Clinical Trial AI Risk Screening Checklist Explainer

This checklist operationalizes 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 for pharmaceutical clinical trials. The MRCT Center and WCG Framework identified the need for more specific, sector-focused tools.

This tool was developed by taking that framework and translating it into questions IRBs actually encounter in pharma protocols. It is an extensive of their foundational work.

The checklist was developed by PACE the Patient Voice Council. PACE was formed to take a leadership role in advancing AI in patient engagement, recruitment, and retention. It is a cross-stakeholder network focused on keeping humanity at the forefront of AI in drug development to reduce risk and maximize outcomes.

PACE members collectively represent 300 years of combined experience with leadership roles at pharmaceutical, biotech, clinical research, and NIH-recognized patient advocacy organizations. They are subject matter experts in patient voice, patient engagement, clinical trial optimization, technology development & integration, advocacy, and health equity. PACE Members also possess lived experiences as patients, survivors, and caregivers across therapeutic areas including oncology, cardiology, rare disease, and chronic conditions.

Together, PACE is synthesizing expertise, with lived experience.

How this checklist extends the MRCT Center and WCG Framework

1. Operationalizes MRCT Center and WCG's 6 ethical consideration areas within pharmaceutical workflows:
    1. Human Agency and Oversight,
    2. Technical Robustness and Safety,
    3. Privacy, Confidentiality, and Data Governance
    4. Transparency
    5. Representativeness and Fairness
    6. Informed Consent
2. Maps them to pharmaceutical clinical trial contexts.
3. Translates them into 14 concrete screening questions.
4. Provides a format IRBs can actually use in protocol review.
5. Includes specific equity risks relevant to drug development.

What it is

The Clinical Trial AI Risk Screening Checklist is a practical tool designed to help Institutional Review Boards (IRBs) identify potential risks when artificial intelligence is used in clinical trial protocols. The checklist does not require IRB reviewers to understand machine learning or algorithm design. Instead, it prompts reviewers to confirm whether sponsors have disclosed critical information about how AI systems were developed, validated, and monitored.

Why it matters

Artificial intelligence is increasingly being used in clinical trials for recruitment, patient matching, synthetic control arms, site monitoring, and clinical decision support. Many IRB members are clinicians, ethicists, and community representatives rather than data scientists. As a result, oversight bodies face a growing gap between the complexity of AI tools and the expertise available to review them.

The checklist helps close this gap by converting complex AI governance questions into clear disclosure prompts. Reviewers simply determine whether the protocol addresses key issues such as training data demographics, subgroup performance testing, algorithm monitoring, human oversight, and consent transparency.

About IRBs and who reviews protocols

IRBs are required by federal regulation to review all human subjects research before it begins. IRBs come in different forms. Academic institutions have their own IRBs, typically made up of faculty, researchers, and community members. Central IRBs review protocols for multiple sites or sponsors. FDA-regulated research, including clinical trials for drug and device approval, must have IRB oversight regardless of the review location.

IRB membership is deliberately diverse. Committees include physicians, nurses, scientists, ethicists, and community representatives. This diversity is a strength of the IRB system because it brings different perspectives to research ethics. However, most IRB members are not AI specialists. When protocols use AI, IRB reviewers may lack technical expertise to assess whether the technology was properly developed, tested, and validated. This creates a vulnerability: reviewers may either approve protocols without adequate scrutiny or request extensive documentation they cannot fully evaluate, causing unnecessary delays.

This checklist addresses that problem. It does not require AI literacy. It requires that sponsors answer specific, concrete questions about how they developed and tested their AI systems. The questions focus on disclosure and transparency, not technical sophistication.

How it works

The checklist uses a YES / NO / UNCLEAR screening format. For each item, the reviewer determines whether the protocol adequately addresses the topic. If a reviewer marks NO or UNCLEAR, the sponsor must provide additional information or clarify the protocol before approval. This approach prevents both rubber-stamping and unnecessary delays, while encouraging sponsors to proactively disclose how their AI systems were developed and evaluated.

Who uses this and why

The checklist is designed for IRB reviewers. For PACE, it represents a way to ensure that patient voice and equity are centered in how IRBs evaluate AI in drug development. By providing IRBs with concrete tools focused on equity risks, we help ensure that oversight bodies protect the populations most affected by gaps in AI oversight. The checklist provides a common language and framework that IRBs can use consistently, whether they are reviewing academic research, industry-sponsored trials, or devices and diagnostics.

Ethical alignment

The questions in the checklist align with established research ethics principles described in the Belmont Report: Respect for Persons, Beneficence, and Justice. In practice, the tool helps IRBs identify risks related to consent transparency, participant safety, and equitable representation in AI-enabled trials. A core purpose of the checklist is to ensure that AI systems do not systematically exclude or underrepresent specific populations from clinical trials and do not validate drugs against populations that do not match real-world users.

Implementation and impact

If adopted by academic IRBs, central IRBs, or used by sponsors preparing protocols, the checklist could improve transparency and consistency in the oversight of AI-enabled clinical trials. Over time, it could encourage sponsors to proactively report AI training data composition, subgroup performance metrics, algorithm stability plans, and monitoring procedures. For IRBs, it provides concrete criteria to assess AI governance without requiring AI expertise. For sponsors, it clarifies what oversight bodies will ask and what documentation to prepare.

For PACE the Patient Voice Council and the field

PACE developed this checklist to ensure that artificial intelligence used in clinical drug development is evaluated with appropriate transparency, fairness, and participant protections. The checklist represents a commitment to making AI governance accessible to IRBs, achievable for sponsors, and protective of research participants, particularly those from historically underrepresented populations in clinical trials.