Stanford MEDICINE Stanford Cancer Institute

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

Stanford Cancer Institute, Clinical Trials Office Monitoring Memo

To: CRO/Sponsor Monitors

Re: Non-Negotiable Monitoring Requirements

Date: October 4, 2024

Dear CRO/Sponsor Monitors,

This memo is intended for all studies conducted at the Stanford Cancer Institute Clinical Trials Office (SCI-CTO). The purpose of the memo is to provide clarity on non-negotiable monitoring requirements and requests. Please refer to the information below as a reference when scheduling monitoring visits.

Note: MedLink = new name for PRISM

Requesting Timelines for MedLink Monitor Accounts (New and Renewal) • MedLink accounts for monitors must be renewed annually.	• Stanford staff, request a new monitor six weeks (42 calendar days) in advance. Monitor, fill out the attestation form and send it to the study coordinator five weeks (35 calendar days) in advance. • Stanford staff, request monitor renewal four weeks (28 calendar days) in advance. Monitor, fill out the attestation form and send it to the study coordinator two weeks (14 calendar days) in advance. • CRO inform Stanford staff when the monitor is no longer monitoring for Stanford as soon as possible.
Record Release Timeline for Approved Monitors	• Record Release: 14-day window submission policy. • A maximum of 16 Medical Record Numbers (MRNs) per Record Release per monitor per study.

Active/Routine Monitoring	• General Monitoring Guidelines
	  ○ Approved monitors will have read-only access to patients' Electronic Medical Record (EMR) through MedLink.
	  ○ Approved monitors will have read-only access to patients' EMR through MedLink between 5:00 AM PST to 8:00 PM PST on their scheduled monitoring days.
	  ○ No International monitoring is allowed.
	  ○ Limit of one monitoring visit per month per study.

	• Remote Monitoring
	  ○ No more than 5 consecutive business days.
	• Onsite Monitoring
	  ○ No more than 2 consecutive business days.
	  ○ Only one onsite visit every three months.
	• Co-Monitoring
	  ○ No co-monitoring is allowed, including for oversight/ training purposes.

Audits: • Sponsor quality audit • NCI • For cause	• Record release remains the same: 14-day window submission policy. • A maximum of 16 MRNs per Record Release per auditor per study. • Co-monitoring is allowed for Audits. ○ Same records cannot be released to multiple monitors
Cancellations for Sponsor and/or Industry Visits	• Rescheduling is not guaranteed and depends on availability. • Inform Stanford staff at least 14 days in advance of cancellations and rescheduling visits. • Cancellations after the request for record release has been submitted will incur a cancellation fee.

For any questions or concerns, please contact your Stanford study team.

Thank you,

Digitally signed by Joel Neal MD PhD
Date: 2024.10.08 15:18:16 -07'00'

Joel Neal, MD, PhD
Medical Director
Stanford Cancer Institute, Clinical Trials Office

Agnes

Digitally signed by Agnes Nika Date: 2024.10.08 12:14:52 -07'00'

Agnes Nika
Associate Director of Research Services
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