare or minimal, you should discuss them in your consent. Examples of readable wording akin to that which the IRB has approved for CDC consent forms include:

“We expect the risks to you for being in this study to be rare, but we cannot rule them out. For instance, it may be hard to talk to your sex partner(s) about your infection. But you should try to do this even if you don’t want to be in this study.”

RISKS/DISCOMFORTS

Rare or Nominal Risks

“All the steps to be carried out by this study have been approved from a child safety standpoint. They are widely used in America. There is a slight sting from the shot. For some children, there may be a small bruise at the site of the shot that will quickly go away.”

2. Risks from taking blood - Serologic testing is one of the most common components of CDC research protocols. Whether this is done by finger stick or taking blood from a vein, the consent needs to explain the risks entailed. Readable wording akin to that which the IRB has approved in CDC consent forms include:

“You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint, but this is rare.”

RISKS/DISCOMFORTS

Risks from Taking Blood

“Drawing the blood may hurt a little. Bruising, bleeding, and rarely, infection could occur where the needle enters your vein.”

“The main risk to you in being part of this study is

taking your blood. There is a small chance you could get germs in the spot where the blood was taken and it could get infected. If the area around the spot gets red and sore, you would need to go to the clinic.”

“Your child will feel a slight sting (like a pin prick) when we take blood from a vein. The hurt will be over quickly. The stick we use is sterile, so it will not harm your child. Also, the amount of blood we take will not harm your child at all. Your child may have a bruise from where the needle went in, but this will go away soon.”

3. Questionnaire/Interview Risks - Nearly all CDC research involves the use of some type of questionnaire or interview as part of their study design. Depending upon the subject of the study, the risk may range from negligible to substantial embarrassment, discomforts, or psychological trauma. As stated earlier, the procedures section should spell out the focus of these proposed interactions and highlight the subject matter which may be problematic for the prospective participant. In this section, the foreseeable risks associated with those questionnaire/interview aspects should be detailed. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

RISKS/DISCOMFORTS
Questionnaire/Interview
Risks

“When we do the survey, none of the private questions we will ask you are about touchy matters. So none of them should make you uneasy. But as we said, you can choose to not answer any of them that you wish, for any reason.”

“As we said, our survey will ask you questions about how you live and what you do. As part of that, we will ask about the type of sex you have, if you’ve had an STD, and drugs you may use. Those questions may trouble you to think about or answer them, or embarrass you. But as we said, you can choose not

to answer any of them that you wish-for any reason.”

“In asking about the child you just lost, we know that this may be hard for you to relive. You face a risk that this may depress you, perhaps a great deal. If you are not ready to be in this study, you may need to see a doctor after to help you cope. But as

Note: Each example above contains a reminder that the participant is free to decline to answer any item. While this repeats what is said in the Procedures section, the importance of this message warrants the redundancy.

On occasion, circumstances of the research may suggest that the risks of answering a questionnaire/interview are balanced by certain risks in declining to respond. For example,

“If you choose to answer our questions, the only risk is perhaps feeling bad if you tell us about giving the tainted vitamins to other children in the house. That was not supposed to happen, but it is OK to talk about this. In fact, it is only bad not to talk about it because one or more children might miss the chance to get a needed test.”

4. Drug Side Effects - Most therapeutic agents that study participants may be asked to take will produce side effects to some degree. Prospective participants need to know about these side effects and their dimensions in order to make an informed decision about joining the study. When you know how often certain side effects occur, include this information in your consent form. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

“Our review of response forms we got between 1992 and 1994 showed that about 12% of person getting

**RISKS/DISCOMFORTS
Drug Side-Effects**

this toxoid had side effects where they got the shot. Most often this is only redness, but it may swell up and limit your arm movement. In about 10% of cases, the reports showed that people had more general reactions. This added up to one or more of the following: pain and soreness; itching; feeling tired; feeling queasy or throwing up; seeing double; a prickling feeling on the face and body; or a rash. If you have any of these, report them to the study person whose name is on this consent form.”

5. After-Effects from Study Procedures - Some CDC studies involve procedures from which participants may expect to experience after-effects. These should be described so that prospective participants can make an informed decision about whether they want to incur those risks. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“The apheresis process may also cause you to feel some effects on your health. One bad effect for donors is that they may have a slight drop in their red cells (anemia) or in their platelet count. This will not be severe and returns to normal over time. The long term effect of the drop in lymphocytes is not known.”

**RISKS/DISCOMFORTS
After-Effects from Study
Procedures**

“Risks of white cell donation are the same as the risks of giving blood. These include feeling queasy, throwing up, having chills, feeling light in the head or fainting. It can also involve blood loss, seizures, and infection and swelling or bleeding around the needle site. The risk of giving white blood cells also includes getting a blood infection and having muscle cramps. It can also involve getting a tingling around the lips due to a reaction between ACD-A (anti-coagulant) and your body’s calcium. These risks are rare and occur less than 1% of the times people donate. Another risk from white cell donation is getting an air embolus (a bubble of air that travels through the blood). The risk of getting an air embolus is very rare. It happens less than

.0002% (less than 1 in 500,000) of the times people donate. An air embolus is a very rare but serious risk, since it could result in stroke or death.”

6. Unforeseeable Risks - When indicated by prior safety research, a statement should be added that a particular treatment or procedure may involve risks which are currently unforeseeable for the subject (or the embryo or fetus, if a participant is or may become pregnant). Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“We do not expect any risks to you from being in this study or our focus group. While our focus group leader is very good, it is an open discussion. Issues discussed could make you feel uneasy, and you could reveal private things that you later regret.”

RISKS/DISCOMFORTS

Unforeseeable Risks

“This vaccine has been used in other countries, but it has not been used in the U.S. until now. This makes its use here experimental. We do not expect risks to your child from taking this vaccine beyond those we have already told you about. But we cannot be certain until we study the vaccine here. We will stop the study at once if we learn of any new risks.”

BENEFITS

Similar to the Risks or Discomforts section, the Benefits section should give a balanced explanation of benefits that prospective participants can expect. It should also address any benefits to others or to society at large. Citing the latter grows in importance proportionate to any decrease in direct benefits to a person’s participation.

1. Benefits to the Participant - Sometimes, CDC studies can have direct benefits to those who participate. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

BENEFITS

_____ *“We expect that if this vaccine works, it will keep your infant from getting the hepatitis infection.”*

“The benefits to you of being in the study are learning if you have this parasite so that you can get proper care and treatment.”

BENEFITS

Benefits to the Participant

“The benefits of being in this study include knowing your present health status and also knowing your risk of developing AIDS.”

2. No Direct Benefits - When there is no foreseeable benefit to the participant, regardless of potential benefits to others, clearly explain this fact. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“You will get no direct benefit from being a part of this study. But helping to carry out this research has a chance to tell us a lot about the disease. If so, that could be of future benefit to you or to someone you know.”

CONFIDENTIALITY - Common Situations

The Confidentiality section must affirm both that study records will be kept confidential (try substituting “private” as an inexact but less complex term) and physically secure from unauthorized access. As study information increases in sensitivity, the urgency to explain confidentiality and security also increases. Making records safer is how you can have a study considered “minimal risk” even though the data, were it ever to be released, could pose a real problem for participants.

BENEFITS

No Direct Benefits

Legally Unprotected Research - The most common situation is that CDC research projects are conducted without specific legal protections. For reference, the legal protection which could apply are sections 301(d) (Certificate of Confidentiality)

CONFIDENTIALITY Common Situations

and 308(d) (CDC Assurance of Confidentiality) of the Public Health Service (PHS) Act. Also, a few states have stringent confidentiality laws which apply to research involving human participants. Except where these specific protections apply, it is inaccurate to use the term “strictly confidential” or its synonyms (e.g., “totally” or “entirely” confidential) in the consent process. That simply assures more protection than the investigators are able to provide, as study records indeed would be subject to disclosure if ordered by judicial or law enforcement authorities. Suggested readable wording akin to that which the IRB has approved in CDC consent forms related to unprotected research includes:

CONFIDENTIALITY Legally Unprotected Research

“What we talk about and your test results will be kept private to the extent allowed by law. To protect your privacy, we will keep the records under a code number rather than by name. We will keep the records in locked files and only study staff will be allowed to look at them. Your name or other facts that might point to you will not appear when we present this study or publish its results.”

CONFIDENTIALITY - Less Common Situations

On occasion, a CDC study will have its records subject to review by regulatory authorities. Or a CDC study may be further protected under the PHS Act. Whenever any of these situations apply, the Confidentiality section needs to explain that information with identifiers will be shared with other agencies.

1. Records are Subject to Review - On occasion, a CDC study will be subject to outside review. The usual example is when the study is conducted in association with a blood banking facility, whose records the Food and Drug Administration may review. Suggested readable wording akin to that which the IRB has approved in CDC consent forms for this situation includes:

CONFIDENTIALITY Less Common Situations

“Emory Clinic will keep a private record of each time you donate. Only staff who are allowed will have access to your records, except as the law may demand. Also members of the Food and Drug Administration may look over your records during their required reviews.”

**CONFIDENTIALITY
Records are Subject to
Review**

2. Allowed Use of “Strictly” in Describing Confidentiality - When a CDC study is covered locally under stringent state confidentiality laws which protect against court-ordered disclosure, or a federal Certificate of Confidentiality issued by CDC, which is even stricter, the consent to use the term “strictly” in describing confidentiality (“privacy” for readability) is allowable. Suggested readable wording akin to that which the IRB has approved in CDC consent forms related to such protected research includes:

“Your records in this study are strictly private. No one other than study staff can ever look at them unless you agree to it. This is because the study has been granted a Certificate of Confidentiality under a federal law [Section 301(d) of the Public Health Service Act]. This means that the records of this study may not even be called into federal, state, or local court without your OK. That applies forever.”

**CONFIDENTIALITY
Allowed Use of “Strictly” in
Describing Confidentiality**

2. CDC Assurance of Confidentiality - Some CDC research projects are granted an Assurance of Confidentiality under Section 308(d) of the PHS Act. An Assurance of Confidentiality also offers stringent protection for study records, denying disclosure from court order or other access. However, it is important to understand that an Assurance only protects study records held at CDC and by its contractors. If the study is conducted through local sites and study records are maintained there, those records are not covered by the Assurance; they are subject to the limits of any coverage afforded by state or local law. The consent form should try to explain how this works. Below is an example of how this can be done in a fairly straightforward fashion, bypassing details. The alternative passage which follows is a more comprehensive explanation, variations of which are found in several CDC consent forms.

**CONFIDENTIALITY
CDC Assurance of
Confidentiality**

[Short Version]

“Your test results at CDC are kept private by an Assurance of Confidentiality under the Public Health Service Act [Section 308(d)]. This means that CDC may not let those out with information that identifies you for any reason unless you agree. The records of what we discuss in the survey will be kept

here in Tampa. We will keep them private to the extent allow by state law.”

[Long Version]

“CDC is that part of the U.S. Public Health Service that collects the nation’s data on HIV and AIDS. The data that come to CDC are reports of persons whose doctors diagnose them with AIDS or suspect they have AIDS. CDC uses the data to count numbers of cases of HIV/AIDS, and to conduct studies of who gets HIV/AIDS and how. Nobody is ever named. State and local public health people use the data to help learn about HIV/AIDS and control its spread.

Any HIV/AIDS data that come to CDC through this system that may identify a person in any way, will be kept private. This is assured under section 308(d) of the Public Health Service Act (42 U.S.C. 242K and 242m(d)). As a rule, CDC does not get reports which include a person’s full name, address, or phone number. Instead, CDC gets data which are tagged with a code. This code is made from letters and numbers based on a person’s last name. In the rare event that CDC does receive your name, CDC can only release the data with your name if you give your written consent for the purpose. Sometimes, CDC needs to confirm the data in reports or to alert doctors or public health people of data in the reports. Each time, CDC will only disclose the minimum amount of facts about you needed to get that done. Your name will not be given. Data kept by state and local public health people are held private as allowed by state and local law.

The Director of CDC approves research projects about HIV/AIDS only under strict conditions that keep private any facts about people. If a research person outside of CDC needs HIV/AIDS facts which could identify a person, that research person must sign a certificate. In this, he or she vows to keep all data private and to disclose nothing about a person without the person’s written consent. This vow has the force of U.S. law.

CDC is not allowed to disclose any HIV/AIDS data that may identify a person without their written consent to anyone for any non public-health reason. This means that CDC may not disclose these data to the public, to parties in any lawsuit or court case, or to private companies, such as insurance companies or employers.”

COST/PAYMENT - Common Situations

Beyond what its title indicates, this section needs to cover three important financial aspects of a research project. These are:

1. Who Pays for Various Procedures - This section needs to clarify who covers the expense of various procedures, e.g., examinations, tests, vaccines, or therapies that the prospective participant would receive by joining the study. In most cases, the study would cover these costs, and the prospective participant needs to know that. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“The only cost to you for being in our study is the time you must spend and what it costs you to get here today.”

2. Payment to Participate - CDC studies commonly pay persons for being part of the research (with money, gift certificates, etc.). It is acceptable in CDC consent forms to describe payment as reimbursement for their time, trouble or inconvenience, discomfort, and out-of-pocket expenses for being in the study. It is not acceptable to describe payment so it may be read as the purchase of a person’s participation in research, which may be viewed as coercion. However, the IRB recognizes that on occasion the amount may be much higher than normal (e.g., \$250 - \$350 for leukapheresis) to meet market prices or to acknowledge the relative risk and/or discomfort of a particular clinical procedure. Ideally, that issue is addressed in this section, but is also appropriate in the Procedures section within the context of what is required of a participant. It should never appear in the Benefits section, because that sends a wrong message. Suggested readable wording akin to that which the IRB has approved

**COST/PAYMENT
Common Situations**

**COST/PAYMENT
Who Pays for Various
Procedures**

in CDC consent forms include:

COST/PAYMENT
Payment to Participate

“We will give you \$25 to repay you for the time you must take and any costs to you for being in our study. We will give you this \$25 if you complete the study, or if you choose to drop out before it ends.”

“After your focus group, we will give you \$20. This is to help repay you for the time you spent with us and the cost of coming to be in our study. We will give you this whether you finish the focus group or decide to withdraw before it ends.”

COST/PAYMENT - Less Common Situations - When any of the following less common situations arise, they must be adequately addressed in the consent form.

1. Who Pays when Research Merges with Care - On occasion, a research project will be conducted as part of a medical procedure for which the participant would normally pay, or a research procedure (e.g., examination or test) may indicate the need for further diagnostic work-up or curative therapy. Your consent form must explain who pays for what pieces of this continuum. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“The test we do for this study will be done at no cost to you. But if the test shows that you may have this health problem, you will need to pay for seeing your doctor. You should also plan to pay for a test to confirm if you have it. If so, you will also pay for the cost of the drugs to treat it.”

COST/PAYMENT
Less Common Situations

2. Payment Tied to Completion - Typically, payment is not tied to the completion of participation in the study in order to avoid the appearance of a penalty for withdrawing from the research. However, a study’s success can depend heavily on participants finishing the research process. These studies usually involve a narrowly defined cohort

COST/PAYMENT
Who Pays when Research
Merges with Care

and multiple steps, such as serial blood testing, repeated questionnaires, or before-and-after testing of some type surrounding an expensive or critical intervention.

To emphasize the importance of completing the study, you may want to break payments into segments, with the value increasing for each succeeding segment of research. Explain this system to prospective participants by indicating that the higher payments recognize a larger time commitment necessitated by participating in successive phases in the study. However, do not overtly characterize any payment as a “bonus” for completion. In order to make the point about the importance of completing the research process, the investigator must:

- (a) be completely clear in the Procedures section of the consent that each participant’s completion is critical to the research and that individuals should reconsider joining the study if they do not now believe they can complete it. For example,

“This study will not succeed unless we have enough people who see it through from start to finish. Thus, we ask you to join the study only if you think that you may be able to do that.”

- (b) break up the payment into increments linked to steps in the research process, so that the payment schedule can be explained in the Costs/Compensation section within the context of the need for completion. For example:

“We will give you \$25 for today’s visit to pay for your time and costs. Since each visit after that adds to the time you must give us, we will add \$5 to that payment each time. Thus, we will be giving you \$40 for the last visit when you complete the study. We have told you why we need you to complete the study, but we know people may drop out. If you decide to drop out of the study, we will only repay you for your time up to the last visit you made.”

- (c) make it clear in the Right to Withdraw section that the

COST/PAYMENT
Payment Tied to
Completion

sacrifice of repayment for withdrawing early is quite apart from any rights or benefits they have and will continue to enjoy regardless of their decision. For example:

“While we hope that you will stay to the end, you are free to drop out of this study at any time. If you do, you will not get any more payments such as those you got when you were in the study. But you will still be able to get all the care that you got before; you will still get the same service that you came to expect from us apart from being in the study.”

3. No Share in Commercial Results of Research - On occasion, CDC studies will contain a possibility that the research could result in the development of patentable products with commercial application and value. The most familiar example today is the immortalization of unique cell lines as the result of some type of genetic research. The CDC Office of General Council recently collaborated with the IRB to craft easy-to-read language to be used whenever a study has the potential of producing a marketable product with any commercial value. That wording is:

"Your sample may be used in our research to help our researchers invent or find something new. The aim is to use the findings and inventions to develop new products that may improve the public health. At times, such findings or inventions may have a value if they are made and sold. The government or its research partners may get a patent on these. They may also license these. You would not share in any money or other things that the government or any company might get for what someone may invent or find using your study samples. We have no reason to believe your samples will be used to invent or find something new, but we want you to know what will happen in case it does."

**COST/PAYMENT
No Share in Commercial
Results of Research**

COMPENSATION

The only use of the term “compensation” in the federal regulations refers to money made available to injured research

participants to compensate them for disability, etc. Investigator often will use this interchangeably with reimbursement (or “Payment” as used in this reference document) which is to cover a participant’s out-of-pocket expenses for being in a study. As to the issue of compensation for injury, the federal regulations requires it be addressed in the consent form when a study involves more than minimal risk.

No Compensation Provision for Injury - When a study involves more than minimal risk, CDC requires a notification in the consent form about compensation for injury. This statement should indicate that CDC has made no provision to pay for needed care or for restitution should a person be injured through participation in the study. This does not preclude an injured participant from taking legal action to seek redress. It only makes it clear that prospective participants should not expect CDC to step forward with financial help or to pay their losses if something goes wrong. Suggested readable wording akin to that which the IRB has approved in CDC consent forms include:

COMPENSATION

“Neither University Hospital nor CDC has set aside funds to pay you if a mishap occurs. If you are harmed as a result of this project, we will give you emergency health care. You should not expect to receive other payment, and we will bill you or your insurer in the usual manner.”

“Doctors at the Clinic will arrange care for any physical harm that happens from being in the study. But neither Emory University nor CDC has funds set aside to pay you for costs from being hurt.”

COMPENSATION No Compensation Provision for Injury

RIGHT TO REFUSE OR WITHDRAW - Common Situations

Each person recruited for a CDC study has the right to refuse to participate. In addition, each participant in every CDC study has the right to withdraw, at any time and for any reason. In either case, the decision should involve no loss or sacrifice of services to which the person has a right to expect to receive.

Refusal/Withdrawal Rights - Note that this reference document calls for citing the first of these assurances in the Procedures section. Given the importance of this message, it is worth repeating here, in a separate section. It is critical that this section be written in a way that prospective participants can understand easily. For example,

“As we said before, you are free to join the study or not. If you do not join, you will not lose any health care service that you expect to get apart from this study. If you decide to join the study, you are also free to drop out later for any reason. In that case too, you will not lose any health care service that you may expect apart from this study.”

RIGHT TO REFUSE OR WITHDRAW - Common Situations

“You are free to join the study or to decide not to join. You may also leave the study at any time, for any reason. If you decide not to join, or to drop out later, you will lose no health care that you may expect apart from this study.”

RIGHT TO REFUSE OR WITHDRAW - Less Common Situations

RIGHT TO REFUSE OR WITHDRAW - Refusal/Withdrawal Rights

Some studies may involve important consequences of withdrawal which may not be apparent to a prospective participant. These studies may involve a more complicated process of withdrawal than simply not showing up. When there are consequences of withdrawing or when there is a need and procedure for an orderly withdrawal, these aspects should be addressed in the consent form. In addition, when the study may include an investigator’s decision that certain participants may lose their eligibility to continue, prospective participants need to know that staying in or dropping out is not necessarily their choice alone.

1. Consequences of Withdrawal - A participant is free to withdraw, at any time and for any reason. However, in the interest of informed consent, the investigator must explain the consequences of a participant's decision to withdraw from the study. Sometimes the circumstances of the study can present a serious challenge to balance the need for candor with the need to avoid coercing study participants.

For example,

“As we said, you have the right to drop out. But you should know that the study may not reach its goal if too many people drop out. Those whom we asked to join are a small number who have been exposed to this chemical.”

**RIGHT TO REFUSE OR
WITHDRAW
Less Common Situations**

2. Orderly Withdrawal - The investigator also needs to explain the procedures for an orderly withdrawal. Extending from the example language above, suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“Also, we need to know if you do not show up because you are ill or because you dropped out. So, if you decide to drop out, please tell a member of the study staff before you do.”

**RIGHT TO REFUSE OR
WITHDRAW
Withdrawal Consequences**

3. Withdrawal by Study Staff - The circumstances in some CDC studies may involve a real possibility that a participant's further involvement may be terminated by study staff without regard to the participant's consent. When that possibility exists the consent form needs to explain circumstances under which this may happen. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“We told you that you are free to drop out of the study at any time and for any reason. You also should know that the study staff could end your part in the study. This may happen if you miss one visit and your return is not within 3 days of that date. You will be dropped from the study if you miss two visits in a row. This is because the drugs you are taking in this study need to be given on or near the set visit dates. If not, our study will not be able to use the results of your blood tests. Staying in the study after that would be of no value to us or to you.”

**RIGHT TO REFUSE OR
WITHDRAW
Orderly Withdrawal**

**STORAGE OF SPECIMENS FOR FUTURE TESTING -
Common Situations**

The Procedures section covered the storage of specimens for future testing when the samples were to be made irrevocably

anonymous. The decision to store “identifiable specimens” - this is, specimens stored in such a way that they could be linked to the donor, involves several issues. It is best to address them in a separate section of the consent form.

RIGHT TO REFUSE OR WITHDRAW Withdrawal by Study Staff

1. Components of Storage Consent for Identifiable Specimens When identifiable specimens are to be stored in a CDC study, several possible components must be weighed as part of the consent form for collecting them. How these components are addressed in the consent form depends upon the clarity of the plans for future testing. The amount of information required in a consent form is proportional to the obscurity of those future testing plans. These components, along with the various possibilities for future testing, are presented below. Along with them is suggested wording akin to that which the IRB has approved in CDC consents related to stored identifiable specimens:
 - a. Explicit Plans for Future Testing - Future plans for testing stored identifiable specimens are usually the clearest whenever that testing directly relates to the study through which they were collected. In this case, the investigator’s explanation is straightforward, and indicates that test results of any health significance will be returned. For example:

“We plan to test your stored samples when we have new methods for finding antibody to measles. If any test results seem to have meaning for your health, we will inform you or your doctor, as you direct.”

SPECIMEN STORAGE Common Situations

SPECIMEN STORAGE Components of Storage Consent for Identifiable Specimens

Under these circumstances, you may want to explain other future tests you anticipate. For example:

“We plan to test your stored samples when we have new methods for finding antibody to measles. The only other testing we might do on your sample is to check your immune status to other childhood diseases. If any test results seem to have meaning for your health, we will inform you or your doctor, as you direct.”

You may also wish to specify any sensitive types of testing that will not be done in order to improve acceptance. For example:

**SPECIMEN STORAGE
Explicit Plans for Future
Testing**

“We plan to test your stored samples when we have new methods for finding antibody to measles. The only other testing we might do on your sample is to check your immune status to other childhood diseases. If any test results seem to have meaning for your health, we will inform you or your doctor. We plan to do no genetic testing on your sample.”

- b. Unclear Plans for Future Testing - Storage with CDC studies, even of identifiable specimens, most often is for unspecified future research purposes. The value of such specimens is enhanced by the ability to link them with other clinical and epidemiologic data on the donor. However, the inability to be specific forces an investigator to cover a range of contingencies, e.g..

“We ask you to agree to freeze part of your blood and other fluid samples at CDC. We will use these samples for research in the future. We are not sure what studies might be done. But if any test results seem to have meaning for your health, we will inform you or your doctor, as you direct. Some tests we do may be experimental and have no clear meaning to your health. In those cases, we will not report any results to you or your doctor. We will not test your samples for HIV or other STDs. Also, we do not plan to do any genetic testing on your samples.”

- c. When Genetic Testing is Possible - CDC is expanding its genetic testing capabilities to study potential links with diseases. Hence, it may be prudent to use these tests with a sample of stored specimens and to anticipate this need when they are collected with no clearly bounded future purpose. However, testing to identify a genetic predisposition to disease is different from most other forms of biomedical testing in its possible benefits and in its potential risks. Therefore,

**SPECIMEN STORAGE
Unclear Plans for Future
Testing**

any possibility of genetic testing on identifiable stored specimens needs to be preceded by a specific consent to do this testing or a re-consent that would fully explain the implications, e.g.,

“At some time we might ask to test your child’s stored sample for a health problem that may affect him in the future or which may run in your family. If so, we will tell you what that could mean and we would only test if you agree to it.”

“We may want to test your stored tissue sample to look at your genes. We would do this to see if you are more likely than many other people to get a disease. If that happens, we will come to you first to explain that testing and what it could mean. We will go ahead only if you agree.”

**SPECIMEN STORAGE
When Genetic Testing is
Possible**

- d. The Right to Exclude Certain Testing - When the storage of identifiable specimens is for uncertain future research purposes, prospective participants should be given the right to identify any testing which they want excluded from research. But because a prospective participant is unlikely to know the range of possible research testing which CDC may do, it is appropriate to cite some of the more sensitive types. For example:

“You may exclude your stored sample from certain types of tests that could be done during future research. Examples include genetic testing to see if a disease may run in your family. It could also include testing for HIV (the virus causing AIDS) or for other STDs. Please note in the space we provide any types of tests CDC should not do on your stored sample.”

- e. The Right to Refuse/Withdraw - The right to refuse to enroll in research, or to withdraw from a project once enrolled-both without penalty-are required components of informed consent. Future research involving stored identifiable specimens nearly always is a project separate from the study in which the specimens are

collected. When that is the case, the consent form needs to state those withdrawal rights. In addition, the procedure for withdrawal from specimen storage will be quite different from withdrawal from the source study. Therefore, the statement of this particular right needs to include directions as to how to go about withdrawing from storage. For example:

SPECIMEN STORAGE
The Right to Exclude
Certain Testing

“You may choose not to have your sample stored for future research and still be part of this study. Also, you may agree to have your sample stored and later decide that you want to withdraw it from storage. If so, you should call the study person listed in this consent form and tell her to discard your sample. The sample will be discarded as you instruct. But any data from testing your sample until that point will remain part of the research.”

ALTERNATIVES (if appropriate)

The required elements of informed consent include the disclosure of appropriate alternative procedures or courses of treatment, if any, that might benefit the prospective participant.

SPECIMEN STORAGE
The Right to Refuse/
Withdraw

1. Specifying Alternatives - Many CDC protocols involve providing diagnostic procedures, therapies, or vaccines. For protocols where this does not apply, there is no need to include a section on alternatives. However, when this does apply, an investigator must inform the prospective participant of what is available. Examples of readable wording akin to that which the IRB has approved in CDC consents regarding alternatives include:

“If you do not want to be in the study, you will receive the standard TB treatment given by the Botswana National TB Program.”

“If you do not wish to join this program, we will give you care using the regular methods we have already explained.”

“You may choose not to be in his study. If so, your child’s care will not be affected in any way, now or in the future. You can get MMR vaccine from your doctor or local health department.”

ALTERNATIVE S

“If you do not wish to join this amended part of the TLC Study, you can get a blood-lead test through your doctor for any of your children who got the tainted vitamins.”

ALTERNATIVES Specifying Alternatives

PERSONS TO CONTACT

This section discusses two elements that are common to nearly every consent form.

1. Study contact - List the name of the study person to contact with questions about participation, or concerning injury sustained as the result of participation. Also, include instructions about how to make that contact. This section is likely to contain several ≥ 3 syllable proper nouns; thus, it is important to try to minimize those where the options exists to do so. Suggested readable wording akin to that which the IRB has approved in CDC consent forms includes:

“If you have any questions about how the study works, contact..., the chief study person, at ...”

2. Contact for Participant Rights - The consent should also provide the name of someone to contact with questions about the person’s rights as a research participant. This should be someone who is not part of the study, i.e., responsible for the ethical conduct of research, such as a local IRB chairperson, the CDC Deputy Associate Director for Science, or the CIO Human Subjects Contact. This can be noted by continuing the sample wording above with the following:

“If you have any concerns about your rights in the study, contact ..., head of the University Human Investigations Committee, at ...”

3. Contact in case of injury - The consent should also provide

PERSONS TO CONTACT

PERSONS TO CONTACT Study Contact

the name of someone to contact in case the participant sustains an injury as a result of the research. This can be either the contact to answer study question (e.g., the Principal Investigator), the contact for questions about the person's rights as a study participant, or someone else all together. Usually that is the Principal Investigator. The following is sample wording to cover that:

“If you think that you have been injured by being in this study, contact..., the chief study person, at...”

YOUR CONSENT

In this section of the consent form, prospective participants are asked to declare whether they will enroll in the study. This statement can be written in two different ways.

PERSONS TO CONTACT Contact for Participant Rights

1. An “I” Construct Statement - The most common approach is to write an “I” construct declarative statement, which basically puts words in the mouth of the prospective participants about everything that is understood. It also says that an opportunity has been given to have all questions answered to the individual's satisfaction. Use care if you use this construct because its tone can be very formal and it can invite the use of complex sentence structures and polysyllabic words. The examples below illustrate how to use the “I” construct and easy-to-understand language akin to what the CDC has approved in consent forms:

PERSONS TO CONTACT Contact in Case of Injury

“I agree to be in this study. I have been given a chance to ask questions and I feel that all of my questions have been answered. I know that being in this study is my choice. I know that after choosing to be in this study, I may leave it at any time. I know that if I wish to leave the study at any time, I may contact ...at...”

“I have read this consent form. I have had my questions answered so that all parts of the study are clear to me now. I have received a copy of this consent form. I agree to my child being a part of this

study.”

2. A Construct Addressing the Prospective Participant - We recommend addressing the prospective participant rather than using the “I” construct. This format may be easier to understand and has a more informal tone. This is the only practical format to use in preparing an oral consent script. An example of easy-to-read wording akin to that which the IRB has approved in CDC consent form includes:

YOUR CONSENT

YOUR CONSENT

An “I” Construct Statement

“We have given you a copy of the consent form. When you sign below, it shows that you agree to let your child be part of the study. If there is any part of this form which is unclear to you, be sure to ask questions about it. Do not sign until you get solid answers to all of your questions. When you are ready to let your child be part of the study, sign your name on the line below.”

SIGNATURE LINES, APPROVAL BOXES, WITNESS SIGNATURE LINES, DESIGNATIONS, AND REFUSAL

The end of the consent form involves some conventions which an investigator needs to observe. These include the positioning of signature lines, using “check-off” boxes to signify special approvals, allowing for designations, explaining what witnesses are witnessing, and the issue of indicating refusal to participate.

1. Signature Line Position - The signature line for the prospective participant to enroll in the study should be positioned after any special “check-off” boxes, such as for storage. This is to reinforce the concept that a prospective participant can disagree to future testing and still take part in the present study.
2. Approval Boxes - Many CDC studies involve procedures, such as specimen storage or identifying who should get test results, which call for separate specific consents. Using separate signature lines can be confusing. The clearest, most efficient way to obtain such special consents is to provide “check-off” boxes. For example:

YOUR CONSENT

A Construct Addressing the Prospective Participant

“Please Check One Box

- I give consent for my blood to be stored at CDC under the conditions outlined in this consent form.***
- I DO NOT give consent for my blood to be stored at CDC for future research.”***

SIGNATURES LINES, etc.

3. Witness Signature Line - CDC consent forms sometimes include a witness signature line. If a witness is required, craft language for that signature line to describe what the person will witness. This can be from just witnessing the prospective participant’s signature to observing the entire consent process, including the signature. The statement accompanying the witness signature line should reflect the witness’ role; it should also be realistic. For example, it should not say “I confirm that the prospective participant completely understood the consent form and got satisfactory answers to all of his/her questions.” More realistic wording might be:

SIGNATURES LINES, etc.
Signature Line Position

“I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept the answers, and signed to enroll in the study.”

SIGNATURES LINES, etc.
Approval Boxes

4. Designations - When a protocol involves current or future testing with participant identifiers, the participant should be given the right to designate the routing of the results of those clinical tests. There are exceptions where the tests are experimental, in which case results will not be returned. However, prospective participants are explicitly informed of this in the consent. Also, there may be tests about which the investigators justly feel uncomfortable having results going to the participant rather than a physician who can interpret them and explain their implications. The consent form should be explicit about this as well when it applies. Otherwise, the consent form should give the prospective participant the option to designate if results should be sent to them or to their doctor. Space should be devoted to designating the physician’s name and address in the event that option is selected, e.g.,

“Please give any facts about my health () directly to me or () directly to my doctor (address below).”

SIGNATURES LINES, etc.

Witness Signature Line

Note: Do not include a line for noting refusal to participate or for a reason for that refusal. Both measures are inherently coercive and inappropriate.

SIGNATURE LINES, etc.

Designations

SIGNATURES LINES, etc.
Refusal

Appendix A

SMOG Readability Formula

The SMOG² formula is a recommended³ and tested⁴ method for grading the readability of written materials. The method is quick, simple to use and particularly useful for shorter materials, e.g., a study's information pamphlet or consent form. To calculate the SMOG reading level, begin with the entire written work being assessed and follow these steps:

1. Count off 10 consecutive sentences near the beginning, in the middle, and near the end of the text. If the text has fewer than 30 sentences, use as many as are provided.
2. Count the number of words containing 3 or more syllables (polysyllabic), including repetitions of the same word.
3. Look up the approximate grade level on the SMOG conversion table below:

Total Polysyllabic Word Count	Approximate Grade Level (±1.5 Grades)
1-6	5
7-12	6
13-20	7
21-30	8
31-42	9
43-56	10
57-72	11
73-90	12
91-110	13
111-132	14
133-156	15
157-182	16
183-210	17
211-240	18

When using the SMOG formula:

- o A sentence is defined as a string of words punctuated with a period, an exclamation mark, or a question mark. Consider long sentences with a semi-colon as two sentences.

² Developed by Harold C. McGraw, Office of Educational Research, Baltimore County Schools, Towson, MD.

³ Doak, Cecilia C., Leonard G. Doak, and Jane H. Root (1995). *Teaching Patients with Low Literacy Skills*. New York: J.B. Lippincott Co. 36-59.

⁴ Ibid: page 59 cites a 1979-81 test of the method conducted by Patient Learning Associates, Inc., of Potomac, Maryland, in which the SMOG formula performed exceptionally when used to grade materials presented to 291 individuals graded by accepted methods as having reading levels between the 4th and 16th grades.

- o Hyphenated words are considered as one word.
- o Numbers which are written should be counted. If written in numeric form, they should be pronounced to determine if they are polysyllabic.
- o Proper nouns, if polysyllabic, should be counted.
- o Abbreviations should be read as though unabbreviated to determine if they are polysyllabic. However, abbreviations should be avoided unless commonly known.
- o If the written piece being graded is shorter than 30 sentences, approach it as follows:
 - Count all of the polysyllabic words in the test.
 - Count the number of sentences.
 - Find the average number of polysyllabic words per sentence, i.e.:

$$\text{Average} = \frac{\text{Total \# of polysyllabic words}}{\text{Total \# of sentences}}$$
 - Multiply that average by the average number of sentences *short* of 30.
 - Add that figure on to the total number of polysyllabic words.
 - Compare the number of polysyllabic words in the SMOG conversion table.

SPANISH READABILITY FORMULAS

Crawford, A.N. (March 1984). *A Spanish language Fry type readability procedure: Elementary level*. Los Angeles: Bilingual Education Paper Series, Evaluation Dissemination and Assessment Center, California State University, Los Angeles, 7:1-17.

Garcia, W.F. (1976). *Assessing readability for Spanish as a second language: The Fry graph and cloze procedure*. Unpublished doctoral dissertation, Teachers College, Columbia University.

Gilliam, B., Pena, S.C., and Mountain, L. (1980). "The Fry graph applied to Spanish readability." *The Reading Teacher*, 33:426-430.

Spaulding, S. (1956). "A Spanish Readability formula." *The Modern Language Journal*. 40:433-441.

Spaulding, S. (1951). "Two formulas for estimating the reading difficulty of Spanish." *Educational Research Bulletin*, 30:117-124

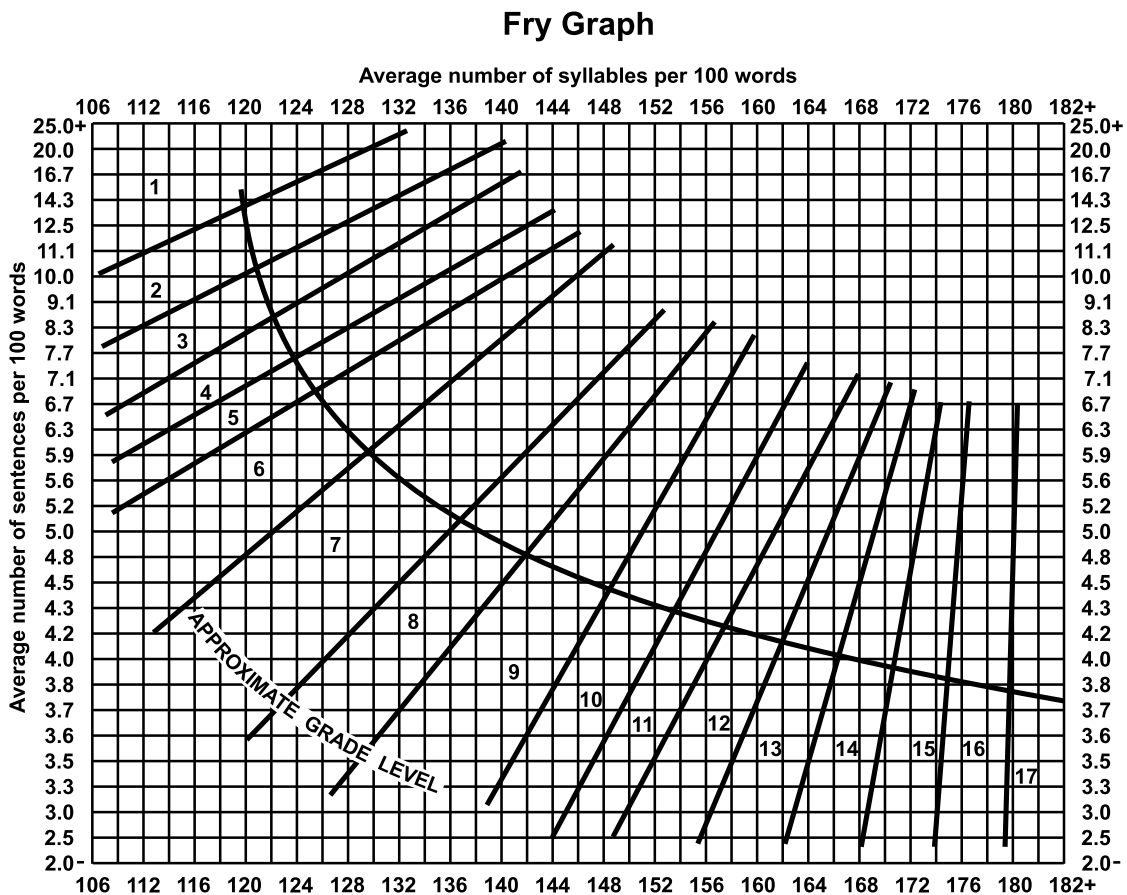
Acknowledgment

Thanks to Dr. Mary S. Neumann, DHAP, NCHSTP, for her research of SMOG and her assistance based on her wide use of the method to improve the readability of materials produced by CDC or through CDC grant support. Thanks also for her research of the Spanish language formulas which appear in the guide "Developing Effective Educational Print Materials" which she authored with the TEB, DSTDP, NCHSTP.

The Fry Readability Scale

Directions:

- Select three 100-word passages from the beginning, end, and approximate middle of the consent form.
- Count proper nouns, numerals, and initializations as words.
- Count the number of syllables, counting each symbol in numerals and initializations as one syllable, e.g., 1997 as 1 word and 4 syllables; CDC as 1 word and 3 syllables. A suggested easy way to count is to put a mark above every syllable beyond 1 in each word, count the number of marks, and add 100.
- Count the number of sentences in each 100 words, estimating the length of the fraction of the last sentence to the nearest 1/10th.
- Add the number of sentences and the number of syllables and divide each total by 3.
- On the Fry Graph below, find the average number of sentences on the side scale and find the average number of sentences on the top scale. Where the points meet indicates the approximate reading level grade of the form.



Appendix B

Easy-to-Read Replacement Words/Phrases for Polysyllabic Terms Common to CDC Consent Forms

<u>Common Polysyllabic Terms in CDC Consents</u>	<u>Possible Replacement Words/Phrases</u>
Additional information about	Other facts about/more facts about
Allowing	Letting
Another	Any other/More/One more
Blood will be collected	We will take blood
By agreeing	If you agree
By telephone	By phone
Comparison group	A group used to compare results
Commonly	Most often
Compensate	Repay
Confidential/Sensitive	Private
Consider	Think about
Continue/Continued	Go on/Keep on going/Kept on going
Contracting	Getting
Convenient	Handy
Currently receiving	Now getting
Decision	Choice
Deleted	Erased
Description	A statement which describes
Determine whether	Learn if
Developed	Put in place
Directly	In a direct way
Discomfort	Worry/woe/aches/soreness
Discover/discovered	Find/found
Dizziness	Feeling dizzy
Educational background	Level of schooling
Enrolling	Joining/being in
Entitled to otherwise	Have a right to receive apart from this
Especially	Mainly
Evidence of	Signs of/proof of
Explanation	A statement which explains
Exposure to	Risk of getting/being exposed to
For example	For instance
For study purposes	To carry out the study
General/generalized	Wide spread
However	But/yet
Implemented	Put in place
In addition	Also
Including	Along with
Infected with the...	Having/with the...
Information	Facts
Injury	Harm
Inoculation/injection	Shot
Interested in...	Would like to know about...
In this community	Around here
Make it possible to..	Allow us to...
Medical record	Health record

**Easy-to-Read Replacement Words/Phrases for Polysyllabic Terms Common to CDC Consent Forms
(Continued)**

<u>Common Polysyllabic Terms in CDC Consents</u>	<u>Possible Replacement Words/Phrases</u>
Monitor	Check on
Nausea	Upset stomach/feeling queasy
Negligible	Small
Participate/participating	Be in/being in
Participation in...	Being part of...
Permitted	Allowed
Personal	Your own
Physician	Doctor
Pregnancy, during	When you are pregnant
Pregnancy outcomes	Birth outcomes
Previous studies	Studies done before
Previously unrecognized virus/ recently discovered...	Virus we did not know about before now
Protected	Kept private
Provide explanations for	Explain why
Provided/providing	Given/giving
Questionnaire	Survey form
Ramifications	Problems/results/outcomes
Receiving	Getting
Regulations	Rules
Relevant	Tied in with
Requested	Asked for
Researchers/Scientists	People doing the study
Resulted	Came from
Satisfactory	OK/fine
Schedule an appointment	Set a time
Several	Some/a few/a number of
Specimens	Samples
Sexual behaviors	Types of sex
Sexually transmitted diseases	VD or (STDs)
Study coordinator	The person who leads the study
Substantial	Large/big
Suggested	Pointed to
Thank you for volunteering to be in...	Thank you, we are glad that you agreed to be in...
The information we collect	What you tell us
To the extent legally permissible	To the extent allowed by law
Transmitted	Passed on to other people
Understand	Learn/see
Vomiting	Throwing up
Your understanding of ...	What you know about...