NIST Human Research Protections Program

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NIST

NATIONAL INSTITUTE OF
STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

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NIST

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About NIST

Credit: J.L. Lee/NIST

Credit: N. Hanacek/NIST

Credit: NIST

NIST Mission:

To promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

Core competencies:
- Measurement science
- Rigorous traceability
- Development and use of standards

NIST AT A GLANCE

3,400+ FEDERAL EMPLOYEES

5 NOBEL PRIZES

2 CAMPUSES GAITHERSBURG, MD [HQ] BOULDER, CO

3,500+ ASSOCIATES

10 COLLABORATIVE INSTITUTES

400+ BUSINESSES USING NIST FACILITIES

ManufacturingUSA®

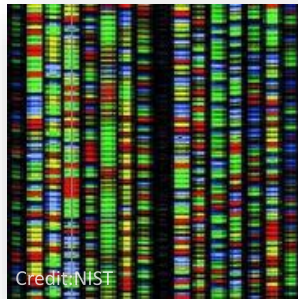NATIONAL OFFICE COORDINATING 16 MANUFACTURING INSTITUTES
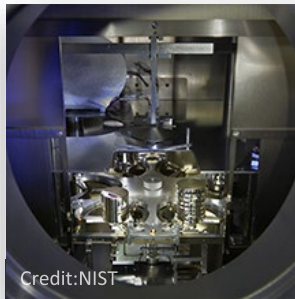
51 MANUFACTURING EXTENSION PARTNERSHIP CENTERS

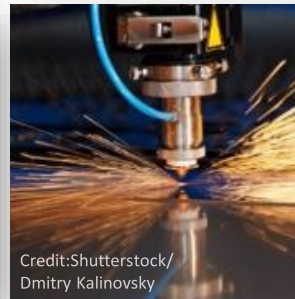U.S. BALDRIGE PERFORMANCE EXCELLENCE PROGRAM

National Metrology Institute

Treaty of the Meter signed by 17 nations.

1875

1889

The International Prototype Kilogram is built.

The International System of Units — the SI — is established.

1960

1967

The second is redefined in terms of the cesium atom.

The meter is redefined in terms of the speed of light.

1983

2011

Proposal to define SI fully in terms of seven natural constants.

Updated values of constants published.

2017

N. Hanacek/NIST

Programs Managed by RPO

Human Research Protections

Animal Care and Use

Scientific Integrity

Publication Clearance

Export Control

Role of the HRPP Team at NIST

Regulatory reviews and approvals

- Intramural research
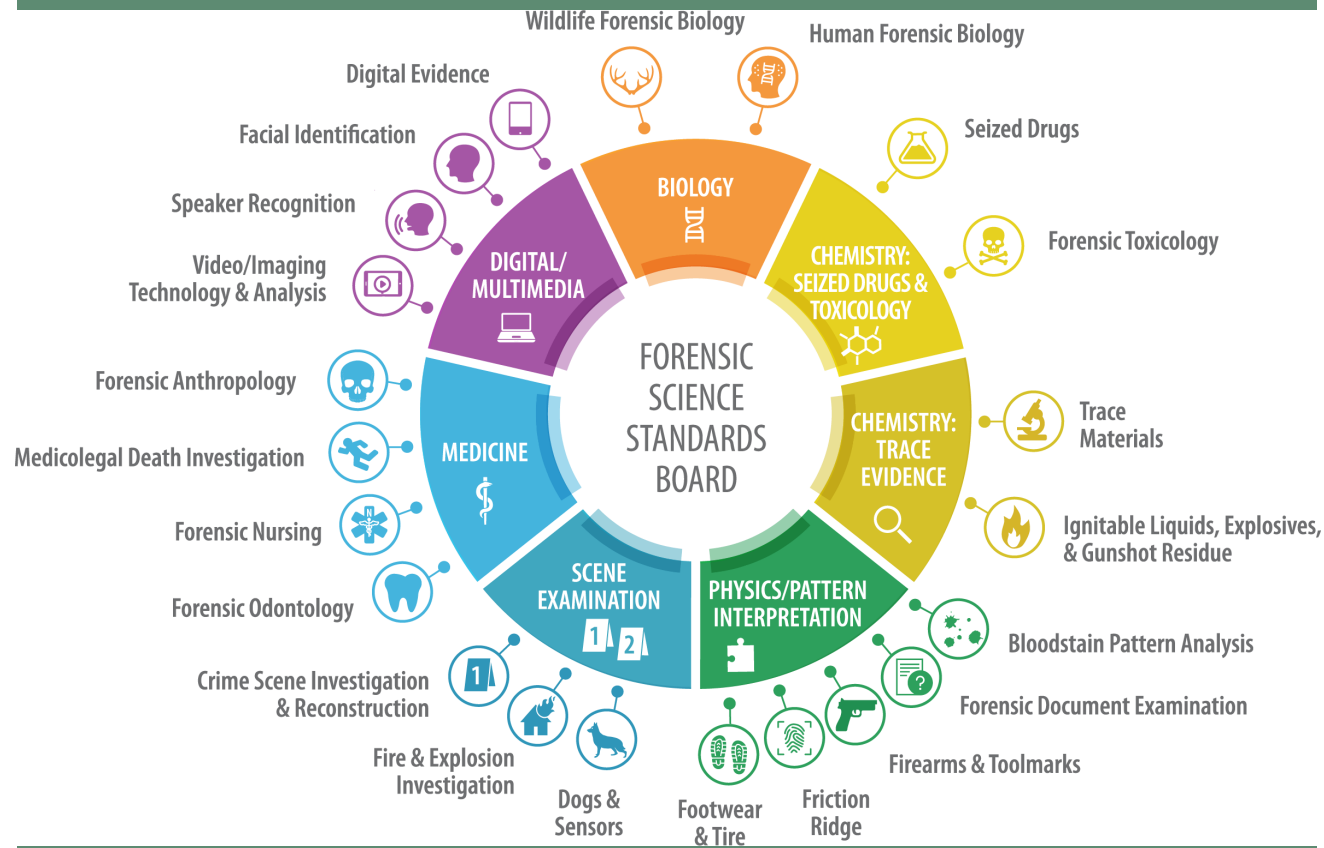- Extramural research

Advise leadership, labs and programs

- Project guidance
- We can, but should we?

Advise and collaborate with other bureaus and NIST programs

- DOC, NOAA, NTIA
- Scientific integrity, publications, GMD

Example: Forensic Science

Key components:
- Science
  - Conduct research in forensic disciplines
  - Develop standards
  - Support CSAFE
- Policy
  - Co-chair (with DOJ) National Commission on Forensic Science
- Practice
  - Administer Organization of Scientific Area Committees for Forensic Sciences (OSAC)

Common Rule: Research
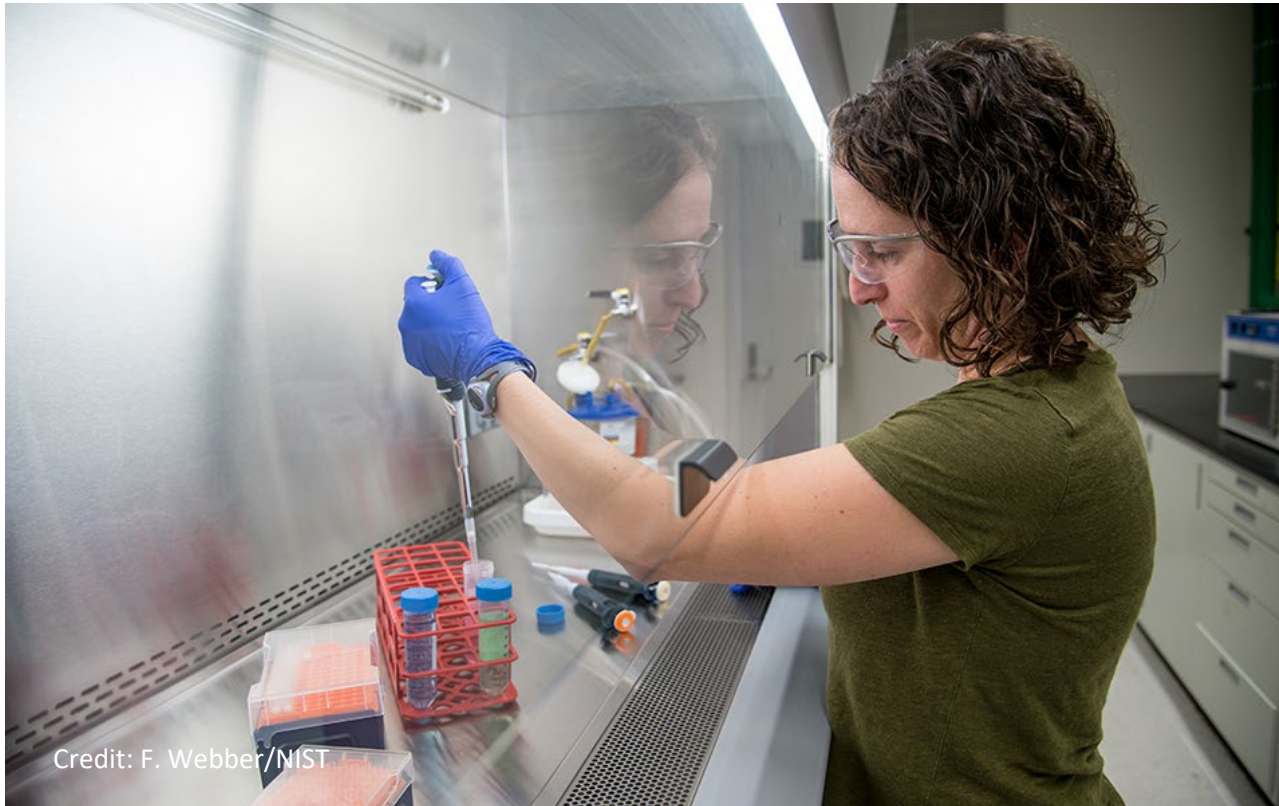
Credit: F. Webber/NIST

- A *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge

At NIST, we default to an activity is research

Common Rule: Not Research

Credit: Center for Domestic Preparedness, Federal Emergency Management Agency, U.S. Department of Homeland Security

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions

What are Operational Activities?

Purpose
- Very specific purpose, related to an ongoing operation, warrant, court order
- Large suite of tests/products

Timeline
- Short or related to a deadline
- Longer term or may be used later for operations

Personnel
- Typically investigative
- Typically researchers

Factors to consider when trying to decide if an activity may constitute an investigation or a research activity

NIST Operational Activities

Credit: NIST

Authorities include:

- Access the site of a building disaster

- Subpoena evidence

- Access key pieces of evidence such as records and documents

- Move and preserve evidence

NIST investigations:

- World Trade Center (pub. 2005 and 2008)

- Station Nightclub Fire (pub. 2005)

- Joplin Tornado (pub. 2014)

- Hurricane Maria (ongoing)

- Champlain Towers South collapse (ongoing)

National Construction Safety Team Act (2002)

- Purpose: establish teams to investigate building failures

NIST and Operational Data

NIST research with operational data that _potentially_ includes human data has several requirements…
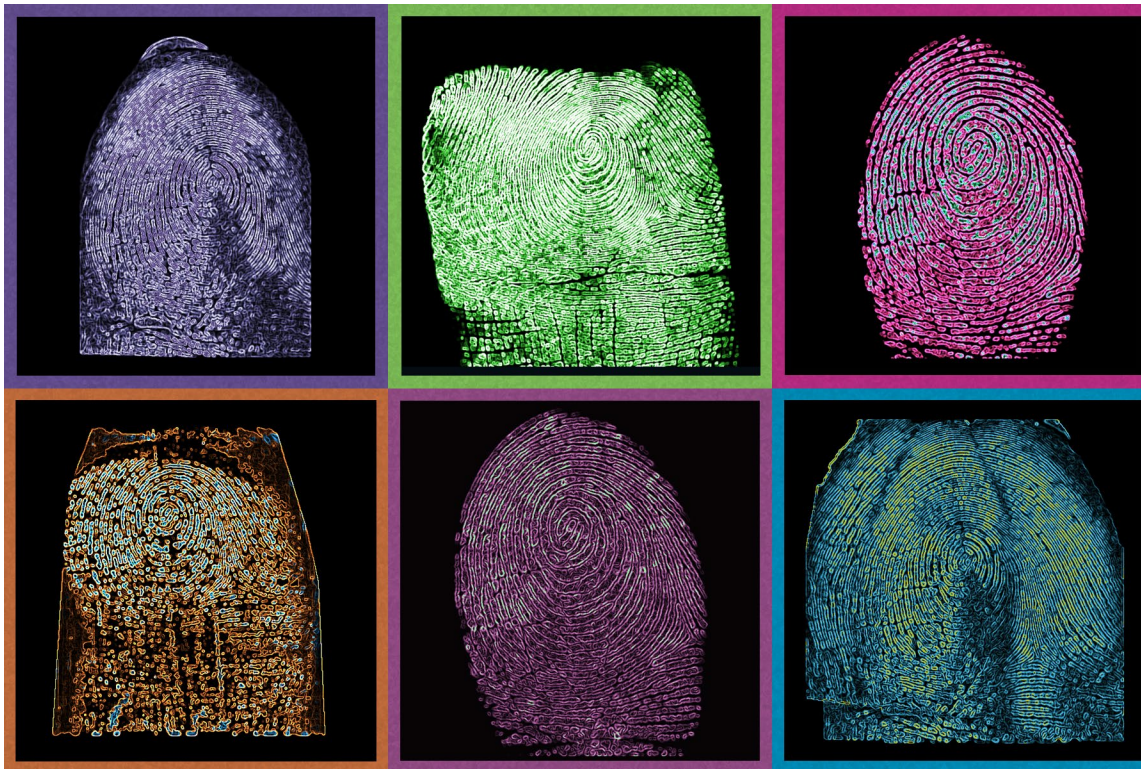
Credit: N. Hanacek/NIST

Some type of agreement that specifies:
- How the data may be used
- Who may access the data
- What must be done with data at end of study

Review by RPO
- Study description
- Additional safeguards and restrictions related to attempts to reidentify and data sharing

IT Security Review
- Data storage
- Data destruction

Artificial Intelligence

NIST's AI goals include:

- Conduct fundamental research to advance trustworthy AI technologies
- Apply AI research and innovation across the NIST Laboratory Programs
- Establish benchmarks, data and metrics to evaluate AI technologies
- Lead and participate in development of technical AI standards
- Contribute technical expertise to discussions and development of AI policies

Fundamental AI Research

Applied AI Research

Test, Evaluation, Validation, and Verification (TEVV)

Voluntary Consensus-Based Standards

RPO Collaborations with AI

Exploring Ethical Artificial Intelligence Research: What Can We Learn from the Common Rule?

- Collaboration with ITL staff

- Series of semi-structured discussions in 2022 which led to a publication
    - K. K. Greene, M. F. Theofanos, C. Watson, A. Andrews and E. Barron, "Avoiding Past Mistakes in Unethical Human Subjects Research: Moving From Artificial Intelligence Principles to Practice," in *Computer*, vol. 57, no. 2, pp. 53-63, Feb. 2024, doi: 10.1109/MC.2023.3327653.

RPO-funded studies for FY25

- Assessing Risks and Impacts of AI (ARIA) evaluation
    - Assess the understandability of the ARIA Field Testing information sheet to improve consent materials for future NIST AI research

- Comparative Analysis of Ethical Standards in Human Subjects Research and AI Research

Questions

Contact RPO:
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