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BLOOMBERG
SCHOOL of PUBLIC HEALTH

Informed Consent: What Contributes to a Good Process

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Overview

- Consent
  - Form
  - Process
    - Assessment
  - Subject-level factors
  - Provider-level factors

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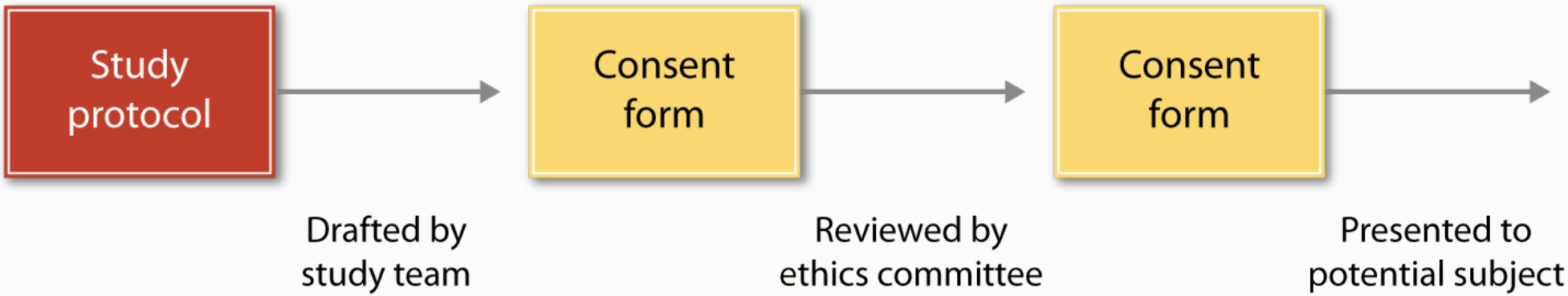
Section A

Form

Form: Lifecycle



Form: Readability

- Readability
  - Consider level of literacy of study population
    - 65 approved forms: average 15th grade (Hammerschmidt and Keane, 1992)
    - Ann Landers columns: average 7.7 grade
    - Reader's Digest: average 9.95 grade readability
    - No IRB review improved by >1 grade level
  - Simplify text
    - Short sentences
    - One idea per sentence

Form: Readability

- Readability
  - Complex concepts
    - Research
    - Randomization
    - Placebo-controlled trial

Form: Randomization

- “A process called randomization is used to select your treatment in this trial”
  - The process will select the best treatment for me
  - Each individual patient has exactly the same chance of receiving the drug, or not receiving the drug, as any other participating patient
  - One treatment is given one time, another is given another time
  - The doctor decides which treatment is the right one for me

Form: Randomization

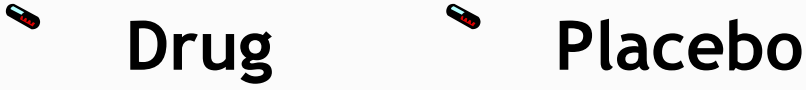
- “A process called randomization is used to select your treatment in this trial”
  - **Each individual patient has exactly the same chance of receiving the drug, or not receiving the drug, as any other participating patient (68%)**

Form: Randomization

- “A process called randomization is used to select your treatment in this trial”
  - The process will select the best treatment for me (14%)
  - **Each individual patient has exactly the same chance of receiving the drug, or not receiving the drug, as any other participating patient (68%)**
  - One treatment is given one time, another is given another time (0%)
  - The doctor decides which treatment is the right one for me (18%)

Form: Placebo

- Placebo
  - What is it?
    - Pill that looks just like the drug but doesn't contain any medicine

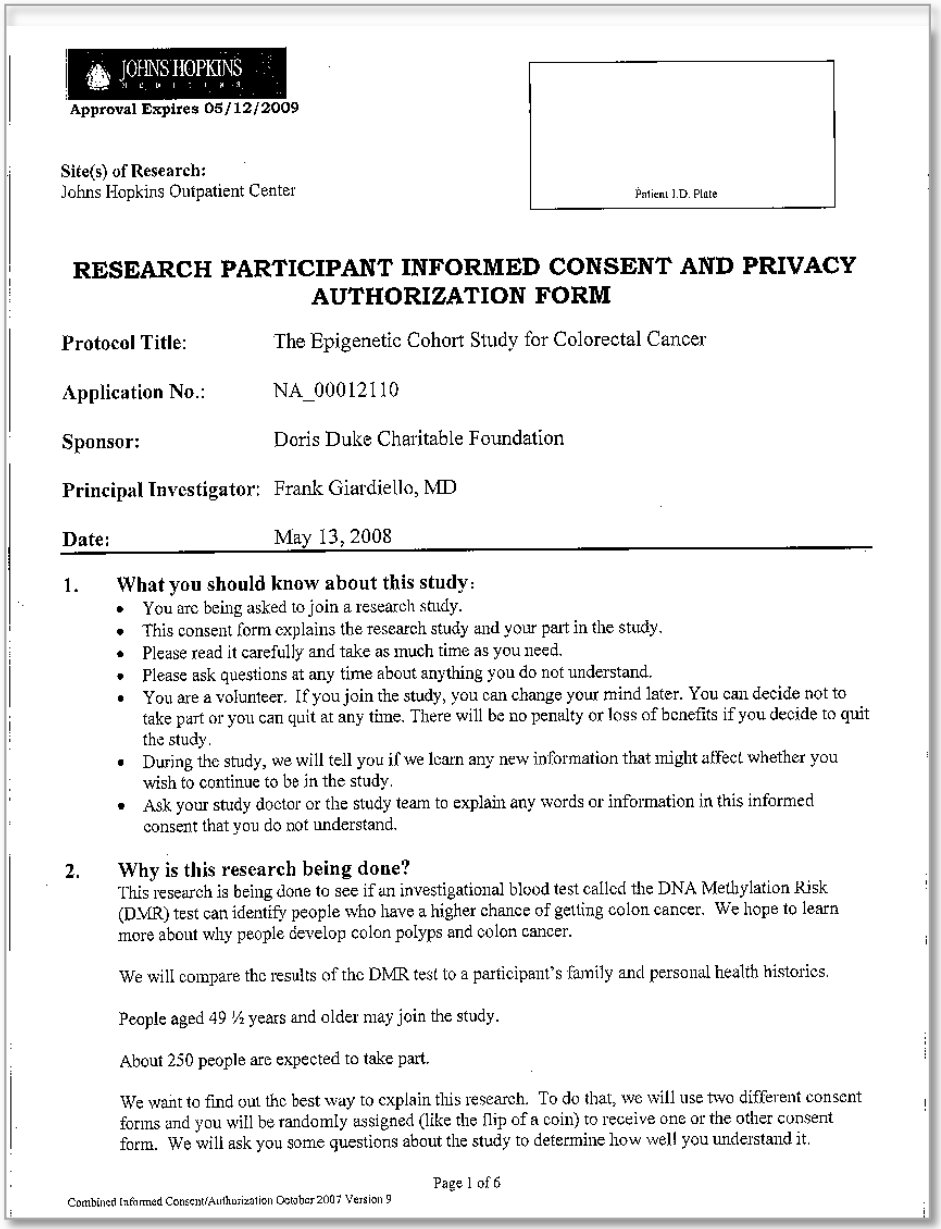


  - Why it is included in study?
    - Want to find out if the real medicine works like they hope it does. Need to compare people who get the real medicine to those don't to see if the medicine works.

Form: Readability

- Readability
  - Format
    - 12-point font; sans serif font (Arial)
    - 50:50 white space
    - Question or meaningful topic sentence headings (e.g., “This research will compare three drugs for pulmonary hypertension”)
    - Use of lists, diagrams, and graphics, as appropriate

Form: Readability



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Approval Expires 05/12/2009

Site(s) of Research:
Johns Hopkins Outpatient Center

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The Epigenetic Cohort Study for Colorectal Cancer

Application No.: NA_00012110

Sponsor: Doris Duke Charitable Foundation

Principal Investigator: Frank Giardiello, MD

Date: May 13, 2008

1. **What you should know about this study:**
   - You are being asked to join a research study.
   - This consent form explains the research study and your part in the study.
   - Please read it carefully and take as much time as you need.
   - Please ask questions at any time about anything you do not understand.
   - You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
   - During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
   - Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

2. **Why is this research being done?**
   This research is being done to see if an investigational blood test called the DNA Methylation Risk (DMR) test can identify people who have a higher chance of getting colon cancer. We hope to learn more about why people develop colon polyps and colon cancer.

   We will compare the results of the DMR test to a participant's family and personal health histories.

   People aged 49 ½ years and older may join the study.

   About 250 people are expected to take part.

   We want to find out the best way to explain this research. To do that, we will use two different consent forms and you will be randomly assigned (like the flip of a coin) to receive one or the other consent form. We will ask you some questions about the study to determine how well you understand it.

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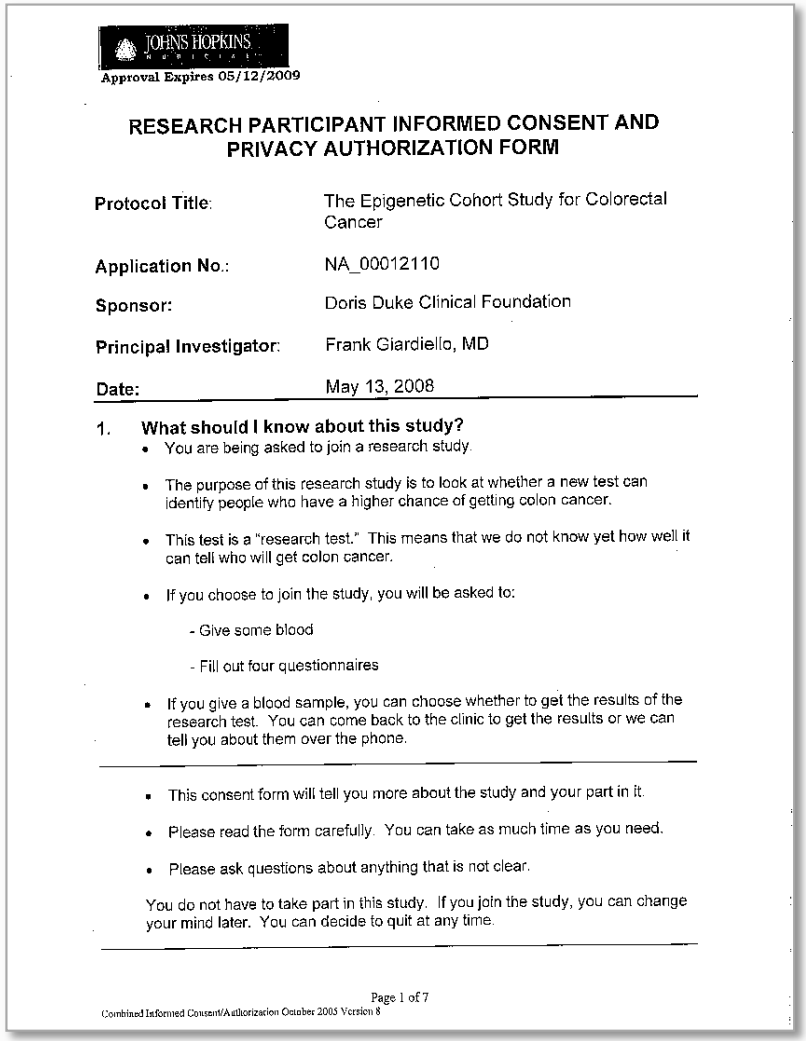
Combined Informed Consent/Authorization October 2007 Version 9



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Approval Expires 05/12/2009

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The Epigenetic Cohort Study for Colorectal Cancer

Application No.: NA_00012110

Sponsor: Doris Duke Clinical Foundation

Principal Investigator: Frank Giardiello, MD

Date: May 13, 2008

1. **What should I know about this study?**
   - You are being asked to join a research study.
   - The purpose of this research study is to look at whether a new test can identify people who have a higher chance of getting colon cancer.
   - This test is a "research test." This means that we do not know yet how well it can tell who will get colon cancer.
   - If you choose to join the study, you will be asked to:
     - Give some blood
     - Fill out four questionnaires
   - If you give a blood sample, you can choose whether to get the results of the research test. You can come back to the clinic to get the results or we can tell you about them over the phone.

   - This consent form will tell you more about the study and your part in it.
   - Please read the form carefully. You can take as much time as you need.
   - Please ask questions about anything that is not clear.

   You do not have to take part in this study. If you join the study, you can change your mind later. You can decide to quit at any time.

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Form: Readability

- Readability
  - Review with potential subject(s)