Research with Human Subjects

CWRU School of Dental Medicine

July 17, 2019

Case Western Reserve University EST. 1826
think beyond the possible℠

Institutional Review Board

- An independent group that is charged with reviewing research to ensure that human subjects' rights and welfare are adequately protected.
  - Scientists
  - Non-scientists
  - Community/non-affiliated representative

Research

- Systematic investigation
  (includes research development, testing and evaluation)

- Designed to develop or contribute to generalizable knowledge

Human Subject

- Living individual
- About whom an investigator conducting research obtains **either**:
  - Data through intervention or interaction with the individual **OR**
  - Identifiable private information

Human Subjects Research

- First, has to be research
- Then, has to meet the definition for human subjects
- In that order

How Research Affects You

- Commission on Dental Accreditation (CODA)
  - Research
- Before conducting research:
  - Publish manuscript
  - Create poster

Criteria for Conducting HSR

- Engaged in human subjects research:
  - Listed as Key Personnel on an federal grant
  - Co-investigator on a CWRU IRB protocol
  - Obtaining informed consent
  - Collecting identifiable data
  - Working with identifiable information

Oversight of Local IRBs

- HHS- Office for Human Research Protection (OHRP)
- Human Subjects Regulations
  - 45 CFR 46
  - Code of Federal Regulation
  - Revised Common Rule
- Federal Drug Administration (FDA)

Common Rule: 45 CFR 46

- Heavily Influenced by Belmont Report:
- Three Principles
  - Respect for Persons
  - Beneficence
  - Justice

Belmont Report

- Respect for Persons
  - Informed consent
  - Protection of vulnerable populations
- Beneficence
  - Risk/benefit analysis
- Justice
  - Equitable selection of subjects

Criteria for IRB Approval

- Risks Minimized
- Risk-Benefit Ratio Reasonable
- Equitable Selection of Subjects
- Privacy / Confidentiality
- Data Safety Monitoring
- Informed Consent Sought
- Informed Consent Documented
- Additional Protections for “Vulnerable Populations”

IRB Purposes & Responsibilities

- Identify Risks
  - Physical Harms
  - Psychological Harms
  - Social and Economic Harms
- Determine that risks are minimized
- Determine that “risks to subjects are reasonable in relation to anticipated benefits”

Types of Reviews

- Exempt (45 CFR 46.101b)
- Expedited (45 CFR 46.110)
- Full Board

Before submitting to the IRB

- Access SpartaIRB
- Complete Smart form- Few questions that give overview of protocol
- Choose Protocol Template
- Required Chair/Departmental sign-off

Informed Consent

- Informed consent is an ongoing PROCESS
  - Begins with Recruitment
- Consent process should empower potential participants
- Risks should be explained in terms that the participants can relate to - everyday life experiences

Before approval of protocol

- The Continuing Research Education Credit Program (CREC) is CWRU's method of certifying that individuals are trained to conduct human subjects research.
  - Complete Education Requirements http://case.edu/research/faculty-staff/education/crec/

Before approval of protocol

- Submit Financial Conflict of Interest Disclosure http://case.edu/research/faculty-staff/compliance/coi/

Active Protocol Requirements

- Modification Requests
  - Submit prior to implementing any change
  - Currently active and exempt studies
- Continuing Review
  - Full Board IRB risk protocols

Active Protocol Requirements

- Adverse Events
- Unanticipated Problems
- Protocol Deviations

- Required reporting of events to the CWRU IRB in a timely manner

Revised Common Rule

- Reliant/Single IRB Reviews
- Not Human Subject Research Categories
- Exempt Research Categories

Revised Common Rule

- 46.109 IRB Review
- 46.116 Informed Consent Process
  - Key Information
  - Posting Clinical Trial ICD for federally funded studies
- 46.117 Consent Document- Waivers

Drugs & Devices in Research

- Drug or Device- FDA
- Off label in Research

Chart Reviews

- If accessing medical/dental records

  -and-

  No contact with participant:
  - Waiver of Informed Consent
  - Waiver of HIPAA authorization

Secondary Data Analysis

- Review of existing data for a specific purpose
- If data de-identified = consult IRB office

Database Research

- DHHS/NIH guidance is clear that the creation and maintenance of a database for future research uses is itself a “research” activity and subject to IRB review and approval

- Must meet HIPAA authorization requirements if it involves PHI

Database Research

Data Use Agreements

Database Research

- Purposes:
  - Limitations
  - Liability
  - Publications rights
  - Privacy rights
  - Access

Why bother with a DUA?

- For data coming IN, a DUA is often required by provider
- If sending data OUT, DUAs help define use & control of your data

Office of Research and Technology Management (ORTM) Website

- Data Use Agreements
- Material Transfer Agreements

Important to Remember

- TTO should be involved
- Only CWRU official has signatory authority
- Expiration dates of DUAs
- Current DUAs required to be included in IRB protocol
- IRB application details

Who to consult?

- Faculty member/Advisor
- Mentor
- Principal Investigator
- Institutional Review Board

Presenter

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