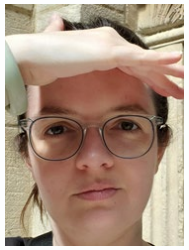
Biden Administrative EO on AI: Agencies' Perspective on Implementation, Challenges, and What Lies Ahead

February 27, 2024

Speakers:



Natalie Klein, Director of Policy & Assurances, OHRP

Syed Mohiuddin, Counselor to the Deputy Secretary, HHS

Elham Tabassi, Chief AI Advisor, NIST

Moderator:

Kristin West, *Research Ethics & Compliance Director, COGR*

COGR

A Few Poll Questions to Get Us Started

Poll 1

- What is your comfort level in discussing AI uses/possible uses **in research administration & compliance**?
  - A. High – ChatGPT told me everything I need to know!
  - B. Moderate – It's pretty complicated, but I have a good handle on the basic concepts.
  - C. Low – It's so complex! Someone needs to explain it to me like I'm five.

Poll 2

- What is your comfort level in discussion AI uses/possible uses **in the conduct of research**?
  - A. High – ChatGPT told me everything I need to know!
  - B. Moderate – It's pretty complicated, but I have a good handle on the basic concepts.
  - C. Low – It's so complex! Someone needs to explain it to me like I'm five.

A Few Poll Questions to Get Us Started

Poll 3

- What AI-related topics are you most interested in hearing more about? (5 = Very interested, 4= Pretty interested, 3 = Somewhat Interested, 2 = Not very interested, 1 = No Opinion)
  - A. How institutions are currently using AI to assist with tasks in research administration/compliance.
  - B. How researchers are using AI in research.
  - C. What policies and processes my institution should consider to govern the use of AI in research and research administration.
  - D. Ethical and privacy considerations regarding the use of AI in research and research administration.
  - E. Other (tell us in the chat!)

A Few Poll Questions to Get Us Started

Poll 4

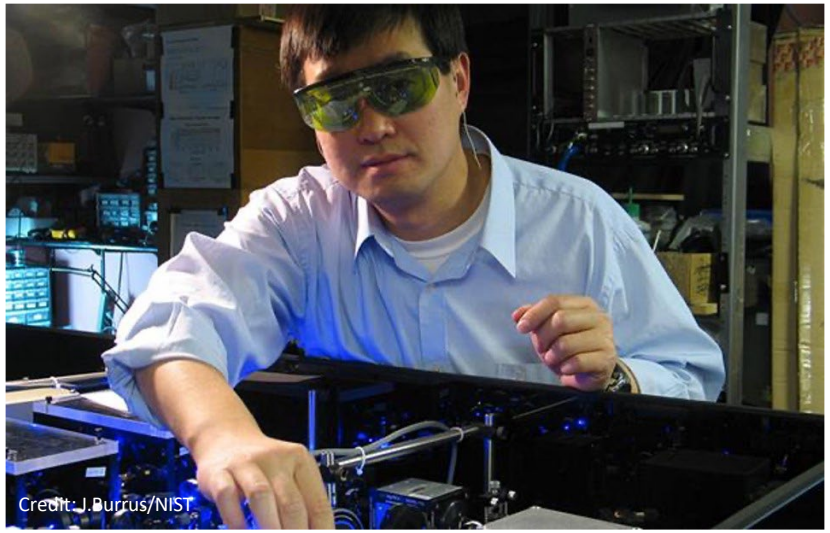
- If COGR offered an AI-focused webinar, would you be interested in attending?
  - A. Yes, I would be very interested.
  - B. Maybe, I would need to see what the agenda looked like.
  - C. Probably not in my role, but there are likely others at my institution that would want to attend.
  - D. No. I've got ChatGPT. No webinars necessary!

NIST Artificial Intelligence Program

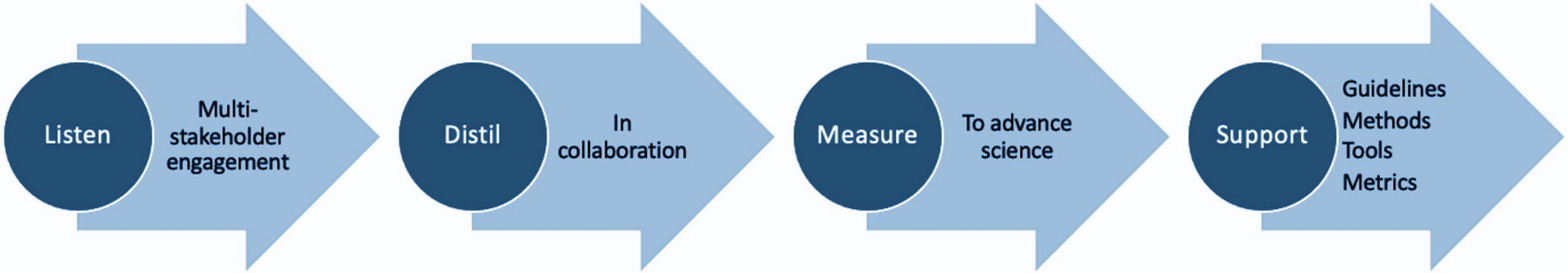
NIST NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

NIST is a federal agency of the Department of Commerce.

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

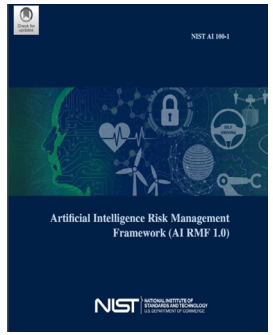


NIST helps industry develop valid, scientifically rigorous methods, metrics and standards.



Major achievements and announcements since 2023

Jan 2023
AI RMF 1.0



March 2023
Trustworthy AI Resource Center

June 2023
Generative AI Public Working Group

October 2023
EO 14110

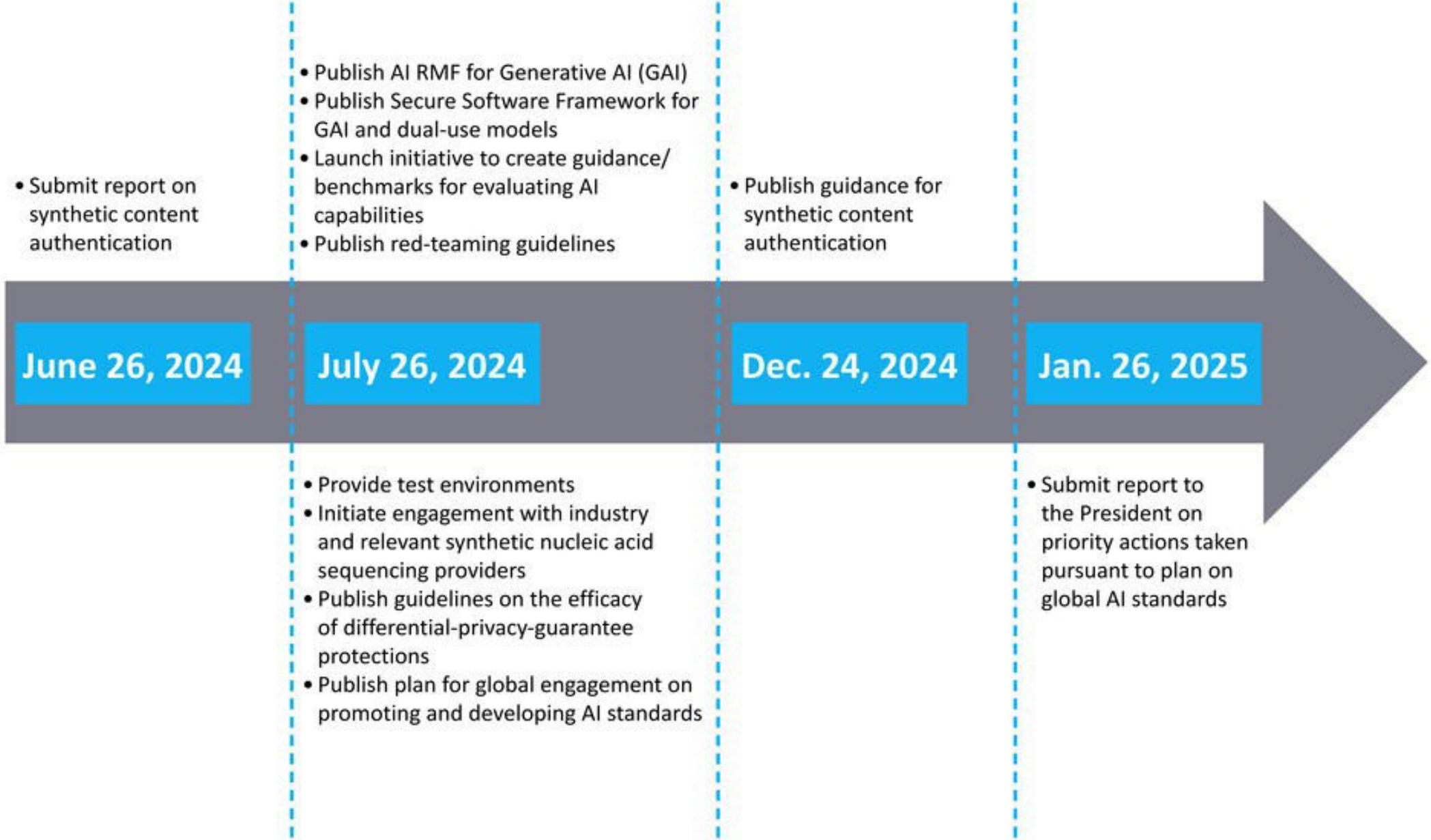
November 2023
US AI Safety Institute Announced

December 2023
RFI published

February 2024
RFI closed.

February 2024
US AI Safety Institute Consortium members announced

NIST's Due Dates Under Executive Order 14110



The USAISI will lead the USG in science, practice and policy of AI safety and trust

Build and expand the science of AI evaluation

Create test environments

Develop guidelines and standards

Conduct evaluations

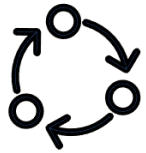
US AI Safety Institute: Three Pillars

Research

GOAL: Improve the science of AI safety

Methods and Outputs:

- Fundamental research
- Technical building blocks
- Synthetic content authentication guidance



Implementation

GOAL: Guide implementation of scientific findings, tests, and risk management frameworks

Methods and Outputs:

- Metrics and methodologies
- Development of testbeds
- Evaluations and red-teaming
- Use-case-specific risk management “profiles”

Engagement & Operations

GOAL: Drive work and oversee research collaboration with outside partners

Methods and Outputs:

- Work plans
- New partnerships
- Scientific collaborations
- Aligned approaches

USAISI Consortium working groups
Sustain, scale, and implement E.O. elements

- Develop a companion **resource to the AI Risk Management Framework, NIST AI 100–1, for generative AI** (E.O. Sec. 4.1(a)(i)(A))
- Develop report on **identifying and labeling synthetic content** produced by AI systems (E.O. Sec. 4.5(a))
- Launch an initiative to **create guidance and benchmarks for evaluating and auditing AI capabilities** (E.O. Sec. 4.1(a)(i)(C))
- Develop **guidelines for AI red teaming** (E.O. Sec. 4.1(a)(ii))
- Develop a **companion to Secure Software Development Framework** (E.O. Sec. 4.1(a)(i)(B)) + Establish a plan for **global engagement on AI standards** (E.O. Sec. 11(b))

Risk Management for Generative AI

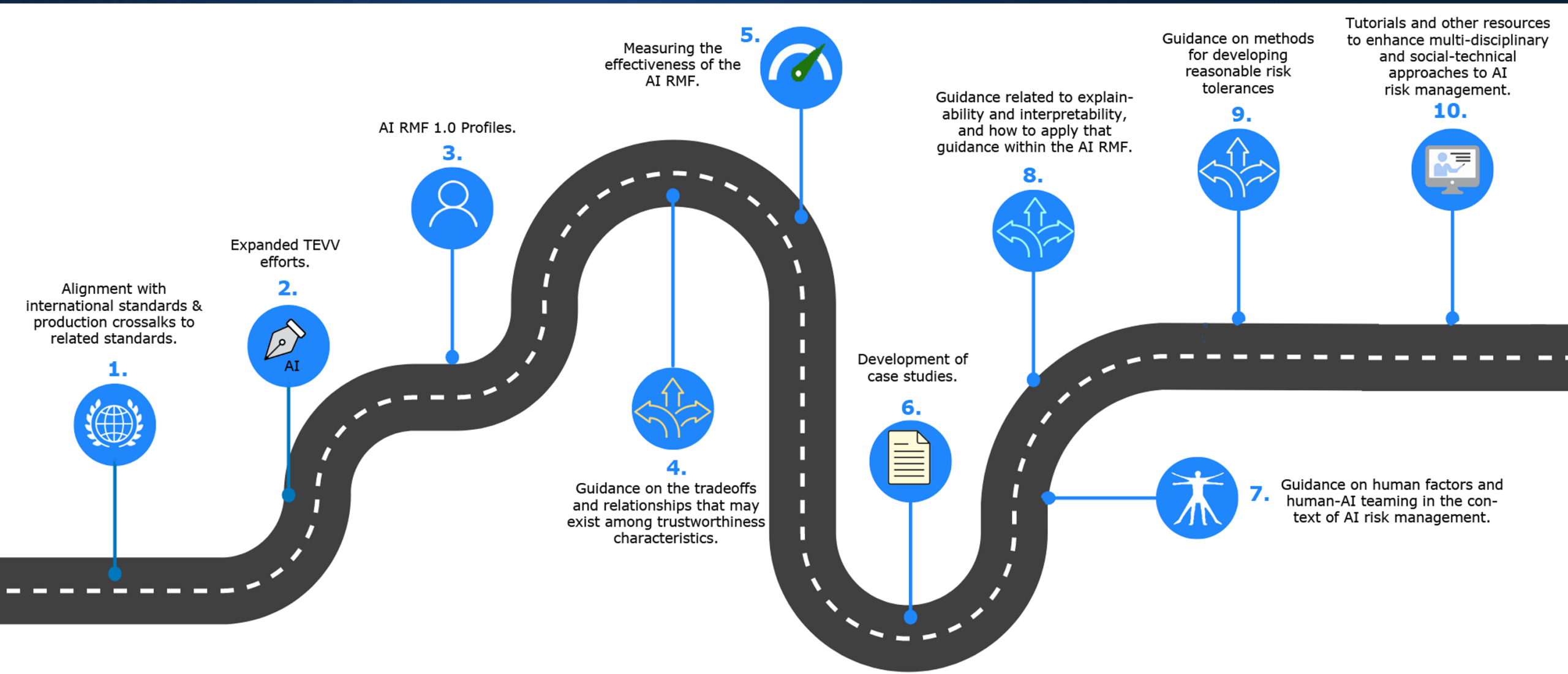
Synthetic Content

Capability Evaluations

Red-Teaming

Safety & Security

A roadmap of future work was released along with the AI RMF in January.



For more information, we encourage you to access NIST resources, or reach out directly!

ww.nist.gov/itl/ai-risk-management-framework airc.nist.gov/

www.nist.gov/artificial-intelligence/artificial-intelligence- safety-institute

AIFramework@nist.go
v usaisi@nist.gov

HHS AI Task Force Introduction

February 27, 2024

HHS AI progress over past 4 months

Executive Order 14110 on Artificial Intelligence (AI) signed by President Biden October 30th, 2023 [details on implementation of EO commitments on next slide and in appendix]

Published ONC's HTI-1 rule on algorithmic transparency in electronic health records in December, then discussed in detail at ONC's annual meeting

Published AHRQ's paper addressing the use of algorithms in healthcare, their impact on racial/ethnic disparities in care, and approaches to identify and mitigate biases in December

Advanced numerous OPDIV-specific AI initiatives, e.g.,

FDA's standup of their cross-cutting PMO to address AI-related priorities

CDC's draft of their AI strategy and 15-page internal guidance on generative AI

Legislative and external engagement

OCIO provided General HHS AI overview to Senate Finance on November 8th

ONC represented HHS on December 13th in E&C full committee hearing, along with Commerce and Energy

Supported safe and responsible AI voluntary commitments group from 28 providers and payers (with next tranche of commitments being announced at ViVE this week)

Troy Tazbaz (FDA), Greg Singleton (OCIO), and Micky Tripathi (ONC) have participated in numerous external engagements on AI[1]

Confirmed ONC, OCAIO, and FDA participation on Coalition for Health AI (CHAI) board

WSJ Interviewed Micky Tripathi on Medical AI Tools (Dec 2)

1) Events over past 4 months include: The Leadership Institute Roundtable Proceeding Together: Opportunities for Industry Collaboration to Achieve Trustworthy AI Deployment; Common Well Health Alliance: Annual Meeting & Fall Summit Keynote; WEDI National Conference; FedGovToday Interview on Use of Generative AI in Healthcare; AWS re:Invent 2023 "Meeting new healthcare data interoperability and AI/ML regulations; Obvious Ventures JPM Healthcare x AI Round Table; The Future of Medicaid Innovation Forum "Futuristic Governance: Navigating AI, Data, and Equity in Medicaid's Transformation"

HHS Strategy & EO Deliverables

HHS Goal: Catalyze whole-of-government-and-industry to improve quality, efficiency, trustworthiness, access, and outcomes in health and human services through the safe, ethical, and responsible use of AI

Objectives

1. Issue AI guidance and policy
2. Advance safety and quality
3. Leverage HHS grants and funding
4. Public education and engagement
5. Deploy AI within HHS

Strategy Domains and Workgroups

Research and discovery	**Health & Human services delivery**
Public health	**Drug and device**
Bio-safety and security	**Ethical and responsible use**
Internal operations	**Critical Infrastructure & Cybersecurity**

Key Enablers

AI Task Force: Steering committee to provide strategic oversight and direction to the AI PMO and Workgroups

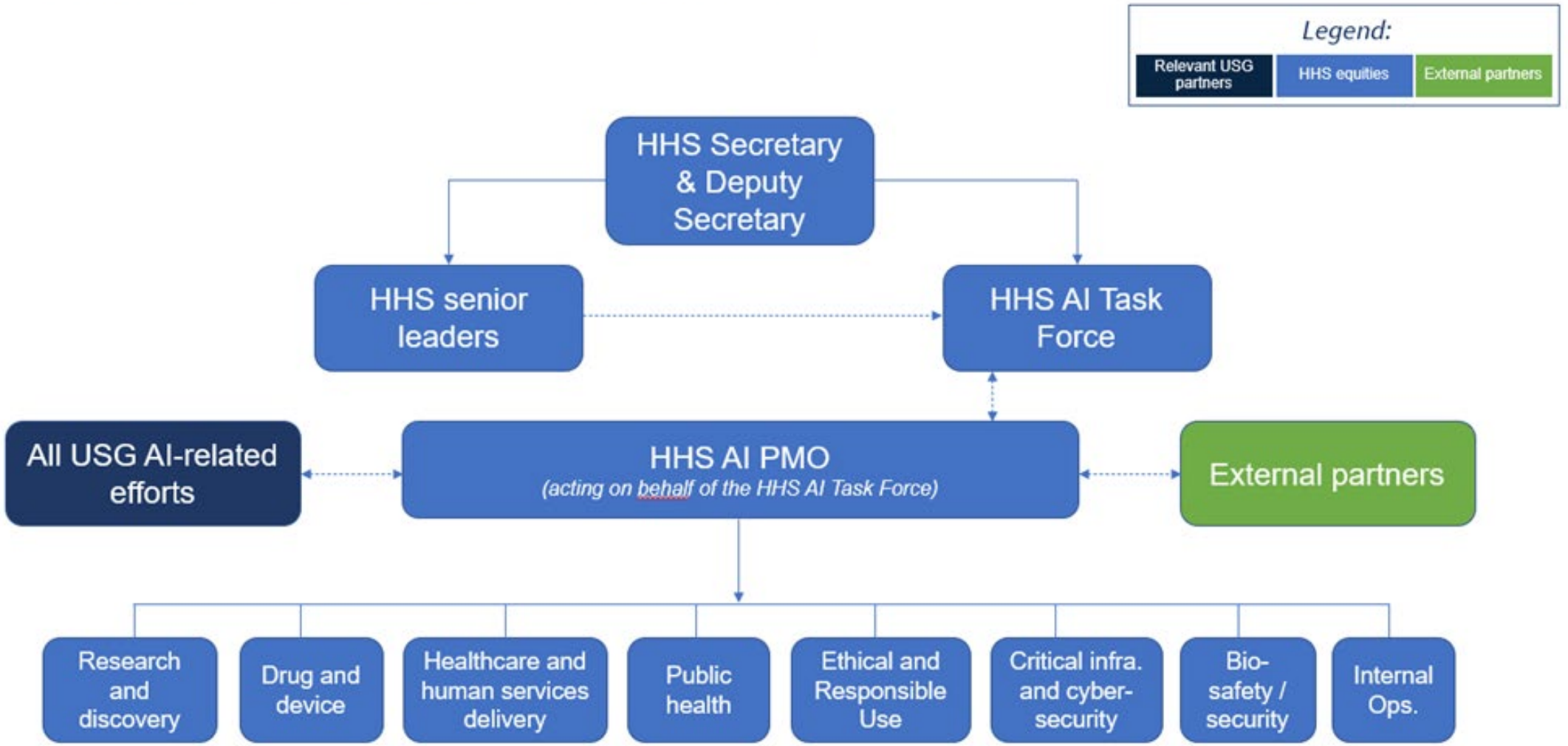
AI PMO: Day-to-day execution planning, tracking, facilitation, and coordination

Workgroups: Each domain will have a workgroup comprising relevant HHS representation. Workgroup will be led by specific OpDiv/StaffDivs. PMO will facilitate bi-directional updates and managing interdependencies.

HHS AI Objectives (Task Force Charter)

- Establish policies to both harness the potential and manage the risks of AI through the safe, equitable, responsible, and ethical adoption and use of AI in health and human services
- Advance Quality and Safety of AI in health through assurance standards and quality management processes
- Evaluate and deploy policy and funding tools (e.g., grantmaking, contracting) as appropriate to advance and manage risk in the safe, equitable, responsible, and ethical development and use of AI across the health and human services delivery value chain
- Provide public education across the healthcare ecosystem and constituents – from individuals to organizations and states – on AI development and use in health and human services delivery
- Where AI offers the opportunity to accelerate the advancement of HHS' mission and the tools meet the Department's quality and equity standards, deploy and evaluate AI capabilities across HHS to drive process innovation and modernization

Governance Structure to Define & Meet HHS Goals on AI



Perspectives on Artificial Intelligence in Human Research

Natalie Klein, PhD
Director, Division of Policy and Assurances
HHS Office for Human Research Protections (OHRP)

February 27, 2024

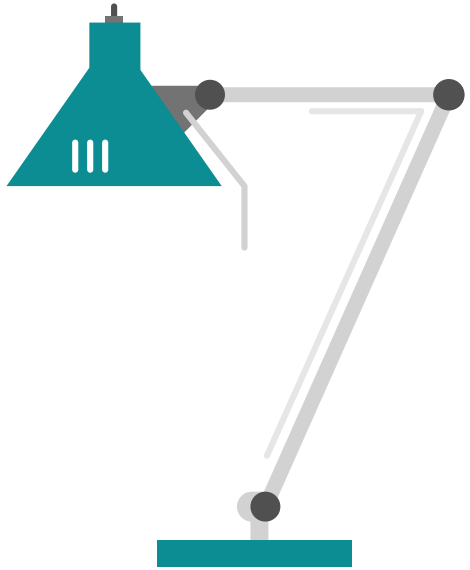
OASH | Office for Human Research Protections

Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

For a complete and accurate description of the regulatory requirements, please refer to the text of the Common Rule available on OHRP's website.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html



Summary

- COGR's original request to OHRP: *Provide thoughts regarding considerations for IRBs when they apply the Common Rule criteria and Belmont Report's ethical framework to research that utilizes AI.*
- I will address:
  - What the Common Rule covers (and what it doesn't)
  - How getting specific can help the human research protections community
- Along the way, I hope to highlight:
  - That ethical AI research is a shared responsibility
  - The ways in which human protections regulations intersect with AI research
  - Useful resources

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What the Common Rule Covers (and What it Doesn't)

What is "Common" About the Common Rule?

- CR is followed by 20 US federal departments and agencies for human subjects research that they conduct or support.
- Each CR department or agency is responsible for oversight of the research that it conducts or supports.
- It is important to seek guidance from the CR department or agency supporting your activities.
- **CR is the floor, not the ceiling!**
- **Compliance with the CR does not mean a study is free from risk or ethical concerns.**

Does the Common Rule Apply?

To determine* whether a project ***supported or conducted by a Common Rule department or agency*** is ***nonexempt human subjects research***†, ask these questions in this order:

1. Does the activity involve ***research***?
2. Does the research involve ***human subjects***?
3. Is the human subjects research ***exempt***?
4. Which institutions are **"engaged"** in the nonexempt human subjects research?

*Neither pre-2018 nor 2018 Requirements prescribe who determines whether projects do or do not constitute "research."

†Use the definitions in the regulations: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102 and OHRP's decision charts: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

Does the Activity Involve Research?

From 45 CFR 46.102(l) with **boldface** added:

*Research means a **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes…*

Does the *Research* Involve *Human Subjects*?

From 45 CFR 46.102(e)(1) with **boldface** added:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) ***Obtains information*** *or biospecimens* ***through intervention or interaction with the individual****, and uses, studies, or analyzes the information or biospecimens; or*

(ii) Obtains, uses, studies, analyzes, or generates ***identifiable private information*** *or identifiable biospecimens.*

Is the Information *Private* and *Identifiable*?

From 45 CFR 46.102(e)(4) & (5) with **boldface** added:

*Private information: Includes information about behavior that occurs in a context in which **an individual can reasonably expect that no observation or recording is taking place**, and information that has been provided for specific purposes by an individual and that **the individual can reasonably expect will not be made public** (e.g., a medical record).*

*Identifiable private information: Private information for which the **identity** of the subject is or **may readily be ascertained by the investigator** or **associated with the information**.*

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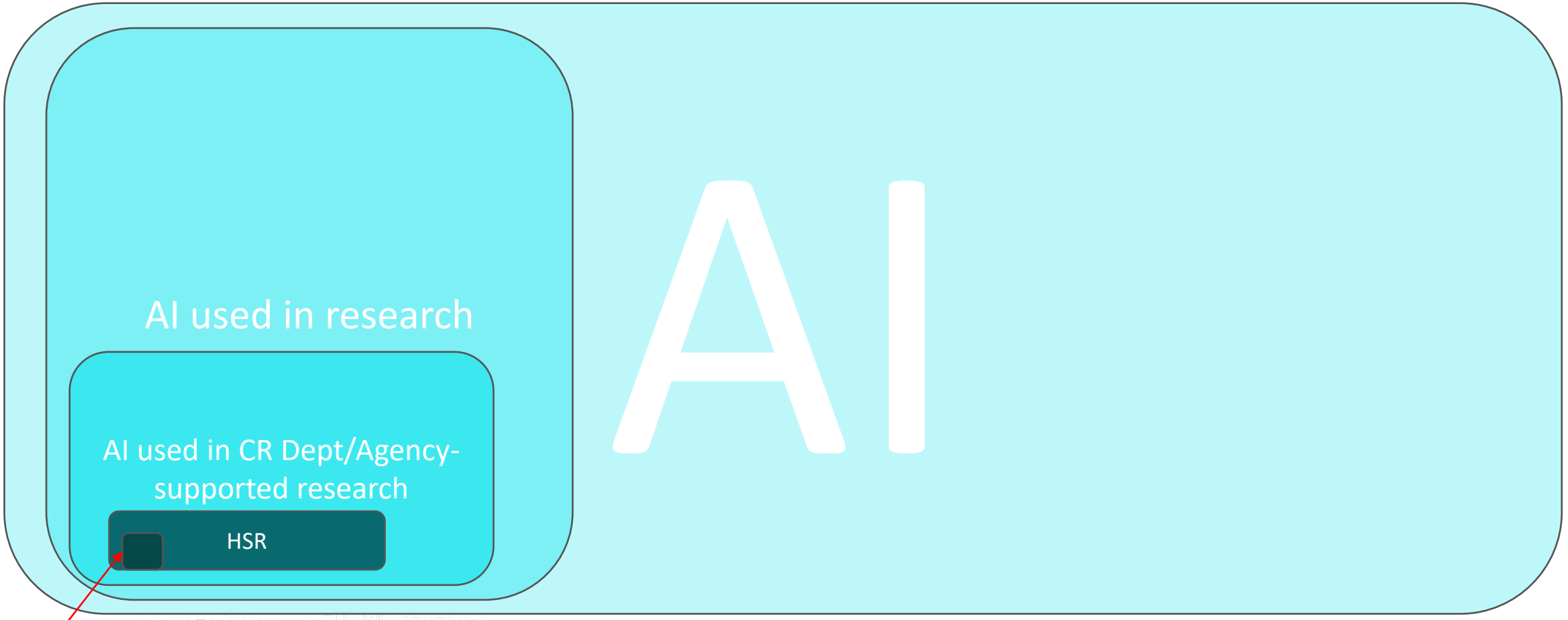
Let's Visualize This…(Not Drawn to Scale)



Why This is Important

- A lot of human research that uses AI/ML will occur outside the scope of the Common Rule.
- Ethical, responsible use of AI/ML in research is a shared responsibility:
  - Institutions, including universities and hospitals
  - Investigators
  - Funders
  - Regulators
  - IRBs
  - Companies developing AI/ML technologies
  - End-users

How Getting Specific Can Help the Human Research Protections Community

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Types of Research Use Case

- One possible taxonomy:
  - Using or collecting data to develop or test AI/ML
  - AI/ML as a study intervention
  - AI/ML used in non-investigational study procedures
  - AI/ML used as a research support tool
- There are other ways to categorize, and…
- Each could present different human research protections considerations.
- *I will talk more about this in the following slides.*

Using Data to Develop or Test AI/ML

- Does the Common Rule apply?
- Are the data representative?
- Are the data coded/labeled appropriately?
- Are the appropriate data elements/variables included?
- Are there any terms or conditions of using or sharing the data for research?
- Did people agree to the use of their data in research?
- Are there anticipated privacy concerns?
  - King and Meinhardt (2024): https://hai.stanford.edu/white-paper-rethinking-privacy-ai-era-policy-provocations-data-centric-world?sf186496729=1
- What is the potential for group harms or misuse?
- *Not exhaustive!*

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AI/ML as a Study Intervention

- Will the AI intervention have human oversight?
- What is known (and unknown) about the research intervention?
- How can risks appropriately be mitigated?
- How should the consent explain the risks and benefits?
- How might participants feel about the use of AI, including in SBER?
- Does the IRB have expertise to review? If not, has the IRB considered a consultant (45 CFR 46.107(e))?
- How can the study ensure equitable subject selection?
  - Plana et al. (2022): https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796833
- *Not exhaustive!*

AI/ML as Non-Investigational Study Procedures

- Are the non-investigational procedures research or clinical care?
- What is known (and unknown) about the AI procedure/tool and any risks or benefits?
- Does it require approval or clearance by the FDA?
- Should the consent document disclose that AI is being used?
- Is there human involvement/oversight?
- If using a third-party algorithm, are there additional considerations for consent, data privacy, data ownership, or other terms of service?
- *Not exhaustive!*

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AI/ML as an Administrative Tool

- Could AI be used to increase human research protections?
  - Hutson (2023): https://www.science.org/doi/pdf/10.1126/science.adj6791
  - Zhang et al. (2023): https://www.nature.com/articles/s43856-023-00425-3
- What evidence exists to support that the AI/ML works as intended?
- What could happen if the AI tool "hallucinated" information?
- Is there human involvement/oversight?
- Is there a need to disclose use of the AI/ML to others (e.g., investigators, IRBs, research participants, scholarly journals, etc.)?
- *Not exhaustive!*

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Why This is Important

- Talking about “how IRBs review AI” is broad and abstract.
- Considering the different ways AI/ML might be used in human research or its development, administration, and oversight, may help our conversations to be more useful in our shared mission.

Resources

OHRP Guidance and Educational Materials

- Human Subjects Regulation Decision Charts
- Coded Private Information or Biospecimens Used in Research, Guidance (2018)
- Human Subject Regulations Decision Charts: 2018 Requirements
- Issues to Consider in the Research Use of Stored Data or Tissues (1996, 1997)
- Quality Improvement Activities FAQ
- OHRP Exploratory Workshop: Privacy & Health Research in a Data-Driven World

Relevant SACHRP* Recommendations

- IRB Considerations on the Use of Artificial Intelligence in Human Subjects Research
- Considerations for IRB Review of Research Involving Artificial Intelligence
- Use of Social Media by Research Subjects: Ethical and Regulatory Considerations for the Protection of Human Research Subjects
- The Protection of Non-Subjects from Research Harm
- Consideration of the Principle of Justice 45 CFR part 46
- Clarifying Requirements in Digital Health Technologies Research
- Human Subjects Research Implications of “Big Data” Studies

References and Related Readings

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Contact OHRP

- Contact us or submit your questions to OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp
- Education page: https://www.hhs.gov/ohrp/education-and-outreach/index.html
- Policy and Guidance page: https://www.hhs.gov/ohrp/regulations-and-policy/index.html

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THANK YOU!