Ethical and Practical Oversight of AI Research

Adapting existing frameworks for emerging technology

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IMPACT METRICS 15+ Years EXPERIENCE 1300+ CITATIONS Diagnostics, Regulatory **PATENTS** & Mechanical Systems

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TECHNICAL EXPERTISE

AI/ML Medical Devices

FDA/CE Regulatory

Diagnostic Biosensors

Clinical Translation

Health Equity

SaMD Governance

KEY CONTRIBUTIONS

Regulatory & Oversight

- AI/ML Expert IRB Reviewer
- FDA/CE-Mark Approvals
- Medical & Scientific Affairs

Technical Achievements

- Biosensor Platforms
- Point-of-Care Diagnostics



CAREER IMPACT

Biosensor Development

AI/ML in Clinical Practice

Healthcare Governance

Regulatory Innovation

Health Equity Research







What causes angst about AI within research communities?

Let me share what I keep hearing...

Traditional research challenges persist in AI — amplified by scale and speed



Navigate



AI Research



AI research starts with human data – there's no pre-human exploration phase

Phases of AI Clinical Evaluation

Exploratory/Discovery

Pre-clinical

- ▶ Identify study aims & hypotheses
- ▶ Literature searches
- ▶ Secondary data analysis
- ▶ Professional society guidelines
- ▶ Initial algorithm development

Pilot/Validation

Early feasibility

- ▶ Preliminary safety assessment
- ▶ Performance evaluation
- ▶ Small study cohorts
- ▶ Analytical validation
- ▶ Clinical validation metrics

Intervention/Treatment

Clinical efficacy

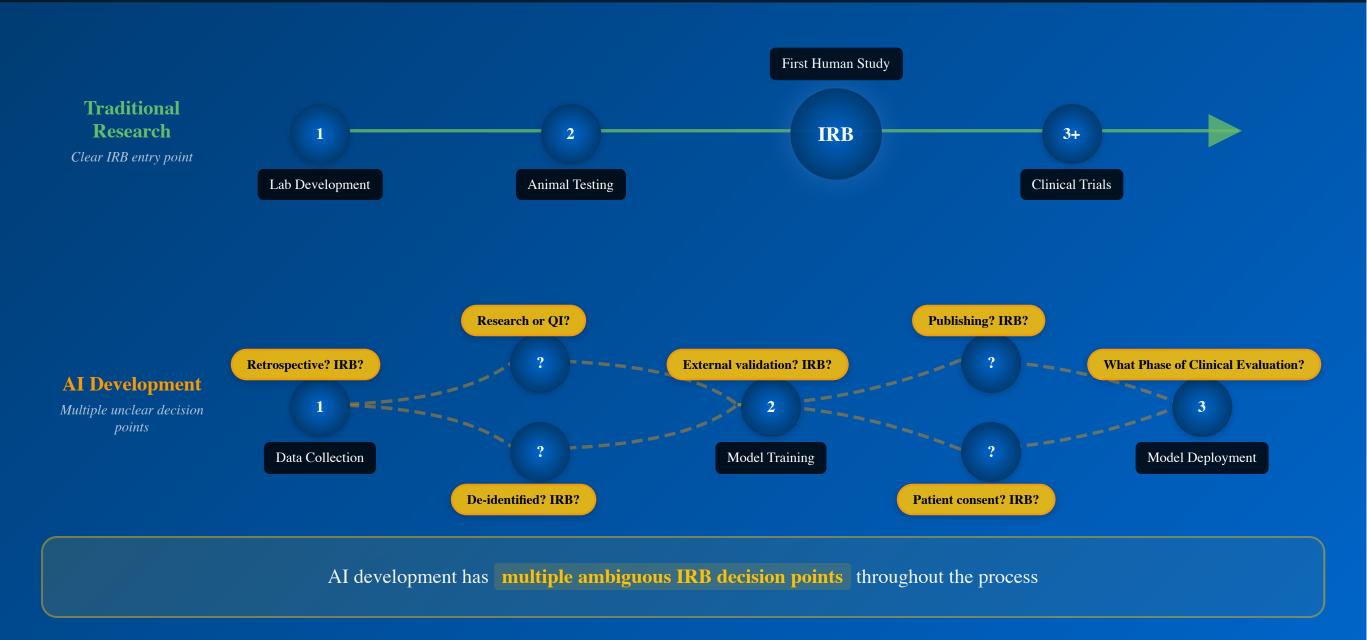
- ▶ Confirms clinical efficacy
- ▶ Safety & risk assessment
- ▶ Impacts patient care
- ▶ Pivotal trials
- ▶ Post-market surveillance

Analytical Validation
Accuracy, Reliability, Precision

Clinical Validation
Sensitivity, Specificity, PPV/NPV

Performance MonitoringLong-term effectiveness & safety

AI requires three distinct phases – each with unique validation requirements



FDA Regulations

Medical Device & Software

ISO Standards

International Standards

IRB/Ethics

Human Subjects Protection

21 CFR 820.30

Design Controls - Standard V&V requirements now applied to AI models

ISO 14971

Risk management - Standard medical device risk framework

45 CFR 46

Common Rule - Human subjects protections from 1991

21 CFR 812

IDE regulations - Clinical trial requirements now covering AI devices

ISO 62304

Software lifecycle - Traditional software development processes

21 CFR 50

FDA human subjects - Standard informed consent requirements

21 CFR 11

Electronic records - Existing compliance rules for digital data

ISO 13485

Quality management - Standard QMS requirements

21 CFR 56

IRB requirements - Traditional institutional review processes

FDA SaMD Guidance

Software as Medical Device - Pre-AI framework being adapted

IEC 62366

Usability engineering - Human factors requirements

32 CFR 219

DoD protections - Military-specific human subjects rules

21st Century Cures Act

Medical software provisions and real-world evidence

ISO/IEC 82304

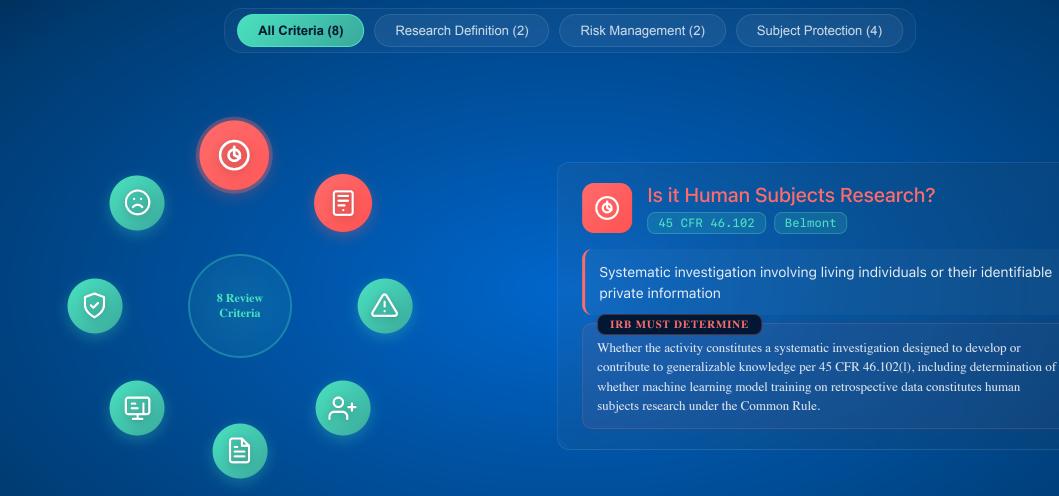
Health software - General software product requirements

Navigate

Belmont Report

Ethical principles - Respect, beneficence, justice (1979)

8 CRITERIA, 1 REVIEW



Based on: **Belmont Report** • Institutional Policy 21 CFR 50, 56, 812, 820 • 45 CFR 46 • FDA SaMD Guidance • ISO 13485, 14971 • 21st Century Cures Act

What Both Sides Want

IRB SPECIALISTS

Speaking Regulatory

"Per 45 CFR 46.111(a)(2), risks must be reasonable in relation to anticipated benefits..."

Need: Complete documentation demonstrating compliance with Common Rule, FDA regulations, and institutional policies



AI RESEARCHERS

Speaking Technical

"Our CNN achieves 94% AUC with cross-validation on the hold-out test set..."

Want: Clear guidance on what's needed without having to learn regulatory frameworks

The Challenge: How do we bridge this gap without requiring either side to become experts in the other's domain?

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The Solution: Three Key Questions

A framework that translates technical complexity into reviewable criteria



Clinical Intended Use?

Determines regulatory pathway and efficacy evidence requirements



Patient Care Impact?

Clarifies risk profile and human subjects protections needed



Technology Risks?

Identifies AI-specific considerations often overlooked

These questions focus oversight where it matters – no AI expertise required

Question 1: Clinical Intended Use

Is there a clinical intended use?

⇔ Clinical Use

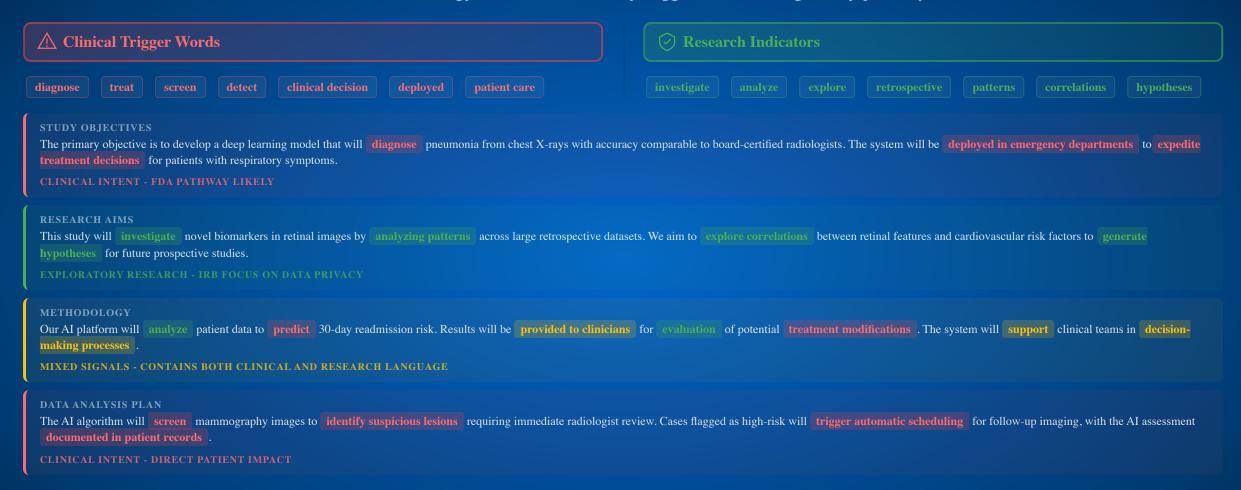
- Diagnostic algorithms for patient care
- Treatment recommendation systems
- ▶ Risk stratification tools
- Clinical decision support
- ▶ Patient monitoring systems

Q Exploratory Research

- ▶ Pattern discovery in datasets
- Hypothesis generation
- ➤ Research-only algorithms
- Retrospective analyses
- Method development studies

E Regulatory Pathway Implications

The same technology described differently triggers different regulatory pathways



Question 2: Patient Care Impact

Does it impact patient care?

(1) Direct Impact

- ▶ AI outputs influence clinical decisions
- ▶ Alerts trigger immediate actions
- ▶ Treatment recommendations provided
- ▶ Real-time decision support active
- ▶ Results documented in patient records

(S) Indirect/No Impac

- Retrospective analysis only
- Research insights for future care
- No real-time clinical influence
- ▶ Results inform protocol development
- Population-level studies only

(! Risk Profile Determines Oversight Level

Patient impact level determines IRB oversight requirements



Question 3: Technology-Specific Characteristics

What technology characteristics require oversight?



- Training data demographics
- ▶ Algorithm transparency level
- Decision pathway complexity
- ▶ Update frequency requirements

Feedback Loops

- ▶ Self-fulfilling predictions
- ▶ Behavior modification
- ▶ Data contamination
- ▶ Perpetual learning risks



System Risks

- ▶ Cascading failures
- ▶ Automation dependency
- ▶ Silent failures
- ▶ Integration complexity

Why Implementation Matters

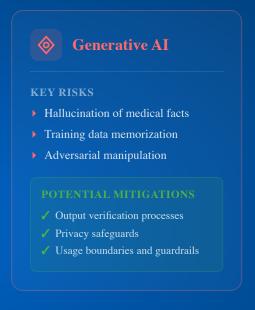
While the risk categories aren't new, AI's speed, scale, and autonomous nature create unique implementation challenges that traditional oversight must adapt to address.

While risks aren't unique to AI, their manifestation requires technology-specific mitigations





Explainability approaches

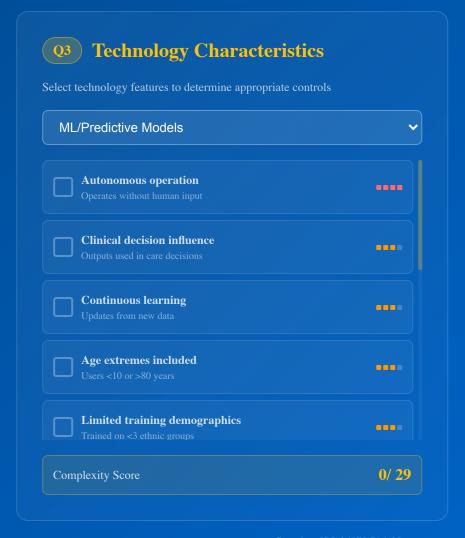


POTENTIAL MITIGATIONS

- ✓ Validation strategies
- ✓ Performance monitoring
- ✓ Documentation of limitations

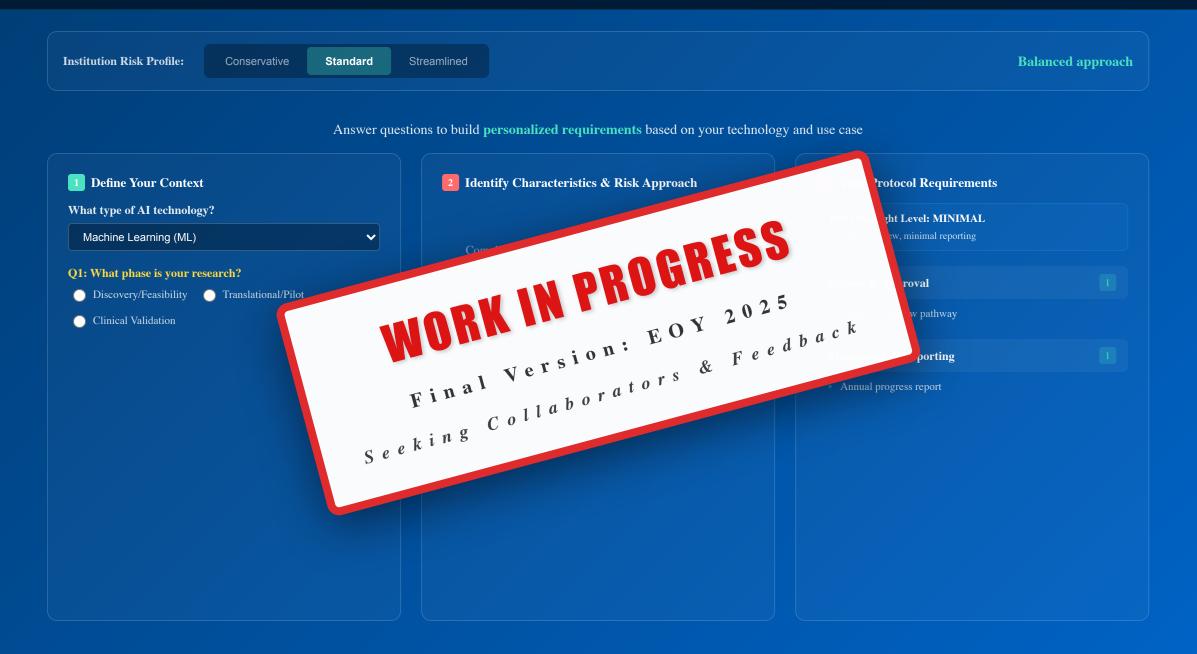
TECHNOLOGY COMPARISON FOR IRB REVIEW





Q1: Clinical Intent →





Questions?

A practical three-question framework for AI research oversight

- Is this human subjects research requiring IRB review?
- What is the potential for impact on human subjects?
- Is the technical risk acceptable relative to benefits?



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