



Disclosing the Role and Use of AI in Human Subjects Research

OHRP's 7th Annual Exploratory Workshop

The Evolving Landscape of Human Research with AI –

Putting Ethics to Practice

September 19, 2024

SARA GERKE

Associate Professor of Law

Richard W. & Marie L. Corman Scholar

University of Illinois Urbana-Champaign

College of Law

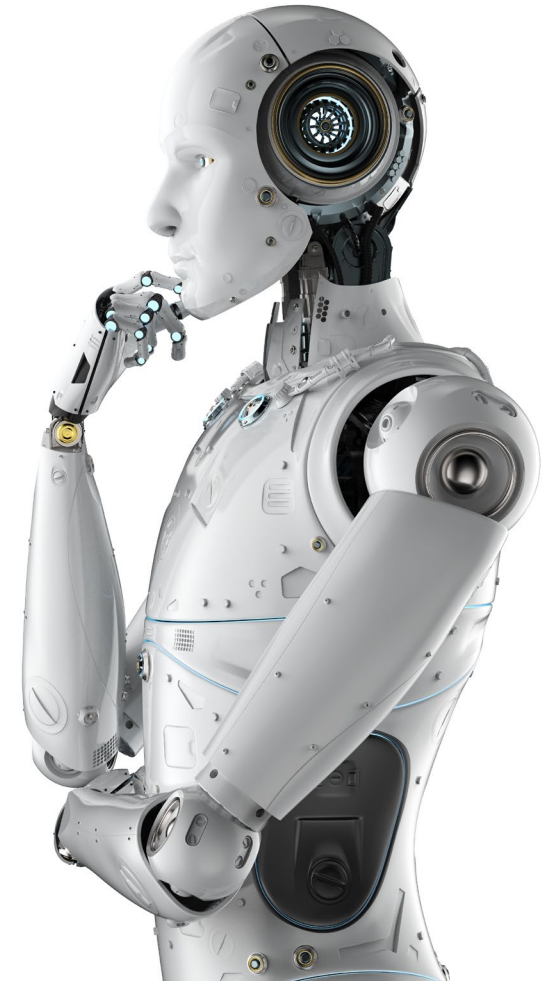
504 E Pennsylvania Ave

Champaign, IL 61820

gerke@illinois.edu

Outline

1. The Role and Use of AI in Human Subjects Research (HSR)
2. Informed Consent
 - Belmont Principles
 - Common Rule
3. Challenges Raised by AI

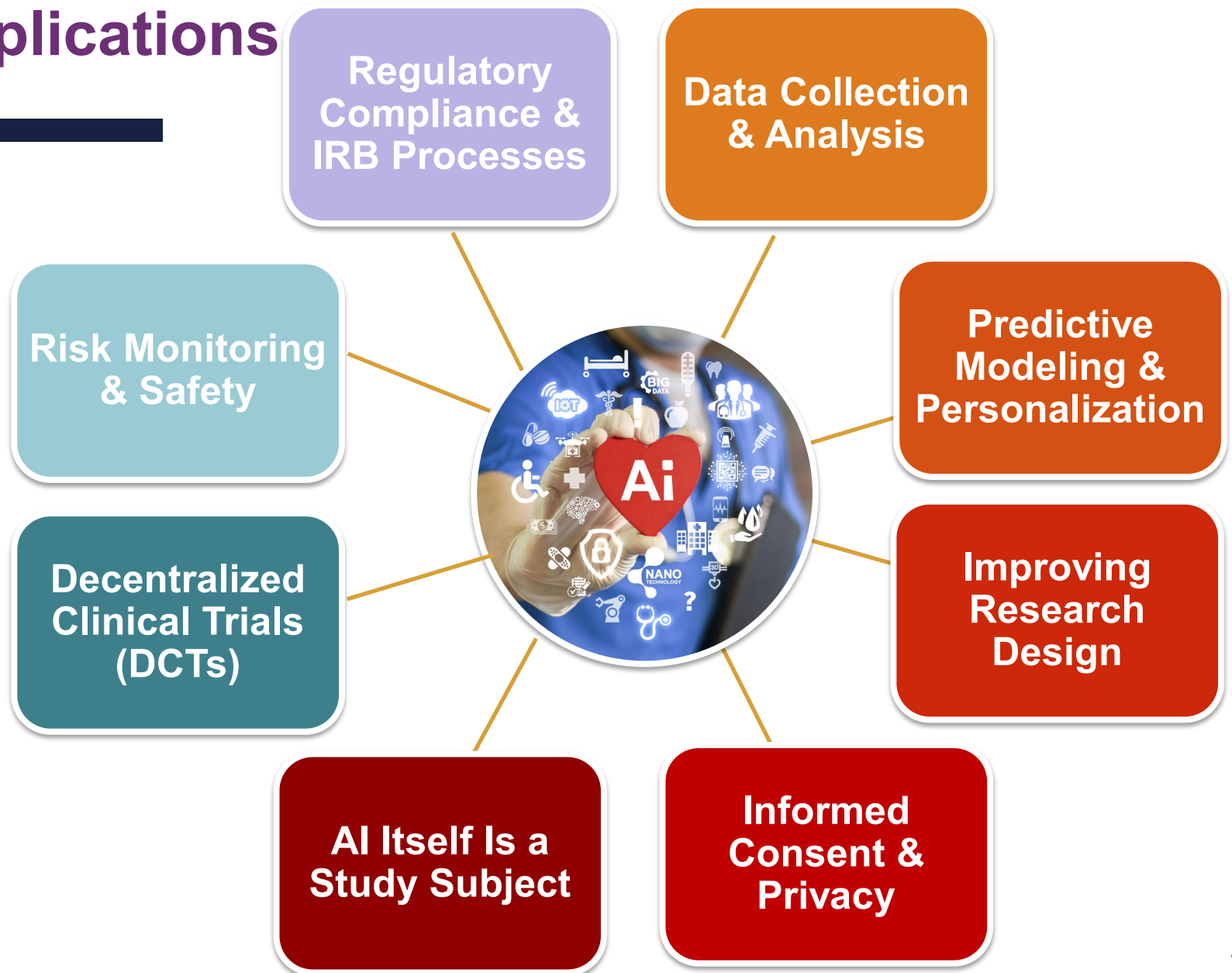




1.

The Role and Use of AI in HSR

Applications



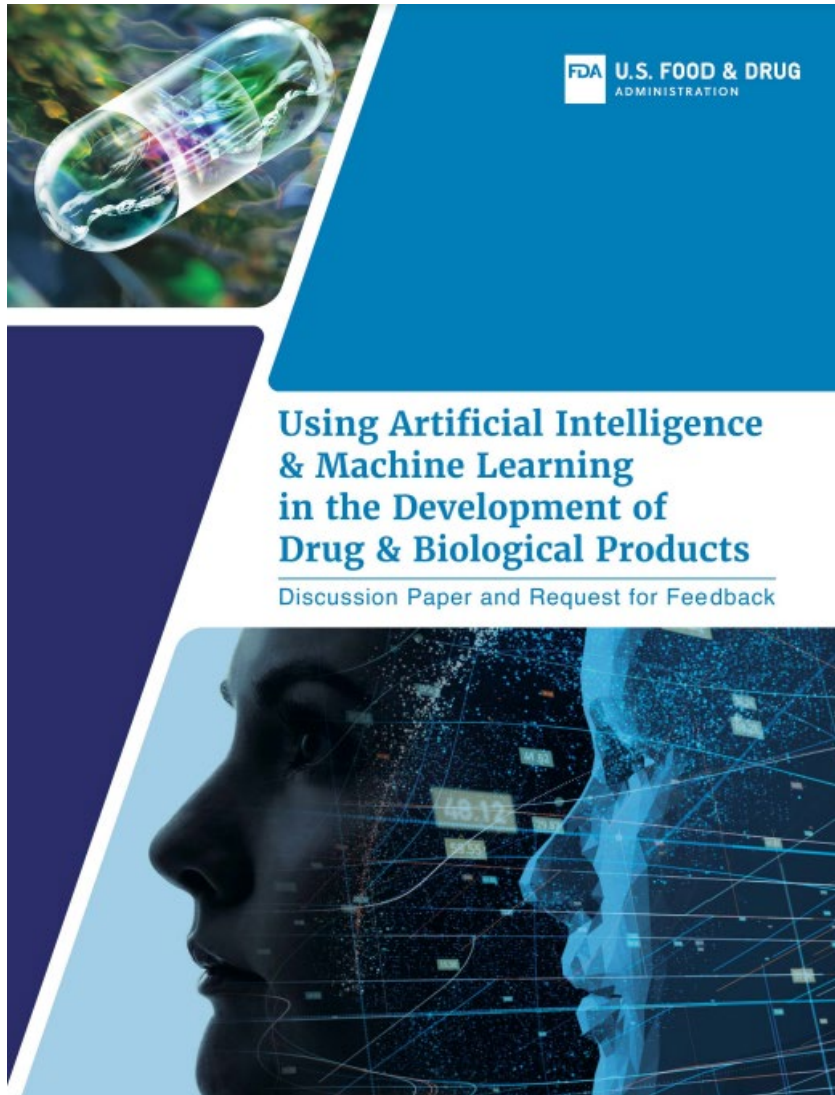
Transformation of the Drug Development Landscape

Rapid increase in the number of submissions to the FDA referencing AI

Approx. 300 submissions (2016–present)

The use of AI ranges from drug discovery to clinical research

FDA Discussion Paper



FDA Review and Marketing Authorization of AI/ML-Based Medical Devices

appropriate program.

Search:

Show entries

Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
06/25/2024	K232111	NeoBeat, NeoBeat Mini	Laerdal Medical AS	Cardiovascular	MWI
06/25/2024	K240582	VEAAlign; spineEOS	EOS imaging	Radiology	QIH
06/21/2024	K240465	O-arm O2 Imaging System	Medtronic Navigation, Inc	Radiology	OWB
06/21/2024	K233196	Medihub Prostate	JLK Inc.	Radiology	QIH
06/21/2024	K233253	eCARTv5 Clinical Deterioration Suite ("eCART")	AgileMD, Inc.	Cardiovascular	MWI
06/21/2024	K240631	V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 Diagnostic Ultrasound System	Samsung Medison Co., Ltd.	Radiology	IYN
06/21/2024	K233549	Tempus ECG-AF	Tempus AI, Inc.	Cardiovascular	SBQ
06/20/2024	K240642	SMART Bun-Yo-Matic CT	Disior Ltd	Radiology	QIH
06/14/2024	K232879	Roche Digital Pathology Dx (VENTANA DP 200)	Ventana Medical Systems, Inc.	Pathology	PSY
06/14/2024	K233955	Clarius OB AI	Clarius Mobile Health Corp.	Radiology	IYN
06/14/2024	K241083	SIS System	Surgical Information Sciences, Inc.	Radiology	QIH



Informed Consent

Research With Human Subjects Governed By the Common Rule (45 C.F.R. Part 46, Subpart A)

Research

45 C.F.R. § 46.102(l)

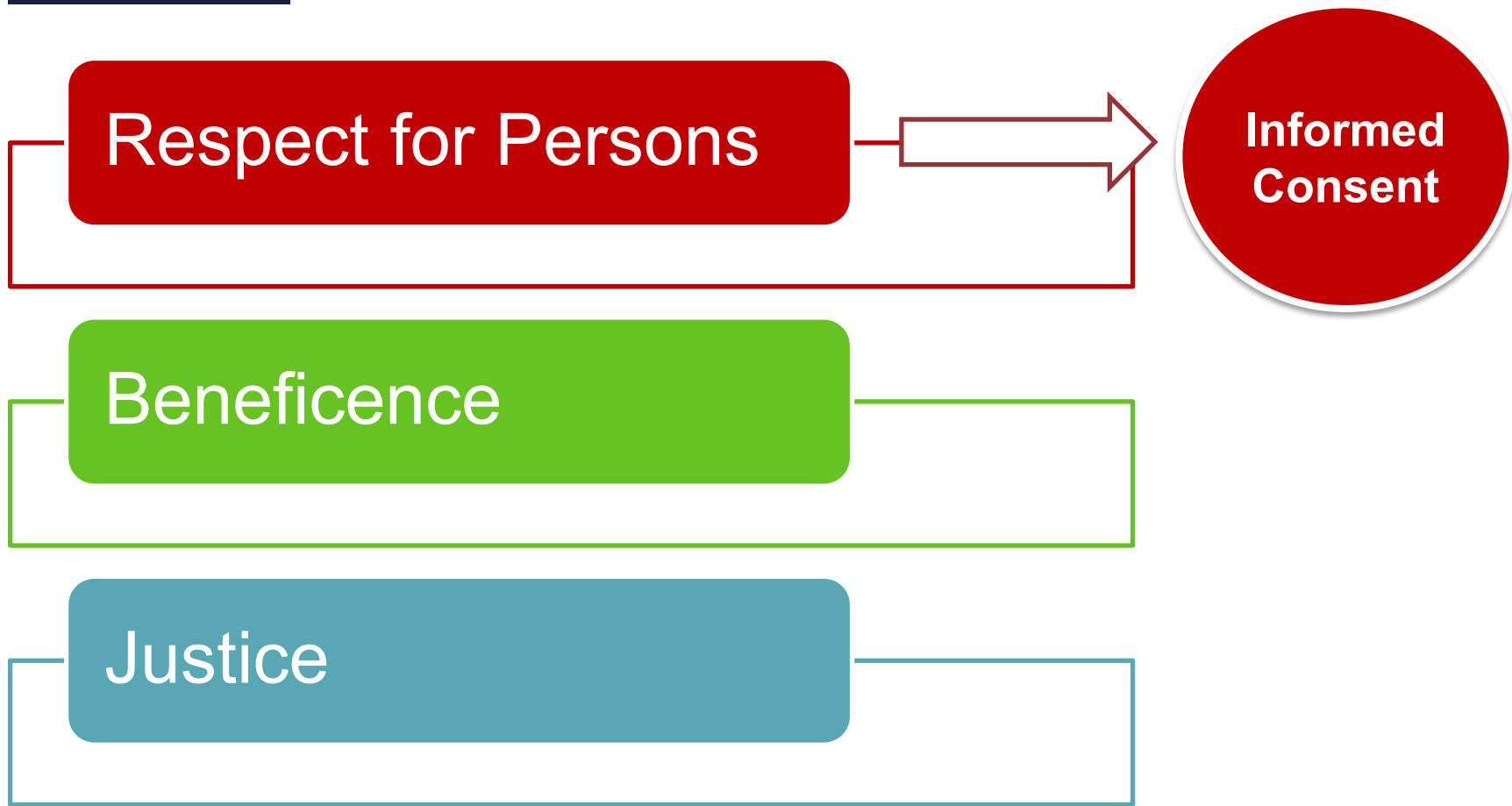
- “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Human Subject

45 C.F.R. § 46.102(e)(1)

- “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.”

Belmont Principles



Informed Consent

General Requirements for Informed Consent
(45 C.F.R. § 46.116(a))

Basic Elements of Informed Consent
(45 C.F.R. § 46.116(b))

Additional Elements of Informed Consent
(45 C.F.R. § 46.116(c))

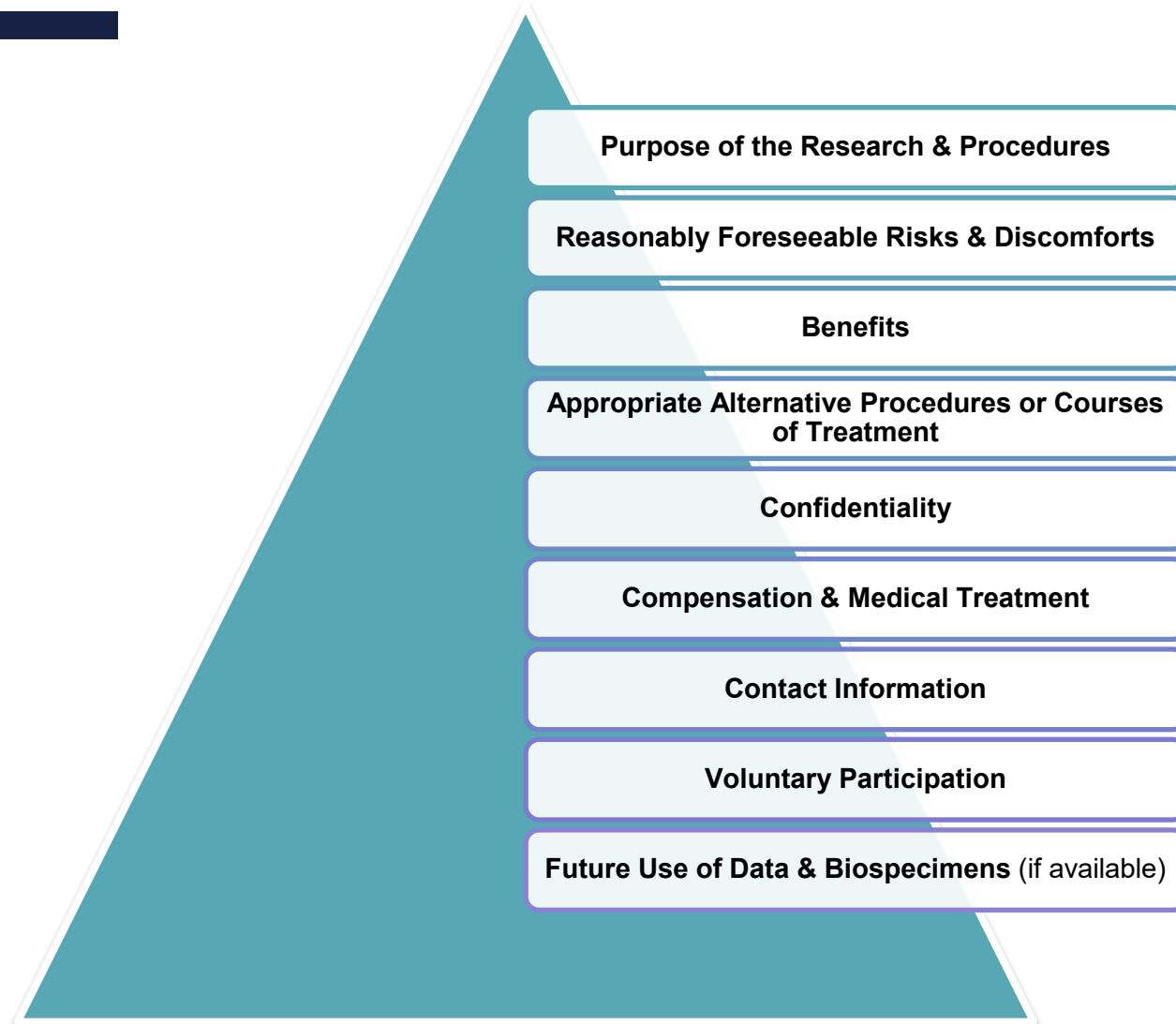
Waiver or Alteration of Informed Consent
(45 C.F.R. § 46.116(e) & (f))

Documentation of Informed Consent
(45 C.F.R. § 46.117)

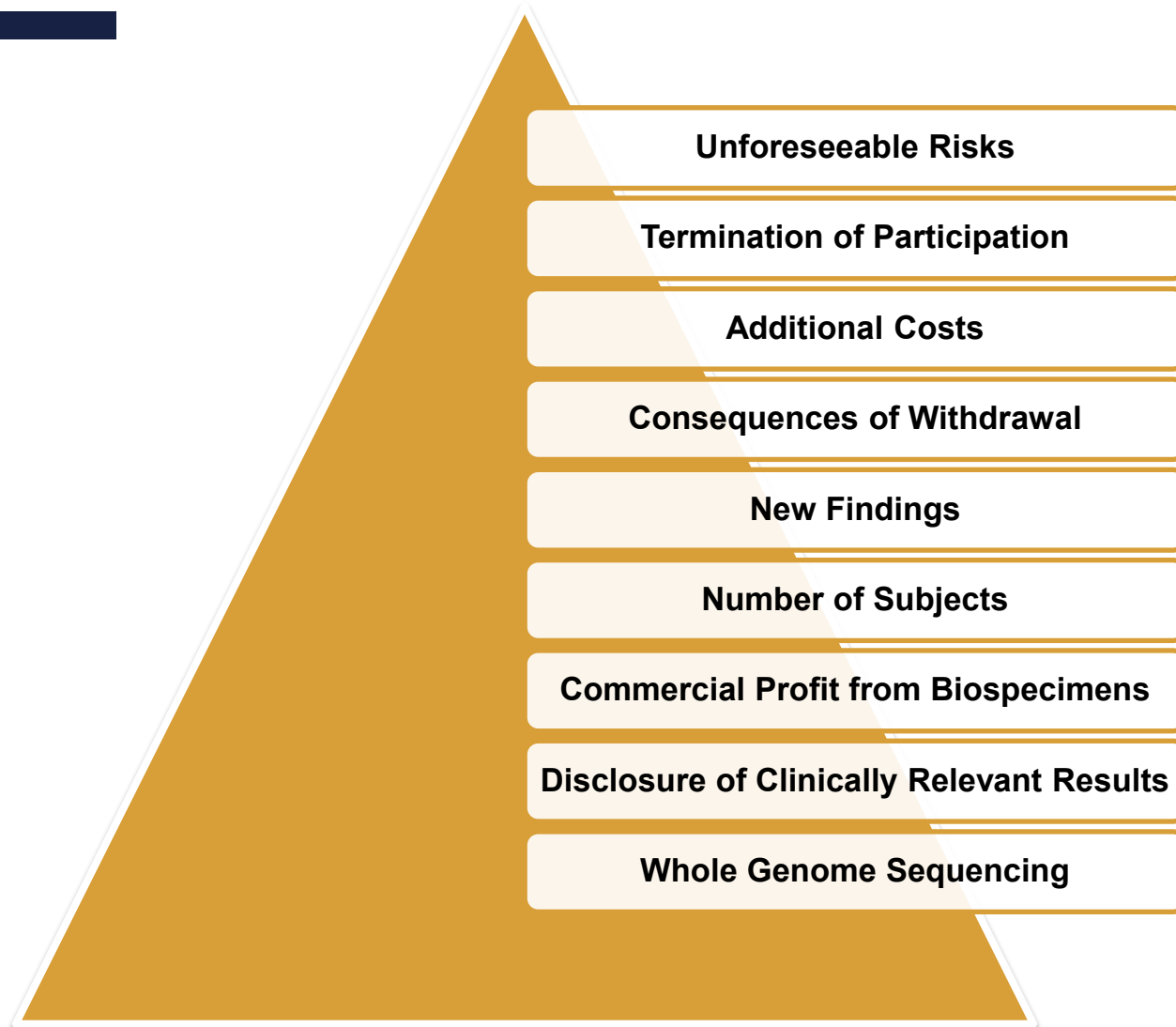
General Requirements for Informed Consent (45 C.F.R. § 46.116(a))

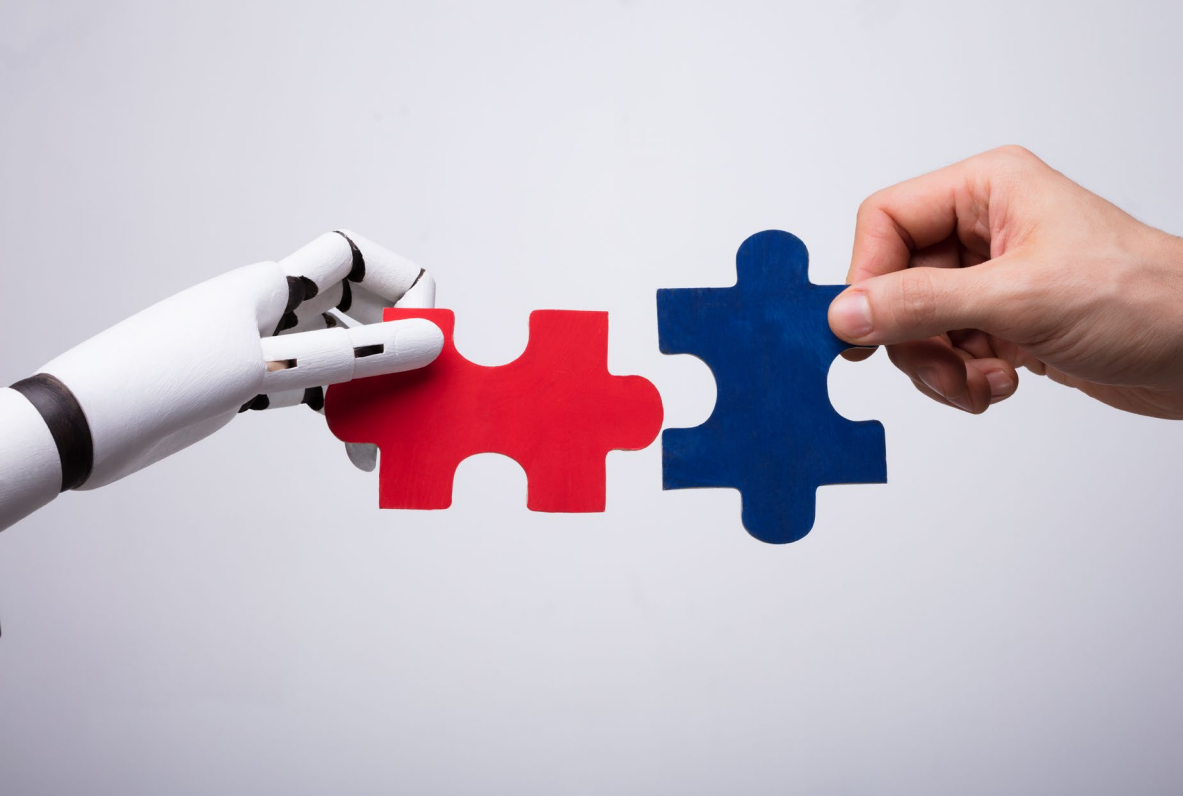


Basic Elements of Informed Consent (45 C.F.R. § 46.116(b))



Additional Elements of Informed Consent (45 C.F.R. § 46.116(c))





3.

Challenges Raised by AI

Challenges Raised By AI

- Do we **have to disclose the use of AI in HSR?**
If not, **should we?**
- **Challenge:** Diverse use of AI in HSR, ranging from data collection & analysis to AI being itself a subject of study.
 - **Promoting transparency and trust**
- If the use of AI in HSR is disclosed, what information must/should be disclosed?
 - **Considering the context of use**

Example: AI Is Itself a Study Subject

Key Types of Information That Should Be Included on the Label of AI/ML-Based Medical Devices

- (1) MODEL IDENTIFIERS
- (2) MODEL TYPE
- (3) MODEL CHARACTERISTICS
- (4) INDICATIONS FOR USE
- (5) VALIDATION & MODEL PERFORMANCE
- (6) DETAILS ON THE DATA SETS
- (7) PREPARATION BEFORE USE & APPLICATION
- (8) MODEL LIMITATIONS, WARNINGS & PRECAUTIONS
- (9) ALTERNATIVE CHOICES
- (10) PRIVACY & SECURITY
- (11) ADDITIONAL INFORMATION



gerke@illinois.edu

@gerke_sara