The Intersection Between Artificial Intelligence and Human Subjects Research- A Regulatory and Ethical Perspective

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Objectives & Disclaimer

- Human subjects research (HSR) primer

- When artificial intelligence (AI) may involve HSR

- Research regulatory and ethical considerations
  - AI Research Ethics
  - Best Practices in Use of Human
    Data in AI Research

- Questions

The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the USAF, the Department of Defense, or the U.S. Government.

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Convergence of Ethics, Big Tech and DoD

Jun 7, 2021, 10:00am EDT

From Inclusion To Influence How To Build An Ethical AI Organization

Ashish Sukhadeve Forbes Councils Member
Forbes Business Council COUNCIL POST | Membership (fee-based)
Small Business

Science · JUNE 8, 2021 5:50 PM AEST · Share

Killer algorithms: how to keep military AI under human control

CMS WiRE

Ethical AI Is Our Responsibility

By Ali Alkhafaji | May 17, 2021

CHANNEL: Digital Experience

Five years ago, Microsoft released its infamous bot, Tay, into the world of Twitter. Tay used a machine learning algorithm to learn from interactions on the platform, to then echo novel responses back based on that learning. Within short time it became obvious that Twitter is not ideal ground for unsupervised

NATO-Private Sector Dialogues focus on NATO 2030 initiative

02 Jun. 2021 - | Last updated: 02 Jun. 2021 16:57

English | French

In June 2020, NATO Secretary General Jens Stoltenberg launched NATO 2030, an initiative to strengthen the Alliance militarily, make it stronger politically and adopt a more global approach. NATO has reached out to civil society, youth and the private sector for their input on NATO 2030, including through a series of six NATO-Private Sector Dialogues held in cooperation with GLOBSEC. These dialogues looked at how

Expect an Orwellian future if AI isn't kept in check says

By Stephanie Pappas - Live Science Contributor 07 June 2021

AI is already being used for widespread surveillance in China.

Military & Aerospace Electronics SUBSC

John Keller
Jun 4th, 2021

WASHINGTON – U.S. Department of Defense (DOD) leaders plan to invest $874 million next year in artificial intelligence (AI)-related technologies to boost deterrence against potential adversaries like China, as well as to enhance efficiencies in computing, command and control, and logistics.

Pentagon experts are asking Congress for AI funding in several projects, as revealed in the federal fiscal year 2022 DOD budget, which was released last week. Federal fiscal year 2022 begins next 1 Oct. The Pentagon's AI efforts now number more than 600, which is up about 50 percent over current-year levels, DOD officials say.

In efforts to keep technological pace with China and other adversaries, DOD is leveraging technological advantages and investing in cutting-edge technologies like AI, hypersonic technology, cyber, and quantum computing, among others,

DETAILS

BY: KATE POLIT
JUN 7, 2021
3:16 PM

DoD Releases Roadmap for "Responsible AI" Implementation

RECENT

To embrace the opportunities of AI, the Department of Defense (DoD)

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Dr. Hicks' *Responsible* AI Memo
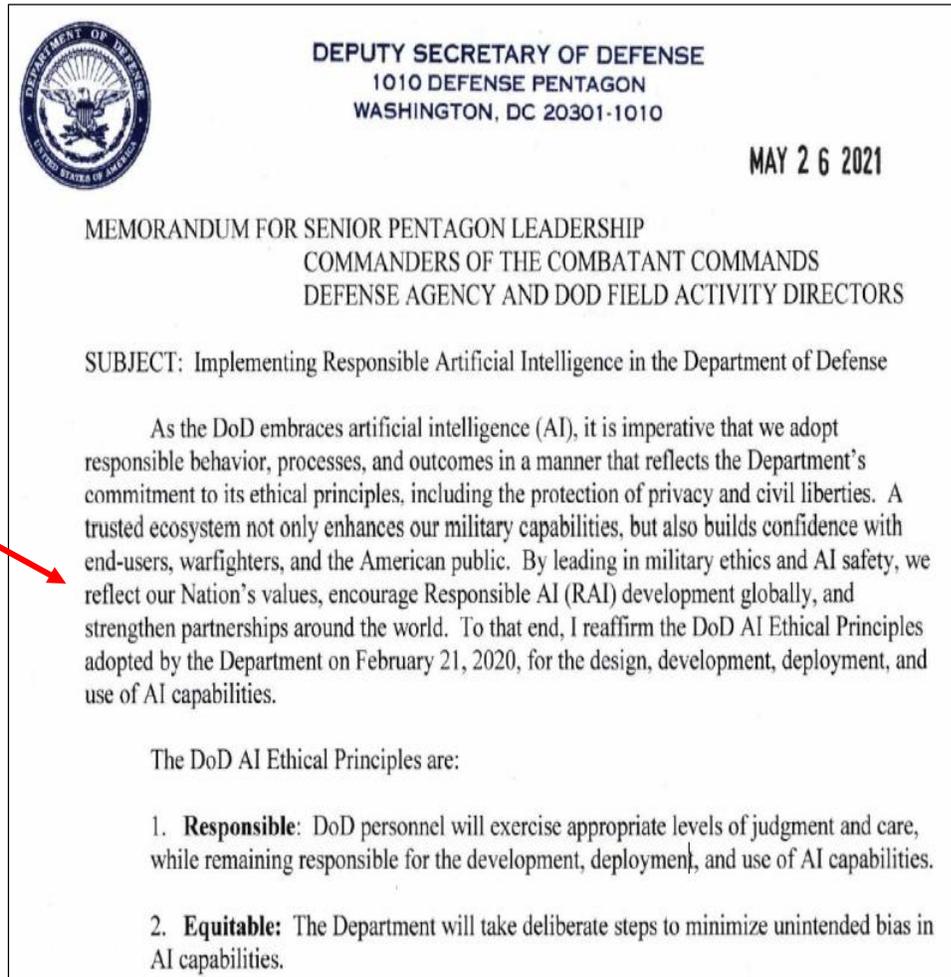
Human Subjects Research Protections: A Brief Overview

The Belmont Report

History: "Belmont" to the Code of Federal Regulations
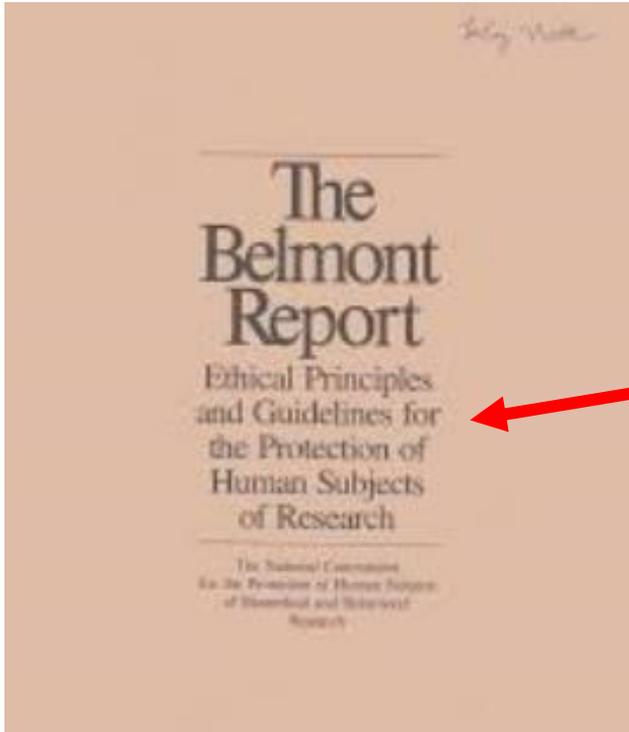
- **The Tuskegee Study**
  Significant ethical lapses were identified, in Tuskegee and many other studies

- **The Belmont Report**
  Fundamental *principles* for the ethical conduct of research were advanced (respect for persons; beneficence; justice)

- **The Code of Federal Regulations, 32 CFR 219**
  Specific regulations were formally adopted and explicit requirements are now found in...

"The Common Rule"

What is human subjects research (HSR)?

**Federal Common Rule Definitions (Implemented via DODI 3216.02)**

- **Research:** 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 the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

- **Human Subject:** A living individual about whom a researcher:

    (a) obtains information or biospecimens through intervention or interaction, and uses, studies, or analyzes it; OR

    (b) obtains, uses, studies, analyzes, or generates *identifiable private information* or biospecimens"

Human-Machine

Medical Devices · Software · Mobile Apps · MMAs
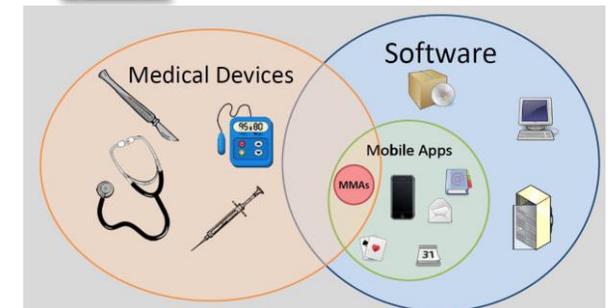
Research Altitude Chambers

Data Sciences

Notable concepts about "identifiable" and "private" information:
- The Privacy Act sets forth what is personally identifiable information (PII)
- The Health Insurance Portability and Accountability Act (HIPAA) sets forth what is protected health information (PHI)
- DoD and DoD Components Civil Liberties instructions discuss privacy
- HHS Office of Research Protections provides guidance as to when there may be reasonable expectation of privacy
- Just because personally identifiable information is on or shared via a social media site, does not necessarily mean it is not "private" (see terms of service, expectations of access/use, etc.)
- Original collection of personally identifiable information may have terms of use that controls downstream uses (e.g., Privacy Act - Statements, Data Sharing Agreements, Consent Forms)
- A myriad of other regulations may control the information (e.g. education records, financial records, genetic information, etc.)
- "Coded" data is NOT de-identified data (code keys re-link the data)
- Indirect identifiers may be combined to re-link data, thus is not always de-identified data

HSR Requirements

Per Federal Common Rule as implemented by DODI 3216.02, if an activity is HSR, then HSR regulatory and ethical requirements apply. In summary:

- **Research personnel work under a Human Research Protection Program (HRPP) and Assurance if applicable.**

- **Four general avenues of HRPP review:**

    (a) Exempt review, by a an officially designated DoD government HRPP reviewer

    (b) Non-exempt review, by a duly established Institutional Review Board (IRB)

    (c) Human Research Protections Official (HRPO) review, for non-DoD conducted research that undergoes a civilian IRB review

    (d) "Research Determination" review, by an officially designated DoD government HRPP reviewer

- **Review ensures Common Rule and DODI 3216.02 regulatory provisions are adhered to:** Details outside the scope of this presentation. FDA regulations would also apply for medical device/drug studies.

- **HRPP reviews ensure Belmont Report ethical principals adhered to**

    (a) <u>Respect for persons</u>: protect autonomy of research subjects, informed consent, privacy

    (b) <u>Beneficence</u>: do no harm, maximize benefits & minimize harm, risk assessment and mitigation

    (c) <u>Justice</u>: equitable selection of subjects, fair distribution of research benefits and burdens

Artificial Intelligence: Overview and when might it be HSR?

What is Artificial Intelligence (AI)?

No single regulatory definition of AI. As describe by Air Force Research Laboratory (AFRL):

- **Artificial Intelligence (AI)** refers to the ability of machines to perform tasks that normally require human intelligence – for example, recognizing patterns, learning from experience, drawing conclusions, making predictions, or taking action – whether digitally or as the smart software behind autonomous physical systems. WWW.AFRESEARCHLAB.COM

   (AI and algorithm development requires data…lots of data.)

- **Algorithm** is an overarching term that describes any processes or set of rules to be followed in calculations or other problem-solving operations. An algorithm takes *some input* and uses mathematics and logic *to produce the output.* Technically, if→then is an algorithm. Statistical tests are algorithms, but this is different than AI algorithms which is a continual process of providing new inputs.

- **AI algorithms** take both *inputs and outputs* simultaneously in order to "learn" the data and produce outputs when given new inputs. An AI system can make assumptions, test and learn autonomously. In Machine Learning, AI algorithms are "fed" data and are asked to process it. AI algorithms are typically consisted of a collection of algorithms.

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AI Ethical Requirements

Many institutions, organizations and governments across the globe have developed AI ethical frameworks, guidance, principals and requirements. The DoD has developed the following AI Ethical Principals:

- **Responsible**

- **Equitable**

- **Traceable**

- **Reliable**

- **Governable**

DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

MAY 2 6 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Implementing Responsible Artificial Intelligence in the Department of Defense

As the DoD embraces artificial intelligence (AI), it is imperative that we adopt responsible behavior, processes, and outcomes in a manner that reflects the Department's commitment to its ethical principles, including the protection of privacy and civil liberties. A trusted ecosystem not only enhances our military capabilities, but also builds confidence with end-users, warfighters, and the American public. By leading in military ethics and AI safety, we reflect our Nation's values, encourage Responsible AI (RAI) development globally, and strengthen partnerships around the world. To that end, I reaffirm the DoD AI Ethical Principles adopted by the Department on February 21, 2020, for the design, development, deployment, and use of AI capabilities.

The DoD AI Ethical Principles are:

1. **Responsible**: DoD personnel will exercise appropriate levels of judgment and care, while remaining responsible for the development, deployment, and use of AI capabilities.

2. **Equitable**: The Department will take deliberate steps to minimize unintended bias in AI capabilities.

When might AI activity involve HSR?
Medical example: Mobile Medical Apps
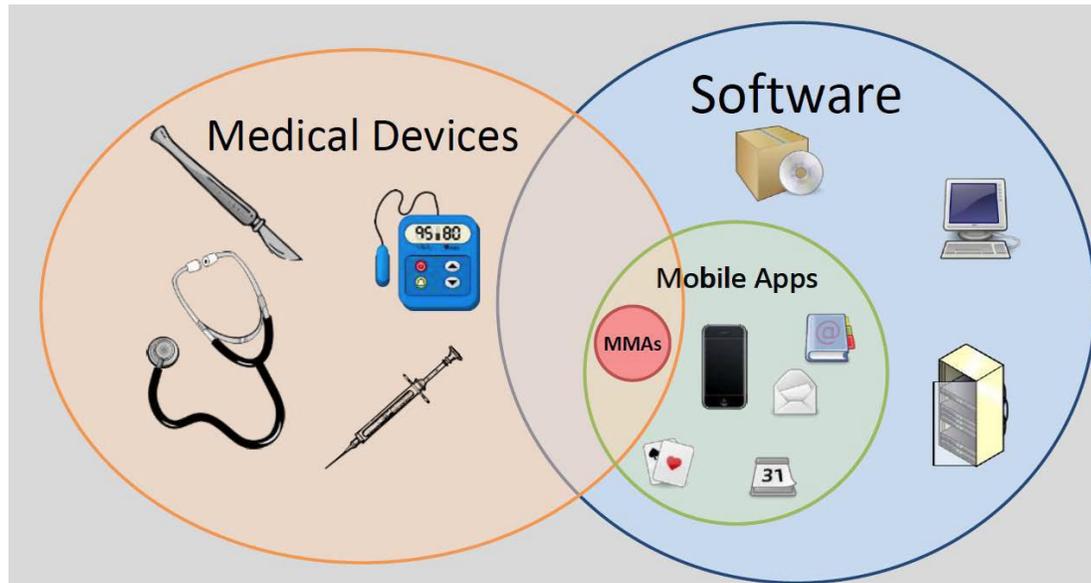
FDA-regulated research and development activity is a sub-set of HSR.

FDA Regulated: AI algorithms intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of.

(Top: Piermatteo, 2019; Bottom: ImPACT, 2021)

Smart devices sold separately.

AI-based Software as a Medical Device (SaMD)

Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow
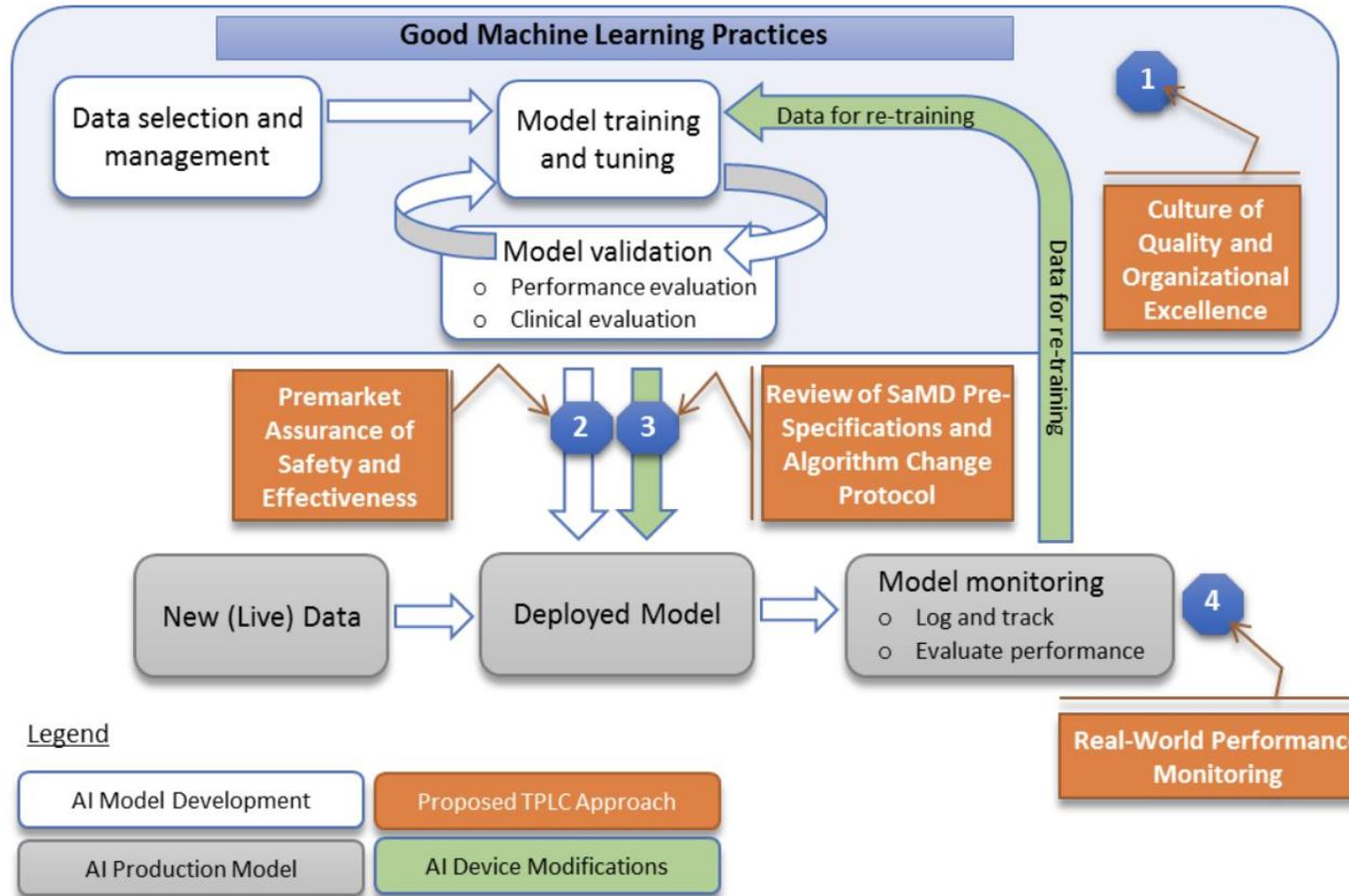
FDA has issued AI based SaMD Guidance, which HRPP reviewers apply to AI-HSR that involves medical devices.

When might AI activity involve HSR?

Non-Medical examples:

- Use of human to interact with robotic or machine to learn about the human trust, response and actions, in order to develop/train the robotic or machine. (Systematic investigation, involving *interaction/intervention* with a living human.)

- AI algorithm development often involves learning from data collected from, on, or about humans. Examples:

    - Access to and use of live human identifiable facial images to develop and validate facial recognition technology. (Systematic investigation, involving access and use of identifiable living human information.)

    - Access to and use of living human identifiable data to develop and validate an algorithm that will identify the readiness level of a military operator.
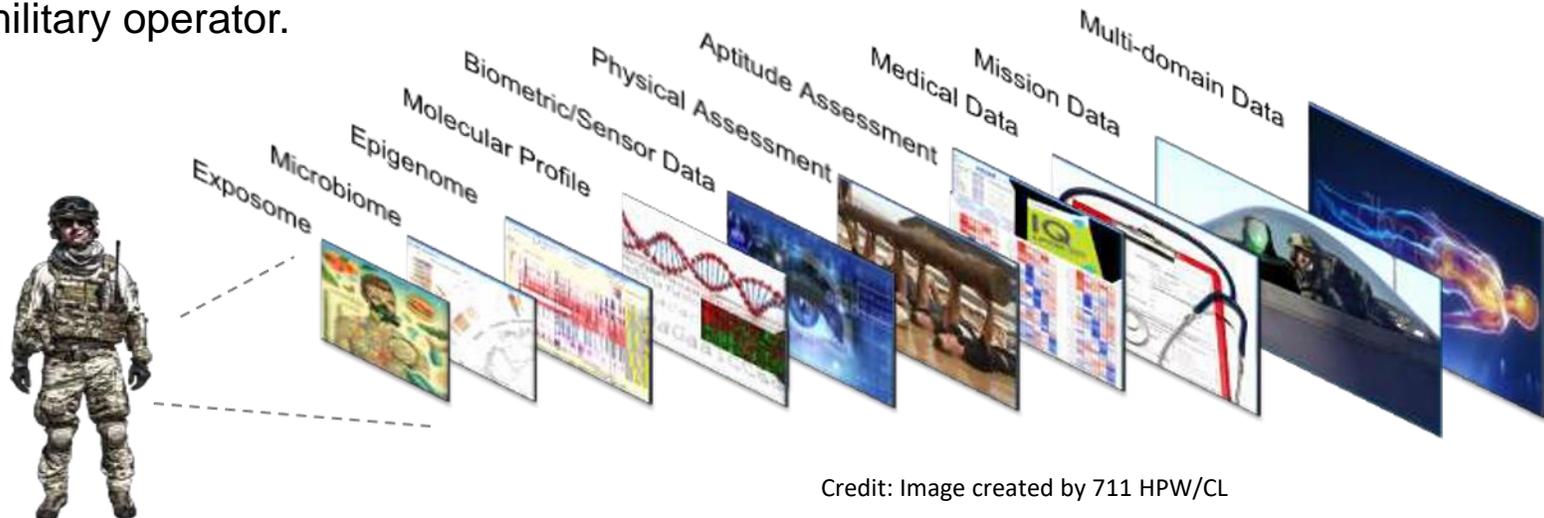
Credit: Image created by 711 HPW/CL

Regulatory and Ethical Considerations when AI intersects with HSR

Regulatory and ethical considerations when AI intersects with HSR

- **Seek guidance/assistance from your servicing HRPP or IRB (early)**

- **If in doubt whether AI activity is HSR, seek official determination by servicing HRPP staff. Proponents of the activity are not permitted to make official HSR determinations.**

- **Navigating regulatory provisions with use of large amounts of human data needed for AI development can by complex. Remember the notable concepts about "identifiable" and "private" information.**

- **Informed consent to access and use private, personal identifying data (or waiver by an HRPP reviewer if appropriate) is a hallmark requirement.**

- **Scientific review of non-exempt HSR required; avoid algorithmic bias, show how bias is mitigated; obtain a qualified data SME for scientific review of AI**

- **Exempt HSR must still comply with the Belmont Report, as such, for DoD, the DOD adopted AI ethical principles would apply. Ensure a provision/means to show compliance.**

Summary

The practice of research ethics and regulatory compliance is well-rooted in the U.S. government, including the DoD.

The national imperative to advance AI does not include a provision to circumvent these well-rooted requirements, grounded in law, regulation, culture, and ethical standards.

CONCLUSION

The proponents of AI work in highly demanding environments. When HSR-driven regulatory matters are raised or standard ethical concerns are identified [human dignities, safety and civil liberties] DoD HRPPs stand ready to assist the research enterprise.

Resources

DoD 3216.02 – Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and- Supported Research

OHRP – HSR Guidance Documents
- https://www.orhp.gov

FDA - Digital Health
- https://www.fda.gov/medical-devices/digital-health-center-excellence
- Digital Health Criteria – Definitions

Joint Artificial Intelligence Center (JAIC) – Publications on AI relevant to the DoD
- https://www.ai.mil

Questions?