Use of Data from Non-Traditional Sources to Conduct Human Research:

Emerging Ethical and Compliance Considerations

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Disclosure

- No funding
- No COI
- Acknowledgement - Substantial Contribution by:
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  Associate Compliance Officer, Human Subjects Research and Academic Affairs
  Regional Compliance Officer – Norwalk Hospital

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Nuvance Health

- Serving all communities throughout New York's Hudson Valley and Western Connecticut
- Integrated health system of 7 community hospitals, primary care and specialty medical practices, outpatient settings, home care services, skilled nursing and rehabilitation
- 3 Institutes - Heart and Vascular, Cancer, Neuroscience
- Global Health Program spanning 7 countries, Undergraduate Medical Education, Graduate Medical Education Residency Program

Personal ***Imaginative*** ***Connected*** ***Agile***

"Where some see impossible, we choose to see possible."

Nuvance Health

- **Norwalk Hospital**
  - Nuvance Health affiliate, 328 bed, not-for-profit, acute care community teaching hospital
  - Serves a population of 250,000 in lower Fairfield County, Connecticut
  - Recognized for superior hospital quality and specialty clinical quality

2022 America's 100 Best Hospitals Award – Healthgrades
Top 2% of Hospitals in the US for Clinical Quality

What to Expect . . .

- Develop further knowledge about emerging sources of data used in human subjects research
- Develop understanding of emerging ethical and regulatory issues in collection and use of data from non-traditional sources
- Equip Research Compliance Officers to apply the knowledge and understanding gained to strengthen compliance programs and train stakeholders in order to support growing strategic needs within organizations to adopt use of data-driven human research

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Overview

- Section I: A Review of Research and the Ethics and Regulation of Research
- Section II: Research Data as Evidentiary Support for Scientific Claims
- Section III: Traditional and Non-Traditional Data Sources - Opportunities and Challenges
- Section IV: Emerging Ethical and Regulatory Compliance Considerations
- Materials for Further Reading and Viewing

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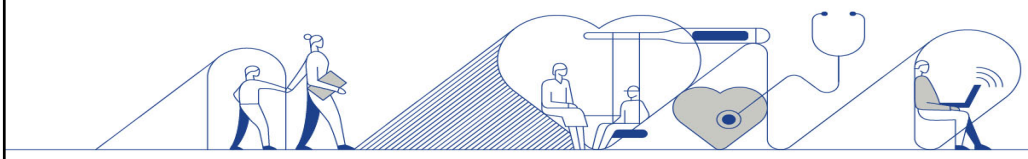
Section I

A Review of Research and the Ethics and Regulation of Research



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Defining Research Involving Humans

- **Health & Human Services (HHS)** - *Human Subjects Research*: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*. Investigation *must involve a living individual* about whom an investigator conducting research obtains information or biospecimens through *intervention* or *interaction* with the individual and uses, studies, or analyzes the information or biological specimens (45 CFR § 46.102(e)(l)).

- **Food & Drug Administration (FDA)** - *Clinical trials:** Voluntary research studies conducted in people; designed to answer specific questions *about safety or effectiveness* of drugs, vaccines, other therapies, or new ways to use existing treatments.

- **State Laws** (*e.g.*, State of New York) - *Human Research:* Any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves *physical or psychological intervention* by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject (NYS Public Health Law § 2441).

IS SECONDARY RESEARCH "HUMAN RESEARCH?"

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Medical Care vs. Research

- Can **Medical Care** cross into **Research**?

Medical Care		Research
• Patient	?	• Research participant, study subject
• Primary focus - to diagnose, treat		• Primary focus – to answer a scientific question about for example drugs or devices
• Patient-doctor relationship; provider judgment, what is best for patient, off-label drug use permitted		• Adheres to a study protocol

The Physician-Researcher Role

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Roles of Industry-Sponsors and Sites

Sponsor

- Conduct study feasibility
- Design protocol and complete other study documents
- Evaluate and recruit study sites
- Establish review boards (*e.g.*, Data Safety Monitoring Board)
- Retain Clinical Research Organization (CRO)
- Approve Site Management Organization (SMO)
- Select Institutional Review Board (IRB)
- Investigator training, site training, and initiation
- **Own data resulting from the study**
- Monitor the study
- **Retain services of a site**
- May end the study at a site
- Right to primary publication

Site

- Conduct study feasibility (at site)
- Investigator meeting(s)
- Patient recruitment and enrollment
- Perform protocol procedures
- Collect and transmit data to sponsor for analysis
- **Might** be invited to be an author on primary paper
- Usually, **may** publish secondary manuscript per study agreement

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Ethical, Legal, and Regulatory Framework for Human Research

- **Ethical Frameworks** (Ex-US / US)
  - The Nuremberg Code
  - The Declaration of Helsinki
  - The Belmont Report
- **Federal Laws and Regulations** (US GCP policies)
  - The Federal Food, Drug, and Cosmetic Act (FDCA) - 1938
  - 21st Century Cures Act - 2016
  - Health & Human Services (HHS) – Human Subjects Research: 45 CFR 46;
  - Food & Drug Administration - Regulations relating to Good Clinical Practice (GCP) and Clinical Trials Link. (Commonly cited research regulations: 21 CFR 11; 21 CFR 50; 21 CFR 312; 21 CFR 812);
  - HHS - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought: 42 C.F.R. Part 50, Subpart F.
  - HHS – HIPAA Privacy Rule: 45 CFR 164
- **State Laws**
  - *e.g.,* New York State – Annual "*Attestation of Compliance*" with the Common Rule **or** must comply with NYS research laws and regulations.
- **Guidance and Compliance Oversight** (Federal Funding)
  - Office of Human Research Protections (HHS-OHRP) – Federalwide Assurance (FWA)
  - Office of Research Integrity (HHS-ORI) - Assurance
- **Other Standards** (Ex-US guidelines)
  - The International ethical guidelines for health-related research involving humans CIOMS
  - The ICH Harmonised Tripartite Guideline – Guideline for Good Clinical Practice (ICH-GCP): E6R2.

WELFARE AND SAFETY OF PARTICIPANTS AND PRESERVATION OF DATA INTEGRITY

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Why All the Regulations? A Look Back into History . . .

Medical experiments in Black Americans	From colonial times to recent past*
The Tuskegee Syphilis study (1932)	Participants not treated even when treatment became available**
The Nuremberg Doctors Trial (1945 - 1949)	Crimes against humanity
Henrietta Lacks (1951)	Biospecimen research without patient's knowledge. John Hopkins Medicine: "Henrietta Lacks was one of a diverse group of patients who unknowingly donated cells at Hopkins in 1951."
Nature vs. Nurture: Triplets separated at birth (1960s)	"Secret scientific study" conducted by child psychiatrist Dr. Peter B. Neubauer. "Three Identical Strangers" (documentary film).
The Jewish Chronic Disease Hospital Case (1963)	Live cells given to patients without their consent as part of a cancer study***
COVID-19 research (2020)	Health inequities considerations and underrepresentation of minority groups****
U.S. commercial IRB approved research (2020)	Unethical research in a population of poor young women in Mexico*****

* Washington, H. (2006). Medical Apartheid. *Doubleday.*
** Brandt, A. M. (1978). Racism and Research: The Case of the Tuskegee Syphilis Study. *The Hastings Center Report*, *8*(6), 21–29. https://doi.org/10.2307/3561468
*** New York Times. Original print, January 21, 1964 p. 31
**** Racial Disproportionality in Covid Clinical Trials (2020). JAMA. Accessed at Link
***** Munné, S. et al. (2020) First PGT-A using human in vivo blastocysts recovered by uterine lavage: comparison with matched IVF embryo controls. Human Reproduction, Vol.35, No.1, pp. 70–80. Accessed at Link , Link and Link.

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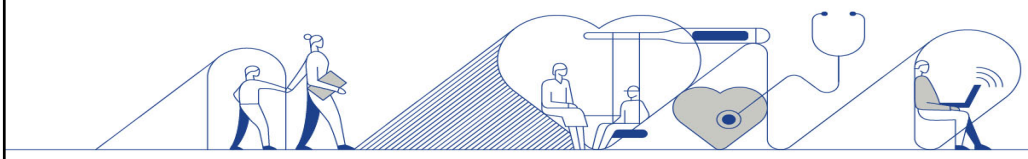
Section II

Research Data as Evidentiary Support for Scientific Claims



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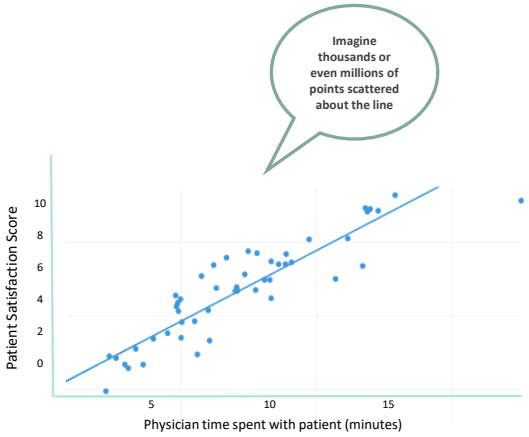
Data in Research

- Data are foundational to research but many unresolved issues in collection
- <u>Research in General</u>
  - **Might not be about people** (A datum or data point - car, building, etc.)
- <u>Clinical Research</u>
  - **It is about people** but . . . does not have to involve a drug, device, or biologic
  - "**Attributes"** – No data manipulation (*e.g.*, demographics)
  - "**Response"** – Manipulable through "**intervention**" or "**interaction**" (*e.g.*, test articles, device, scan, discussion with study participants, dosage, environment)



Collected or Existing Data → Analysis and Results → Information → Evidenced - Based Knowledge → Patient Care Decision

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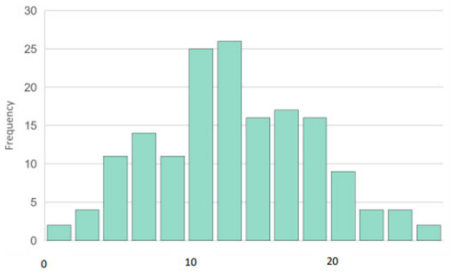
DNA Exonerations – A Human Touch to Data!



The Innocence Project

0-1	2-3	4-5	6-7	8-9	10-11	12-13	14-15	16-17	18-19	20-21	22-23	24-25	26-27
Villasana Green	Alexander Piszczek Bravo O'Donnell	Matthews Sutton Salazar Callace Woodall Durham Johnson Alejandro Brison Vasquez	Gonzalez Gregory Mitchell Webb Scruggs Snyder Dabbs Cowans Reid Cromedy Willis Hicks Saecker Jones	Dixon Wardell Reynolds Moto Davis Davis Nelson Gray Harris Chalmers Bloodsworth	Rollins Mercer Danziger Fritz Williamson Jimerson Kotler Holland Johnson Krone Criner Miller Richardson Jones Miller Smith Hernandez Cruz Cotton Shepard Bullock Honaker Daye Linscott Dotson	Tonev Webb Sarsfield Watkins Robinson Ochoa Velasquez Green Bradford Ollins Ollins Saunders McSherry McGee McCray Richardson Salaam Santana Wise Ortiz Byrd Mahan Mahan Atkins Dominguez Powell	Holdren Youngblood Lavernia Pierce Pope Thomas Godschalk Bromgard Echols Scott Bauer Mitchell Smith Washington Webb Kordonowy	Adams Rainge Williams Charles Butler Lloys Sutherlin Erby Avery Harrison Moon Green Johnson Abdal Washington Bibbins Laughman	Brown Jean Anderson Mayes Webster Maher Charles Hunt Doswell Nesmith Waters Fain Johnson Goodman Booker Rodriguez	Townsend Lowery Willis Yarris Woods Gray Scott Good Brown	Mcmillan Ruffin Dedge Whitefield	Diaz Gray Williams Waters	Evans Terry
Years in Prison													

https://innocenceproject.org/exonerate

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Data Collection in Research

Interventional Prospective

- Data collection is **specifically** for research purposes
- Intervention (*e.g.*, drug administration) or interaction (*e.g.*, discussion)
- **Involves living individuals**

Observational Prospective

- Also known as "*non-interventional*" *e.g.*, Health outcomes research with a clinical trial
- Patient receives Standard of Care; researcher collects data for research
- Quality of Life research (*e.g.*, using health surveys)
- Data from patient journaling or use of new technologies
- **Involves living individuals**

Observational Retrospective

- Using "*existing data*" previously collected for non-research purposes (*e.g.*, data from EHR systems)
- Data in public domain
- **Does not involve living individuals**

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Primary vs. Secondary Research

Primary

- Data collected for research purposes (*e.g.*, Investigator may participate directly in data-gathering process or retain others' services)
- Sources of data: *e.g.*, Clinical intervention, interaction, surveys, interviews, focus groups, observation techniques

Secondary

- Data **collected for other purposes** but **used for research**
- Sources of data: *e.g.*, Government, academia, business, health systems

Do you know where the Research Data in your organization live?

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Clinical Trials . . . They Cost a Pretty Penny!

Cost Component	Phase 1		Phase 2		Phase 3		Phase 4	
	$	% of Subtotal	$	% of Subtotal	$	% of Subtotal	$	% of Subtotal
Data Management Costs	$50,331 ($8,467)	2.36%	$59,934 ($21,060)	0.79%	$39,047 ($19,416)	0.34%	$49,702 ($9,489)	0.44%
Cost Per IRB Approvals	$11,962 ($6,305)	0.56%	$60,188 ($16,092)	0.79%	$114,118 ($46,404)	1.00%	$137,813 ($112,543)	1.21%
Cost of IRB Amendments	$1,094 ($255)	0.05%	$1,698 ($447)	0.02%	$1,919 ($277)	0.02%	$1,636 ($302)	0.01%
SDV Costs	$326,437 ($65,659)	15.32%	$406,038 ($80,573)	5.34%	$400,173 ($66,429)	3.52%	$353,602 ($62,942)	3.10%
Patient Recruitment Costs	$37,050 ($21,666)	1.74%	$161,140 ($102,066)	2.12%	$308,672 ($174,702)	2.71%	$298,923 ($252,042)	2.62%
Patient Retention Costs	$6,145 ($4,745)	0.29%	$15,439 ($6,970)	0.20%	$24,727 ($15,868)	0.22%	$30,568 ($40,466)	0.27%
RN/CRA Costs	$178,237 ($90,473)	8.36%	$441,053 ($140,390)	5.80%	$939,540 ($614,943)	8.25%	$820,775 ($880,644)	7.20%
Physician Costs	$109,681 ($57,626)	5.15%	$381,968 ($117,217)	5.03%	$805,508 ($499,426)	7.08%	$669,464 ($402,072)	5.88%
Clinical Procedure Total	$475,667 ($371,586)	22.32%	$1,476,368 ($633,448)	19.43%	$2,252,208 ($1,033,618)	19.79%	$1,733,576 ($2,251,401)	15.22%
Central Lab Costs [d]	$252,163 ($203,342)	11.83%	$804,821 ($313,577)	10.59%	$849,180 ($600,134)	7.46%	$419,758 ($377,823)	3.68%
Site Recruitment Costs	$51,904 ($32,814)	2.44%	$233,729 ($83,799)	3.08%	$395,182 ($195,983)	3.47%	$168,343 ($101,311)	1.48%
Site Retention Costs	$193,615 ($79,974)	9.09%	$1,127,005 ($544,068)	14.83%	$1,305,361 ($1,382,296)	11.47%	$1,835,341 ($1,335,892)	16.11%
Administrative Staff Costs	$237,869 ($128,547)	11.16%	$1,347,390 ($427,859)	17.73%	$2,321,628 ($1,910,047)	20.40%	$3,323,081 ($2,534,406)	29.17%
Site Monitoring Costs	$198,896 ($128,142)	9.33%	$1,083,186 ($392,798)	14.25%	$1,624,874 ($717,034)	14.28%	$1,549,761 ($979,371)	13.60%
Subtotal (in $ Million)	**$2.13 ($0.86)**	**100%**	**$7.60 ($1.46)**	**100%**	**$11.38 ($4.93)**	**100%**	**$11.39 ($8.53)**	**100%**
Site Overhead [c]	$528,685 ($235,862)	NA	$1,741,811 ($302,049)	NA	$2,541,313 ($1,091,082)	NA	$2,575,007 ($2,082,161)	NA
All Other Costs [c]	$1,139,887 ($468,077)	NA	$4,003,615 ($752,108)	NA	$5,967,193 ($2,577,692)	NA	$5,986,008 ($4,543,505)	NA
Total (in $ Million)	**$3.80 ($1.56)**	**NA**	**$13.35 ($2.51)**	**NA**	**$19.89 ($8.59)**	**NA**	**$19.95 ($15.15)**	**NA**

Note: Reported numbers represent weighted average costs and standard deviations.
[a] The numbers in parentheses represent standard deviations. [b] The cost for each phase assumes that a single trial (*i.e.*, study) is conducted. [c] These are extrapolated figures based on those cost components for which estimates were available from Medidata. [d] Please note that Phase 1 study sites tend to have inhouse or local labs as opposed to central labs.

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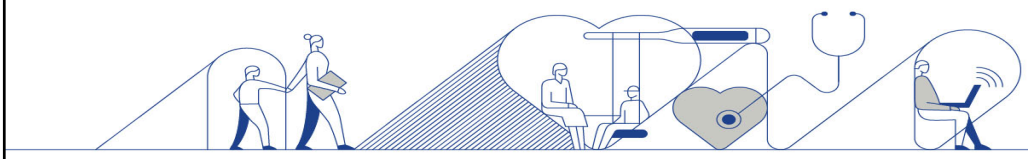
Section III

Traditional and Non-Traditional Data Sources: Opportunities and Challenges



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Traditional Data Sources

- **Clinical Trials**: Testing substantial evidence of effectiveness of drugs and biologics
- **Outcomes Research**: Real-World Evidence (RWE) from Real-World Data (RWD)
- **Health Surveys**: In populations
- **Medical Records**: Using Electronic Health Records (EHR) systems
- **Public Health Surveillance**: To evaluate population health
- **Registries**: For longitudinal data

PROS
- ✓ **Trusted**
- ✓ **Well-established**

CONS
- ✓ **Slow process**
- ✓ **Costly**
- ✓ **Attrition**
- ✓ **Missing Data**
- ✓ **May be limited by responder bias**

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Traditional Data Sources - Types of Clinical Research

Treatment Research	Interventional (*e.g.*, medication, psychotherapy, new devices, or new approaches to surgery).
Prevention Research	Looks for better ways to prevent disorders from developing or returning (*e.g.*, may study medicines, vitamins, vaccines, minerals, or lifestyle changes).
Diagnostic Research	Practice of looking for better ways to identify a particular disorder or condition.
Screening Research	Aims to find the best ways to detect certain disorders or health conditions.
Quality of Life Research	Explores ways to improve comfort and the quality of life for individuals with a chronic illness.
Genetic studies	Aim to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.
Epidemiological studies	Seek to identify patterns, causes, and control of disorders in groups of people.

Accessed at Link

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What is Happening Now?

January 22, 2020

Per FDA (2022):

- Rapid acceleration of use of computers, mobile devices, wearables and other biosensors to gather and store huge amounts of health-related data.
- Data with potential to allow better design and conduct of clinical trials and studies in the health care setting to answer questions previously thought infeasible.
- Data from mobile devices and patient-generated data in home-use settings as **decision-grade data to support observational studies** (prospective and/or retrospective).*

*Accessed at Link

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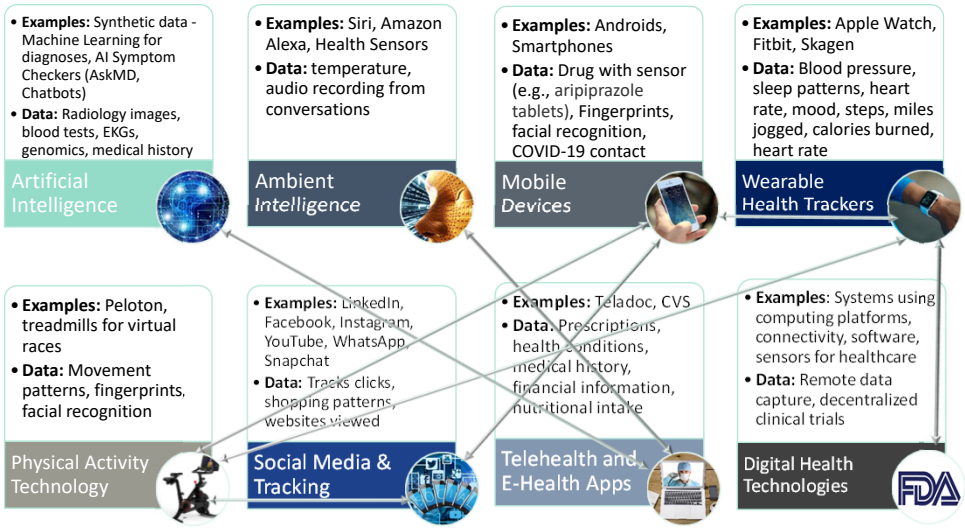
Non-Traditional (NT) Data Sources



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Non-Traditional Data Sources – Example Research Scenarios

Determining access to health care and levels of health literacy among patients in underserved rural areas	• Sources used: surveys on **Mobile Devices** (*e.g.*, smartphone)
Type of health information accessed by different age groups through public and closed group pages	• Sources used: **Social Media** (*e.g.*, Facebook, LinkedIn)
Prescription drug consumption and nutritional intake to determine patient compliance and patterns for disease management in between visits to practitioners	• Sources used: **Mobile Devices, Telehealth and E-health Apps** (*e.g.*, AskMD)**, Wearable Health Trackers**
Determining percentage of hospital workers presenting to work with a fever during COVID-19	• Sources used: **Ambient Intelligence** (*e.g.*, temperature sensors)

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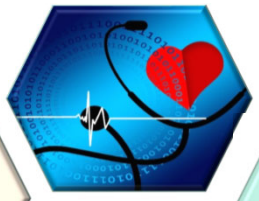
Real-World Evidence (RWE) Under the 21st Century Cures Act
From Doubt to Belief: We've Come a Long Way . . .

Public Law 114-255*

2016 – Prescribed program to evaluate *"potential use of RWE"* to help to support approval of new indication of a pre-approved drug



RWE Defined
Data regarding usage, or potential benefits or risks, of drug derived from **sources other than** randomized clinical trials

Sources include: ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research

2021 FDA Guidance**
Considerations for the Use of RWE to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry

2021 FDA Guidance***
Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders

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*Accessed at Link
**Accessed at Link
***Accessed at Link

Nuvance Health

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Opportunities with Non-Traditional Data Sources

Efficient, rapid access to data	• Increased accessibility (*e.g.*, health surveys through SurveyMonkey, real-time data from wearables)
Complements traditional data sources	• Traditional sources may be incomplete (*e.g.*, missing data from medical records) • RWD to complement traditional clinical trials; provide decision-grade data for approval of new drug indication
Higher participant engagement	• Interactive technologies encourage participant interaction • Decreased geographic barriers/limitations
Patient-centered focus for research	• "Natural language processing" for surveys to improve accuracy of responses • Insights into vulnerable or geographically-isolated populations • Enables whole-person care (*e.g.*, Apps create a user health "profile")
Decreased healthcare costs	• Fewer in-person office and ED visits
Lower attrition in research	• Participants less likely to drop out
Faster study start-up	• Increased efficiency due to technology for patient recruitment

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Nuvance Health

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Challenges with Non-Traditional Data Sources

Data Integrity

- Quality of data – is the collection and reporting accurate?
- Selection bias – data from mobile phones and social media may not be representative of the target population
- Online data collection – deciphering data from humans or bots
- Reliability and validity concerns: Are data missing?
- Trustworthiness of data

Data Sharing

- Privacy and security
- Lack of public trust
- Ownership of data

ESG* Issues

- Corporate responsibility
- Reputational risk – bad press
- Financial implications

Ethical Considerations

- Principles of the Belmont Report – respect for persons, beneficence, justice
- Informed consent (*e.g.,* Ambient Intelligence)

*Environmental, Social, and Governance

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Audience Interaction

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Is this Human Subjects Research? If So, What Are the Rules of the Road?

Courtesy of Fox 5 New York: https://youtu.be/bhP6qyI9v1Q

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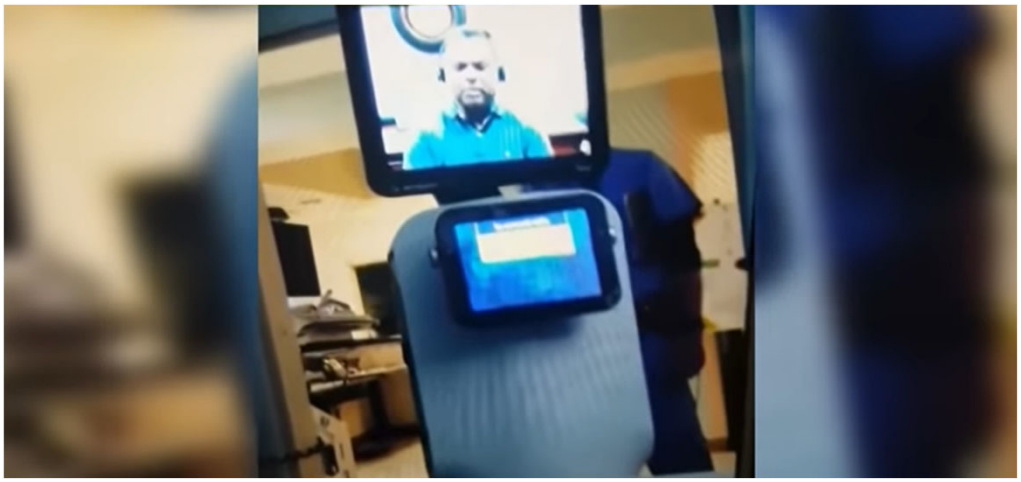
A Challenge or an Opportunity?



Courtesy of East Bay Times/Mercury News: https://www.youtube.com/watch?v=2om6vymc-sw

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Remaining Ahead of the Curve . . .

- Technology-enabled **data-driven human research** is here to stay!
- Innovative non-traditional sources for acquiring data for research purposes are burgeoning!
- 21st Century Cures Act (2016)
  - § 2012 - Privacy protection for human research subjects
  - § 2013 - Protection of identifiable and sensitive information
- Office of Civil Rights 21st Century Cures Act Guidance: Researchers may access PHI through remote access connection as review preparatory to research. Accessed at Link
- December 2021: **FDA Draft Guidance** for Industry on *"Considerations for the Use of RWD and RWE to Support Regulatory Decision-Making for Drug and Biological Products."*
- December 2021: **FDA Draft Guidance** for Industry, Investigators, and Other Stakeholders on *"Digital Health Technologies for Remote Data Acquisition in Clinical Investigations."*
- March 2022, signal that there might be upcoming **legislative action**
  - On March 1, President Joe Biden declared in his State of the Union address** that "*we must hold social media platforms accountable for the **national experiment** they're conducting on our children for profit*."

Lack of regulatory framework governing NT data use for research

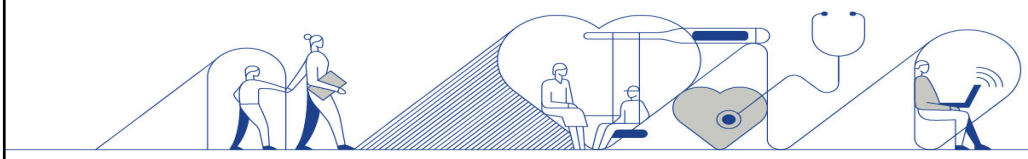
* Accessed at Link
** Accessed at Link

Excusez-moi? Parlez-Vous X-Health?

- **A new language for Research Compliance Officers . . .**
  - Telehealth
  - mHealth
  - E-health
  - Digital Health
  - Telemedicine
  - eConsent
  - Decentralized Clinical Trials
  - eMonitoring
  - Etc.

Section IV

Emerging Ethical and Regulatory Compliance Considerations



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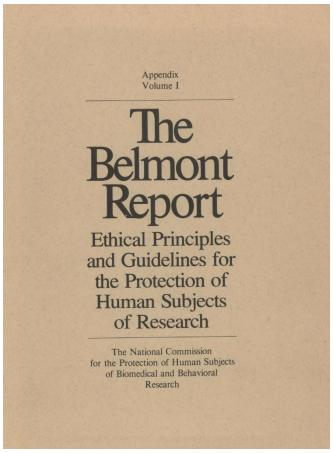
Ethical Considerations

- **Respect for Persons**
  - Individual Autonomy: Participation must be voluntary
  - Protection of the vulnerable: Individuals with diminished capacity to consent (*e.g.*, Limited-English proficiency),
  - Knowledge that research is being conducted
- **Beneficence**
  - Minimize harms: (*e.g.*, privacy breach as harm, cultural context, moral objection to certain research)
- **Justice**
  - Equitable distribution of costs and benefits: Health inequities (*e.g.*, Can all afford costs of apps?)



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Example of Privacy Policy - Peloton®

Peloton® collects biometric data – biological measurements or physical characteristics that can be used to identify individuals (*e.g.*, sitting/standing patterns, fingerprint mapping, facial recognition, retina scans)

Behavioral data collected can lead to medical information ("content") disclosed from health websites

Peloton® uses personal information for research purposes

Members who use Peloton Guide should be aware that we may collect and use Biometric Data, a type of sensitive personal information, with your consent as part of your use of Peloton Guide. More information about how we may collect and use Biometric and Fitness Data is available in our Peloton Biometric and Fitness Data Privacy Policy.

1.2 Information that we collect automatically

- **Information generated through use of the Services**. Such as classes registered for and participated in, Peloton members you are following and who are following you, details of workout performances such as leaderboard rank, total workout output, workout speed, distance and calories burned, in-studio attendance history and, if you have chosen to connect a heart rate monitor, your workout heart rate.
- **Information from your device**. Information from and about the device you use when you use our Services (whether your desktop, mobile, tablet, bike or fitness tracker) including IP address, identifiers, type, mobile carrier, browser type and language, location (see below) and operating system. We may also collect information about how your device interacts with our Services, such as the content you access, pages and sites visited before and after you reach the Services, the date and time of your use, the amount of time spent on the Services, and other actions taken through use of the Services such as preferences.

2. HOW WE USE PERSONAL INFORMATION

We use your information for the following purposes:

- **For analytics, research and product and Service improvement purposes**: Including monitoring and measuring your use of our products and Services and conducting research/surveys, to understand how they are being used and how they can be improved.

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Example of Terms of Services – Meta Platforms, Inc. (Facebook)

This terminology has been open to debate between Privacy Advocates and Facebook.

Facebook Terms and Service:

You own all of the content and information you post on Facebook, and you can control how it is shared through your privacy and application settings. In addition:

1. For content that is covered by intellectual property rights, like photos and videos (IP content), you specifically give us the following permission, subject to your privacy and application settings: you grant us a non-exclusive, transferable, sub-licensable, royalty-free, worldwide license to use any IP content that you post on or in connection with Facebook (IP License). This IP License ends when you delete your IP content or your account unless your content has been shared with others, and they have not deleted it.

2. When you delete IP content, it is deleted in a manner similar to emptying the recycle bin on a computer. However, you understand that removed content may persist in backup copies for a reasonable period of time (but will not be available to others).

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The Right to Be Left Alone . . .

- ❖ Consumers targeted
- ❖ Spyware/malware infection
- ❖ Hacking/information leaking
- ❖ Unauthorized disclosures
- ❖ Selling of information
- ❖ Other unknown vulnerabilities

- ✓ Installed via text messages, apps, email
- ✓ Can activate microphone and/or camera, record calls, document chats, access email/calendar/photos/videos, record GPS data

https://www.bbc.com/news/technology-57881364

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Navigating the New Landscape . . . Thinking Outside the Boxes!

Data Ownership
- Purchased
- Donation
- Data sharing

Informed Consent
- How should Compliance handle consent in research using NT data?
- Video surveillance monitoring – when is consent required?
- How broad is the Broad Consent?

Vulnerable populations
- Who is providing the data (*e.g.*, minors on social media apps, people with diminished mental capacity)?

ESG* Risks
- Do you have an ESG Program that covers Research Compliance?
- If not, how are ESG risks related to NT data managed?

Adverse Events
- Patient safety issues: How will adverse events be monitored?
- How does NT data use impact Pharmacovigilance?

Privacy and Security
- In a data breach, sheer number of individuals impacted could have devastating organizational impact
- Bad press!
- Heavy fines and penalties!

Collaboration
- Compliance
- Legal
- IT
- Risk
- Quality

Executive Leadership
- Knowledge
- Misconceptions
- Interest
- Address or assume the risk

*Environmental, Social, Governance

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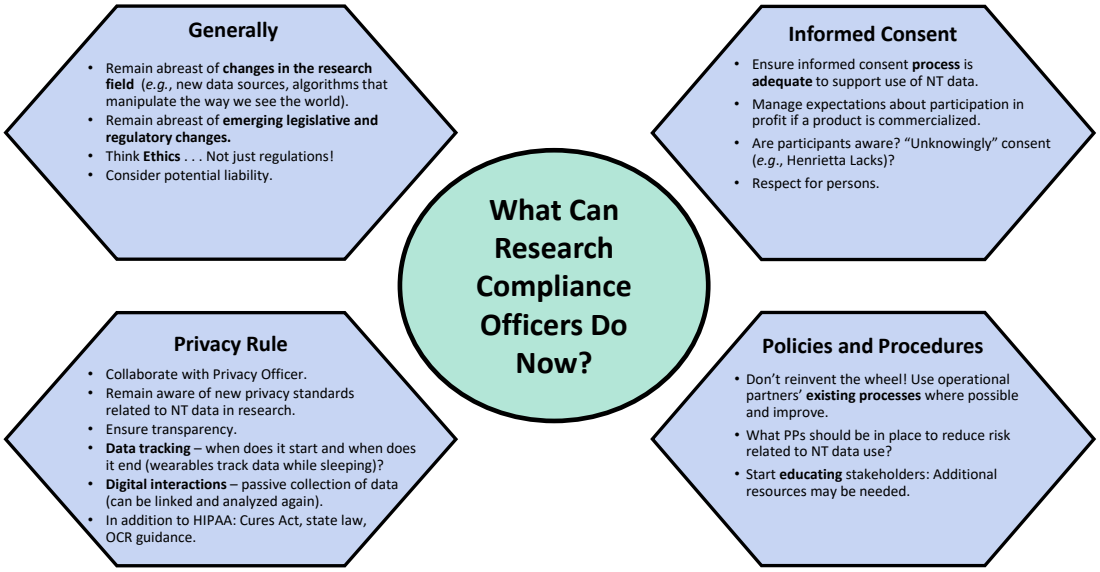
What Does this Mean to You?



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Food for Thought . . .

- What processes could Research Compliance Officers put in place to mitigate ESG risk when using NT data in research?
- How can autonomy be preserved (*e.g.*, FDA-approved digestive pill for vulnerable populations trackable through Bluetooth-enabled sensor? Are individuals aware of the uses of their health data?)
- Exclusion and Inclusion
  - What or who is being studied?
  - What or who is not being studied?
- What does an informed consent process that is adequate to support use of NT data look like?
- What other ethical implications should be considered?
- When is use of certain NT data sources too risky for an organization?

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Materials for Further Reading and Viewing

- **Commentary**: Lamensch, M. (2001). Putting Our Bodies Online: The Privacy Risks of Tech Wearables. Available at Link
- **FDA Draft Guidance:** Considerations for the Use of RWD and RWE to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry (December 2021). Available at Link
- **FDA Draft Guidance**: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders (December 2021). Available at Link
- **FDA Press Release**: FDA approves pill with sensor that digitally tracks if patients have ingested their medication (2017). Available at Link
- **Research Article**: Dayer, L., Heldenbrand, S., Anderson, P., Gubbins, P. O., & Martin, B. C. (2013). Smartphone medication adherence apps: potential benefits to patients and providers. *Journal of the American Pharmacists Association: JAPhA*, *53*(2), 172–181. Available at Link
- **Video Clip**: FDA-approved ingestible pill with sensor. Data accessible through Bluetooth technology via Smartphones: Abilify MYCITE® (Available at Link)

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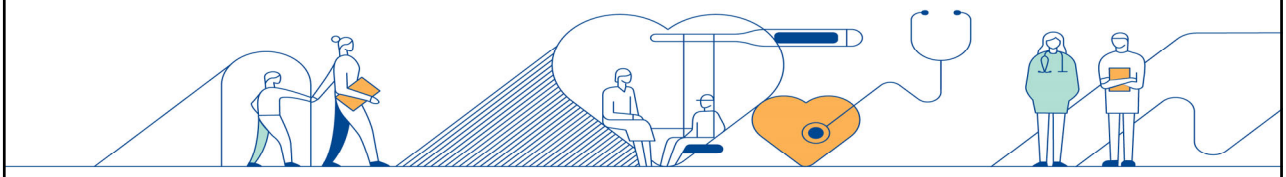

Thank you!

Contact Information

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