

## No Withholding / Holdbacks Policy

**Origination Date: July 1, 2025**

**Version: 1.0**

### **I. Purpose:**

This document outlines the University of Rochester Medical Center (URMC) policy prohibiting withholdings or holdbacks when contracting for clinical studies.

### **II. Definitions:**

A withholding or holdback is a contractual term used in Clinical Studies. It enables study sponsors and/or their designated Clinical Research Organization (CRO) to withhold or hold back payments from clinical study sites until various study milestones have been completed or queries have been resolved. While the structure of holdbacks may differ by sponsor, they usually include withholding payment for up to 10% of the total study for services already performed (e.g. study visits or procedures) until study closeout. Reimbursement may be months or years after the procedures have been completed and paid for locally. Withholding has been a feature of some industry, but not NIH sponsored clinical trials.

The concept of withholdings or holdbacks was introduced when much of the clinical study industry was still paper based, making mistakes more common and resolving queries more time-consuming. With the current industry standard of electronic case report forms (eCRFs) and Electronic Data Capture (EDC) for immediate visibility and full transparency into study site activities, such withholdings or holdbacks are no longer justified.

### **III. Policy:**

Effective 01 July 2025 URMC will no longer accept withholding or holdback terms on any new clinical study contracts.

### **IV. Related Documents**

- 1) [Site Payment Best Practices: The Burden of Holdbacks | Greenphire](#)
- 2) [Site Dissatisfaction and Challenges in Clinical Trial Financial Management | Medidata Solutions](#)
- 3) [The 4 Biggest Investigator Site Payment Issues — And How To Solve Them](#)

<b>Policy Owner:</b>	University of Rochester Clinical and Translational Science Institute
<b>Author:</b>	Ashlee Lang, Office of Clinical Research
<b>Review History:</b>	