Chicken Soup
for the Busy Coordinator

NHG Health

MARCH 2026
Ensuring Ethical & Compliant Study Start-Up & Initiation

Scenario: Urgent Initiation of Study

1. Dr Ace, a new PI conducting his first clinical research, has identified a potential subject who meets current eligibility criteria but will exceed the age limit in one month. Eager not to lose this subject, he asked CRC Mr Perfect to fast-track study initiation.

2. This concerned Mr Perfect, who recalled a past study that fell into serious non-compliance. To ensure a smooth start while avoiding common pitfalls, the following guidance was shared with Dr Ace.

Key Requirements

1 Ethics Approval First Before Study Initiation and Pre-Screening

Common mistake: Rushing to pre-screen and enroll before all approvals are in place

- Ensure **agreements with service providers/sponsors/CROs** are signed and finalized
- Never approach potential subjects until IRB and/or regulatory approvals are received
- After approval, **document** every potential subject pre-screened
- Ensure that screening is performed only **after informed consent has been obtained** from subjects

2 Obtaining IRB and/or Regulatory Approval Does Not Mean You're Ready

Common mistake: Assuming obtaining approvals means you're ready to start recruitment

- Verify all study staff are **qualified**, completed **minimum training** requirements and are properly **trained**
- Ensure **investigational products** are **ready-for-use** and properly **stored** (if applicable)
- Confirm laboratory certifications and reference ranges are current (if applicable)
- Validate all electronic systems before first subject is enrolled (if applicable)
- **Pro tip:** Create a site readiness checklist

3 Informed Consent Process Cannot Be Rushed

Potential Major Compliance Risk: Pressuring and rushing consent due to eligibility window

- Allow adequate time for subjects to consider participation
- Explain that participation is voluntary with no impact on their care
- **Document the consent process** thoroughly in source records
- **Ethical reminder**: Coercion invalidates consent, regardless of study type

4 The Delegation Log Protects Everyone

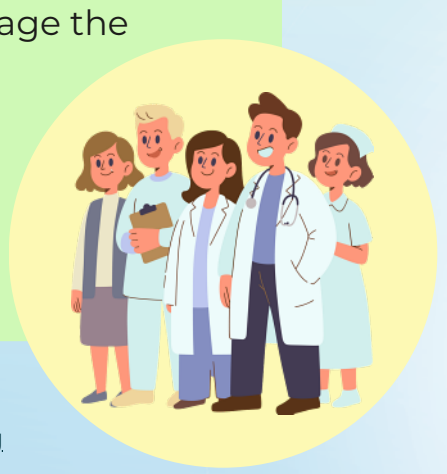
Frequent Deviation: incomplete documentation

- **Every person involved in any research activity** (e.g. collecting data or interacting with subjects) must be **delegated** by the PI
- Include specific research tasks, not just general responsibilities
- **Reality check**: Performing undelegated activities are protocol deviations

Key Reminders

- Before initiation, complete all regulatory, ethics, and institutional approvals and finalise protocol preparations.
- The PI and the study team should discuss the recruitment strategy and timelines to manage the study accordingly. (Including screening procedures, window period, assessments)

Proper study initiation is essential for valid, ethical research outcomes. Comprehensive preparation prevents problems throughout your study lifecycle.



Reference: NHG Health PCR Standard Operating Procedures 501-B03: Study Initiation
NHG Health PCR Standard Operating Procedures 501-C02: Subject Recruitment and Screening

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