

CORE TRAINING WORKSHOP

Hands-On Training on Artificial Intelligence

Understanding AI Research Oversight in Healthcare

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AI/ML Director

Core Training Workshop Series

2025

AI vs Traditional Research

Clinical Intent

Risk Assessment

Oversight Framework



IMPACT METRICS

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

Mark Lifson, PhD

Director, AI/ML Engineering

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TECHNICAL EXPERTISE

- Medical AI/ML
 - FDA/CE Regulatory
 - Diagnostic Biosensors
 - Clinical Translation
 - Health Equity
 - SaMD Governance
- Regulatory & Oversight**
 - AI/ML Expert IRB Reviewer
 - FDA/CE-Mark Approvals
 - Medical & Scientific Affairs
 - Technical Achievements**
 - Hematology AI Systems
 - Biosensor Platforms
 - Point-of-Care Diagnostics

CAREER IMPACT

Biosensor Development
*Label-free detection platforms***AI/ML in Clinical Practice**
*FDA-approved diagnostic algorithms***Healthcare Governance**
*Frameworks for responsible AI deployment***Regulatory Innovation**
*Automated oversight systems & patents***Health Equity Research**
Bias mitigation in diagnostic AI



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 Monitoring

Long-term effectiveness & safety

AI requires **three distinct phases** - each with unique validation requirements

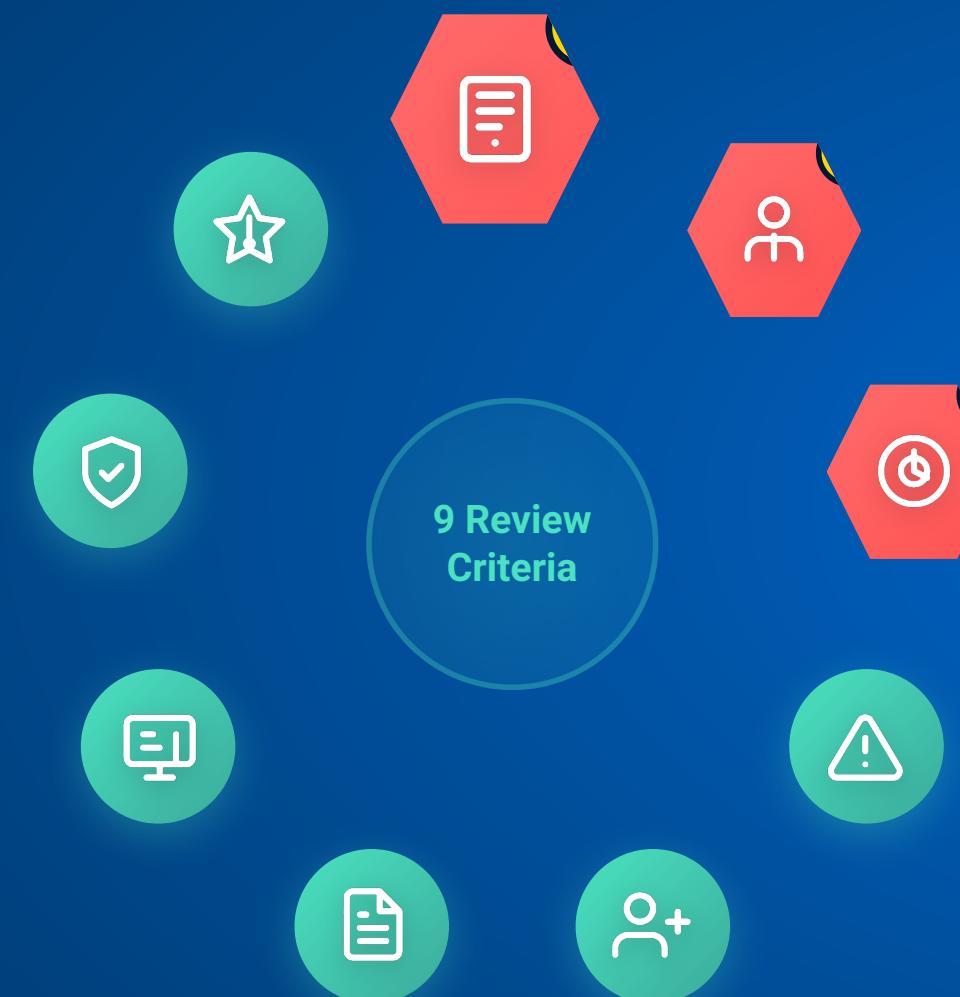
9 CRITERIA, 1 REVIEW

All Criteria (9)

Research Definition (3)

Risk Management (2)

Subject Protection (4)



FDA-Regulated Device?

21 CFR 812, 820 Policy FDA Guidance ISO Standards

Software intended for diagnosis, treatment, prevention, or mitigation of disease with quality system requirements

IRB MUST DETERMINE

Compliance with FDA Quality System Regulation (21 CFR 820) design controls, including verification and validation activities per 21 CFR 820.30(g), software validation per 21 CFR 820.70(i), and determination of significant risk vs non-significant risk device classification under 21 CFR 812.

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?

The same technology described differently triggers different regulatory pathways

⚠ Clinical Trigger Words

- △ diagnose
- △ treat
- △ screen
- △ detect
- △ clinical decision
- △ deployed
- △ patient care

🛡 Research Indicators

- ✓ investigate
- ✓ analyze
- ✓ explore
- ✓ retrospective
- ✓ patterns
- ✓ correlations
- ✓ hypotheses

STUDY OBJECTIVES

The primary objective is to develop a deep learning model that will △ diagnose pneumonia from chest X-rays with accuracy comparable to board-certified radiologists. The system will be △ deployed in emergency departments to △ expedite treatment decisions for patients with respiratory symptoms.

⚠ CLINICAL INTENT - FDA PATHWAY LIKELY

RESEARCH AIMS

This study will ✓ investigate novel biomarkers in retinal images by ✓ analyzing patterns across large retrospective datasets. We aim to ✓ explore correlations between retinal features and cardiovascular risk factors to ✓ generate hypotheses for future prospective studies.

✓ EXPLORATORY RESEARCH - IRB FOCUS ON DATA PRIVACY

METHODOLOGY

Our AI platform will ✓ analyze patient data to △ predict 30-day readmission risk. Results will be ? provided to clinicians for ✓ evaluation of potential △ treatment modifications. The system will ? support clinical teams in ? decision-making processes.

? MIXED SIGNALS - CONTAINS BOTH CLINICAL AND RESEARCH LANGUAGE

DATA ANALYSIS PLAN

The AI algorithm will △ screen mammography images to △ identify suspicious lesions requiring immediate radiologist review. Cases flagged as high-risk will △ trigger automatic scheduling for follow-up imaging, with the AI assessment △ documented in patient records.

⚠ CLINICAL INTENT - DIRECT PATIENT IMPACT

Patient impact level determines IRB oversight requirements

Minimal

Moderate

Significant

Silent/Shadow Mode

AI runs in background without clinical use

Example: Algorithm validation study

IRB Oversight: Standard data review + annual reports

Advisory Mode

AI provides recommendations for review

Example: Risk scores shown in EHR

IRB Oversight: Performance monitoring + quarterly safety reviews

Active Intervention

AI triggers actions or alerts directly

Example: Auto-schedules follow-ups

IRB Oversight: Real-time monitoring + DSMB + FDA consultation

Oversight Intensity: Proportional to the degree of patient care impact

RISK CONTROL PRIORITIZATION MATRIX



Q1: Clinical Intent