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Best Practices: Managing Involvement of Service Providers in Research

SCENARIO



A research team engages a service provider (an external laboratory) for specimen analysis. Under pressure to begin quickly, they start before formal agreements are in place. Communication with the laboratory is handled informally via email.

Good research starts with strong partnerships & sound oversight!



Service provider: A person or organisation (commercial, academic or other) providing a service used by either the sponsor or the investigator to fulfil research-related activities.



ARE YOU UP TO DATE WITH THE PCR SOP REQUIREMENTS FOR PRINCIPAL INVESTIGATORS (PI)?

KEY RESPONSIBILITIES



Maintain proportionate oversight covering service provider selection, training, record access, and document retention. The level of oversight should match the risk to participant safety and data reliability.



Maintain accountability for the research conduct, including the quality and integrity of data even when activities are delegated. Delegation of tasks does not mean delegation of accountability.



Ensure service agreements clearly outline roles, activities, and responsibilities.

KEY ISSUES IDENTIFIED



INADEQUATE OVERSIGHT OF SERVICE PROVIDERS

Outsourcing work does not transfer responsibility. The PI remains accountable for study conduct. Oversight should be proportionate to the risk to ensure research integrity is maintained.

What Should Be Done?

Best practices include:

- **Qualification checks:** Verify that the laboratory holds the necessary accreditations and that staff performing the analysis and handling the storage of the samples are adequately trained for study-specific requirements
- **Clear communication protocols:** Any deviations, equipment failures, or processing issues should be flagged to the study team promptly rather than discovered retrospectively



ABSENCE OF FORMAL SERVICE AGREEMENTS

Without a formal service agreement, roles, deliverables, timelines, and quality expectations are undefined. This leaves no basis to hold anyone accountable.

What Should Be Done?

Service agreements form the foundation of collaboration. They should:

- **Define scope of work:** Specify tasks, deliverables, and timelines.
- **Outline compliance requirements:** Ensure adherence to NHG Health PCR SOPs, regulatory policies, data protection laws, and institutional policies where applicable.
- **Include performance metrics:** Establish measurable indicators for quality and timeliness.
- **Detail financial arrangements:** Clarify payment schedules and contingencies.



DATA GOVERNANCE CONCERNS

If sharing of study or subject data is involved, ensure that there are proper safeguards to avoid putting the subjects and the study at risk.

What Should Be Done?

Ensure agreements include:

- Confidentiality clauses
- Data protection measures
- Access controls
- Secure data transfer methods
- Breach notification requirements
- Data destruction procedures
- Compliance with applicable privacy regulations



TO NOTE



The PI should be reminded that pressure to begin recruitment does not override the obligation to have governance structures in place before the study commences; starting without them does not save time if it results in protocol deviations, data integrity issues, or regulatory findings later.



Reference: NHG Health PCR Standard Operating Procedures 501-A02 Responsibilities of the Research Team
501-C04 Biological Specimen Collection and Handling
NHG Health Responsible Conduct of Research (RCR) Manual, Chapter 5. Data Management Practice

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental.
Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.