

# Informed Consent Documentation

DMID/ICSSC

11/24/09

# Informed Consent Form

- ◆ Information given to subject “shall be in a language that is understandable...”
- ◆ Guidelines for writing Informed Consent Form
  - Use short sentences and paragraphs
  - Use one or two syllable words, if possible
  - Avoid scientific or medical jargon; define scientific or medical terms in lay language
  - Write in the second person “you”
  - Verbs should be in the active voice
  - Be concise

# Informed Consent Form

## Basic Element 1

### ✦ Describe the overall research process

- Statement that the study involves research
- Purpose of the research
- Expected duration of subject's participation
- Description of procedures that will be followed
- Identification of procedures which are experimental

45 CFR 46.116

# Informed Consent Form

## Basic Element 2

- ◆ Describe the reasonably foreseeable risks or discomforts to the subject

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# Informed Consent Form

## Basic Element 3

- ✦ Describe any benefits that the subject or others may reasonably expect from the research

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# Informed Consent Form

## Basic Element 4

- ✦ Describe alternative procedures or courses of treatment, if any, that may be of benefit to the subject

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# Informed Consent Form

## Basic Element 5

- ◆ **Confidentiality of Records** - inform subjects of extent to which their records will be kept confidential

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# Informed Consent Form

## Basic Element 6

- ◆ **For research – related injury that could occur in greater than minimal risk studies**
  - Explanation as to whether any compensation is available if injury occurs and whether any medical treatments are available if injury occurs
  - If so, what it consists of, or whom to contact for more information

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# Informed Consent Form

## Basic Element 7

### ◆ Contact information:

- Identification of persons to be contacted to answer questions about research
  - Usually investigator
- Identification of persons to be contacted to answer questions about research subjects' rights
  - Usually IRB office
- Identification of persons to be contacted to answer questions in the event of research-related injury
  - Can be investigator

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# Informed Consent Form

## Basic Element 8

- ◆ A statement that participation is **voluntary**
- ◆ A statement that **refusal to participate** will involve no penalty or loss of any benefits to which the subject is otherwise entitled
- ◆ A statement that subject may **discontinue participation** without penalty or loss of any benefits to which the subject is otherwise entitled

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# Informed Consent Form

## ◆ Compensation

- Amount, if any, to be stated
- State schedule of payment (if any); should be prorated
- Should not be so large as to be coercive

# Informed Consent Form

Additional (not optional) elements to be included when appropriate:

- A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if pregnant) which are currently unforeseeable

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# Informed Consent Form

**Additional (not optional) elements to be included when appropriate:**

- A statement about anticipated circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent

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# Informed Consent Form

Additional (not optional) elements to be included when appropriate:

- ◆ Any additional costs to the subject that may result from participation in the research

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# Informed Consent Form

**Additional (not optional) elements to be included when appropriate:**

- ◆ **Consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject**

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# Informed Consent Form

Additional (not optional) elements to be included when appropriate:

- ◆ A statement that new significant findings that may influence a subject's willingness to participate will be provided to the subject

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# Informed Consent Form

Additional (not optional) elements to be included when appropriate:

- ◆ Approximate number of subjects involved in the study

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# Documentation of Informed Consent

- ◆ Informed consent must be documented - written informed consent form that has been approved by IRB
- ◆ Signed by subject or subject's legally authorized representative
- ◆ Subject or representative - adequate time to read the consent form before signing it

45 CFR 46.117

18

# Documentation of Informed Consent

- ✦ The written informed consent form may be read to subject or subject's legally authorized representative
- ✦ Copy of the informed consent form to be given to the person signing the form

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# Documentation of Informed Consent

## Short form written consent document

- ◆ This document to state that required elements of consent presented orally to subject or their representative
- ◆ When this method used – must have witness to oral presentation
- ◆ IRB/IEC approves written summary
- ◆ Only short form signed by subject or representative
- ◆ Witness signs short form and summary
- ◆ Person obtaining consent signs copy of summary

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20

# Assent of Children

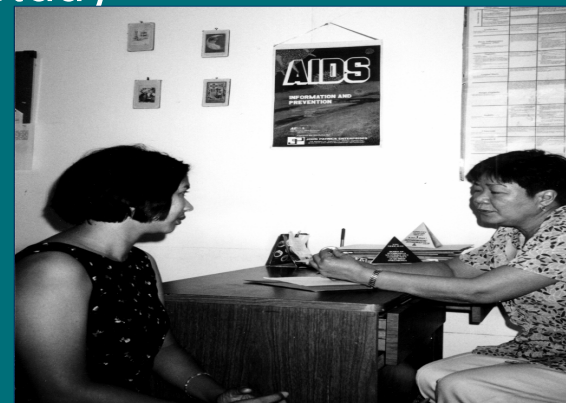
- ◆ Assent of children should be obtained whenever possible
- ◆ IRB/IEC determines whether children are capable of assenting
  - Age
  - Maturity
  - Psychological state
- ◆ If IRB/IEC determines that consent is required, must specify how assent is documented
- ◆ Consent of child's parents or guardians also required
  - Both parents or guardians?

45 CFR46 Subpart D

# The Process

## Consent Is Communication Process

- ✦ Between the researcher and the participant
- ✦ Starts before the research is initiated
- ✦ Continues throughout the duration of the study



# The Process: Four Key Considerations

## ◆ Information exchange

- Prior to any study procedures
- Understandable to participants
- New information as study progresses
- Adequate time

# The Process: Four Key Considerations

## ◆ Comprehension

- Judge competency and literacy level
- Encourage questions and discuss thoroughly

# The Process: Four Key Considerations

## ◆ Voluntariness

- Obtain consent in a private setting, free of coercion
- Emphasize no penalty for refusal
- Right to change mind at any time

# The Process: Four Key Considerations

## ◆ Documentation

### In summary:

- IRB-approved ICF
- Signed by subject or rep
- Copy to person signing form

### Best practice:

- In addition to consent form, write note in the participant's record that consent was obtained



L. Phillips read the consent form in private; M. Immelman discussed the information with her and answered her questions. Pt. stated she understood the content and wished to enroll. Consent was signed prior to any study activities at 9 a.m.  
MI 03 Jan 09

## Exercise 1

Review the following informed consent form and comment on the following sections:

- Voluntariness of participation
- Risks and discomforts
- Benefits
- Confidentiality
- Problems or questions

**Informed Consent Form**  
***Male Tolerance of ISO 2000/5 Gel***

***Version 1.0***

Sponsor: DMID

Principal Investigator  
John Doe, M.D.  
Fullam University  
Aftville, AB  
98675 Tel: (919)  
236-5768

***Introduction***

You are being asked to take part in the clinical trial named above. This is a clinical trial of a gel developed as a vaginal microbicide. Vaginal microbicides are designed to be inserted into the female vagina to prevent HIV passing from one person to another during sex. HIV is the virus that causes AIDS. The gel we are testing is called ISO 2000/5 Gel. Before you decide to take part in this clinical trial, we want to explain the purpose of this clinical trial, the risks and benefits to you, and what is expected of you.

***Your Participation Is Voluntary***

This consent form gives you information about the clinical trial that we will discuss with you. Once you understand the clinical trial, and if you agree to take part, we will ask you to sign this consent form. We will offer you a copy of this consent form to keep.

Before you learn about the clinical trial, it is important that you know that your participation is entirely voluntary.

## ***Purpose of the Clinical Trial***

The purpose of the clinical trial is to find out if there are any bad effects when ISO 2000/5 Gel is applied to the penis of men.

Before we conduct the clinical trial to find out if the gel prevents HIV from being passed from one person to another during sexual intercourse, we must test the gel to make sure it is safe. In this clinical trial, we test the safety of ISO 2000/5 Gel on the penis compared to a gel that has been approved for use as a lubricant during sex.

## ***Procedures***

If you agree to participate in this clinical trial, we will ask you to return to the clinical weekly for 4 weeks. Each weekly visit will take approximately 30 minutes.

### **Visit 1**

At the first visit, we will give you a tube of gel.

We will ask you to follow the procedures listed below:

- Apply the gel to your penis every night and leave it on overnight (6-10 hours).
- Wash the gel off your penis the next morning.
- Every day, record in a diary card the following information:
  - The time you applied the gel
  - The time you washed it off
  - Any medication you took
  - Any symptoms you experienced
- Do not have sexual intercourse or masturbate while you are using the gel.
- Bring all tubes of gel to the clinic at your next visit.

Neither you nor the research staff will know which gel you are using each week. The experimental gel and lubricant gel look and feel about the same. After all subjects have finished the trial, and we find out the results of the trial, if you wish, we will tell you the results of the trial.

Different trial subjects will use the gels in different orders. The order in which you will use the gels will be chosen "at random" by a computer. "At random" means "by chance," like flipping a coin.

## **Visit 2**

We will ask you to give us the tubes containing experimental gel that you used during the previous week.

At this visit, we will ask you to answer questions about your health, review your diary card, examine your penis, and test your urine for evidence of infection.

During the next week, you will not need to apply any gel to your penis. However, we will ask you to record in a diary card, on a daily basis, the following information:

- Any medication you took
- Any symptoms you experienced

## **Visit 3**

At this visit, we will ask you questions about your health, review your diary card, examine your penis, and test your urine for evidence of infection.

At this visit, we will give you another tube of gel.

We will ask that you to follow the procedures listed below:

- Apply the gel to your penis every night and leave it on overnight (6-10 hours).
- Wash the gel off your penis the next morning.
- Every day, record in a diary card the following information:
  - The time you applied the gel
  - The time you washed it off
  - Any medication you took
  - Any symptoms you experienced
- Continue with these procedures for one week.
- Do not have sexual intercourse or masturbate while you are using the gel.
- Bring all tubes of gel to the clinic at your next visit.

## **Visit 4**

At this visit, we will ask you questions about your health, review your diary card, examine your penis, and test your urine for evidence of infection.

We will ask you to give us the tubes containing experimental gel.

### ***Risks and Discomforts***

We have tested ISO 2000/5 Gel in women. Now we want to find out if men who use ISO 2000/5 Gel experience any bad effects and that is why we are conducting this clinical trial.

### ***Benefits***

We will pay you \$300 every time you visit the clinic.

ISO 2000/5 Gel contains a microbicide so we think it will probably protect you from getting sexually transmitted diseases.

### ***Alternatives to Participation***

ISO 2000/5 Gel contains a microbicide and so it will probably protect you against HIV during sex. The only proven way to protect against HIV during sex is to use a condom every time you have sex.

### ***Confidentiality***

We will keep your research records confidential to the extent permitted by law. If FDA inspectors want to review the trial records, they will have to get permission from you and from all the other subjects.

### ***Research-Related Injury***

The research staff will give you immediate necessary treatment if you become injured because of being in this clinical trial. We will not bill you or your insurance company for the cost of that treatment. We have no program for monetary compensation or other forms of compensation for such injury. You do not give up any legal rights by signing this consent form.

### ***Problems or Questions***

If you have questions about this research, your rights as a research subject, or if you become sick or have a health problem at any time during your participation in the research, please contact John Doe, M.D. at telephone number (919) 236-5768.

## Signatures

If you have read this informed consent form, or if you have had it read and explained to you, and you understand the information, and you voluntarily agree to join this clinical trial, please sign your name or make your mark below.

\_\_\_\_\_  
Subject Name  
(printed)

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Name  
(printed)

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

## **Exercise 2 – Informed Consent**

### **Case Study**

A cohort study to determine the incidence of genital herpes in women 18 – 25 years of age is being conducted in Harare Zimbabwe. The duration of the study is one year and participants will visit the clinic once every three months.

After two visits, a participant tells the investigator that she no longer wants to participate in the study. She says that she has a new, well paying job and it will be difficult for her to take time off work to come to the clinic.

The investigator does his best to persuade the participant to agree to return for the two remaining visits. He tells the participant that she will badly affect the study results if she drops out. He offers to pay her a little extra if she agrees to return to the clinic for the remaining visits since she will be taking time off work and her new job pays her well. The investigator also tells the participant that she will be foregoing the benefit of the physical examination that she receives at each visit. The investigator hands the participant a printed pamphlet which helps explain the purpose of the study and describes the study procedures. This is the same pamphlet that the investigator provided to each participant at the time of obtaining informed consent to aid their understanding of the consent form.

1. Is it permissible to describe the physical examination as a benefit?
2. Is it permissible to increase the compensation to offset the loss of wages from her new, well paying job?
3. Is it permissible to provide the participant with another copy of brochure that describes the purpose of the study?
4. Should the participant have been allowed to leave the study without any questions asked?

## Exercise 3 - Informed Consent

### Case Study

A site is executing a clinical study in which 15 ml of blood is collected from healthy participants every four months over 3 years for cholesterol tests, as well as genetic testing. The goal of the study is to identify genes that contribute to high HDL levels in the hopes that some day this may facilitate the development of a new generation of medicines for people with severe arteriosclerosis.

A participant who has been in the study for two years comes into the clinic and says that he wants to quit. The counselor asks him why and he replies that he finds the burden of taking the bus to the clinic too great (he lives far away) and he doesn't really understand the point of the study anyway. The counselor re-explains the purpose of the study, using a brochure she has been developing for enrollment consent visits. She gives a copy to the participant to keep in case he wants to refer back to it. The investigator is alerted to the situation and comes in to explain to the participant that it will be very hard on the study if he leaves since enrollment has closed at the site and he cannot be replaced, and besides, he has already spent two years on the study and only has one year left. The investigator also agrees that if the participant will stay in the study, he can increase the participant's reimbursement for travel expenses since he has a longer way to travel than most participants in the study. The participant agrees to continue in the study.

### Questions – *Per GCP...*

- 1) Should the study staff have allowed the participant to quit the study without questioning him about his decision? Why or why not?
- 2) Should there be any concern about the counselor providing the participant with written materials as described above to help clarify the purpose of the study? Explain.
- 3) Identify two possible concerns that the actions of the investigator raise (one of which pertains to an element of the informed consent).
- 4) What characteristic concerning possible benefits of this study (from the first paragraph) should be explicitly described in the informed consent form?