AFRL

ASSESSING BIOSECURITY RISKS AND MITIGATION: CONSIDERATIONS FOR DOD SUPPORTED RESEARCH INVOLVING GENOMIC DATA

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Disclosures

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Learning Objectives

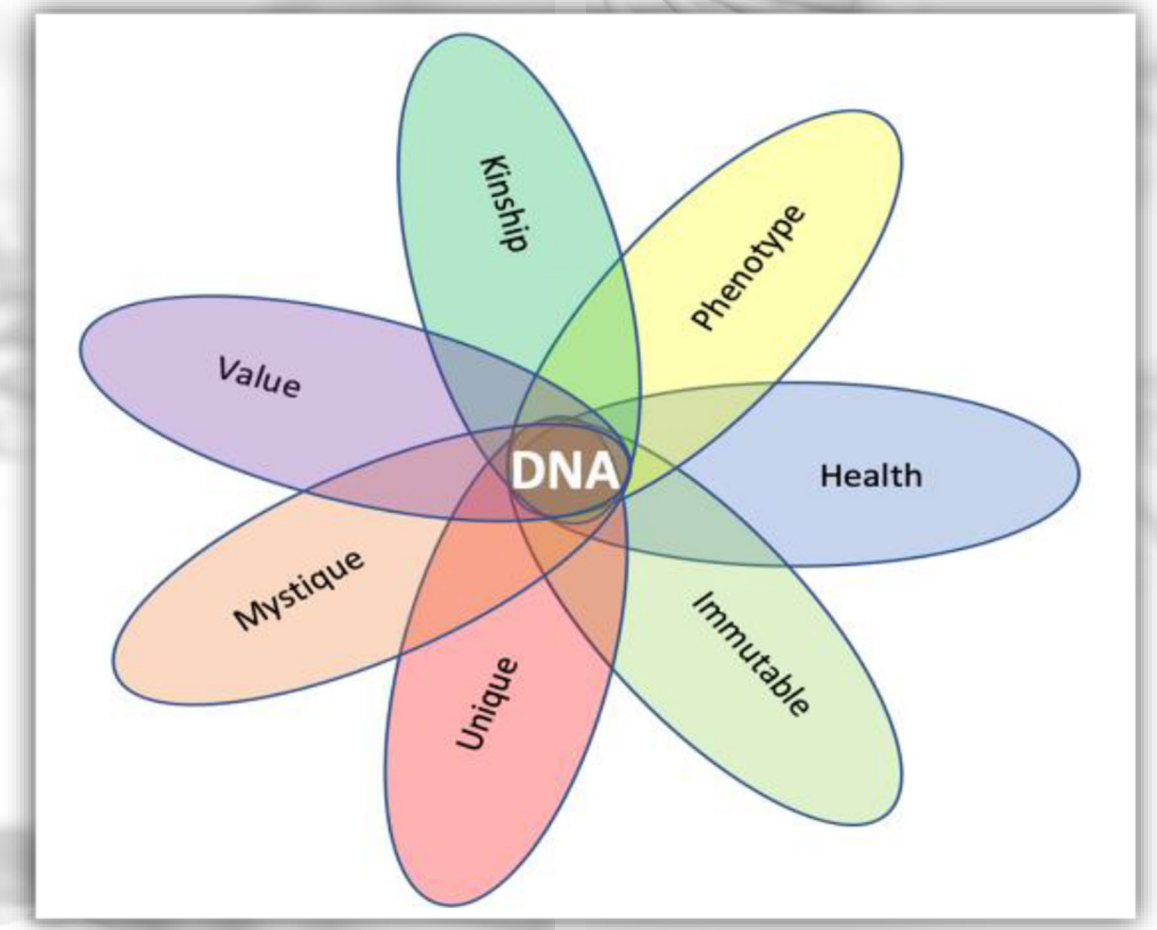
1. Recognize the unique attributes of human genetic data, and the importance of protecting it, particularly collected from DoD-affiliated personnel.

2. Identify the risks associated with collection, transfer, and storage of human genomic data.

3. Understand scaled mitigation strategies and current era controls to protect genomic data in DoD-supported human research.

Uniqueness of Human Genetic Data

Genetic data is not anonymous, but it is exceptional.



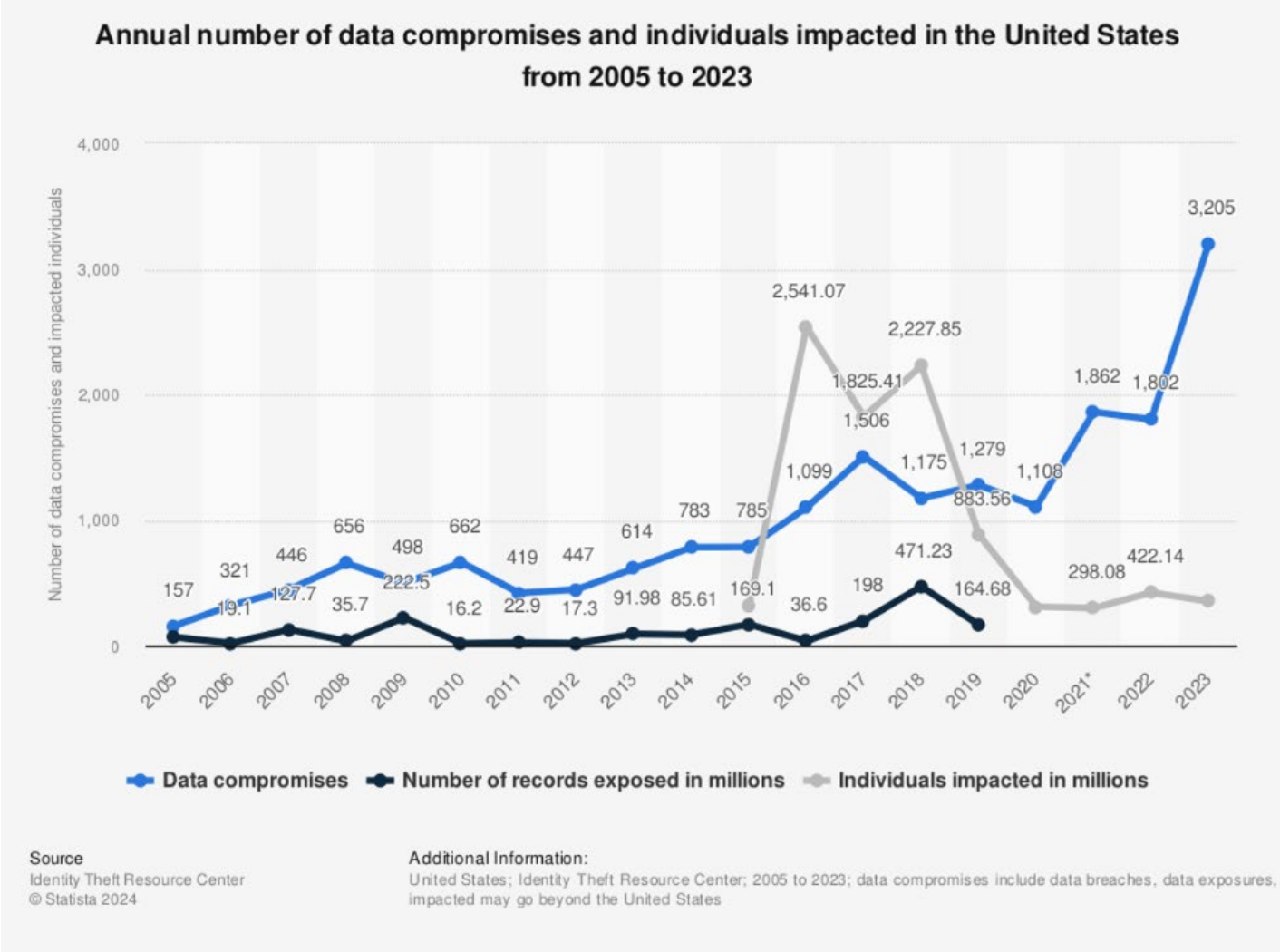
NIST IR 8432, DEC 2023

Risks Related to Human Genetic Data, Particularly DoD-affiliated Personnel

Risks involved with access to human genetic information

- National Security Concerns
- Bio-Economic Concerns
- Personal Privacy Concerns
- Discrimination and Reputational Concerns

➢ **These risks exist without biosecurity breaches but are increased with data breaches and bad actors.**



Ani Petrosynan, Statista, 12 Feb 2024, [Number of data breaches and victims U.S. 2023 | Statista]

Great Power Competition

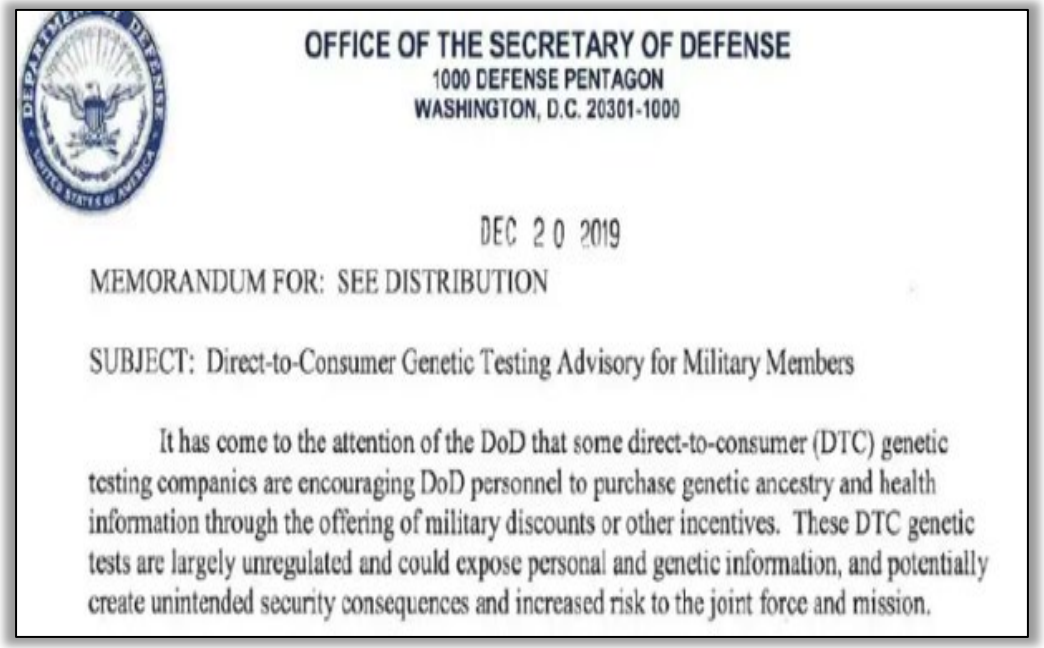
"The continuing effort of certain countries of concern to access Americans' sensitive personal data and United States Government-related data constitutes an unusual and extraordinary threat, […], to the national security […]. Access to Americans' bulk sensitive personal data […] increases the ability of countries of concern to engage in a wide range of malicious activities."

Individual Level Risks

- Discrimination
  - Genetic Information Nondiscrimination Act (GINA) has limitations
- Identity theft
- Reputation, black mail, extortion *(Who do you not want to know if you have APOE4 gene?)*

Risks Amplified for DoD-affiliated Personnel

- In 2019 Dept of Defense warned military members about Direct-to-Consumer genetic testing and associated risks:
  - Targeted bio-weapons, compromised operational security (identity of special operators/covert missions/family)
- NDAA FY2024: Dept of Defense to consider policy/ethical implications of Army research showing genetic pre-disposition to post traumatic stress disorder (PTSD).



OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-1000

DEC 20 2019

MEMORANDUM FOR: SEE DISTRIBUTION

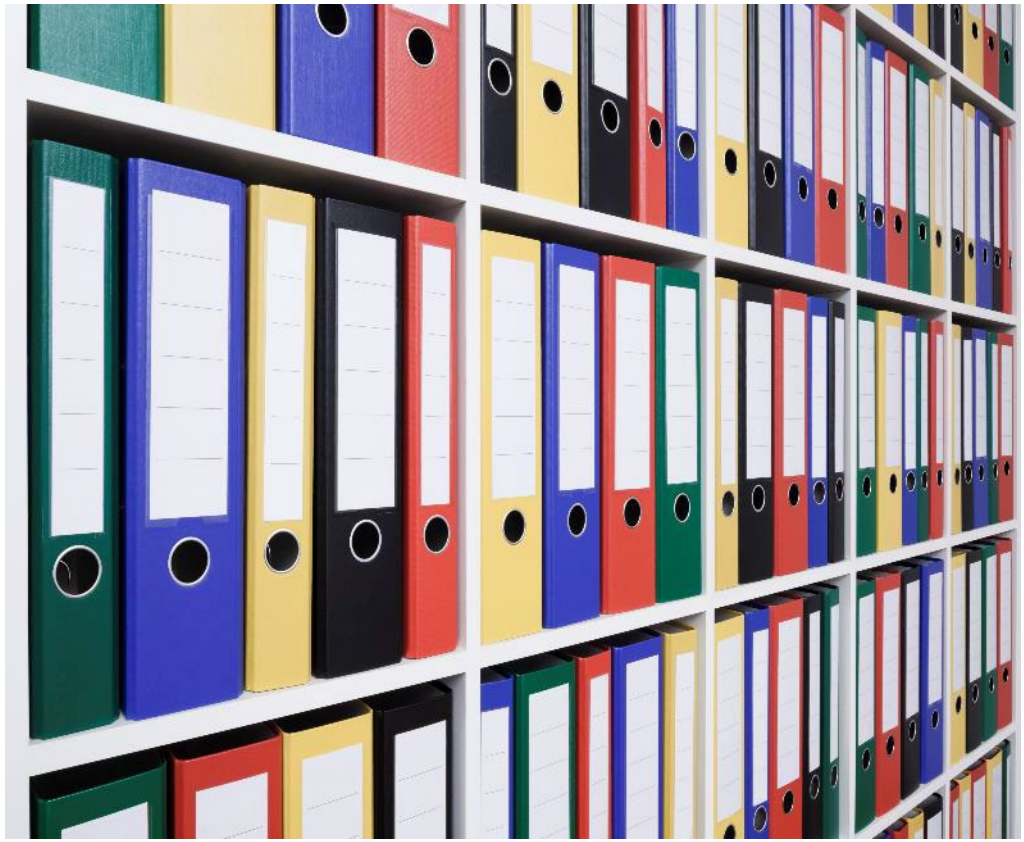
SUBJECT: Direct-to-Consumer Genetic Testing Advisory for Military Members

It has come to the attention of the DoD that some direct-to-consumer (DTC) genetic testing companies are encouraging DoD personnel to purchase genetic ancestry and health information through the offering of military discounts or other incentives. These DTC genetic tests are largely unregulated and could expose personal and genetic information, and potentially create unintended security consequences and increased risk to the joint force and mission.

Mitigation Strategies Trifecta:
Administrative
Physical
Technical/Cyber

Scalability of Risk Mitigation for DoD Personnel

Mitigation Strategies – Administrative



Key Regulations

DoDI 3216.02
- Security Review
- HHS Certificate of Confidentiality

GINA
- Limited Protection for Military

32 CFR 219 “DoD Common Rule”

HIPAA

Standards

NIST Cybersecurity/Privacy Framework

Institutional Policy

Utilize Data Sharing Agreements

Contractual terms data ownership/security

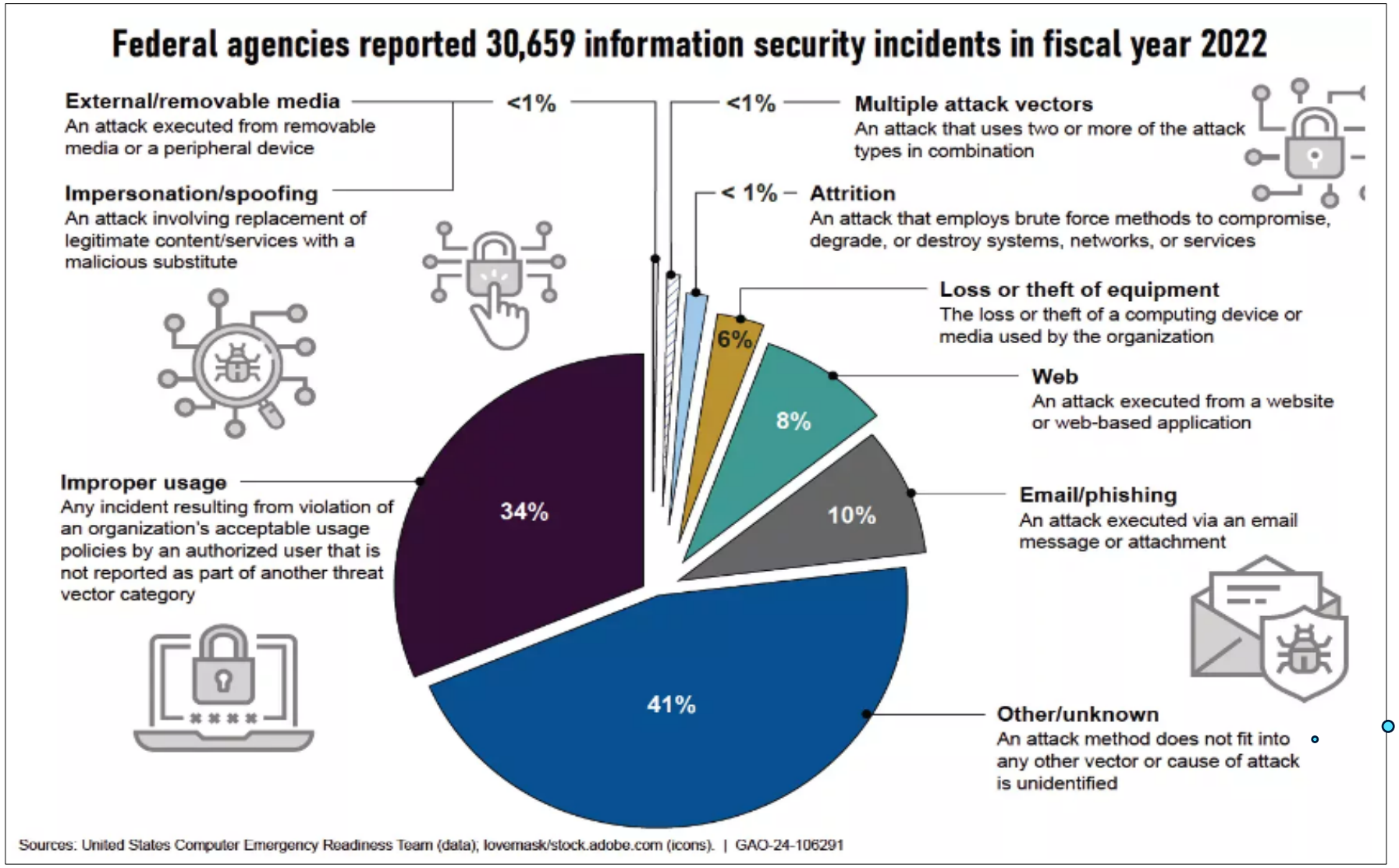
Limit access and redact sensitive data

Informed Consent Documents

Mitigation Strategies – Physical

- ✓ Secured Laboratories
- ✓ Restricted Access
- ✓ Supervised Access
- ✓ CAC Enabled Protection
- ✓ Additional Passwords
- ✓ Access Logs

Mitigation Strategies - Technical/Cyber



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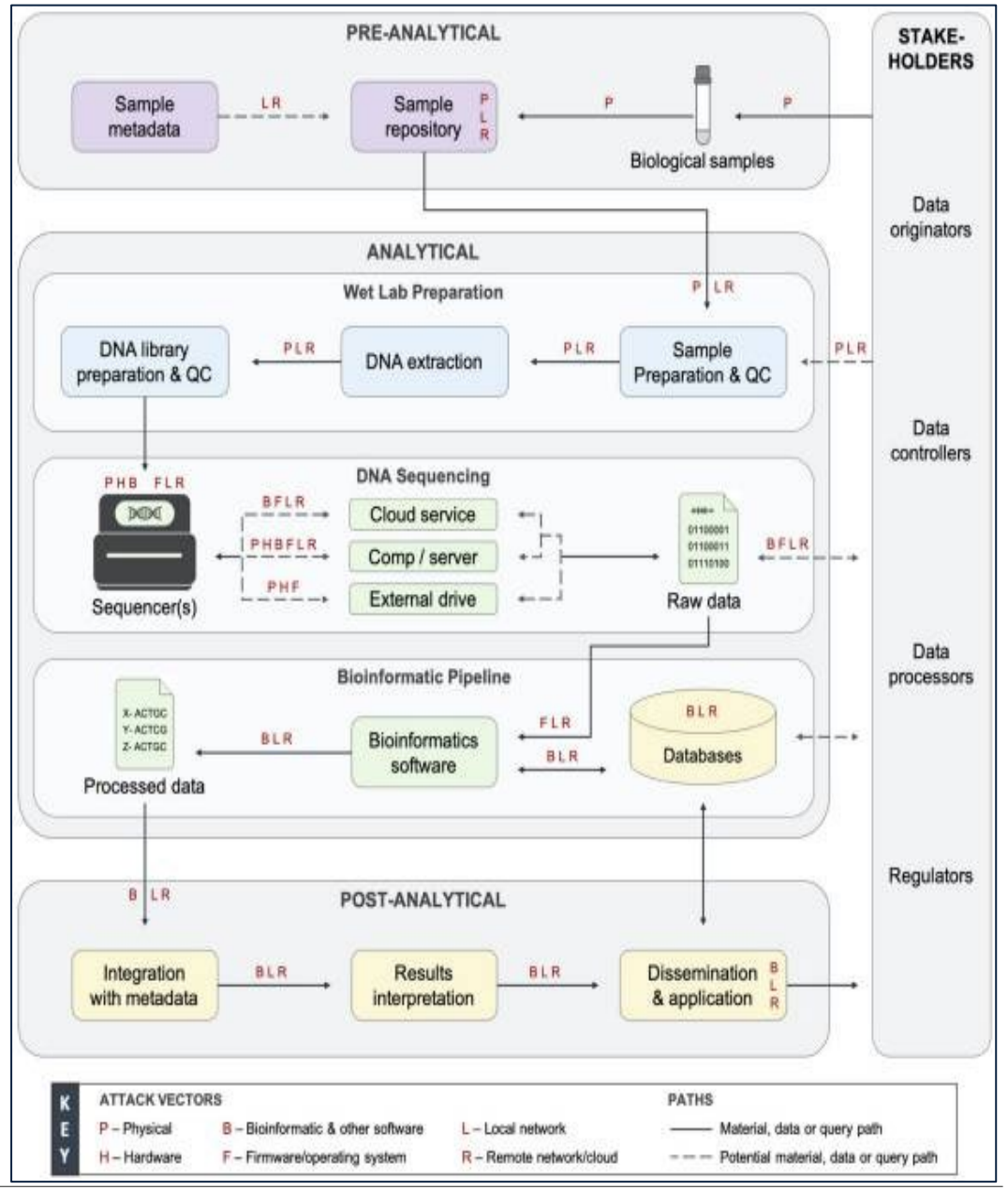
Mitigation Strategies - Technical/Cyber

"Data flow diagram of a generalized genetic information system and the accompanying threat landscape.

Genetic information systems are cyber-physical systems divided into three phases with people interacting with system components throughout. [….]

Every system component and stakeholder are vulnerable to exploitation via the attack vectors denoted by red letters. Figure modified from *Fayans et al. (2020)* with permissions." (*Schumacher, G* 2020)



Mitigation Strategies - Technical/Cyber

- Review carefully data flow from collection, to transmission and usage, to disposition and identify the many technical compromise risks as the data flows.

- Get an IT security and/or bioinformatics expert in the review process.

  - Encryption/Cryptographic solutions
  - Laws and frameworks for IT systems
  - Genomic data governance for IT systems
  - Identification and authentication controls

Summary/Conclusion

- Genetic information IS exceptional, particularly to military personnel and mission.
- Risks range from national security, bio-economy, to individual privacy concerns.
- In DoD-supported research, must carefully consider mitigation strategies including administrative controls, physical and technical/cyber controls—scale strategy to risk level. When DoD-affiliated genetic data is involved, higher risk requires tighter mitigation.

“What a 5,700-Year-Old Piece of Gum Reveals About Its Chewer”

Permission granted: Photo by Theis Jensen, Wired, 17 Dec 2019.

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QUESTIONS?

