

**Clinical Research Personnel Onboarding Checklist**

|  |  |
| --- | --- |
| **Name of Employee** | **Start Date** |

*Attach CV, certifications and completion records*

|  |  |
| --- | --- |
| Qualifications/certifications | |
| Title |  |
| Supervisor |  |
| PI(s) |  |
| Degree(s) |  |
| Certifications received upon entering the position |  |
| Previous relevant training |  |

Note: to acquire this document electronically go to <http://med.stanford.edu/mchri/crso.html> and click on ‘Onboarding Checklist’

**ASSIGNED PEER RESOURCE OR MENTOR**

|  |  |
| --- | --- |
| **Name Of Mentor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Contact Information:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| REQUISITE TRAINING & ONBOARDING |  |  |  |  |  |
| **DAY 1: Welcome Center** | **Location**  **(Duration)** | **Mandatory/ Recommended/ Optional** | **Date**  **Completed** | **Trainee Initials** | **Trainer Initials** |
| **Stanford University Orientation for New Hires**  Peds HR schedules this Orientation for all staff new to the University | **Welcome Center**  **(All Day)** |  |  |  |  |
| **Payroll & Automatic Deposit**  <http://med.stanford.edu/asg/staff/paychecks-and-direct-deposit.html> | **Included in Orientation** |  |  |  |  |
| **Your Benefits**  <https://cardinalatwork.stanford.edu/benefits-rewards/my-benefits> | **Included in Orientation** |  |  |  |  |
| **DAY 2: Human Resource**  Note: HR will provide all these classes – they will be in your STARS portal | **Location**  **(Duration)** | **Mandatory/ Recommended/ 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) | **Peds HR**  **(2 hrs)** |  |  |  |  |
| **Employee Security Awareness Video**  STARS: <https://axess.sahr.stanford.edu/> | **Peds HR**  **(20 min)** |  |  |  |  |
| **Stanford University Acknowledgement of Mandated Reporter Status**  STARS: <https://axess.sahr.stanford.edu/> | **Peds HR**  **(10 min)** |  |  |  |  |
| **Patent Agreement** | **Peds HR**  **(5 min)** |  |  |  |  |
| **Obtain Badge Access Form** | **Peds HR** |  |  |  |  |
| **Complete Photo/Video Release** | **Peds HR** |  |  |  |  |
| **Axess Time Card Instructions** | **Peds HR** |  |  |  |  |
| **DAY 2: Office** | **Location**  **(Duration)** | **Mandatory/ Recommended/ Optional** | **Date**  **Completed** | **Trainee Initials** | **Trainer Initials** |
| **HIPAA Privacy For Researchers**  STARS: <https://axess.sahr.stanford.edu/>  Class code: CLIN-YYYY-WEB (add current year) | **Online:**  **STARS** |  |  |  |  |
| **Badge & Badge Access Form**  Take the form given to you by HR and collect all appropriate signatures for access to SoM and Hospital doors. After all signatures are obtained, take the form to the main hospital basement, office B06 | **Stanford Hospital, Office B06**  **(1-3 hrs)** |  |  |  |  |
| **Register for Staff Respectful Workplace Training**  STARS: <https://axess.sahr.stanford.edu/>  Class code: MHRG-1000 | **Online: STARS** |  |  |  |  |
| **Register for Sexual Harassment Training**  STARS: <https://axess.sahr.stanford.edu/>  Class code: SHP-2000-WEB | **Online: STARS** |  |  |  |  |
| **Complete SoM Data and Device Security Attestation**  <https://med.stanford.edu/datasecurity/attestation.html> | **Online** |  |  |  |  |
| **Complete Computers/Mobile Devices**  <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** |  |  |  |  |
| **Complete Two-Step Authentication by either:**  Follow the instructions presented in this link: <https://uit.stanford.edu/service/webauth/twostep>  or  Going in person to the Tech Bar: <http://med.stanford.edu/irt/personal-computing/tech-bar.html> | **Online/**  **Person** |  |  |  |  |
| **Schedule Occupational Health Screening Appointment**  Phone: (650) 725-5308  THIS HEALTH SCREEN IS **REQUIRED** BEFORE WORKING/SHADOWING/TRAINING IN PATIENT CARE AREAS.  NOTE: REQUEST ADDITIONAL ACCESS TO THE OPERATINGROOM (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. | **484 Oak Road, Room B15**  **(1 hr)** |  |  |  |  |
| **WEEK 1** *\*NOTE: The hiring manager should retain copies of all certificates for any trainings completed below, especially HIPAA and CITI.* | **Location**  **(Duration)** | **Mandatory/ Recommended/ Optional** | **Date**  **Completed** | **Trainee Initials** | **Trainer Initials** |
| **Request Stanford Children’s Health Epic Access**  <http://med.stanford.edu/mchri/crso/epic.html> | **Online** |  |  |  |  |
| **Request Stanford Health Care (Adult) Epic Access**  <http://med.stanford.edu/mchri/crso/epic.html>  Request that your manager email [epicenteruniversity@stanfordmed.org](mailto:epicenteruniversity@stanfordmed.org) to obtain epic training. Only once training is completed your EPIC access will be activated. | **Online** |  |  |  |  |
| **Complete CITI Training**  [www.citiprogram.org](http://www.citiprogram.org)  Select “Stanford University” as your organization affiliation. Complete Training for “Group 7” (Includes basic GCP Training) | **Online**  **(6-8 hrs)** |  |  |  | **.** |
| **Register for Bloodborne Pathogens training**  STARS: <https://axess.sahr.stanford.edu/>  Class code: EHS-PROG-1600 | **Online: STARS** |  |  |  |  |
| **Register for Clinical Research Operations Certificate Program**  Complete all requirements throughout 1-2 years  For more information: <http://med.stanford.edu/spectrum/b2_education/b2_2_clinical_research_operations_program.html> | **Online** |  |  |  |  |
| **Complete Desk Phone Set Up**  If interested in Jabber, visit <https://uit.stanford.edu/service/jabber> to learn about Jabber. | **Office Admin** |  |  |  |  |
| **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** |  |  |  |  |
| **Review study assignment(s) with manager**  Protocol (e.g. nature study, staff personnel, sponsor, etc.) | **Manager** |  |  |  |  |
| **Request IRB eProtocol Access from Lead CRC/Manager to Assigned Studies**  For more information: <http://humansubjects.stanford.edu>  <https://eprotocol.stanford.edu> | **Online** |  |  |  |  |
| **Order/Download/Configure necessary software on employee’s computer**  See list of recommended software below; Search <https://uit.stanford.edu/> for access | **Manager** |  |  |  |  |
| **Review Axess & Internal Vacation Calendar(s)/Requests** | **Manager** |  |  |  |  |
| **Register for Slack**   * [Log in to the Stanford University Slack](https://stanford.service-now.com/kb_view.do?sysparm_article=KB00015016); * [Join the workspace](https://stanford.enterprise.slack.com/signin/find-workspaces): SoM-Research Staff   Add our Channel:  #pediatrics-help-forum ([click for guide to add channels](https://get.slack.help/hc/en-us/articles/205239967-Join-a-channel)) | **Manager** |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Stanford-Specific trainings (As Needed)** | **Location (Duration)** | **Date Completed** | **Trainee Initials** | **Trainer Initials** |
| **Review Clinical Lab Services for Research Studies Guide**  <http://med.stanford.edu/mchri/crso/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/research-scholarship/clinical-research> | **Online** |  |  |  |
| **Review Clinical Research Invoicing System for Participants (CRISP)**  <https://doresearch.stanford.edu/research-offices/srm-sponsored-receivables-management#clinical-research-invoicing-system-for-participants-(crisp)> | **Online** |  |  |  |
| **Register for OnCore**  <https://axess.sahr.stanford.edu/>  For more information:  <http://med.stanford.edu/spectrum/b1_researcher_resources/b1_7_oncore_resources/b1_7_1_oncore_training.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** |  |  |  |

|  |  |  |
| --- | --- | --- |
| Self Assessment - Job Fundamental Check List | | |
| **Topic** | | **Specifications** |
| **Institutional Review Board (IRB) -** <https://eprotocol.stanford.edu/mydashboard> | | |
| ☐ | **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* |
| ☐ | **HIPAA** | 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 docs 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>
* <https://clinicaltrials.gov/>
* Stanford Clinical Trials Directory: <http://clinicaltrials.stanford.edu/>
* Spectrum Coordinator’s Toolkit: <http://med.stanford.edu/spectrum/b1_researcher_resources/b1_2_forms_templates.html> (paste URL in browser)
* Cancer Clinical Trials Office: <http://cancer.stanford.edu/trials/admin/>
* Clinical and Translational Research Unit (CTRU): http://med.stanford.edu/spectrum/b1\_researcher\_resources/b1\_4\_ctru.html
* CCTO Coordinator Corner: <http://med.stanford.edu/ccto/staff-resources/coordinators-corner.html> (paste URL in browser)
* Spectrum: <http://spectrum.stanford.edu>
* Maternal & Child Health Research Institute (MCHRI): <http://med.stanford.edu/chri.html>
* Stanford IRB: <http://humansubjects.stanford.edu>
* Research Management Group: <http://rmg.stanford.edu>
* DoResearch: <https://doresearch.stanford.edu/research-scholarship/clinical-research>
* Dept. of Pediatrics AdHub website: <http://med.stanford.edu/pediatrics/adhub.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>

|  |  |  |
| --- | --- | --- |
| **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 List to Be Added** | | |
| **Resource** | **Link** |
| Email Lists - Recommended | * SCCR Learning Opportunities – email Kiera Larsen ([klarsen5@stanford.edu](mailto:klarsen5@stanford.edu)) * 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) |

|  |  |  |  |
| --- | --- | --- | --- |
| 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.