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

2018 Common Rule

ICH GCP
https://ichgcp.net/4-investigator
Questions?