

# Beyond the Project Manager: Developing a Prioritization Decision Framework to Optimize Protocol Amendment Processing



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## BACKGROUND

Protocol amendment processing has become an increasingly resource-intensive function at academic cancer centers. From 2022 to 2025, the UFHCI Clinical Research Office (CRO) averaged 185 amendments per year, each requiring coordination across more than 10 contributors, seven handoff points, and five operational areas. In 2025, 94 amendments were fully activated. Although the Project Manager role has strengthened transparency and collaboration, no formal risk-stratified framework currently exists to systematically prioritize amendments by urgency, complexity, or financial impact.

## GOALS

- ❖ Design and implement a formal priority scoring framework to guide amendment processing order when competing demands exist.
- ❖ Develop a decision tree to standardize routing of amendments across regulatory, finance, and clinical teams based on amendment type, study status, and complexity.

## SOLUTIONS AND METHODS

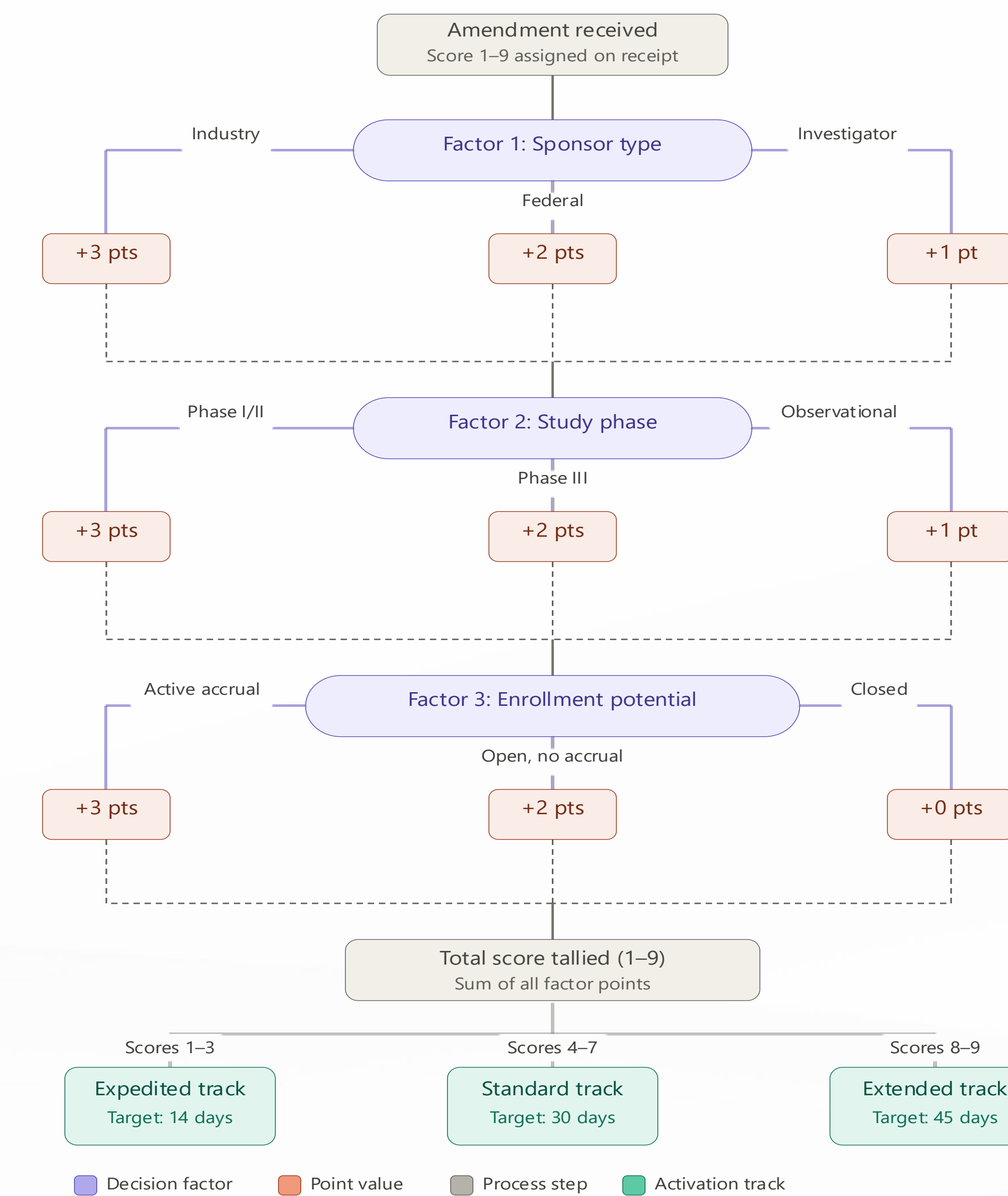
The proposed initiative builds upon the existing amendment tracking infrastructure by introducing two interrelated enhancements: a priority scoring system and a decision tree for amendment routing.

### Priority Scoring Framework:

Each amendment will receive a priority score (1 through 9) upon receipt, based on sponsor type, study design, phase, and enrollment potential, mirroring the existing Protocol Activation Coordinator (PAC) prioritization schema used in study start-up. Scores 1 through 3 will route to an expedited track with a target completion window of 14 calendar days; scores 4 through 7 to a standard track of 30 days; and scores 8 and 9 to a 45-day window.

### Amendment Routing Decision Tree:

A structured decision tree will be embedded within the amendment notification email template, introduced in the 2024 process enhancement, to guide coordinators through a consistent triage sequence. The tree evaluates whether an amendment requires calendar, budget, or Medicare Coverage Analysis (MCA) updates; whether the trial is currently active with patients accrued or not; and which teams must be engaged. Amendments requiring only regulatory action (IRB/SRMC review) will be routed separately from those with financial implications, preventing unnecessary engagement of the finance team and reducing task volume.



## ANTICIPATED OUTCOMES

Implementation of a structured priority scoring framework and amendment routing decision tree is anticipated to reduce variability in activation timelines by establishing standardized, score aligned completion windows across the full amendment lifecycle. Systematic triage at the point of receipt is expected to minimize reliance on individual judgment, ensuring consistent prioritization and routing decisions across regulatory, clinical, and finance teams regardless of staff experience or competing workload demands.

By directing amendments requiring only regulatory action away from the finance team, this framework is projected to reduce unnecessary task volume and protect staff capacity. Collectively, these process enhancements position the CRO to manage a growing amendment workload with finite resources, advancing UFHCI's operational excellence goals, billing compliance standards, and NCI designation requirements for efficient clinical trial administration.

## CONCLUSIONS

The proposed amendment prioritization and routing framework represents a logical and necessary evolution of the Project Manager model implemented at UFHCI in 2024. By moving from process visibility to structured triage and risk stratification, the CRO will be better positioned to manage a growing amendment volume with finite staff resources. This initiative aligns with the center's operational excellence goals, its commitment to billing compliance, and its NCI designation standards for efficient clinical trial administration.

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