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# The Informed Consent Process: Ethical and Legal Considerations in Human Subject Research

Philip A. Cola, PhD and Madeleine Williams, MA

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# INTRODUCTIONS

# Today's Presenters

## PHILIP COLA

T 216.368.6932  
E pac4@case.edu

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- + Phil is the designated Chris Winkle Professor of Healthcare Management\*\* and Professor of Management and Associate Professor of Medicine at Case Western Reserve University (CWRU). He has more than 20 years of experience leading research administration in an Academic Medical Center where he was instrumental in designing and developing reliant IRB review mechanisms. Presently, he is also the Director of the Regulatory Knowledge component of the CWRU Clinical Translational Science Award.

## MADELEINE WILLIAMS

T 312.479.3374  
E mwilliams@hcg.com

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- + Maddie is a Senior Director in Huron's Research Enterprise Solutions practice. She has over 25 years of research experience and assists clients with institutional review board (IRB) operational support, regulatory compliance evaluations, human research protection program (HRPP) evaluation and accreditation, and biorepository assessments and infrastructure development.

# Learning Objectives

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1. Learn about the critical components of informed consent, including the process of providing information and the documentation required to ensure fully informed consent.
2. Gain knowledge of the ethical and legal standards necessary for creating comprehensive consent forms and the methods or processes to ensure participant understanding and voluntary participation.

# AGENDA

# Agenda

1. Introductions and Learning Objectives
2. Overview of Informed Consent
3. Ethical Foundations of Informed Consent
4. Elements of Informed Consent
5. Informed Consent Document and Process
6. Case Studies and Examples
7. Conclusions and Questions & Answers

# Overview of Informed Consent Ethical Foundations

**T**HE CONSENT PROCESS...



Don Mayne

# Informed Consent Overview

- Informed consent ensures participants voluntarily agree to participate with full understanding of the study
- Key Principles
  - ❖ **Voluntariness**
  - ❖ **Comprehension**
  - ❖ **Disclosure of all information**
- Intended to protect the rights and welfare of research participants

# Definition of Informed Consent

- Informed consent in human subject research refers to **the process by which a participant is fully informed about the research study**, including its purpose, procedures, potential risks, benefits, and their rights.
- The participant must be provided with sufficient information to make an informed and voluntary decision about whether to participate in the research. This includes clear communication of all relevant details in a way that is **understandable** to the participant, ensuring comprehension.
- Informed consent also involves **documenting the participant's agreement** to participate, typically through a signed consent form, and it upholds ethical principles of respect for autonomy, beneficence, and justice.



# Importance of Informed Consent in Human Subject Research



**Respect for Autonomy:** Ensures participants have the right to make informed choices about their involvement in research.



**Ethical Obligations:** Upholds fundamental ethical principles, including respect for persons, beneficence, and justice.



**Legal Compliance:** Adheres to legal and regulatory requirements governing human subject research (e.g., Common Rule, FDA regulations).



**Voluntary Participation:** Ensures that participation is free from coercion or undue influence, maintaining the integrity of the research process.



**Transparency and Trust:** Builds trust between researchers and participants by fostering openness about the study's purpose and procedures.



**Accountability:** Helps hold researchers accountable for ethical conduct by documenting the consent process.

# Research Ethics Background for the Informed Consent Process

**Nuremberg Code (1948)** “Voluntary nature of informed consent of the human subject is absolutely essential.”

**Declaration of Helsinki (1964)**  
“Human Subject Research protocols must be submitted to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor, or any other kind of undue influence.”

**Tuskegee Syphilis Study (1932-72)**

“US Public Health Service 600 low-income African-American Males completed without the process of informed consent”

**National Research Act (1974)**

“Law enacted in response to public recognition of research misconduct (i.e., Tuskegee Syphilis Study). Requires IRB review and approval.”



# Elements of Informed Consent

# Elements of Informed Consent

- Required by federal regulations (21 CFR 50 for FDA research and 45 CFR 46.116 for DHHS funded research)
- Includes Basic Elements (required) and Additional Elements (as applicable)
- Should begin with presentation of “key information” – focused information that is prospective participants most likely want to know

# Core Elements of Informed Consent

## Study Purpose

- clear explanation of the research objectives and that this is indeed “research”

## Duration of Participation

- expected time commitment for participants total and by “visit or event”

## Procedures

- detailed description of what participants will do during the study

## Risks

- disclosure of any potential risks or discomforts, including physical, psychological, or social risks

# Core Elements of Informed Consent

## Benefits

- description of any potential benefits to the participant or to others

## Confidentiality

- explanation of how the privacy and data confidentiality of participants will be protected

## Voluntary Participation

- statement that the participation is voluntary and that the participants can withdraw at anytime without penalty.

# Core Elements of Informed Consent

## Contacts for Questions

- information on who to contact with questions about the research and the rights of the participants

## Alternatives to Participation

- disclosure of alternative to participating in the study

## Compensation

- disclosure of any compensation or reimbursement or treatment in case of injury is handled (when research is greater than minimal risk)

# The Informed Consent Document and Process

# The Informed Consent Document

- **Purpose** – the document serves as a formal record that ensures participants receive all necessary information about the study, helping them make an informed decision about participation.
- **Documentation**– the document provides documentation of the agreement of participants to be in the study, safeguarding both the rights of the participant and the ethical obligations of the research institution.

# The Informed Consent Document (continued)

- **Tool for Participant Reference** – all participants must receive a copy for their records, many participants will share it with others close to them and refer to it later.
- **Investigator Copy** – investigators or researchers should also maintain an executed copy for their study records.
- **IRB approved version** – when obtaining consent ensure that you are using the current IRB approved version with no crossed-out language or markings not approved by the IRB.

# Waiver of Written Informed Consent

- **Minimal Risk** – the research presents no more than minimal risk and obtaining written consent is impractical (e.g., in emergency situations or when anonymity is crucial) and when waiving consent will not adversely affect the rights and welfare of the participants.
- **Risk of Identification** – the consent form is the only record linking the subject and the research and the principal risk would be the potential harm resulting from a breach of confidentiality.

# Overview of the Informed Consent Process

- Informed consent is more than just obtaining a signature or verbal agreement
- It is a continuous process of education and decision-making that ensures potential participants fully understand the study before agreeing to participate
- Ethical and legal obligations require transparency, respect for persons (autonomy), and comprehension from the participant

# Key Elements of the Informed Consent Process

- **Clear Communication** – provide all necessary information in a way the participant can easily understand, including study purpose, risks, benefits and alternatives
- **Voluntary Participation** – participants must understand that they are free to join or decline without any consequences to their decision
- **Ongoing Process** – informed consent does not end after the participant signs the form or agrees, but rather it is a continuous dialogue throughout the study

# Informed Consent Process Recruitment

- Recruitment is the start of the informed consent process and therefore is a very important component that study staff need to link together in the overall process
- Study staff should ensure that all information shared during recruitment is accurate and aligns with the IRB approved informed consent document and that participants have enough time to decide.
- If subjects are being recruited in group settings (i.e., focus groups or classrooms, etc.) staff must provide a private way for potential participants to ask question or agree to participate and be fully informed.

# Maintaining Informed Consent Throughout the Study

- **Ongoing Communication** - keep participants informed of any new findings, changes to the study, or emerging risks that may affect their participation.
- **Right to Withdraw** - remind participants of their right to withdraw from the study at any time without penalty.
- **Continuous Monitoring** - ensure comprehension and voluntary participation through regular check-ins with participants.

# Ethical and Legal Considerations

- **Cultural Sensitivity** - adapt recruitment and consent discussions to cultural norms and preferences. Consider group or one-on-one settings based on context
- **Privacy** - especially in group settings, ensure private opportunities for participants to ask questions and decide without peer pressure.
- **Compliance with Regulations** - follow ethical guidelines and legal requirements, including IRB/ethics committee approvals and adherence to consent documentation standards.

# Ethical and Legal Considerations

- **Capacity to Provide Consent** – ensuring that an individual has the ability to understand the information in the consent form and be able to make a voluntary and informed decision to participate.
  - Factors such as neurological conditions, situational experiences, medications, etc. may impact an individual’s capacity to provide consent.
  - Research that includes populations that may have diminished capacity to provide consent should include a description of how capacity will be assessed.
  - For those who cannot provide consent for themselves, consent should be obtained from an appropriate legally authorized representative.

# Case Study Examples

# Kanuszewski v. MDHHS

- Every state operates a newborn screening program that takes small blood sample from a newborn's heel to screen for diseases (blood spot screening).
- Often these leftover blood spots are kept for a variety of purposes.
- In Michigan, these leftover dried blood spots could be kept for NBS test QA/QI and for research (if de-identified).
- In 2018, 9 families filed a suit against Michigan Department of Health and Human Services (MDHHS) alleging that MDHHS collected and used the children's blood samples without their parents' consent or knowledge.

# Kanuszewski v. MDHHS (continued)

- Michigan law requires informed consent for all DBS-related conduct (except the initial testing) including storage, transfer, sale, research, and any other use of all DBS, as well as drawing an additional DBS.
  - Michigan law does not apply 45 CFR 46.116's standards of obtaining or waiving consent.
- Consent was signed allowing for DBS to be used for health research, but consent for storage was not explicitly included.

# Kanuszewski v. MDHHS (continued)

- July 2023 - the court found that the record did not show that MDHHS confirmed that the parents understood all aspects of what they were consenting to.
- Court ruled that MDHHS's storage and use of the samples and data violated the parents' Fourteenth Amendment right to direct their children's medical care. The court also ruled that the storage, transfer, and use of the samples and data violated the Fourth Amendment.

# Example Scenario for Discussion

- Scenario: A research study is evaluating the effectiveness of an investigational drug for individuals who have genes that have been linked to Alzheimer's disease and have borderline scores on neurocognitive tests. Study participation is expected to last 5 years.
- What are some considerations when obtaining informed consent from participants for this study?

# Conclusion and Questions and Answers