DATA HERE, THERE, AND EVERYWHERE (M212)

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DISCLOSURES
CERTIFICATE INFORMATION

• I have no financial disclosures to declare.

• I am not representing the University of Utah Health in this presentation.
OBJECTIVES

1. Describe critical data regulations that study teams and research administrators should be familiar with when working in research settings.

2. Identify ways to securely collect, protect, and share data throughout the research cycle.
REGULATIONS

• RESPONSIBLE CONDUCT OF RESEARCH (RCR)

• GOOD CLINICAL PRACTICE (ICH GCP)

• GENERAL DATA PROTECTION REGULATION (GDPR)
RESPONSIBLE CONDUCT OF RESEARCH (RCR)

- Ownership
- Collection
- Storage
- Sharing

Introduction to the Responsible Conduct of Research

Nicholas H. Steneck
illustrations by David Zinn

2019 ANNUAL MEETING
OCTOBER 19 - 23
RCR – DATA OWNERSHIP

- **GOVERNMENT**
  - Bayh-Dole Act and use of data for public good

- **PRIVATE ENTITIES**
  - Commercial use of data for profit

- **PHILANTROPIC ORGANIZATIONS**
  - Depends on interests of the organization

- **RESEARCH INSTITUTIONS**
  - Institution vs. Investigator
RCR – DATA OWNERSHIP

• CONSIDER DATA SOURCES AND OWNERSHIP

• PUBLICATION RIGHTS

• OBLIGATIONS OF COLLECTING AND STORING COLLECTED DATA
RCR – DATA COLLECTION

ATTENTION TO DETAIL

• Proper set-up
• Record
• Interpretation
• Publication
RCR – DATA COLLECTION

AUTHORIZATION

- HUMAN AND ANIMAL SUBJECTS
- HAZARDOUS MATERIALS AND BIOLOGIC AGENTS
- LIBRARIES, DATABASES, ARCHIVES
- WEB SITES
- PHOTOGRAPHS, ETC.
- COPYRIGHTED OR PATENTED PROCESSES AND/OR MATERIALS
RCR - DATA COLLECTION

- PAPER COLLECTIONS

- ELECTRONIC COLLECTIONS
RCR – DATA PROTECTION

• WHY
  ▪ Confirm research findings
  ▪ Establish priority of research and development
  ▪ Replicate research

• HOW
  ▪ Storage
  ▪ Confidentiality
  ▪ Retention Periods
RCR – DATA PROTECTION

• DATA STORAGE
  ▪ Physical storage of paper documents
  ▪ Electronic storage
  ▪ Samples
  ▪ Catastrophic events

• CONFIDENTIALITY
• RETENTION PERIODS
  - NIH – 3 years following submission of final financial report
  - Other government programs – 7 years
  - Institutional policy
  - Other reasons for possible extended retention?
RCR – DATA SHARING

• PRELIMINARY DATA

• VALIDATED DATA
  ▪ Before publication
  ▪ After publication

• FREEDOM OF INFORMATION ACT (FOIA)

• NIH DATA SHARING PLAN REQUIREMENTS (2003)
  ▪ >$500,000 direct costs in single year
Dr. Marion W. long ago learned that good data management practices are essential to responsible research. She therefore carefully supervises the work of her assistants and students, checking notebooks, backing up computer files, and from time to time verifying results for herself.

As she is wrapping up work on one project before starting another, the technology transfer officer at her university calls. A graduate student who previously worked in her laboratory has moved to another university and filed a patent for work that may have been done in Dr. W.’s laboratory on her research funds? If this is the case, the graduate student may not be able to lay claim to the patent.

What records will Dr. W. need to prove that the work was done in her laboratory?

Who owns and controls the data collected in her laboratory?

Do computer records pose any unique problems in this case?
ICH GOOD CLINICAL PRACTICE (ICH GCP E6)

• International standard
  ▪ European Union, Japan, US mutual acceptance
  ▪ Influenced by EU, Japan, USA, Australia, Canada, Nordic countries, and World Health Organization

• Principles based on Declaration of Helsinki
• Ensure credibility of clinical data
GCP–INVESTIGATOR RESPONSIBILITIES

• SOURCE DOCUMENTS
  ▪ ALCOA – Attributable, Legible, Contemporaneous, Original, Accurate + Complete

• CHANGES AND CORRECTIONS APPROPRIATELY DOCUMENTED

• FINANCIAL DOCUMENTS

• AUDIT AVAILABILITY
GCP – SPONSOR RESPONSIBILITIES

• DATA VERIFICATION
• DATA MONITORING COMMITTEES
• ELECTRONIC SYSTEMS
  ▪ Monitoring of accuracy
  ▪ Validation
  ▪ Audit trails of data changes

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GCP – RECORD RETENTION

• AT LEAST 2 YEARS AFTER MARKETING APPROVAL (AND)
  ▪ No pending/contemplated marketing applications in an ICH region OR
  ▪ At least 2 years since formal discontinuation of investigation of product

• ALL RECORDS MUST BE ACCESSIBLE (DIRECT ACCESS) TO AUDITORS, REGULATORY AUTHORITIES
GCP – ESSENTIAL DOCUMENTS

- BEFORE CLINICAL PHASE OF TRIAL
- DURING CONDUCT OF TRIAL
- AFTER COMPLETION OR TERMINATION OF TRIAL

8.3 During the Clinical Conduct of the Trial
In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Purpose</th>
<th>Located in Files of</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.3.1 INVESTIGATOR’S BROCHURE UPDATES</td>
<td>To document that investigator is informed in a timely manner of relevant information as it becomes available</td>
<td>Investigator/Institution: X</td>
</tr>
</tbody>
</table>
GCP – SHARING DATA

• CONSENT DOCUMENT

• CONTRACT AND GRANT STIPULATIONS

• TECHNOLOGY AND COMMERCIALIZATION OFFICES
GCP - DISCUSSION

What does GCP have to do with Research Administration?
GENERAL DATA PROTECTION REGULATION (GDPR)

- European Union
- Processing by individual, company, or organization of personal data related to individuals.
• Information that is created and used within the EU nations
• Information created within the EU (monitoring behavior of someone in the EU), but company established outside EU
GDPR – PRINCIPLES

• DATA THAT CAN PROCESSED/CONDITIONS

• PURPOSE OF DATA PROCESSING

• AMOUNT OF DATA COLLECTED

• RETENTION OF DATA AND UPDATE

• TRANSPARENCY TO INDIVIDUALS
GDPR – DATA TO PROCESS

• LAWFUL AND TRANSPARENT
• SPECIFIC PURPOSE
• DATA MINIMIZATION
• UP-TO-DATE DATA
• USE OF DATA FOR OTHER PURPOSES
• STORAGE LIMITATION
• SECURITY OF PERSONAL DATA
GDPR – PURPOSE OF DATA PROCESSING

• DATA COLLECTED FOR A SPECIFIC PURPOSE

• OTHER PURPOSES – COMPATIBILITY TEST
  ▪ New purpose must be compatible with original purpose
GDPR – AMOUNT OF DATA COLLECTED

• Adequate

• Relevant

• Limited to what is necessary for the purpose
GDPR – RETENTION AND UPDATE

• RETENTION
  ▪ Shortest time possible
  ▪ Time limits to erase or review should established
  ▪ Exception: public interest, scientific or historical research with appropriate measures (e.g., anonymization, encryption)

• UP-TO-DATE AND ACCURATE
GDPR - TRANSPARENCY

- WHO AND WHY
- CATEGORIES OF PERSONAL DATA
- LEGAL JUSTIFICATION
- HOW LONG DATA RETAINED
- DISCLOSURES, INCLUDING ANY OUTSIDE EU
- RIGHT TO COPY AND BASIC RIGHTS
  - RIGHT TO FILE COMPLAINT
  - RIGHT TO WITHDRAW CONSENT
- AUTOMATED DECISION-MAKING
GDPR - DISCUSSION

• ABC, Corp. established in Los Angeles, CA

• US citizen downloads app offered by US company to keep up on the news while touring Europe

• University of Utah conducts a research study on a particular population in Russia. They use a processor in Canada.

• A Finnish research institute conducts research on a specific population in Russia. The processor is based in the US.
GDPR – TUG OF WAR

CLINICAL TRIALS REGULATION

Image by Darby Browning from Pixabay
GDPR – CTR VS. GDPR

• PROCESSING OPERATIONS RELATED TO RELIABILITY AND SAFETY PURPOSES

• PROCESSING OPERATIONS PURELY RELATED TO RESEARCH ACTIVITIES
  ▪ Explicit consent
    ○ Imbalance between CTR & GDPR
    ○ Withdrawal of consent
  ▪ Public interest
  ▪ Legitimate interest of controller
CURRENT LACK OF CLARITY

- Consent issues
  - GDPR Recital 33 v. imbalance assumptions in GDPR
  - CTR requires consent
    - Participation consent \( \text{CTR}=\downarrow \)
    - Processing consent \( \text{GDPR}=\uparrow \)

- Secondary Use consent
  - CTR less exacting than GDPR

- Legitimate Interest as basis
  - GDPR: balance interests
  - GDPR: Sensitive data requires another basis (public health based in EU law)
REFERENCES

• ORI Introduction to the Responsible to the Responsible Conduct of Research
  https://ori.hhs.gov/sites/default/files/rcrintro.pdf
• E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
  https://www.fda.gov/media/93884/download
• European Data Protection Board
• European Commission Principles of the GDPR
SUMMARY

• RESPONSIBLE CONDUCT OF RESEARCH (RCR)

• GOOD CLINICAL PRACTICE (GCP)

• GENERAL DATA PROTECTION REGULATION (GDPR)
QUESTIONS

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