

Dear New Hire:

Congratulations and welcome to the Department of Pediatrics at Stanford!

Please find attached a general onboarding checklist to be used as a guidance for new Clinical Research Personnel (including CRCs, CRMs, LSRPs, lab personnel, etc.).

The purpose of the onboarding checklist is to assist you in identifying appropriate trainings (e.g., workshops, online courses, etc.) that may be required during your first days/weeks at work. Please check with your supervisor and review which trainings should be completed for your new role. You may also want to use the checklist to take any specific trainings that may be helpful to support your role even though your supervisor does not require it.

In addition, this document provides reference to several websites and other resources that may be helpful during your first weeks.

Finally, the last page contains a useful guide for when a research study or clinical trial is being transitioned from one research coordinator to another research coordinator (or new hire).

We hope you find this checklist helpful during your initial week(s) at Stanford. This checklist is updated periodically and can be found on the MCHRI website here under Quick Links. You can check back here in the future or share with clinical research colleagues outside of the department if they find it useful.

Should you have any questions, please feel free to contact May Zepeda, Clinical Research Manager, at zepeda@stanford.edu or refer to our website: https://med.stanford.edu/mchri/crso/services.html

Warm Regards, Stanford Maternal and Child Health Research Institute (MCHRI)



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Clinical Research Personnel Onboarding Checklist

Name of Employee:		Start Date:
Attach CV, certifications and c		
QUALIFICATIONS/CERTI	FICATIONS	
Title		
Supervisor		
PI(s)		
Degree(s)		
Certifications received upon entering the position		
Previous relevant training		
Checklist' under the Research (ASSIGNED PEER RESOU	Coordinator Services Quick Link	
Name of Mentor:		Contact Information:

* NOTE: The Stanford Welcome Center provides guidance for all new staff. Some tasks will be coordinated by the university human resource (HR) group or hiring managers. Please follow the links below for further guidance. https://cardinalatwork.stanford.edu/welcome-center

For questions about COVID-19: https://med.stanford.edu/mchri/about/covid19.html (COVID-19 Updates & Resources)

REQUISITE TRAINING & ONBOARDING					
DAY 1: Welcome Center -Virtual Onboarding	Location (Duration)	Mandatory/ Recommende d/ Optional	Date Completed	Trainee Initials	Trainer Initials
Stanford University Welcome Orientation for New Hires HR schedules this live virtual orientation for all staff new to the University	Virtual. Provided by Welcome Center	MANDATORY			
Payroll & Automatic Deposit http://med.stanford.edu/asg/staff/paychecks-and-direct-deposit.html	Virtual. Provided by Welcome Center	MANDATORY			

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Your Benefits https://cardinalatwork.stanford.edu/benefits-rewards	Virtual. Provided by Welcome Center	MANDATORY			
Obtain Badge Access Form & Badge	Provided by Welcome Center	MANDATORY			
Schedule your I-9 Form within first 3 working days, if applicable: Stanford I-9 website	Provided by Welcome Center	MANDATORY			
DAY 2: Human Resources Note: HR will provide all these classes – they will be in your STARS portal	Location (Duration)	Mandatory/ Recommende d/ Optional	Date Completed	Trainee Initials	Trainer Initials
HIPAA/Protecting Patient Privacy STARS: https://axess.sahr.stanford.edu/ Class code: PRIV-YYYY-WEB (add current year for YYYY)	Peds HR (2 hrs.)	MANDATORY			
Stanford University Acknowledgement of Mandated Reporter Status STARS: https://axess.sahr.stanford.edu/ Class code: OGC-0001-WEB	Peds HR (10 min)	MANDATORY			
Sexual Harassment Training STARS: https://axess.sahr.stanford.edu/ Class code: SHP-2020-WEB	Peds HR (2 hrs.)	MANDATORY			
Administrative Guide Acknowledgement STARS: https://axess.sahr.stanford.edu/ Class code: HRC-3161-AGA	Peds HR (1-2 hrs.)	MANDATORY			
Employee Information Security Awareness Video https://accounts.stanford.edu/	Peds HR (20 min)	MANDATORY			
Patent Agreement Sign the patent agreement in the Employee Center Tab in Axess	Peds HR (5 min)	MANDATORY			
Complete Photo/Video Release Form	Peds HR	MANDATORY			
Axess Time Card Instructions	Peds HR	MANDATORY			
DAY 2: Office	Location (Duration)	Mandatory/ Recommende d/ Optional	Date Completed	Trainee Initials	Trainer Initials
Register for HIPAA Privacy for Researchers STARS: https://axess.sahr.stanford.edu/ Class code: CLIN-YYYY-WEB (add current year for YYYY)	Online: STARS	MANDATORY			
Register for Staff Respectful Workplace Training STARS: https://axess.sahr.stanford.edu/ Class code: MHRG-1000	Online: STARS	MANDATORY			
Badge & Badge Access Form Take the form given to you by HR (with all signatures obtained) to the main hospital basement (office HC021) in order to obtain badge, as needed.	Stanford Hospital, Office HC021 (1-3 hrs.)	MANDATORY			

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https://med.stanford.edu/news/all-news/2017/02/new-location-hours-for-photo-id-office.html					
Complete SoM Data and Device Security Attestation https://amie.stanford.edu/attestation (paste URL in browser)	Online	MANDATORY			
Complete Computers/Mobile Devices Encryption https://uit.stanford.edu/service/mobiledevice/management https://amie.stanford.edu/datasecurity/amie/ (paste URL in browser) Personal cell phone encryption is optional, but cannot access work email or communicate with patients on cell phone if it is not encrypted.	Online	MANDATORY			
Complete Two-Step Authentication by either: Follow the instructions presented in this link: https://uit.stanford.edu/service/webauth/twostep or	Online/ In Person	MANDATORY			
Going in person to the Tech Bar: http://med.stanford.edu/irt/personal-computing/tech-bar.html					
Schedule Occupational Health Screening Appointment Phone: (650) 725-5308 https://ehs.stanford.edu/about-us/occupational-health-center	484 Oak Road, Room B15 (1 hr.)				
THIS HEALTH SCREEN IS REQUIRED BEFORE WORKING/SHADOWING/TRAINING IN PATIENT CARE AREAS.					
NOTE: REQUEST ADDITIONAL ACCESS TO THE OPERATING ROOM (OR), if required.					
Bring your vaccination history from your primary care provider & other required documents. For males only: if a respirator mask is necessary for your job position, be sure to shave your face for the fitting process.					
WEEK 1 *NOTE: The hiring manager should retain copies of all certificates for any trainings completed below, especially HIPAA and CITI.	Location (Duration)	Mandatory/ Recommende d/ Optional	Date Completed	Trainee Initials	Trainer Initials
Request Stanford Children's Health Epic Access and Training http://med.stanford.edu/mchri/crso/epic.html	Online				
Request Stanford Health Care (Adult) Epic Access http://med.stanford.edu/mchri/crso/epic.html					
Please contact MCHRI Epic Access Intake team (Grisel Arrue). MCHRI will submit the SHC Access Request Form on your behalf after verifying your training records, PI attestation, and obtaining information on your SHC Epic request.	Online				
Also, email <u>epicenteruniversity@stanfordmed.org</u> to request epic training. Once training is completed, your SHC Epic access will be activated.					
Request Stanford Children's Health Safety & Infection Prevention Training in HealthStream E-mail crso@stanfordchildrens.org and provide your name, e-mail address and title to request trainings Due within 30 days of assignment	Online (~2 hours)	MANDATORY			

Complete CITI Training www.citiprogram.org Select "Stanford University" as your organization affiliation. Complete Training for "Group 7" (Includes basic GCP Training)	Online (6-8 hrs.)	MANDATORY		
Register for Bloodborne Pathogens training STARS: https://axess.sahr.stanford.edu/ Class code: EHS-PROG-1600	Online: STARS	MANDATORY		
Register for Clinical Research Operations Certificate Program Complete all requirements throughout 1-2 years. For more information: https://med.stanford.edu/spectrum/education-and-training/clinical-research-operations-program.html	Online			
Review study assignment(s) with manager Protocol (e.g. study nature, staff personnel, sponsor, etc.)	Manager			
Request IRB eProtocol Access from Lead CRC/Manager to Assigned Studies For more information: https://eprotocol.stanford.edu https://eprotocol.stanford.edu	Online			
Complete Desk Phone Set Up If interested in Jabber, visit https://uit.stanford.edu/service/jabber to learn about Jabber.	Office Admin			
Review Axess & Internal Vacation Calendar(s)/Requests	Manager			
Complete Tour of Hospital & Important Locations on Campus Manager or senior personnel in office should take new employees for a tour of relevant locations around campus.	Various Locations			
Order/Download/Configure necessary software on employee's computer See list of recommended software below; Search https://uit.stanford.edu/ for access	Manager			
Register for Slack • Log in to the Stanford University Slack • Join the workspace: SoM-Research Staff Add our Channel: #pediatrics-help-forum (click for guide to add channels)	Manager			

Stanford-Specific trainings (As Needed)	Location (Duration)	Date Completed	Trainee Initials	Trainer Initials
Review Clinical Lab Services for Research Studies Guide https://med.stanford.edu/mchri/crso/crso-resources/lab-services.html	Online			
Review REDCap Video Trainings https://redcap.stanford.edu (paste URL in browser), click on 'Training Resources' AND 'Help & FAQ Sections'	Online			

Review Guide for Doing Clinical Research at Stanford https://doresearch.stanford.edu/policies/research-policy-handbook	Online		
Review Clinical Research Invoicing System for Participants (CRISP) https://ora.stanford.edu/ora-units/sponsored-receivables- management #Clinical Research Invoicing System for Participants (CRISP)	Online		
Register for OnCore https://axess.sahr.stanford.edu/ For more information: https://med.stanford.edu/spectrum/researcher- resources/oncore-for-non-cancer.html	Online: STARS		
Register for Department of Transportation (DOT): Shipping Biological Goods or Dry Ice https://axess.sahr.stanford.edu/ Class code: EHS-PROG-2700	Online: STARS		
Register for Ergonomics: Computer Workstation https://axess.sahr.stanford.edu/ Class code: EHS-PROG-3400	Online: STARS		

SEI	SELF ASSESSMENT - JOB FUNDAMENTAL CHECK LIST				
	Торіс	Specifications			
	Institutional Review Board (IRB) - https://eprotocol.stanford.edu/mydashboard (paste URL in browser)				
	eProtocol	Submission; overall review of sections, regulatory sections (NSR vs SR, IDE/IND exempt vs commercial use, completion)			
	Children's Findings	50.51 vs 50.52; signatory requirements and risk levels			
	Consent Process Practice	Follow Consent and Assent Do's and Don'ts from IRB website; have new hire do several mock Consent Process practice runs			
	Consenting and Assenting	Adult vs. children signatory requirements; process completion; HIPAA and checkboxes, copies sent to Medical Records with patient labels			
	Short Form Consent	Definition; Signatory requirements; witness and translator roles, short form vs translated forms			
	Adverse Event and UP Reporting	Definitions; prompt reporting vs continuing review vs notes to file			
	Clinicaltrials.gov	Site navigation; training manual, basics (why and when)			
	Regulatory Binders	Documentation review; SIR vs Sponsored trials, ALCOA Share PPT			
	НІРАА	Definition, signatory requirement, expiration dates, access to PHI, PHI vs identifiers			
	Documentation in eProtocol	Attachment section, updating, sponsor requirements			

Ethics in Children's Research	Belmont report, regulatory requirements, history
Deviations and Noncompliance	Definition, when to create note to file, when to report/how
Phone Screens	Purpose, definition, IRB requirements (waivers and signatory), performance do's and don'ts
Consent Form and Assent Form - Creation	Creation; IRB requirements, Stanford templates
Waivers (IRB)	Requirements, definitions, uses
	Other Topics
FDA IND/IDE Submissions	Creation, documentation, attachments, packaging, eCopy and binder/department document retention
Clinical Research Workflow	Schedule of events, process flow, funding and sponsor vs IRB schedules, investigator-initiated trials, roles of the RA and CRC
CRF (case report forms)	Definition and purpose, design and creation, data entry, retention, sponsor requirements, source does vs CRFs
Device Accountability	Data entry, logging and shipping
Budget and Billing	Workbook completion and creation, LPCH vs CTRU vs SHC; internal study budget vs sponsor budget
Audits	Requirements, FDA vs sponsor vs IRB vs internal, how to prepare
Subject Binders	Purpose, design and creation, sponsor requirements, documentation and retention, access to information
Laboratory Requisitions	Completion and timeliness
Reporting Deadlines	FDA, IRB, Sponsor
Retrospective Data Acquisition in EMR	Demonstrate how certain data is pulled from Epic/Cerner for data capture
Viewing patient schedules & printing labels	Demonstrate which schedules are valuable in Epic and how to print patient labels

Web Resources

- Pediatrics website: http://med.stanford.edu/pediatrics.html
- Clinical Trials.gov website: https://clinicaltrials.gov/
- Stanford Clinical Trials Directory: http://clinicaltrials.stanford.edu/
- Spectrum Researcher Resources: https://med.stanford.edu/spectrum/researcher-resources.html
- ♦ Cancer Clinical Trials Office: http://cancer.stanford.edu/trials/admin/
- Clinical and Translational Research Unit (CTRU): https://med.stanford.edu/ctru.html
- CCTO Coordinator Corner: http://med.stanford.edu/ccto/staff-resources/coordinator-corner.html
- Spectrum: https://med.stanford.edu/spectrum.html
- ♦ Maternal & Child Health Research Institute (MCHRI): http://med.stanford.edu/mchri.html
- Stanford IRB: http://humansubjects.stanford.edu
- Research Management Group: http://rmg.stanford.edu
- ♦ DoResearch: https://doresearch.stanford.edu/policies/research-policy-handbook
- Pediatrics Human Resources website: https://med.stanford.edu/pediatrics/AcademicAffairs-HR/HR.html
- Lane Library website: http://lane.stanford.edu/index.html

- Research IT (help with STRIDE, REDCap, data pull requests, cohort discovery tool, etc.): https://med.stanford.edu/researchit.html
- ♦ Computer IRT website for computer setup/issues: http://med.stanford.edu/irt.html
- ❖ Stanford Website Hosting: http://med.stanford.edu/web/websites.html

Reco	Recommended Computer Software for Researchers			
Software	Main Use			
Adobe Acrobat Pro	Annotating or modifying PDFs			
Office 365 Word, Excel, PowerPoint, OneNote, Outlook etc. (Downloadable from webmail.stanford.edu within your email account)				
Zoom	Stanford's teleconference hosting platform			
Medicine Box	PHI-secure cloud-based file sharing platform			

	Recommended Email Lists to Be Added				
Resource	Link				
Email Lists - Recommended	 SCCR Learning Opportunities – email Kiera Larsen (klarsen5@stanford.edu) https://med.stanford.edu/sccr/research-services/education-training.html 				
	Education and Training Digest - https://app.e2ma.net/app2/audience/signup/1849003/1799019.96218987/				
	❖ Stanford-staffers (optional)				

	Other Resources			
Resource Description/URL				
Email Lists - Automatic	https://uit.stanford.edu/service/mailinglists/tools peds-all-staff som-all OnCore (automatically added once sign up for training) CTRU (automatically added once you use it) CRISP (automatically added once you use it)			

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CHANGING DELEGATION OF AUTHORITY FOR A STUDY/CLINICAL TRIAL

Task	Trainer	Delegated To	Date Completed
IRB eProtocol transfers (once CITI is completed): - Change personnel (Main Admin or Other Contact for editing rights) - Change names within protocol (personnel descriptions) - Change names on Consent and/or Assent Forms - Submit modification			
Add to REDCap and/or other electronic data capture systems			
Change Main Admin Billing Contact on all budget and billing workbooks for LPCH and SHC to ensure new billing documents are routed to the correct contact			
Change name on any Clinical Labs Requisition Forms for studies using hospital clinical labs for lab tests billed to research			
Update all Regulatory Binder Documents, especially the Delegation of Authority Logs			
Inform RMG and OSR of new coordinator name and contact for any sponsored projects			
Contact Sponsor – setup training (protocol, EDC, etc.) and update contact for new personnel			
Update CRISP access & notify relevant financial manager/analyst/research administrator			
Update the Investigational Pharmacy, if applicable			
Inform CTRU, if applicable			
Share passwords for external hard drives, etc.			
Transfer over any STRIDE/STARR databases by submitting a request online			
Share relevant files via Medicine Box and the location of files in the shared drive			
Ensure access to outside resources has been transferred (outside REDCap databases, outside cloud file storage, etc.)			
Add to/transfer admin contact for any clinicaltrials.gov listings			
Share recurring calendar reminders			
Share Outlook/Office 356 contacts (email vCards)			
Archive all relevant email folders and send to new team member *NOTE: This step is critical for anyone working on sponsored clinical trials that are subject to any type of auditing by a sponsor or federal agency.			

The above checklist is only a guide of recommended task items in the case that a research study/clinical trial is being transitioned from an existing research staff employee to a new employee.

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