

Disclosing the Role and Use of Al in Human Subjects Research

OHRP's 7th Annual Exploratory Workshop

The Evolving Landscape of Human Research with AI -

Putting Ethics to Practice

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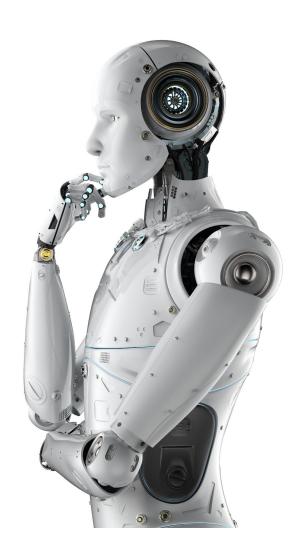
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Outline

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





1.

The Role and Use of Al in HSR

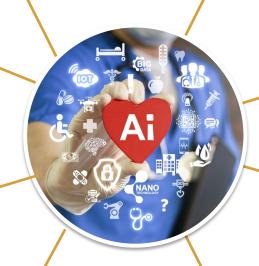
Applications

Regulatory
Compliance &
IRB Processes

Data Collection & Analysis

Risk Monitoring & Safety

Decentralized Clinical Trials (DCTs)



Predictive
Modeling &
Personalization

Improving Research Design

Al Itself Is a Study Subject

Informed Consent & Privacy

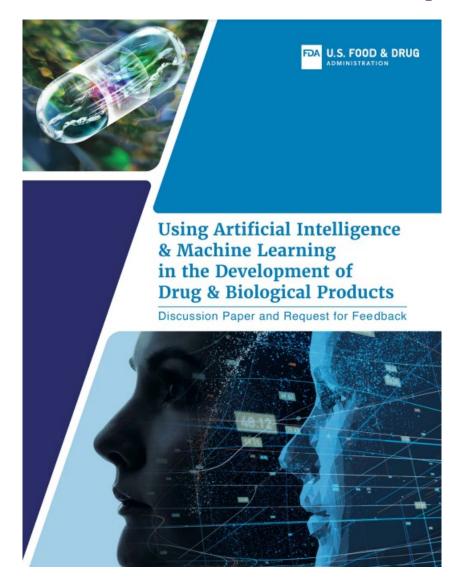
Transformation of the Drug Development Landscape

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

Approx. 300 submissions (2016–present)

The use of Al ranges from drug discovery to clinical research

FDA Discussion Paper



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

appropriate program.											
Search:				Device					Show	50 🗸	entries
Date of Final Decision	•	Submission Number	\$		\$	Company	\$	Panel (lead)	\$	Primary Product Code	\$
06/25/2024		K232111		NeoBeat, NeoBeat Mini		Laerdal Medical AS		Cardiovascula	ar	MWI	
06/25/2024		K240582		VEAAlign; spineEOS		EOS imaging		Radiology		QIH	
06/21/2024		K240465		O-arm O2 Imaging System		Medtronic Navigation Inc	١,	Radiology		OWB	
06/21/2024		K233196		Medihub Prostate		JLK Inc.		Radiology		QIH	
06/21/2024		K233253		eCARTv5 Clinical Deterioration Suite ("eCART")		AgileMD, Inc.		Cardiovascula	ar	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.		Cardiovascula	ar	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 Al		Clarius Mobile Health Corp.	n	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(I)

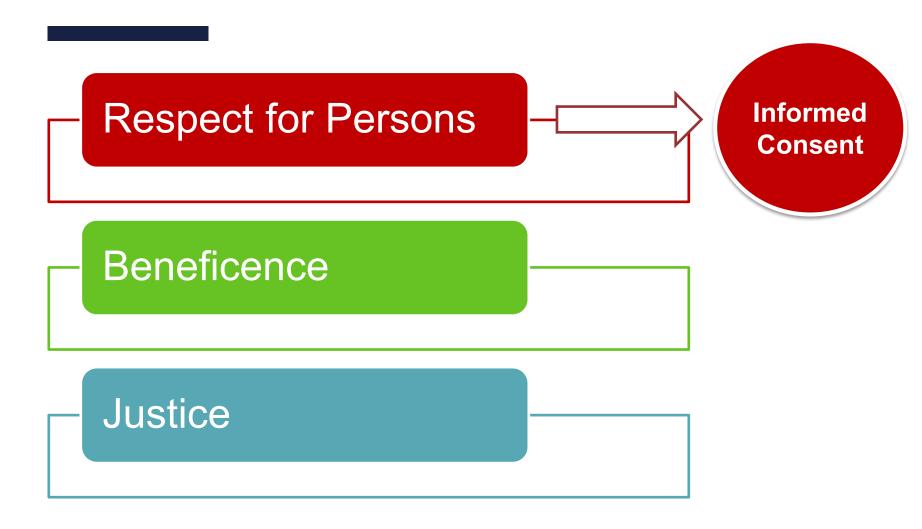
 "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

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))

Purpose of the Research & Procedures

Reasonably Foreseeable Risks & Discomforts

Benefits

Appropriate Alternative Procedures or Courses of Treatment

Confidentiality

Compensation & Medical Treatment

Contact Information

Voluntary Participation

Future Use of Data & Biospecimens (if available)

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

Unforeseeable Risks

Termination of Participation

Additional Costs

Consequences of Withdrawal

New Findings

Number of Subjects

Commercial Profit from Biospecimens

Disclosure of Clinically Relevant Results

Whole Genome Sequencing



3.

Challenges Raised by Al

Challenges Raised By Al

- Do we have to disclose the use of Al 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: Al 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



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