UNIVERSITY of MARYLAND
SCHOOL OF NURSING

Informed Consent in Human Subjects Research

Part 1: History, application, and process

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Goals

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

-Historical events regarding consent/non-consent

-Informed consent considerations

-Determining the need for informed consent

-Informed consent processes and applications

Warm Up!

Why is consent important?

Why is there a consent process in research?

Belmont Report

-Research vs. Standard of Care

-Ethics

- Respect for persons (individual choice)
- Beneficence
- Justice

-Applications

- Informed Consent (respect for persons)
- Risk vs Benefit (beneficence)
- Subject Selection (justice)

Benefits to consent process in research

Public trust/investment in science

Informed decision

- Participant buy-in, excited to contribute to science, reduce "lost-to-follow-up"

Autonomy; self-determination

- Upholding respect for persons

History Lesson!

U.S. Public Health Service Syphilis Study (1932-1972)

Tuskegee Institute, Alabama

- Ethical issues:
  - Withholding treatment, once available (in 1943), to study disease progression
  - **No informed consent or full disclosure (told participants they had “bad blood”)**
  - Coercion (participation in exchange for free food, burial insurance, medical screening)
  - Risks outweighed benefits (weak study results)
  - Justice (inequitable subject selection)

Adversely affected African American/Black trust in research, medicine, and government

History Lesson!

Henrietta Lacks (1951-current)

Johns Hopkins, Baltimore

Ethical issues:

- Autonomy, respect for persons- privacy, patient rights
- **No informed consent**
- No disclosure around potential for widespread sample sharing

Adversely affected African American/Black trust in research; community trust in research

https://en.wikipedia.org/wiki/Henrietta_Lacks

History Lesson!

Baltimore Lead Paint Study (1993-1995)

Johns Hopkins Kennedy Krieger Institute, Maryland

- Ethical issues:
  - Failure to protect vulnerable population (economically disadvantaged, pediatric)
  - **Consent Document failed to disclose full information about foreseeable harm**
  - Coercion (incentivized moving into homes with lead paint)

Adversely affected trust in community, pediatric research

History Lesson!

Havasupai Tribe (1990's) Arizona State University, Arizona

Ethical issues:

- **Lack of consent; deviation from described intent**
- Lack of consideration for cultural impact of study results

Adversely affected minority group/community trust in research and outsiders

Regulations

- Common Rule

-Federal law, 45CFR46 subpart A

- GCP 4.8

-International guidance, ICH

Consent Process

- From pre-enrollment through the end of the study
- Investigator should always document the *process*
- Documentation
  - Consent with Signature (long form)
  - Waiver of Documentation of Consent
  - Waiver of Consent

Consent with Signature
(Participant, PI/Designee)

Full form

- Applies to:
  - GTMR and MR Expedited research
- Appearance:
  - Long form
  - Signature line for participant, PI/designee, witness/LAR when applicable
- Considerations:
  - Lay language (8th grade level), cultural sensitivity, avoid information overload, must use UMB template*, etc.

**exemptions under special circumstances*

Consent with Participant Signature

Legally Authorized Representative (LAR)

- Applies to:
  - GTMR and MR Expedited research with disabled/cognitively impaired participants
- Appearance:
  - Additional signature line on long form consent document
- Considerations:
  - Legalities, assurance of understanding
- Examples of LAR

Consent with Participant Signature

Assent

- Applies to:
  - Children (Pediatric research)
  - Cognitively impaired (any human subjects research)
- Appearance:
  - Shorter than long form
  - Signature
- Considerations:
  - Age-appropriate language, cultural sensitivity, avoid patronizing, etc.

Consent with Participant Signature

HIPAA

- Applies to:
  - HIPAA covered entities; access to HIPAA covered data
- Appearance:
  - Short, included at end of UMB template
  - Signature
- Considerations:
  - No editing of institutional language
  - Only remove from consent if HIPAA does not apply

Consent with Participant Signature

Short Forms

- Applies to non-targeted populations who may be:
  - Illiterate/visually disabled
  - non-English speaking
- Appearance:
  - Short (summary of long form)
  - Signature (PI/designee, participant, AND witness)
- Considerations:
  - Still requires IRB approval
  - Translation (if appropriate)

Waiver of Documentation of Consent

- Removes requirement to obtain signature
- IRB approved consent form/information sheet/script required
- Applies to :
  - Studies where the consent is the only documentation of participant identifiers, and the major risk is a breach of confidentiality
  - Minimal risk studies whose activities only involve procedures that do not require written permission

Information Sheet

Information Sheet (if applicable)

- Applies to:
  - SON exempt studies (studies that meet one of the DHHS exemption criteria (chart reviews with identifiable data, non-sensitive survey/interview studies, etc.))
  - Studies where IRB grants waiver of documentation of consent
- Appearance:
  - Short, typically 1 page
  - No signature required
- Considerations:
  - Must contain certain elements of consent document
  - Study team documentation of consent process still required

Waiver of Consent (No Consent)

Applies to:

- studies that involve no more than **minimal risk** to the subjects AND
- **could not practicably be carried out without the requested waiver** AND
- **will not adversely affect the rights and welfare of the subjects**

Note! HRPO/IRB determines this, not the researcher

Hard Copy vs. Electronic Consent

(where signature is required)

Hard Copy

Expectation to print & sign, provide signed hard copy to participant, maintain documents according to funder, regulatory, and institutional requirements.

Electronic (i.e. RedCap)

Expectation to obtain verifiable electronic signature, provide signed electronic copy to participant, maintain documents according to funder, regulatory, and institutional requirements.

Note! Must be secure, must have audit trail, may be subject to further regulation (21CFR11), must be approved for use by IRB

Stay Tuned!

Informed Consent in Human Subjects Research Part 2

August 19th, 2021 12:00pm – 1:00pm

Resources

UMB HRPO Consent Form Templates (Long Form, Assent, HIPAA)

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

2018 Common Rule

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

ICH GCP

https://ichgcp.net/4-investigator

Questions?