Overview of the Changes to Informed Consent in the Revised Common Rule

Jaime O. Hernandez, J.D., M.Be.
Office for Human Research Protection
Department of Health and Human Services

OHRP Office for Human Research Protections

1

Regulatory Requirement for Informed Consent

No investigator may involve a human being as a subject in research…unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

§46.116

Must be obtained and documented before beginning research procedures (unless waived)

OHRP Office for Human Research Protections

2

What's New in Informed Consent

- Definitional changes and Clarifications
- General Improvements to Informed Consent (including posting of consent forms)
- Changes to the Basic and Additional Elements of Informed Consent
- Broad Consent

OHRP Office for Human Research Protections

3

DEFINITIONAL CHANGES AND CLARIFICATIONS

OHRP Office for Human Research Protections

4

Legally Effective Informed Consent

Who is the human subject?

- Living individual about whom an investigator obtains:
  1. Data through intervention or interaction with the individual, or
  2. Identifiable private information §46.102(f)
- Clarifying changes in Revised Common Rule

Who provides consent?

- Subject or legally authorized representative (LAR)
  - LAR determined by state or local laws
  - Parental permission/child assent
- Modified definition in Revised Common Rule

OHRP Office for Human Research Protections

5

Definition of Human Subject in Revised Common Rule

No substantive changes in interpretation

Human subject: a living individual about whom an investigator conducting research

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

§_.102(e)(1)

OHRP Office for Human Research Protections

6

Definition of LAR: Modified in Revised Common Rule

Legally Authorized Representative means an individual or … body authorized under applicable law to consent on behalf of a prospective subject to … participation in the procedure(s) involved in the research.

If there is no applicable law addressing this issue… individual recognized by institutional policy as acceptable for providing consent in the nonresearch context … to the subject's participation in the procedure(s) involved in the research.

§_.102(i)

OHRP Office for Human Research Protections

7

GENERAL IMPROVEMENTS IN INFORMED CONSENT

OHRP Office for Human Research Protections

8

General Improvements (1)

The revised Common Rule explicitly establishes a new standard:

> Provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate

§__.116(a)(4)

OHRP Office for Human Research Protections

9

General Improvements (1)

Reasonable person standard used to determine more specifically what information to include

- Long used for clinical informed consent
- Considered most consistent with ethical principles

§__.116(a)(4)

OHRP Office for Human Research Protections

10

General Improvements (2)

Information presented in *sufficient detail*, and *organized and presented* in a way that facilitates subject's understanding of reasons why one might or might not want to participate

- *Not merely a list of isolated facts*

§__.116(a)(5)(ii)

OHRP Office for Human Research Protections

11

Concise and Focused

That key information must be provided in a *concise and focused* presentation

§__.116(a)(5)(i)

OHRP Office for Human Research Protections

12

General Improvements (3)

There is a new requirement that certain *key information* must be provided *first*

§__.116(a)(5)(i)

OHRP Office for Human Research Protections

13

Why Participate – or *Not*

That *key information* must be about *why one might or might not want to participate*.

§__.116(a)(5)(i)

OHRP Office for Human Research Protections

14

Key Information Provided First

- Key information likely to include:
  - The fact that consent is being sought for research and that participation is voluntary;
  - The purpose of the research and the expected duration of the subject's participation;
  - The reasonably foreseeable risks or discomforts;
  - Any reasonably expected benefits to subjects or others;
  - Appropriate alternatives to participation, if any

OHRP Office for Human Research Protections

15

CHANGES TO THE BASIC AND ADDITIONAL ELEMENTS OF INFORMED CONSENT

OHRP Office for Human Research Protections

16

Basic Elements of Informed Consent

One new element:

- Notice about possible future research use of data stripped of identifiers

§__.116(b)(9)

OHRP Office for Human Research Protections

17

Additional Elements of Informed Consent

New additional elements:

- Notice about possible commercial profit
- Notice about whether clinically relevant research results will be given to subjects
- Notice about whether research might include whole genome sequencing

§__.116(c)(7)-(9)

OHRP Office for Human Research Protections

18

Posting of Consent Forms for Clinical Trials

For clinical trials supported by Federal funding, one IRB-approved consent form used to enroll participants must be posted on publicly available Federal website to be designated

- Form must be posted after recruitment closes, no later than 60 days after the last study visit
- Federal department or agency may permit or require redactions

§__.116(h)

OHRP Office for Human Research Protections

19

Definition of Clinical Trial

A research study in which one or more human subjects are **prospectively assigned** to **one or more interventions** (which may include placebo or other control) to **evaluate the effects of the interventions** on **biomedical or behavioral health-related** outcomes.

§__.116(h)

OHRP Office for Human Research Protections

20

BROAD CONSENT FOR SECONDARY RESEARCH

OHRP Office for Human Research Protections

21

What is Secondary Research?

- Research use of information or biospecimens <u>collected</u> for:
  - Research studies other than the one proposed, **<u>or</u>**
  - Non-research purposes (e.g., clinical care, public health, education)

OHRP Office for Human Research Protections

22

Allowing the Use of Broad Consent for Secondary Research

- **Optional:** An alternative to traditional informed consent or waiver of informed consent
- Applicable to:
  - The storage, maintenance, and secondary research use of **identifiable** private information or **identifiable** biospecimens
  - Collected for either a different research study, or for non-research purposes
- Creates future regulatory flexibilities

OHRP Office for Human Research Protections

23

Applicable to **Identifiable** Private Information or **Identifiable** Biospecimens

Human subject: a living individual about whom an investigator obtains information or biospecimens through intervention or interaction or **obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens**

§_.102(e)(1

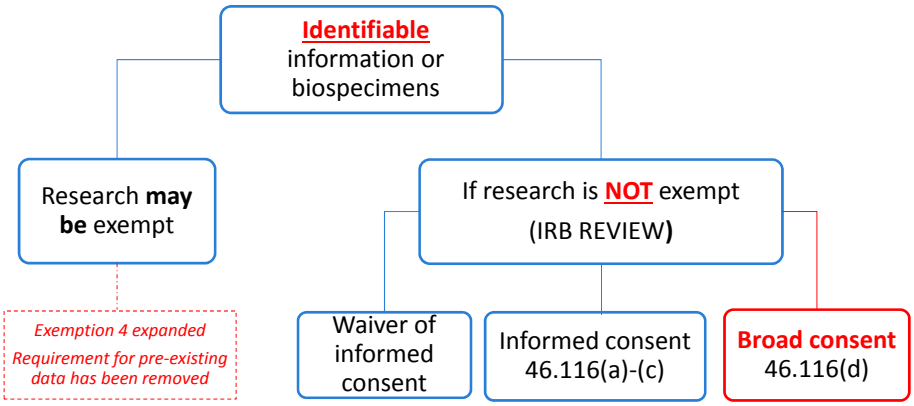
Obtains, uses, studies, analyzes, or generates **UNIDENTIFIABLE** private information or **UNIDENTIFIABLE** biospecimens

NOT HUMAN SUBJECT RESEARCH

OHRP Office for Human Research Protections

24

What are the Options for Secondary Research with **Identifiable** Information or Biospecimens in the Revised Common Rule?



OHRP Office for Human Research Protections

25

Conditions for Waiver or Alteration of Informed Consent for Research with Identifiable Private Information or Identifiable Biospecimens

1. No more than minimal risk;
2. Will not adversely affect the rights and welfare of subjects;
3. Could not practicably be carried out without the waiver; AND
4. Whenever appropriate, the subjects will be debriefed.
5. The IRB must determine that the research could not ***practicably*** be carried out without identifiers

§_.116(f)(3)(iii)

OHRP Office for Human Research Protections

26

Elements of Broad Consent _46.116(d)

- A description of any reasonably foreseeable risks or discomforts and any reasonably expected benefits;
- A description of any privacy and confidentiality protections;
- A statement of voluntary participation;
- A statement that the IPI/IB may be used for commercial profit;
- Whether the research include whole genome sequencing;
- A description of the types of research that may be conducted;

OHRP Office for Human Research Protections

27

Elements of Broad Consent _46.116(d), *Cont.*

- The type of IPI/IB that might be used in such research;
- The period of time that the IPI/IB may be stored, maintained, and used for research;
- A statement that subjects will not be informed of the details of any specific future research;
- A statement that individual and clinically relevant research results may not be disclosed to the subject;
- Whom to contact regarding the subject's rights, the storage and research use their IPI/IB, and in the event of a research-related harm.

OHRP Office for Human Research Protections

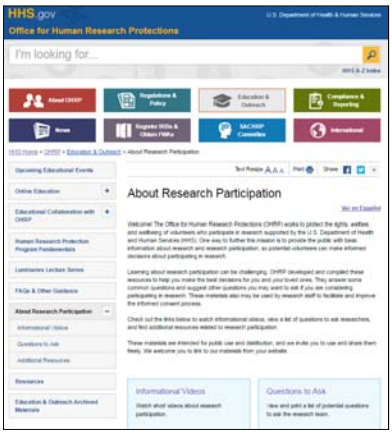
28

OHRP PUBLIC OUTREACH

OHRP Office for Human Research Protections

29

Facilitating Informed Consent: New Resource from OHRP

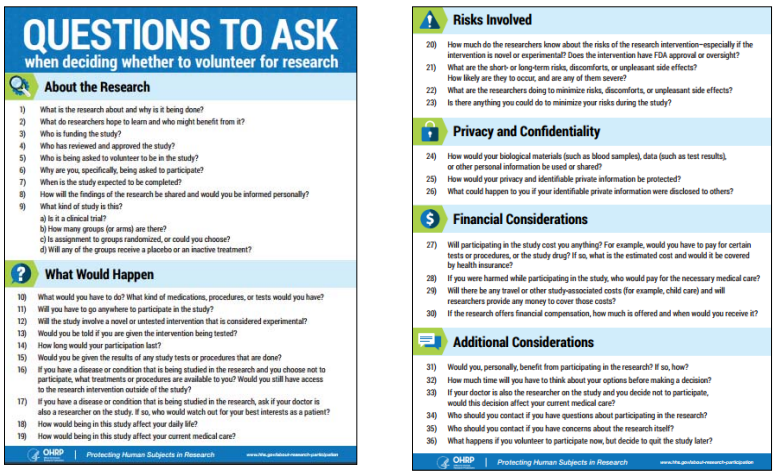


https://www.hhs.gov/about-research-participation

OHRP Office for Human Research Protections

30

Facilitating Informed Consent: New Resource from OHRP



QUESTIONS TO ASK
when deciding whether to volunteer for research

About the Research

1) What is the research about and why is it being done?
2) What do researchers hope to learn and who might benefit from it?
3) Who is funding the study?
4) Who has reviewed and approved the study?
5) Who is being asked to volunteer to be in the study?
6) Why are you, specifically, being asked to participate?
7) When is the study expected to be completed?
8) How will the findings of the research be shared and would you be informed personally?
9) What kind of study is this?
   a) Is it a clinical trial?
   b) How many groups (or arms) are there?
   c) Is assignment to groups randomized, or could you choose?
   d) Will any of the groups receive a placebo or an inactive treatment?

What Would Happen

10) What would you have to do? What kind of medications, procedures, or tests would you have?
11) Will you have to go anywhere to participate in the study?
12) Will the study involve a novel or untested intervention that is considered experimental?
13) Would you be told if you are given the intervention being tested?
14) How long would your participation last?
15) Would you be given the results of any study tests or procedures that are done?
16) If you have a disease or condition that is being studied in the research and you choose not to participate, what treatments or procedures are available to you? Would you still have access to the research intervention outside of the study?
17) If you have a disease or condition that is being studied in the research, ask if your doctor is also a researcher on the study. If so, who would watch out for your best interests as a patient?
18) How would being in this study affect your daily life?
19) How would being in this study affect your current medical care?

OHRP | Protecting Human Subjects in Research

Risks Involved

20) How much do the researchers know about the risks of the research intervention—especially if the intervention is novel or experimental? Does the intervention have FDA approval or oversight?
21) What are the short- or long-term risks, discomforts, or unpleasant side effects? How likely are they to occur, and are any of them severe?
22) What are the researchers doing to minimize risks, discomforts, or unpleasant side effects?
23) Is there anything you could do to minimize your risks during the study?

Privacy and Confidentiality

24) How would your biological materials (such as blood samples), data (such as test results), or other personal information be used or shared?
25) How would your privacy and identifiable private information be protected?
26) What could happen to you if your identifiable private information were disclosed to others?

Financial Considerations

27) Will participating in the study cost you anything? For example, would you have to pay for certain tests or procedures, or the study drug? If so, what is the estimated cost and would it be covered by health insurance?
28) If you were harmed while participating in the study, who would pay for the necessary medical care?
29) Will there be any travel or other study-associated costs (for example, child care) and will researchers provide any money to cover those costs?
30) If the research offers financial compensation, how much is offered and when would you receive it?

Additional Considerations

31) Would you, personally, benefit from participating in the research? If so, how?
32) How much time will you have to think about your options before making a decision?
33) If your doctor is also the researcher on the study and you decide not to participate, would this decision affect your current medical care?
34) Who should you contact if you have questions about participating in the research?
35) Who should you contact if you have concerns about the research itself?
36) What happens if you volunteer to participate now, but decide to quit the study later?

OHRP | Protecting Human Subjects in Research

https://www.hhs.gov/about-research-participation

OHRP Office for Human Research Protections

31

QUESTIONS?

OHRP Office for Human Research Protections

32

Contact OHRP

- Website: http://www.hhs.gov/ohrp/
- Email: ohrp@hhs.gov
- Phone: (240) 453-6900

  (866) 447-4777
- Join OHRP's ListServ for Event Updates: https://www.hhs.gov/ohrp/news/sign-up-for-announcements/index.html

OHRP Office for Human Research Protections

33