UNIVERSITY of MARYLAND
SCHOOL OF NURSING

Informed Consent in Human Subjects Research

Part 2: Elements of Consent

August 19th, 2021

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Goals

By the end of this seminar, you should have an increased knowledge of:

- Required elements of the long form (standard) consent
- Considerations for certain required elements
- Process of UMB IRB/HRPO consent review

Pop quiz!

Where do the required elements of informed consent in research come from?

A) World Health Organization

B) US Federal Code

C) American Medical Association

Research Consent Related Regulations

- Common Rule

-Federal Law, 45CFR46 subpart A

Elements of consent: 45 CFR § 46.116

- FDA

-Federal Law, 21CFR50 subpart B

Elements of consent: 21 CFR § 50.25

Standard Research Consent Document

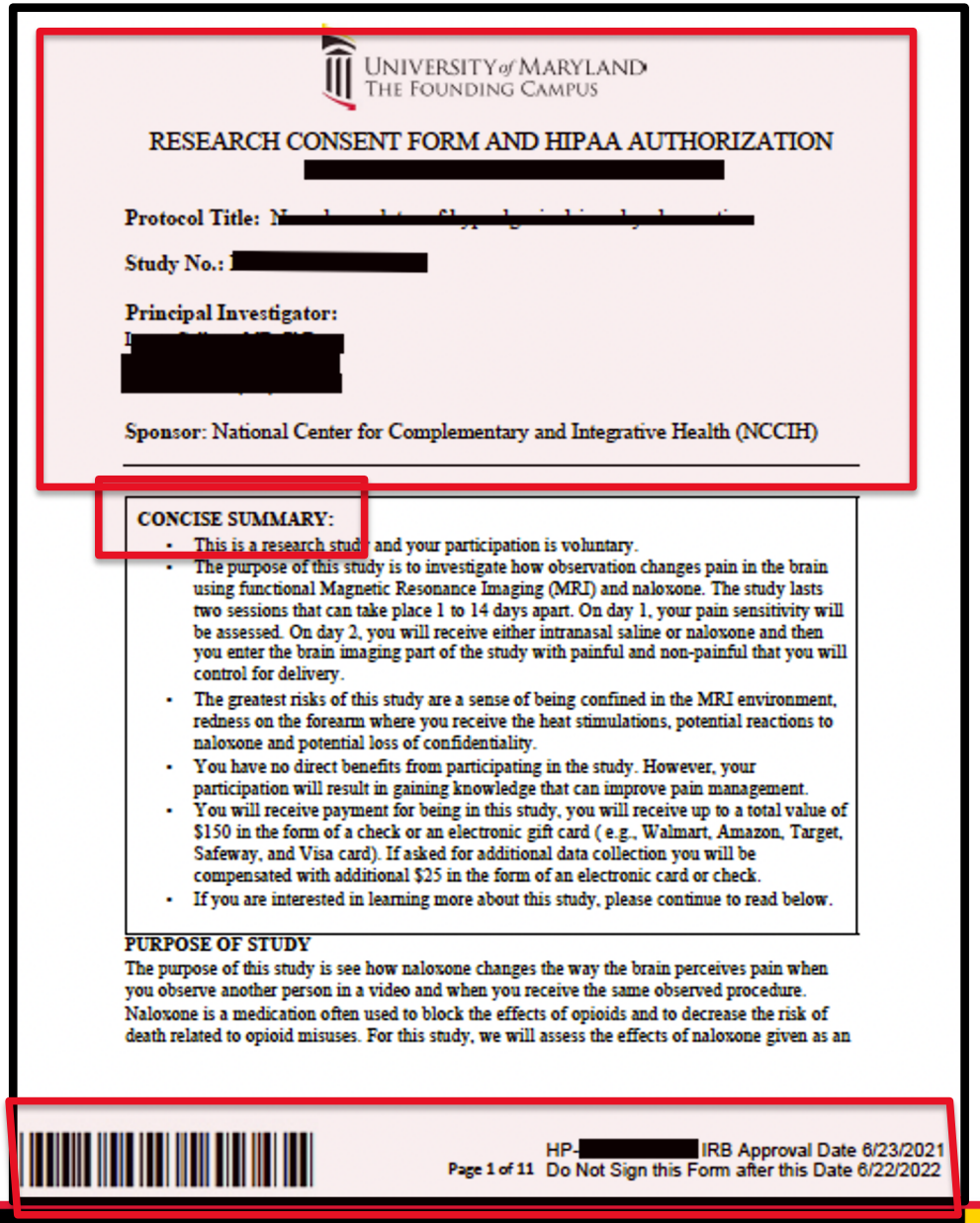
To what does it apply?

All research activities unless they qualify for a waiver

Standard UMB Research Consent Document

What does it look like?

- UMB template
- UMB Header
- Concise summary
- Can be many pages
- Pages should be numbered
- Stamped by HRPO
- ! Version control !



UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

[redacted]

Protocol Title: [redacted]

Study No.: [redacted]

Principal Investigator:
[redacted]

Sponsor: National Center for Complementary and Integrative Health (NCCIH)

CONCISE SUMMARY:

- This is a research study and your participation is voluntary.
- The purpose of this study is to investigate how observation changes pain in the brain using functional Magnetic Resonance Imaging (MRI) and naloxone. The study lasts two sessions that can take place 1 to 14 days apart. On day 1, your pain sensitivity will be assessed. On day 2, you will receive either intranasal saline or naloxone and then you enter the brain imaging part of the study with painful and non-painful that you will control for delivery.
- The greatest risks of this study are a sense of being confined in the MRI environment, redness on the forearm where you receive the heat stimulations, potential reactions to naloxone and potential loss of confidentiality.
- You have no direct benefits from participating in the study. However, your participation will result in gaining knowledge that can improve pain management.
- You will receive payment for being in this study, you will receive up to a total value of $150 in the form of a check or an electronic gift card (e.g., Walmart, Amazon, Target, Safeway, and Visa card). If asked for additional data collection you will be compensated with additional $25 in the form of an electronic card or check.
- If you are interested in learning more about this study, please continue to read below.

PURPOSE OF STUDY

The purpose of this study is see how naloxone changes the way the brain perceives pain when you observe another person in a video and when you receive the same observed procedure. Naloxone is a medication often used to block the effects of opioids and to decrease the risk of death related to opioid misuses. For this study, we will assess the effects of naloxone given as an

https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/

Concise Summary

Key information should:

- State that the project is research
- State that participation is voluntary
- Summarize purpose, duration, procedures, key risks, discomforts, and benefits

Also, (as appropriate):

- summarize costs, payment info, alternatives to joining the research (esp. in treatment studies)

Concise summary should not:

- list isolated facts
- be repeated verbatim elsewhere in the consent

General Requirements of Consent (45CFR46.116)

(1) Investigator must obtain legally effective consent from the subject or their LAR before involving a human subject in research

(2) Investigator must provide sufficient opportunity for participant or their LAR to discuss and consider whether to participate and minimize possibility of coercion or undue influence.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Consent (45CFR46.116)

(3) Study information given to the subject or their LAR must be in a language understandable to them

(4) The prospective subject or their LAR must be given enough information to make an informed decision to participate be provided an opportunity to discuss said information

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Consent (45CFR46.116)

(5) Consent document must begin with a concise summary of key information.

(6) Informed consent cannot include exculpatory language which appears to waive or waives any of the subject's legal rights, or releases or appears to release any research agents from liability for negligence.

Pop quiz!

Which of the following are <u>required</u> elements of consent?

a. Duration of participation

b. Explanation of risks and potential benefits

c. Name of the lawyer to contact if there is a research injury

d. None of the above

Belmont Report: Informed Consent Elements

- **Information**
  Ensure the subject receives all information necessary to make an informed decision
- **Comprehension**
  Provide sufficient opportunity for the participants to answer questions to determine whether to participate in the research
- **Voluntariness**
  The process takes place in a setting that minimizes undue influence and offers sufficient time to consider whether to participate in the study

General Requirements of Informed Consent Document (45CFR46.116)

- A statement that the study involves research
- An explanation of the purposes of the research
- The time commitment for participation
- The number of subjects involved in the study

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Informed Consent Document (45CFR46.116)

- A statement that:
  - participation is voluntary,
  - refusal to participate will involve no penalty or loss of entitled benefits
  - the subject may withdraw at any time without penalty or loss of entitled benefits

General Requirements of Informed Consent Document (45CFR46.116)

- A description of the procedures involved
  - Ok to use charts, infographics
  - What is done for research? What is done for standard of care?

- Identify experimental procedures
  - Avoid treatment misconception!

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Informed Consent Document (45CFR46.116)

- A description of foreseeable risks or discomforts

- A statement that the treatment or procedure may involve unforeseeable risks (for example, risks to fetus or women if they become pregnant)

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Informed Consent Document (45CFR46.116)

- A description of any expected benefits to the subject or to others
  - personal
  - societal

- A disclosure of alternative procedures or courses of treatment
  - If none, state as such

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Informed Consent Document (45CFR46.116)

- A statement describing how confidentiality will be maintained

  Examples:

  – *We store all research records in locked cabinets and password protected, encrypted computer files.*

  – *Your name will not be attached to any research data. Instead, we give your name a code number. The master list that links your name to your code number is stored separate from the research data.*

  – *Your name won't appear in any study reports.*

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html
https://www.nhlbi.nih.gov/files/docs/ghchs_readability_toolkit.pdf

General Requirements of Informed Consent Document (45CFR46.116)

- Research, Rights or Injury:
  - Explain whom to contact for study related questions and their rights, and
  - whom to contact in the event of a research-related injury
  - an explanation as to whether any compensation*, and
  - an explanation as to whether any medical treatments are available, if injury occurs* and,
  - if so, what they consist of, or where further information may be obtained*

** For research that is greater than minimal risk*

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

General Requirements of Informed Consent Document (45CFR46.116)

- Anticipated circumstances under which the subject's may be withdrawn by the investigator without subject's consent
  - Avoid stating that this will never happen
- Consequences of subject's withdraw from the research
- Procedures for orderly withdraw
  - Explain what this will look like and how you will communicate to the subject

General Requirements of Informed Consent Document (45CFR46.116)

- Any costs to the subject that may result from joining the study
  - Some may not be obvious (time away from home, gas/transportation, missed work, etc.)

- A statement that significant new findings will be communicated to the participant if the findings could affect their willingness to stay in the study

2018 common rule additional elements

General Requirements of Informed Consent Document (45CFR46.116)

If applicable, must state that information or biospecimens collected for the research may have identifiers removed and be used in outside/future unrelated/related research

2018 common rule additional elements

General Requirements of Informed Consent Document (45CFR46.116)

Notices *(where applicable)*

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

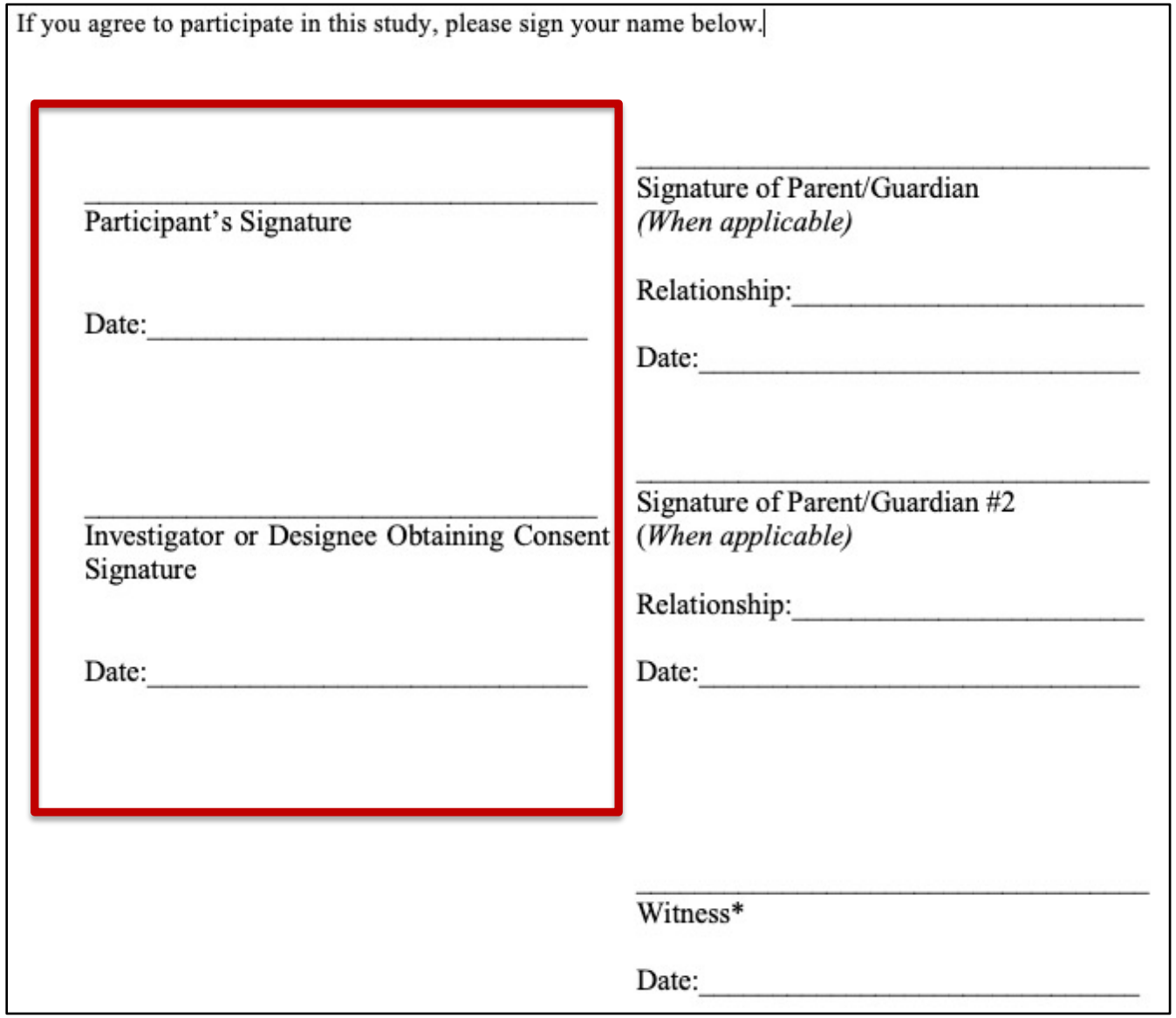
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

Consent Signature

Signature line for:

- Participant
- PI/designee
- Witness, LAR, parent/guardian

(when applicable)



If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

_____
Signature of Parent/Guardian
(When applicable)

Relationship:_____

Date:_____

_____
Signature of Parent/Guardian #2
(When applicable)

Relationship:_____

Date:_____

_____
Witness*

Date:_____

IRB Consent Review: Operations at UMB

- Submit in CICERO Informed consent form section for review
  - ✓Departmental reviewer
  - ✓IRB/HRPO administrative review
  - ✓IRB/ HRPO regulatory review

- Approved by IRB
  - ✓HRPO stamps IRB approved consents (version control by PI essential!)
  - ✓Stamped consent uploaded in CICERO along with IRB approval letter

Stay Tuned for Further Research Seminars!

Why should we care about protecting human research participants and how can we do it well?

September 16th, 2021

12:00pm – 1:00pm

Informed Consent in Human Subjects Research Part 3

October 21st, 2021

12:00pm – 1:00pm

Resources

UMB HRPO Consent Form Templates

https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/

Belmont Report

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

45CFR46

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

Questions?