Clinical Trial AI Risk Screening Checklist For IRB Review

Identifying potential bias, transparency, and data governance risks in AI-enabled clinical trials.



Purpose

This checklist supports Institutional Review Boards (IRBs) in identifying potential risks associated with artificial intelligence used in clinical trial protocols. It highlights areas where additional sponsor clarification, documentation, or protocol modification may be necessary to protect participants and ensure fairness, transparency, and appropriate oversight.

This tool extends the MRCT (MULTI-REGIONAL CLINICAL TRIALS) CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD, and WCG Framework for Review of Clinical Research Involving AI (June 2025). The MRCT framework provides foundational guidance for IRB review of AI in research and explicitly identifies the need for 'additional, more specific tools' tailored to particular research contexts and populations. This checklist is intended to provide one such specialized tool for pharmaceutical clinical trials, with emphasis on equity risks in patient recruitment, trial design, site selection and monitoring, and synthetic/historical control arm validation.

The questions align with established human subjects research ethics principles from the Belmont Report (Respect for Persons, Beneficence, and Justice) and are designed to operationalize the equity considerations identified in the MRCT framework for pharmaceutical-specific research contexts.

AI Presence Screening

Does this protocol use artificial intelligence in any of the following areas? If YES is selected for any item, complete the checklist sections that follow.

☐ YES ☐ NO — Recruitment / patient matching

☐ YES ☐ NO — Trial design / synthetic controls

☐ YES ☐ NO — Site selection or monitoring

☐ YES ☐ NO — Clinical decision support

☐ YES ☐ NO — Safety monitoring

☐ YES ☐ NO — Data analysis affecting trial operations

Protocol Information

Protocol Title: _____

IRB ID: _____

Date of Review: _____

Reviewer Name: _____

Section A – AI in Recruitment & Patient Matching

Question #1: Does the protocol disclose the demographic composition of populations used to train the AI recruitment tool?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Algorithms trained on historical trial populations may replicate existing enrollment biases.

Sponsor Must Provide if NO/UNCLEAR: Demographic breakdown of training data.

Reviewer Notes: _____

Question #2: Does the protocol include recruitment performance metrics stratified by subgroup?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: AI systems may perform differently across populations.

Sponsor Must Provide if NO/UNCLEAR: Side-by-side subgroup performance metrics.

Reviewer Notes: _____

Question #3: Does the protocol include a plan to monitor enrollment diversity?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: AI recruitment systems may unintentionally narrow the trial population.

Sponsor Must Provide if NO/UNCLEAR: Real-time demographic monitoring plan.

Reviewer Notes: _____

Section B – AI in Trial Design & Control Arms

Question #4: Are the source datasets disclosed if synthetic or historical control arms are used?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Drug performance may be validated against populations that differ from real-world users.

Sponsor Must Provide if NO/UNCLEAR: Demographics of source datasets.

Reviewer Notes: _____

Section C – AI in Site Selection & Monitoring

Question #5: Are the criteria used to select trial sites disclosed?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: AI-driven site selection may deprioritize sites serving underrepresented populations.

Sponsor Must Provide if NO/UNCLEAR: Description of site selection algorithm or criteria.

Reviewer Notes: _____

Question #6: Does monitoring account for under-resourced sites?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Sites with fewer resources may produce irregular data patterns.

Sponsor Must Provide if NO/UNCLEAR: Explanation of monitoring safeguards.

Reviewer Notes: _____

Section D – AI as Clinical Decision Support

Question #7: Does the protocol require clinician review before AI output changes care?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Autonomous AI decision-making may introduce safety risks.

Sponsor Must Provide if NO/UNCLEAR: Protocol language requiring clinician oversight.

Reviewer Notes: _____

Question #8: Are AI limitations communicated to investigators and participants?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Clinicians and patients may over-rely on AI.

Sponsor Must Provide if NO/UNCLEAR: Training plan and plain-language description.

Reviewer Notes: _____

Section E – AI System Stability & Transparency

Question #9: Is the algorithm locked or adaptive with a defined update plan?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Adaptive algorithms may drift during trials.

Sponsor Must Provide if NO/UNCLEAR: Model card or algorithm documentation.

Reviewer Notes: _____

Question #10: Is algorithm performance monitored during the trial?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Performance degradation or bias may go undetected.

Sponsor Must Provide if NO/UNCLEAR: Monitoring plan and thresholds.

Reviewer Notes: _____

Section F – Data Governance & Consent

Question #10: Does informed consent explain AI use in plain language?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Participants may not understand how AI affects their participation.

Sponsor Must Provide if NO/UNCLEAR: Revised consent language.

Reviewer Notes: _____

Question #12: Are safeguards against re-identification described?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Integrated datasets increase re-identification risk.

Sponsor Must Provide if NO/UNCLEAR: Data governance and de-identification plan.

Reviewer Notes: _____

Section G – Equity Risk Considerations

Question #13: Does the protocol acknowledge differences between training and trial populations?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Algorithm performance may vary across populations.

Sponsor Must Provide if NO/UNCLEAR: Explanation of population differences.

Reviewer Notes: _____

Question #14: Are clinical standards embedded in the AI validated across populations?

☐ YES ☐ NO ☐ UNCLEAR

Why This Matters: Standards developed in one population may misclassify others.

Sponsor Must Provide if NO/UNCLEAR: Evidence of validation.

Reviewer Notes: _____

AI Risk Classification

This classification is intended as a screening aid and does not replace IRB judgment.

0 issues: Low AI Risk — Standard IRB review.

1–2 issues: Moderate AI Risk — Sponsor clarification required.

3+ issues: High AI Risk — Full board review or protocol modification recommended.

Sponsor Response Section

Item #: _____

Sponsor Response: _____

Supporting Documentation: _____

Final IRB Determination

☐ Approved

☐ Approved with Conditions

☐ Deferred for Clarification

☐ Not Approved

IRB Chair Signature: _____

Date: _____