National Institute of Allergy and Infectious Diseases

HIV/AID Network Coordination webinar series: Electronic Informed Consent (e-Consent) in Practice

E-Consent 101: Regulatory Foundations DAIDS Perspective

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NIAID

National Institute of Allergy and Infectious Diseases

Jui Shah, PhD Branch Chief

Linda Ehler, RN, MN Health Science Policy Analyst

DAIDS/OPCRO/ProPEP

Road Map

- What is “e-Consent”?
- What “rules” apply?
- What are some e-Consent Considerations?
- Resources

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What is “e-Consent”? 1

- “e-Consent” (or eICF) is the use of electronic processes and systems to obtain informed consent.

- Electronic processes and systems can be used to either:
  - Convey study information and/or
  - Document consent (participant, LAR), parental/guardian permission, or assent

- e-ICF may use a single (text) or multiple (text + graphics + video + biometric ID) electronic media types within the same consent

What is “e-Consent”? 2

- Different electronic approaches can be used to supplement or replace paper-based informed consent processes:
  - In-Person eICF: Investigator/staff and potential participant are physically in the same location
  - Remote eICF: Potential participant and investigator/staff are not physically in the same location

What "Rules" Apply? 1

- HHS and FDA regulations permit the use of eICF for obtaining and documenting consent
  - All DAIDS-supported clinical research (HHS): 45 CFR 46.116 and §46.117
  - For studies under an IND/IDE (FDA): 21 CFR 50.25 and §50.27

- NIH, NIAID, and DAIDS' policies and guidance
  - DAIDS' Requirements for Informed Consent Forms policy
  - DAIDS' SCORE Manual - Informed Consent of Participants - Electronic Informed Consent Guidance section
  - DAIDS PRO requirements – Collection of paper ICF regardless of method of consent

What "Rules" Apply? 2

- ICH E6 (R2)
  - Does not specifically mention eICF
  - IC is documented by "written", signed, & dated ICF
- EMA
  - Permits the use of eICF and alternative methods of consent
- All other applicable regs, laws, and policies
  - Most stringent applies

E-Consent Considerations 1

- Must meet all usual ICF process considerations such as ensuring privacy, security, & confidentiality
- Accounting for a potential participant's preferred method for the consent process
- Appropriateness of eICF for the intended study population (ability to comprehend the required information in electronic format)
- Accessibility

E-Consent Considerations 2

- IRB/EC-Related considerations to allow IRB/EC access and review
- Documentation considerations:
  - Maintain version control
  - Archive eICF versions and storage/retention of “signed” eICF
- Planning for unusual consent process situations e.g. witnesses and translators
- HIPAA Authorizations and other data-sharing laws/guidelines

Resources

- OHRP/FDA Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors (12-2016)
- FDA Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors (Draft 7-2014)
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: Guidance for Industry, Investigators, and Institutional Review Boards (3-2020; updated 4-2020)
- NIH Obtaining Consent Using a Remote or Other Alternative Process
- DAIDS Memorandum Use of Alternative/Remote Informed Consent Process during the COVID-19 Pandemic (4-2020)
- DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual (Version 1.0; 1-2021)
- EMA Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic (Version 5; 10/2/2022)
- ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (3-2018)

Questions? Contact the Protection of Participants, Evaluation, and Policy Branch (ProPEP) at: niaidopcropropep@niaid.nih.gov

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Electronic Informed Consent: Regulatory Requirements and Considerations

Jose Pablo Morales, MD
Senior Medical Advisor/Bioethics Consultant
Office of Clinical Policy (OCLiP), Office of Clinical Policy and Programs (OCPP)
US Food and Drug Administration (FDA)

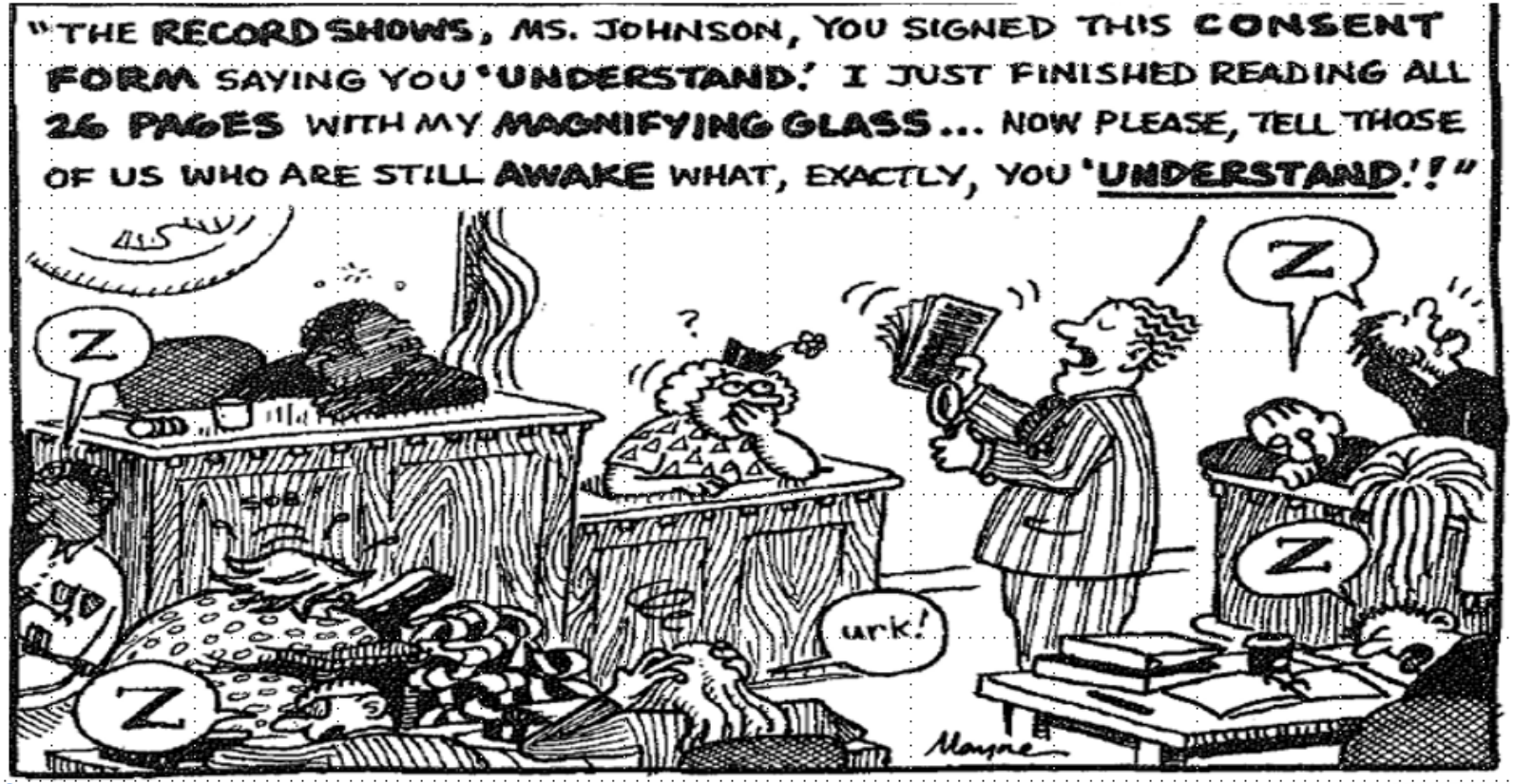
Disclaimer

- This presentation reflects the opinions and views of the speaker and should not necessarily be interpreted as the position of the US FDA
- No official endorsement by the US FDA is intended or should be inferred
- No conflict of interest

Objectives

- Discuss informed consent (IC) and IC process
- Provide a brief history of informed consent
- Introduce the joint OHRP/FDA guidance document regarding use of electronic informed consent (e-consent)
- Review the regulatory framework and recommendations in the e-consent guidance

What is Informed Consent?



What is Informed Consent?

- **Not** just a signature or a document

- An **ongoing <u>process</u>** that must occur before any study-related procedures/tests are conducted

What is Informed Consent?

- A dialogue that includes:
  - An **assessment** of the **participant's comprehension** of the research they are considering
  - **The disclosure of the relevant and adequate information** to research participants and allows for an informed decision about participation in a clinical investigation.

Informed Consent Process

- **Begins** with the potential subject's initial exposure to information about the clinical investigation

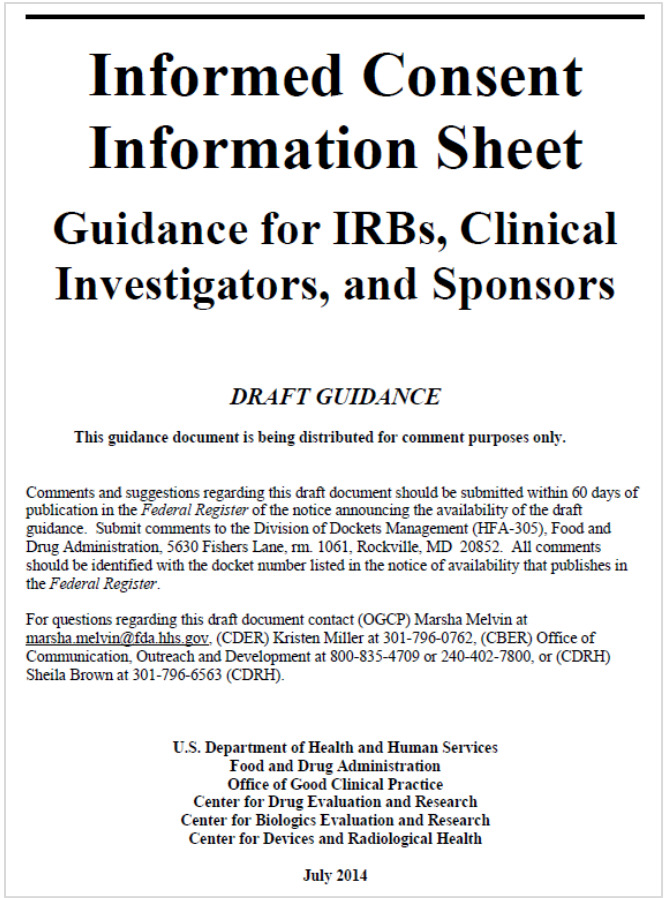
- **Continues** through the completion of the subject's involvement in the study

Informed Consent Process

- Provides the subject with adequate information to allow for an informed decision about participation
- Facilitates the subject's comprehension of the information
- Allows sufficient opportunity for the subject to ask questions and consider whether or not to participate

Informed Consent Information Sheet

[Guidance for IRBs, Clinical Investigators, and Sponsors]



Informed Consent Information Sheet

Guidance for IRBs, Clinical Investigators, and Sponsors

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (OGCP) Marsha Melvin at marsha.melvin@fda.hhs.gov, (CDER) Kristen Miller at 301-796-0762, (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800, or (CDRH) Sheila Brown at 301-796-6563 (CDRH).

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

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Ethical & Regulatory Basis for Human Subjects Research Protections

- **1949 Nuremberg Code - Standards**
  - Certain basic principles must be observed in order to satisfy moral, ethical and legal concepts

- **1964 Declaration of Helsinki**
  - Guidance for medical doctors undertaking biomedical research with human subjects

Ethical & Regulatory Basis for Human Subjects Research Protections

- **1974 National Research Act**
  - signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

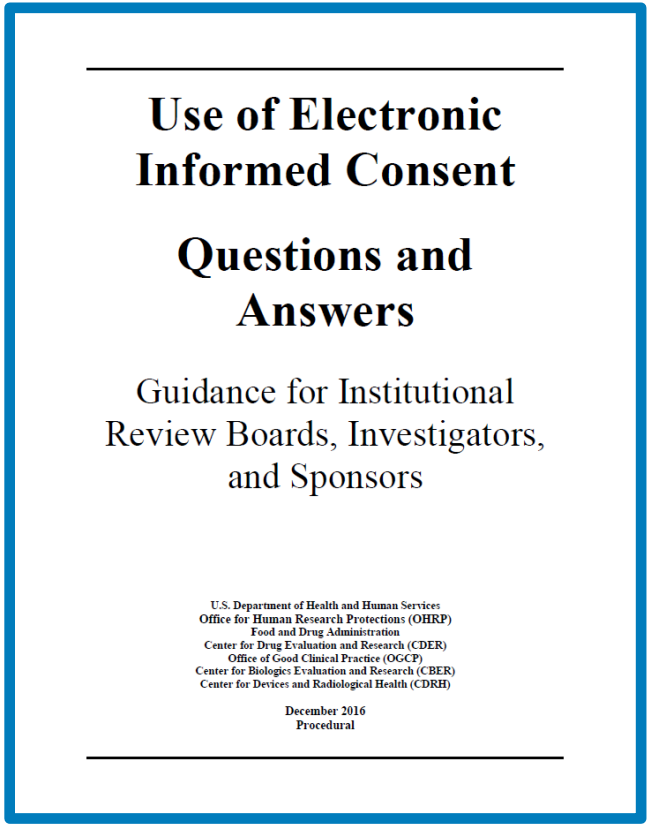
- **1979 The Belmont Report**
  - "…respect for persons demands that subjects enter into the research voluntarily and with adequate information."

FDA Regulations for Human Subjects Research Protections

- **1981:** 21 CFR Part 50 (including Informed Consent Regulations)
- **1981:** 21 CFR Part 56 (Institutional Review Board (IRB) Regulations)
- **2013**: 21 CFR Part 50, Subpart D – Additional Safeguards for Children in Clinical Investigations

Electronic Informed Consent

- Final Guidance published in December 2016
- Joint guidance with OHRP
- Promotes and permits the use of various electronic media (e.g., text, graphics, audio, video, podcasts and interactive Web sites) to obtain and document informed consent



Advantages of Electronic Informed Consent

- May improve study participant's comprehension
- May be obtained on site or remotely
- Offers the opportunity for study participants to review informed consent programs and sign consent in the comfort of their own home
- Allows for investigators/study personnel to interact electronically with study subjects

Potential Benefits for Researchers

- Subjects potentially better informed
- More compliant participants
- Convenience
- Increased capability
- Higher enrollment/recruitment strategies
- Paperless

Electronic Informed Consent Guidance Overview of Recommendations

- Must meet the requirements for required content as per 21 CFR part 50.25
- Must provide opportunity for study participants to ask questions and receive answers to those questions as per 21 CFR 50.20
- Must include a method to ensure that the person signing the consent is the person participating if any or all of the consent process takes place remotely

Electronic Informed Consent Guidance Overview of Recommendations

- Must include some method to verify study subjects identify if signing the informed consent electronically as outlined in 21 CFR 11.100(b)
- Must provide an adequate electronic equivalent of a copy of the informed consent
- Must be secure with restricted access (see 21 CFR 11.10 and 11.30)
- Should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained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