# Session 4. Mastering Event Reporting  
**Thurs, FEB. 16, 12 – 2 PM (virtual)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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| Adverse Events & Reporting  
  (10 slide max; 15 min each speaker) | 12:00-12:15  **What is a serious adverse event?** - **Bruno Petinaux, MD**  
  12:15-12:30  **Event reporting and the IRB** - **Elissa Malkin, DO, MPH**  
  12:30-12:45  **Event reporting in longitudinal studies** - **Nickie N. Andescavage, MD** |
| Clinical Trial Safety Management  
  (10 slide max; 15 min each speaker) | 12:50-1:05  **Types of safety management plans and processes** - **Robin McGarry, MD**  
  1:05-1:20  **FDA Findings in Clinical Trials** - **Adelaide Robb, MD**  
  1:20-1:35  **What data can you use (or not use) from the EHR** - **Kristen Breslin, MD** |
| 1:40-2:00 Breakouts: Institutional Solutions to Challenges: Lessons Learned  
  (20 min breakout; 2 facilitators per session) | *Emails and discoverability? Who keeps consent forms – paper, “e”, and hybrid? When to involve the IRB? Pharmacovigilance?* |
| *GW: Radwa Aly, MSc; Sarah Ford-Trowell, MPA*  
*CNH: Kristen Breslin, MD; Caitlin Joffe, MBA, CCRP; Marissa Horrigan, PharmD* |
GW Hospital
Adverse Event Reporting in Research
Bruno Petinaux, MD
February 2023
Definitions

The Joint Commission
• Patient Safety event that results in death, permanent harm or severe temporary harm
  • Definition of Harm
    • An event or condition that reaches the individual, resulting in life threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring and/or surgery, invasive procedure, or treatment to resolve the condition.

FDA
• An adverse event is any undesirable experience associated with the use of a medical product in a patient.
GW Hospital

- Protection of Patients
  - Safety
  - Privacy
  - Quality

- Regulatory Compliance

- Medical Staff Bylaws
a. The PI and/or designee is responsible for all training, education, competencies, documentation, reporting, and auditing of research studies.
b. The PI must notify the CMO of any privacy, information security, protocol violations or clinical complications within 24 hours.
c. The PI must notify the CMO of study participants who withdraw their consent while participating in a study while hospitalized at GW Hospital.
d. Should the primary stakeholders (PI or GWUH, sponsor, etc.) become aware of a complaint regarding to research, they should notify the CMO and the CMO will engage the relevant stakeholders to work in addressing the complaint.
e. GWUH will collaborate with all relevant regulatory bodies in the reporting of any complaint as necessary.
GW Hospital – Event Discovery

• Unexpected patient safety event/harm
• Breach in protocol
• Privacy concern
• Medication error
• Safety Culture
GW Hospital – Event Notification

• Safety Team Action Report
  • STAR, Event Reporting
• Email notification to CMO
• Tiger Connect or call to CMO
• Patient Complaint
• Institutional Review Board review
• Audit
GW Hospital – Response
Mobilization

https://medium.com/@TerriPouliot/five-ws-and-one-h-3c9dae7354d
GW Hospital – Response

Safety/Quality

Regulatory

Privacy

https://medium.com/@TerriPouliot/five-ws-and-one-h-3c9dae7354d
GW Hospital – Organizational Learning

• Root Cause Analysis (RCA2)
• Policy/Process
• Action Items
• Education
GW Hospital – Reporting

• Primary: Office of Civil Rights
• Secondary: Collaboration with GWU
Collaboration

• The George Washington Office of Clinical Research (GW OCR)
Event reporting and the IRB

Elissa Malkin, DO, MPH
Clinician, GW Vaccine Research Unit
Assistant Research Professor of Medicine

16 Feb 2023
Objectives

- Understand importance of reporting events to IRB
- Define unanticipated problems
- Define adverse events
- Review reporting to IRB
  - What to report
  - Timelines for reporting
  - How to report

IRB: Institutional Review Board
Clinical studies are reviewed/approved by an IRB before a study starts to “assure the protection of the rights and welfare of the human subjects”*

For approved studies:

• Reporting of AEs & unanticipated problems helps ensure safety of participants in human subject research
• Investigators must promptly report unanticipated problems (events) involving risk to human subjects
• Required by oversight/regulatory agencies

AE: Adverse Event  *US FDA CFR 56.102(g)
Unanticipated problem

Any incident, experience or outcome that meets all of the following criteria*:

1. An **unexpected** (nature, severity or frequency) event given the IRB-approved research protocol & informed consent document and the characteristics of the study population

2. An event **related or possibly related** to participation in the research

3. An event that suggests the research places subjects or others at a **greater risk of harm** than previously known or recognized
   - May be physical, psychological, economic or social harm

*OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)
Examples of unanticipated problems

• Higher than expected volume of adverse events
• Higher than expected volume of protocol deviations
• Higher than expected volume of subject drop-out rates
• Breaches of privacy/confidentiality
• Unauthorized use or disclosure of protected health information (PHI)
• Unresolved subject complaints
• Adverse audit or enforcement actions
• Loss of study records
• Incarceration of a study subject
• Research staff misconduct affecting the research
• Suspension or termination of the research by the sponsor/institution
• Injury sustained by research staff relating to the study
• Suspension of principal investigator’s medical license
• Complaint from a subject involving an unanticipated risk that cannot be resolved by the research staff

Adverse Event

Any untoward occurrence (physical or psychological) in a human subject participating in research

• Includes any abnormal lab finding, sign, symptom or disease associated with the research

  EXAMPLE: An increase in a blood test value after receiving a study drug as compared to that same test done prior to receipt of study drug

• Does not have to have a causal relationship to the research

  EXAMPLE: The increased blood test may be related to a concomitant illness

• Can be unfavorable and unintended
...not all AEs are unanticipated problems

- Only a subset of AEs are required to be reported to the IRB
- Most AEs occurring in human subjects are not unanticipated problems (A)
- A small proportion of AEs are unanticipated problems (B)
- Unanticipated problems also include other incidents/experiences/outcomes that are not AEs (C)

Under 45 CFR part 46: Do not report A; Report B and C.
How to determine if an AE is reportable

1. Is the adverse event unexpected in nature, severity, or frequency?
   - NO
   - YES

2. Is the adverse event related or possibly related to participation in the research?
   - NO
   - YES

3. Does the adverse event suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized? NOTE: If the adverse event is serious, the answer is always □YES.□
   - YES
   - NO

Report the adverse event as an unanticipated problem under 45 CFR part 46

The adverse event is not an unanticipated problem and need not be reported under 45 CFR part 46
Reporting to the IRB

GW IRB:
Promptly Reportable New Information
- Report within 5 business days of knowledge of the event
- Submit a Promptly Reportable Information Form (PRIF) via iRIS

Children’s National IRB:
Reportable New Information
- Report within 7 business days of knowledge of the event
- An unexpected death (related/possibly related) of a Children’s National research subject: report within 1 business day of learning of event
- Submit Reportable New Information (RNI) in IRBear 2.0

GW: https://humanresearch.gwu.edu/problems-and-reportable-events-research
Children’s: https://cnmc.sharepoint.com/sites/research/SitePages/OPHS-IRB.aspx

Research overseen by other IRBs, must follow requirements of that IRB
What to report to the IRB

- Research study title, investigator name, IRB number
- Detailed description of event
  - Date of event; date learned of event; # of subjects affected
- In the case of AE(s), explain the basis for why the event is an unanticipated problem
  - Unexpected/related/increased risk of harm
- Describe any changes to the study (protocol, ICF) or corrective actions
Possible IRB actions

• Require a modification to the research
• Provide additional information to subjects
• Modify informed consent form
• Educational plan
• Require additional monitoring
• Suspend or terminate IRB approval
Thank You
Event Reporting in Longitudinal Studies
Event Reporting: What to Report

- Adverse Events
- Unanticipated Problems
- Protocol Deviations
Plan Ahead
Plan Ahead: Adverse Events
Plan Ahead: Unanticipated Problems
Plan Ahead: Retention
Thank You!
Bootcamp for New Investigators in Clinical Research

Safety Management Plans and Processes

16 Feb 2023
Robin J. McGarry, M.D.
Agenda

• Overview of key concepts underlying data management standards and processes in clinical trials
• High level overview of clinical trial data “management” from planning, collection, ensuring data quality, analysis, and reporting
• Investigator role/responsibilities
Fundamental Concepts of Clinical Trial Safety Data Assessment and Management

• Data management processes are designed to ensure that the data meet quality standards
  – Meet legal/ethical requirements for clinical research
  – Ensure the rights and safety of patients are protected
  – Ensure the integrity, reliability, and accuracy of the results

• Ethical principles of clinical research underly all standards and regulatory requirements applicable to clinical trials\(^1\)
  – Principles have evolved since the Nuremberg Code was drafted in 1947
  – Principles → codified into laws, regulations, guidance documents, and standards
  – Adherence to regulations and ethical responsibilities cannot be thought of as separate requirements.

• ICH E6 (Good Clinical Practice)\(^2\) and ICH E8 (General Considerations for Clinical Trials)\(^3\)
  – Comprehensive “road map” for the implementation of ethical principles
  – “The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.” \(^2\)

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\(^1\) Emanuel, JAMA, 2000
\(^2\) International Council for Harmonisation (ICH) E6(R2), 2018
\(^3\) International Council for Harmonisation (ICH) E8(R1), 2021
Quality by Design

- QbD is a set of principles developed by the Clinical Trials Transformation Initiative (CTTI)
- Recently incorporated into ICH guidelines
- “Quality in clinical trials may be defined as the absence of errors that matter....the likelihood of a successful, quality trial can be dramatically improved through prospective attention to preventing important errors that could undermine the ability to obtain meaningful information from the trial.”¹

¹ CTTI Recommendations: Quality by Design, 2015
Safety Data Interpretation (1)

• Identification of signals
  – Newly identified risks/ “unanticipated problems”
  – In order to protect the safety of patients:
    • Does the protocol need to be revised to add additional monitoring (increased number of visits/lab assessments), data collection, or risk mitigation procedures?
    • Revision of ICF, Investigator’s Brochure, product label?
    • Make investigators/ IRBs aware of new safety signals

• Regulatory reporting of SAEs based on investigator/company causality assessment of SAEs

• Characterization of the safety profile of the product to inform benefit-risk assessment
Safety Data Interpretation (2)

Assessment of individual cases
- Detection of safety signals
- Fulfill regulatory reporting requirements (SUSARs)

Preparation and assessment of aggregate data
- DSMB/adjudication committee data review
- Formal, protocol-specified interim analyses (stopping rules)
- Ongoing data review by Safety Management Teams for signal detection (quarterly/monthly)
- Development Safety Update Reports
- Post-marketing Benefit-Risk Reports
- Briefing books for Health Authority meetings
- Clinical study reports
- Marketing authorization applications (NDA)

NDA = New Drug Application
SUSAR = Suspected Unexpected Serious Adverse Reaction
Planning: Protocol and Statistical Analysis Plan Development

• Critical review of relevant nonclinical/clinical data (product under development/other drugs in class)
• Identification/revision of adverse events of special interest/potential risks (safety topics)
  • Definition
  • How will these AESI be collected?
• Do they need to be reported by investigator to sponsor on an expedited basis (within 24 hours)?

Planning: CRF Design

• Most CRFs for collection of safety variables (AEs, lab data) are standard
• For some AEs, specific CRFs need to be developed
• Fit for purpose – checklist?
• Collect sufficient information to permit assessment of individual cases/aggregate data
## Systems Approach to Clinical Trial Safety Data Assessment and Management (2)

### Planning: Databases/ Monitoring

- CRF annotation
- Configuration of electronic data capture/ clinical and safety databases
- Design of edit checks and standard queries
- Design/configuration of metrics (e.g., investigator queries)
- eCRF Completion Guidelines and Study Manual
- Data Management Plan
- Safety Management Plan/ risk-based monitoring plan

### Training: Safety Data Management/ Monitoring

- Investigators/ study coordinators
- Protocol requirements for safety data reporting/definitions (AEs, labs, SAEs, AESIs)
- CRF completion guidelines
- Responsibilities for query responses
- Contract research organization staff
- Safety elements of the protocol
- Monitoring, source document review, query generation
# Systems Approach to Clinical Trial Safety Data Assessment and Management (3)

## Monitoring During the Study
- Source document verification → Queries
- Edit checks → Queries
- SAE assessment for identification of SUSARs/ expedited reporting to health authorities → Queries
- SAE/ clinical database reconciliation → Queries
- MedDRA coding of adverse events → Queries
- Tracking/metrics reports for investigator performance
  - #Queries/site
  - # Outstanding queries, queries older than [6 mon]

## Post-Study
- Resolution of outstanding queries
- Confirmation of MedDRA coding
- Soft database lock → Review of draft tables/listings
- Generation and resolution of outstanding queries
- Hard database lock → Unblinding → Generation of draft tables/listing
- Programming modifications/ additional analyses
- Production run tables, listings, figures
- Clinical study report generation

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AESI = Adverse Event of Special Interest  
CRF = Case Report Form  
MedDRA = Medical Dictionary for Regulatory Activities  
SUSAR = Suspected Unexpected Serious Adverse Reaction
Investigator Roles/Responsibilities

• Understand the protocol and adhere to protocol requirements for AE reporting
• Oversight of study coordinators
• Timely data entry (especially documentation of AEs)
• Timely, complete, and accurate query resolution
• SAEs
  – Report to sponsor within protocol-specified timelines (24 hours)
  – Report complete information and supplement as new information becomes available
  – In order for the company to assess the event, meet regulatory reporting requirements and determine if the event represents a new safety signal, critical information must be provided:
    • The event must be adequately described - what was the diagnosis?
    • What was the clinical course, outcome?
    • What factors may have contributed to the event?
      **EXPLAIN THE RATIONALE FOR YOUR ASSESSMENT OF CAUSALITY**
  – Investigator: Report unanticipated problems to IRB after receipt of IND Safety Report (SUSAR)

IND = Investigational New Drug
SUSAR = Suspected Unexpected Serious Adverse Reaction
Selected References

CTTI Quality by Design Overview


International Council on Harmonisation. 2018. Good Clinical Practice: Integrated Addendum to ICH E6(R2)


FDA FINDINGS IN CLINICAL TRIALS

Adelaide Robb MD
Distinguished Endowed Professor and Chair
Department of Psychiatry and Behavioral Sciences
Overview

• FDA is designed to monitor and regulate clinical trials
• They conduct inspections (companies conduct audits)
• They can inspect for a number of reasons
  • Drug is pre FDA approval
  • For cause someone called FDA
  • High or low enrolling site
• Common findings and how to avoid them
• Outcomes of FDA Inspection
FDA Role

• The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
FDA Inspection

• Announced or unannounced
• Routine or for-cause
• On studies that are open or closed
• Study-specific or investigator-specific
• Of a single study or multiple studies
FDA Inspection of investigator

- Routine surveillance
- High-enrolling study site
- Coinciding with the review of a marketing application
- Based upon current and ongoing public health issues
- As a result of complaints received
- As a result of reports of non-compliance
- Due to sponsor concerns
- To verify the implementation of corrective actions following a previous inspection
Top 5 FDA Findings

1. Failure to follow investigational plan 51%
2. Inadequate and inaccurate records 33%
3. Inadequate drug accountability 7%
4. Failure to obtain/document subject consent 5%
5. Inadequate consent form 4%
Failure to follow the protocol

• FDA code 21 CFR 312.60
• Missing consent documents
• Failure to perform protocol-required procedures
• Missing documentation of required IRB review of study changes or initial approval

• Solutions
• Keep original of all signed consents in pt binder
• Keep good source documents-use the protocol schedule of events
• Keep a regulatory binder with copies of all IRB submissions, correspondence and approvals as well as sponsor approvals
Inadequate and inaccurate records

• 21 CFR 312.62 failure
• Failure is a missing or incomplete subject record.

• Solution
• Keep progress note and document in source documentation everything that happens
• IF IT IS NOT WRITTEN DOWN IT NEVER HAPPENED
Inadequate drug accountability

• 21 CFR 312.62
• Specifically with the record keeping of drugs used in research.
• Absence or inadequacy of records on receipts, preparation, use, and/or disposition of the investigational drug/product

• Solution
• Use the study +/- or pharmacy record keeping
• Ensure research pharmacy keeps storage and temperature logs
• Log in all samples
• Take xerox of medication at dispensation and return
Failure to obtain/document subject consent

- 21 CFR 312.62 problem
- Missing consent documents or omission of a description of required elements when obtaining consent.

Solution

- Again IRB and companies have templates that include the FDA needs and local needs for a consent document; most here also include HIPAA elements
Inadequate consent form

• 21 CFR 50.25 failure
• Communication about withdrawal and refusal to participate
• Right to refuse to participate in any aspect of the study and missing documentation that shows that subjects were informed of their right to withdraw without penalty

• Solution
• Ensure that is part of the consent form and that medical record, study record and patient have a copy of the form
Surviving and Outcomes

- If FDA calls contact sponsor, legal/risk and IRB immediately
- Review all records especially regarding top 5
- Make sure things are easy to find and navigate
- Ask for notice of inspection on arrival
- Copy everything they ask you for
- Review findings with inspector before leaving
- No action indicated (not mean no findings)
- 483 requires a response and plan of action
QUESTIONS?
Consent documentation

Informed Consent/Audit Worksheet
Psychiatric Clinical Trials
Children’s National Medical Center

Full Study Title: Informed Consent: LC36-AD-14: A Double-blind, Placebo- and Active-controlled Evaluation of the Safety and Efficacy of Levonorgestrel ER in Pediatric Patients: 7-12 Years With Major Depressive Disorder

DOB Protocol Number: 1111111111111
DOB Approval Date: 11/11/2011
DOB Exploration Date: 11/11/2011

Details of Contacting Process:

ACP-103-069: A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Pimavanserin for the Treatment of Irritability Associated With Autism Spectrum Disorder Disorder

DATE: _______    SUBJECT INITIALS: _______    SUBJECT NUMBER: _______

SCREENING VISIT 1

- Informed consent/Assent
- Inclusion/Exclusion criteria
- Medical Hx and demographics
- Autism disease Hx
- HBV, HCV and HIV history
- Covid-19 Hx
- ADI-R
- MINI-KID
- Swallow test
- AEs
- ConMeds
- Syncope Hx
- Somnolence Hx
- Medication Hx
- Physical Exam
- Vital signs
- Height, Weight and BMI
- 12-lead ECG
- ABC
- CGI-S
- RBS-R
- VABS- Socialization
- CGSQ
- C-SSRS
- ESR-A
- Labs (CHEM, Hematology, UA, Urine Drug, Serum Pregnancy, thyroid function)
# Schedule of events

## Panel 2: Study Procedures and Assessments – Open-label Period for *de novo* Patients and Rollover Patients from Study 12709A

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<tr>
<th>Visit Name</th>
<th>Screen&lt;sup&gt;a&lt;/sup&gt; of <em>de novo</em> Efficacy</th>
<th>Screen&lt;sup&gt;b&lt;/sup&gt; of <em>de novo</em></th>
<th>Baseline&lt;sup&gt;a&lt;/sup&gt; of <em>de novo</em></th>
<th>Baseline&lt;sup&gt;b&lt;/sup&gt; of rollover</th>
<th>Baseline&lt;sup&gt;c&lt;/sup&gt; of 12709A</th>
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### Screening and Baseline Procedures and Assessments

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### Efficacy Assessments

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### Pharmacokinetic Assessments

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### Safety Assessments

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<th>Baseline&lt;sup&gt;c&lt;/sup&gt;</th>
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What data can I use from the EMR?

Kristen Breslin, MD, MPH
Chair, Children’s National IRB
Division of Emergency Medicine
Secondary Use of Data

Use of data collected for non-research purposes

• Clinical purposes – EMR
• Service purposes – Press Ganey
• Business purposes – Billing
• Education purposes – Test scores
Electronic Health Record Advantages

- Data collected for clinical purposes
- Ordered by the clinical team when clinically indicated
- Paid for by insurance or billed to the individual
- Risk of accessing the EHR primarily breach of confidentiality
- Risks of clinically indicated procedures and tests to collect information from the medical record are not part of research
Regulations – HHS Common Rule

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention,
OR
Identifiable private information is used/studied/analyzed/generated
(Revised) Common Rule

Research must
- Minimize risks to participants
- Favorable risk/benefit
- Equitable selection of subjects
- Informed consent
- Data & safety monitoring
- Privacy & confidentiality protections
- Safeguards for vulnerable subjects (assent)

Pitfalls in Secondary Use
- Secondary use for inclusion criteria may impact selection of subjects
- Adequate confidentiality protection
- Disclosure of access in consent form or justification for waiver of consent
Timing of Secondary Use

• Data created prior to the trial
  • May be unethical to repeat testing purely for research purposes, but ok to use results already available
  • May need HIPAA authorization or release of medical records form

• Data created during the trial
  • Billing insurance for research tests is medical fraud
  • Coverage Analysis as evidence testing is clinically indicated
  • Data that may impact study retention must be disclosed

• Data created after the trial
  • Must include in consent form the duration of access to EHR
Research Procedure vs Standard of Care

Research
• Intends to address a question with volunteers
• Intent to help future patients
• Uncertain benefit to patient
• Oversight by IRB

Standard of care
• Intends to address an individual’s health needs
• Intent to help the patient
• New knowledge is incidental
• Oversight by state boards
Non-identifiable Private Information

If you are opening the EHR, you are viewing/accessing/using IDENTIFIABLE private information

Doc Fired for Accessing Medical Records of Women He Wanted to Date
— Artificial intelligence software alerted hospital to unusual activity

Private Practice Revises Policies and Procedures Addressing Activities Preparatory to Research
Covered Entity: Private Practice
Issue: Impermissible Disclosure-Research

Outpatient Surgical Facility Corrects Privacy Procedure in Research Recruitment
Covered Entity: Outpatient Facility
Issue: Impermissible Uses and Disclosures

EXCLUSIVE: Dozens Of Northwestern Hospital Workers May Have Been Fired For Improperly Reviewing Jussie Smollett's Records

Hospital Implements New Minimum Necessary Policies for Telephone Messages
Covered Entity: General Hospital
Issue: Minimum Necessary; Confidential Communications
Non-identifiable Private Information

Information downloaded from the medical record that is not identifiable may not be Human Subjects Research

No names, dates, emails, MRNs, account numbers, etc

Children’s National has a RedCap workflow to obtain documentation of non-Human Subjects Research

Usually applies to datasets that are available to the public; use with caution with institutional EHR

If you or the study team can reidentify the data or link it to an individual, it is identifiable
Regulations - HIPAA

Health Insurance Portability and Accountability Act of 1996
• Standardizes confidentiality protections for medical record
• Allows individuals access to their medical records
• Applies to health plans and health providers that conduct electronic health care transactions (billing)
• Applies to medical records up to 50 years after death
• Allows use of information:
  1. for billing, continuity of care, and public health
  2. for research purposes with either direct authorization or a waiver of authorization by a Privacy Board
HIPAA Identifiers

List of PHI (Protected Health Information)

- Names
- Dates
- Addresses / Zip Codes / Geocodes
- Phone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate / License Numbers
- Device Identifiers
- Vehicle Identifiers
- URLs
- IP Addresses
- Biometric Identifiers
- Facial Images
- Any Other Unique Identifiers
Re-Identification

• 1990s Release of health care records of state employees in MA to researchers, including zip code, birth date and gender
• Latanya Sweeney purchased Cambridge voter rolls ($20) and identified health records for Gov. William Weld
• In 2001, she used age, gender and zip code to match anonymous hospital records in Washington state ($50) with newspaper reports, correctly identifying 43% of patients
• In 2006, AOL published “anonymized” user’s search histories
• Bloggers identified 62 year old Thelma Arnold as User 417729
Transmission of Data

Minimize risk by exposing the minimum necessary information

Voicemail, Faxes
- Risk of unintended recipients
- Human error or shared access

Email
- Message encryption
- Attachment encryption
- Vulnerability of commercial emails
- Is patient authorization enough?

Hospital Implements New Minimum Necessary Policies for Telephone Messages
Covered Entity: General Hospital
Issue: Minimum Necessary; Confidential Communications

Physician Revises Faxing Procedures to Safeguard PHI
Covered Entity: Health Care Provider
Issue: Safeguards
Ask for Help

OPHS (IRB)
• [OPHS@childrensnational.org](mailto:OPHS@childrensnational.org)
• Analyst assigned to a protocol
• OPHS Zoom Office Hours

Compliance
• Involved for any HIPAA breach

IT Security
• Policy portal for acceptable use of emails, faxes
• Policy portal on HIPAA-secure data storage