

IA45 Fast Track Pilot Guidelines — for Industry Sponsors

UHN is embarking on a major transformation of its Institutional Authorization process in a project called Institutional Authorization 45 (IA45). The goal of IA45 is to reduce research study authorization time to an average of 45 days and speed up overall trial activation, with commitment from all stakeholders. Before initiating the IA45 Fast Track process, we ask sponsor teams to review the expectations below. IA45 Fast Track is designed for speed and consistency—but success depends on active, timely participation from all parties.

Expectations

- ✓ **Quick Turnarounds:** Return reviews, feedback, or responses within **five calendar days** of receiving materials. UHN review teams will commit to the same response timeframe.
- ✓ **Streamlined Agreements:** Use a pre-negotiated streamlined or templated agreement with UHN (e.g., the Universal Agreement for Clinical Trials (UACT))
- ✓ Pre-Reviewed Submissions: Submit clean, complete documentation. Informed consent forms (ICFs) must adhere to the <u>UHN/CTO templates</u>. Well-prepared packages help avoid delays and reduce unnecessary back-and-forth.
- ✓ **Hands-On Engagement:** Remain involved during the review period, which may include joining quick alignment meetings, responding to clarifications, and helping resolve issues in real-time.

Is IA45 right for your team?

If your team is positioned to meet the expectations listed above, the study can proceed through the IA45 Fast Track process. If your team is unable to allocate the resources needed to align with the above expectations, the review will proceed through UHN's standard Institutional Authorization process. This keeps the fast track available for teams ready to meet its pace.