Title: Research Study Handover Tool	Version Number: 01	Effective Date: Dec 2024	Page **1** of **6**

Revision History		
Version No.	**Effective Date**	**Description**
V1	18APR2025	Revised and expanded tool to accommodate observational studies, including clarifications and N/A options for study-specific applicability.

Purpose:

The Research Project Handover Tools is designed to ensure a smooth and comprehensive transition of responsibilities between outgoing and incoming research staff. It serves as a centralized summary of essential study details, status updates, subject progress, vendor access, pending task, and study-specific considerations.

This tool promotes continuity, data integrity and regulatory compliance by capturing all critical operational elements during staff transitions.

Scope and Responsibilities:

This Standard Operating Guidance applies to Clinical Research Coordinators, Study Managers and Research Assistances as well as to Principal Investigators and any staff involved in research operations and handovers.

Procedures

1. Complete all sections with the most current and accurate information available at the time of handover.
2. Use the checkboxes and free-text field to indicate the current study status, pending tasks, and important contacts.
3. For each category (e.g. vendors, subject status, training records), indicate the relevant details and mark *N/A* when not applicable.
4. The outgoing staff member is responsible for initiating and filling in this tool, and the incoming staff member should review and confirm the information provided is clear and that all questions have been answered before singing and finalizing the tool.
5. Recognizing that observational studies often have fewer operational and regulatory requirements, the form includes “N/A” options, as such should be marked as not applicable when justified.

Applicability Across All Study Types

This handover tool is suitable for all types of research studies, including:

- Interventional/Therapeutic Trials (e.g. drug/device trials)
- Observational Studies (e.g. chart reviews, longitudinal studies)

Document Approval

- Name and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By: Date:

_____ _____

Insert Name and Title

1. Handover Details	
Date of Handover:	
Last Working Day:	
Name of Outgoing Study Coordinator:	
Name of Incoming Study Coordinator:	Signature:

2. Project Information	
Protocol Name/Number:	
Study Type:	□ Observational □ Interventional/Therapeutic
IRB of Record:	□ UCSD/Kuali Research □ Advarra □ WCGI □ Other_____
IRB Number (UCSD/RCHSD):	#
Key Staff /Sponsor Contact(s): (include name, role, email address and other relevant details):	Clinical Research Associate (CRA), if applicable:
	Sponsor/Funder/PI Contact:
	Invoicing Contact, if applicable:
Other key contacts:	

3. Project Status		
Site Initiation Visit (SIV) Date:	____/____/_____	
Enrollment Target:		
Current Study Phase:	□ Start-Up	□ Active (Enrolling)
	□ Active (Closed Enrollment)	□ Closing/Close-Out
Enrollment Progress: Subject Status and Counts	Status	Number of Subjects
	□ In Screening	
	□ Enrolled	
	□ Completed	
	□ Withdrawn	
	□ Screen Failed	
	□ Other_____	
Next Scheduled Monitoring Visit (IMV), if applicable	____/____/_____ N/A □	
Has CRA Scheduled IP Review with Pharmacy for Next IMV?, If applicable	Yes □ No □ N/A □ If *No*, request CRA to coordinate directly with the pharmacy	

4. Study Staff Contacts

Principal Investigator	
Main Study Coordinator	
Email Main Study Coordinator	
Back-up Coordinator	
Email back-up coordinator	
Other Relevant Contact	
Email relevant contact	
Other Relevant Contact	
Email relevant contact	

5. Vendors Access Details: (Include contact for access credentials for each platform/tool)		
EDC Name	Yes □ No □ N/A □	
IRT/IXRT	Yes □ No □ N/A □	
Local Lab	Yes □ No □ N/A □	
Central Lab	Yes □ No □ N/A □	
Clarion/ECG	Yes □ No □ N/A □	
RedCAP	Yes □ No □ N/A □	
Other:		
Other:		
Other:		

6. Critical Pending Items: (Items that require urgent attention or follow -up)		
Task	**Completed?**	**Notes/Next Steps**
Sponsor and Vendors Notified of Staff Change	Yes □ No □	
Updated CITI Certifications & CV shared with Sponsor	Yes □ No □	
New Staff Added to DOA Log?	Yes □ No □	
All Required Trainings/CVs from New Staff Collected	Yes □ No □	
Study Protocol Reviewed and Training Log Updated by New Staff	Yes □ No □	
Budget Update Required?	Yes □ No □	
If yes, describe:		
Contract Update Required?	Yes □ No □	
If yes, describe:		
Additional Pending Tasks		
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7. Subject-Related Activities (e.g. upcoming scheduled visits, upcoming deadlines, data entry in Velos or EDC, submission of OPRX to pharmacy, AE assessment and PI signature, etc.)	
Subject Identifier	Action Needed
• Subject ID:	
• Subject ID:	
• Subject ID:	

8. Recurring Study Specific Meetings & Communication Channels (e.g. Weekly Study Meetings with PI, Sponsor Calls, Communication Tools Used, MS Teams, Email).
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9. Identified Challenges or Risks
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10. Key Documents & Storage Location (e.g. ISF and Subject Binders , Training Materials , Cabinet or Cubicle Number)
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11. Study-Specific Equipment & Tools (Include access instructions, locations and use of all items (e.g. tablets, ECG device, Access Tokens, etc.)
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12. Additional Notes & Recommendations (e.g. Visits workflows, vendor URLS, lessons learned, suggestions for improved operations, upcoming concerns)