|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| New Employee Training and Orientation Checklist | | | | | |
| On Boarding Tasks | Trainer Initials | Date | New Employee Initials | Date | N/A |
| Parking Pass |  |  |  |  |  |
| HR to Complete Paperwork |  |  |  |  |  |
| ID Badge and Department Access |  |  |  |  |  |
| Employee Health for Physical Exam |  |  |  |  |  |
| TB Test, Drug Screen & Proof of Testing for Vaccinations |  |  |  |  |  |
| Attend OSUMC Employee Orientation |  |  |  |  |  |
| Department Based Orientations |  |  |  |  |  |
| Tour of Facilities |  |  |  |  |  |
| Meet with Team Members and Supervisor |  |  |  |  |  |
| Obtain Lab Coat and Pager |  |  |  |  |  |
| Review Process for Timesheets and Leave Requests |  |  |  |  |  |
| Receive Departmental Contact Lists |  |  |  |  |  |
| Added to all Mandatory Meeting Invitations |  |  |  |  |  |
| Receive Codes for Door, Copier and Fax, |  |  |  |  |  |
| Orient to location of supplies, envelopes, letterhead, etc. |  |  |  |  |  |
| Telephone and Voicemail Setup |  |  |  |  |  |
| Review Outlook Calendar |  |  |  |  |  |
| Review of Department SharePoint |  |  |  |  |  |
| Receive Copies of Department SOPs |  |  |  |  |  |
| Required Training | Trainer Initials | Date | New Employee Initials | Date | N/A |
| HIPAA Privacy and Research CBLs |  |  |  |  |  |
| Other Applicable Employee CBLs |  |  |  |  |  |
| IHIS CBLs and Training Classes |  |  |  |  |  |
| CITI Training (Basic and GCP) |  |  |  |  |  |
| [IATA](http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html) Training |  |  |  |  |  |
| COM Clinical Research Orientation |  |  |  |  |  |
| OSU Financial Conflict of Interest Disclosure (eCOI) |  |  |  |  |  |
| [EHS Training Biological Safety Training for BSL2](http://ehs.osu.edu/training/default.aspx) |  |  |  |  |  |
| [EHS Online training Bloodborne Pathogens Initial Training](http://ehs.osu.edu/training/default.aspx) |  |  |  |  |  |
| [Infectious Biological Waste Disposal](http://ehs.osu.edu/training/default.aspx) |  |  |  |  |  |
| [EHS Online Training Bloodborne Pathogens Refresher](http://ehs.osu.edu/training/default.aspx) |  |  |  |  |  |
| Other |  |  |  |  |  |
| Computer Systems | Trainer Initials | Date | New Employee Initials | Date | N/A |
| OneSource |  |  |  |  |  |
| Outlook |  |  |  |  |  |
| Personal and Shared Network Drives |  |  |  |  |  |
| IHIS Read Only |  |  |  |  |  |
| IHIS Research Documentation |  |  |  |  |  |
| BuckIRB/ WIRB Connexus |  |  |  |  |  |
| IHIS Billing Workqueue |  |  |  |  |  |
| PI Portal |  |  |  |  |  |
| OnCore |  |  |  |  |  |
| Proper encryption of mobile devices and flash drives |  |  |  |  |  |
| Other |  |  |  |  |  |
| Required Reading | Trainer Initials | Date | New Employee Initials | Date | N/A |
| [Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) |  |  |  |  |  |
| [Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/) |  |  |  |  |  |
| [ICH E6 GCP](http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf) |  |  |  |  |  |
| [21 CFR 50](http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol1/pdf/CFR-2012-title21-vol1-part50.pdf) , [54](http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol1/pdf/CFR-2012-title21-vol1-part54.pdf), [56](http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol1/pdf/CFR-2012-title21-vol1-part56.pdf), [312](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312), [812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812) ; [45 CFR 46](https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf) , [160](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr160_main_02.tpl) , [164](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr164_main_02.tpl) |  |  |  |  |  |
| [OSU HR Policies](https://medcensearch.osumc.edu/sites/policies/Documents/Forms/AllItems.aspx) |  |  |  |  |  |
| [OSUMC policy 09-11 - Use of Patient Information](https://policytech.osumc.edu/dotNet/documents/?docid=52366) |  |  |  |  |  |
| [COM SOPs](https://onesource.osumc.edu/sites/Audience/Research/Pages/ClinicalResearchPracticeSOP.aspx) |  |  |  |  |  |
| [FDA Guidance Documents](http://www.fda.gov/regulatoryinformation/guidances/) |  |  |  |  |  |
| Research Overview | Trainer Initials | Date | New Employee Initials | Date | N/A |
| Protection of Human Subjects |  |  |  |  |  |
| Role of Research Staff |  |  |  |  |  |
| Review of NIH Clinical Trials |  |  |  |  |  |
| Review of Investigator Initiated Clinical Trials |  |  |  |  |  |
| Review of Industry Sponsored Clinical Trials |  |  |  |  |  |
| Institutional Review Board (IRB) Overview |  |  |  |  |  |
| Site Qualification Process |  |  |  |  |  |
| Study Start-Up Process |  |  |  |  |  |
| Study Design (multicenter, double-blind, etc) |  |  |  |  |  |
| Research Billing Process |  |  |  |  |  |
| Study Calendar/Visit Overview |  |  |  |  |  |
| Inclusion/Exclusion Criteria |  |  |  |  |  |
| Subject Recruitment (Process and Documentation) |  |  |  |  |  |
| Subject Screening |  |  |  |  |  |
| Obtaining Informed Consent |  |  |  |  |  |
| Subject Visits (scheduling, orders, etc) |  |  |  |  |  |
| Source Documentation |  |  |  |  |  |
| Data Completion (paper and electronic Case Report Forms) |  |  |  |  |  |
| Biological Samples (processing, storage, shipping requirements) |  |  |  |  |  |
| SAE Documentation and Reporting |  |  |  |  |  |
| Protocol Deviations and Reporting |  |  |  |  |  |
| Monitoring Visits |  |  |  |  |  |
| Query Management |  |  |  |  |  |
| Sponsor and FDA Audits |  |  |  |  |  |
| Advertising |  |  |  |  |  |
| Regulatory Overview | Trainer Initials | Date | New Employee Initials | Date | N/A |
| Essential Documents/Filing |  |  |  |  |  |
| Correspondence |  |  |  |  |  |
| IRB Approvals |  |  |  |  |  |
| IND Safety Reports |  |  |  |  |  |
| Amendments |  |  |  |  |  |
| Continuing Review |  |  |  |  |  |
| Study Termination |  |  |  |  |  |
| Notes To File |  |  |  |  |  |
| Fireproofing Research Records |  |  |  |  |  |
| Fiscal Overview | Trainer Initials | Date | New Employee Initials | Date | N/A |
| Contracts, Grants and other Business Processes |  |  |  |  |  |
| CDA Processing |  |  |  |  |  |
| Budget Development |  |  |  |  |  |
| Research Procedure Rate Request (ROWA) |  |  |  |  |  |
| IHIS Study Upload (Research Billing Office) |  |  |  |  |  |
| Subject Stipends/Subject Travel |  |  |  |  |  |
| Invoice Tracking |  |  |  |  |  |
| Employee Travel Reimbursement |  |  |  |  |  |
| Death Certificate Requests |  |  |  |  |  |
| Supply Ordering |  |  |  |  |  |
| Clinical Trial Overview | Trainer Initials | Date | New Employee Initials | Date | N/A |
| Observe Consent Process |  |  |  |  |  |
| Perform Consent Process w/Assistance |  |  |  |  |  |
| Perform Consent Process w/Trainer Present |  |  |  |  |  |
| Review Eligibility Process |  |  |  |  |  |
| Review Lab Result Interpretation |  |  |  |  |  |
| Review Informed Consent Source Documentation |  |  |  |  |  |
| Review Visit Note Source Documentation |  |  |  |  |  |
| Review On-Study Source Documentation |  |  |  |  |  |
| Review Off-Study Source Documentation |  |  |  |  |  |
| Review Process for Ordering Study Specific Tests |  |  |  |  |  |

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| **Protocol Training Log** |

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| **Trial** | **Sponsor Notified** | **Added at IRB** | **Protocol Training\*** | **Device/Procedure Training** | **Training Log** | **DOA/Signature Log** | **EDC Access** | **IVRS Access** | **Other** | **Consent Process\*\*** | | | | **Study Visits (e.g., Screening, Implant, Follow-up etc.)** | | | | **Training Complete (Date & Trainer’s Initials)** |
|  | | | | | | | | | | O | A | M | P | O | A | M | P |  |
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*O= Observe*

*A= Assist*

*M= Mock*

*P= Perform independently with coordinator present*

\* Protocol training includes : I/E , overview, aim, objectives, study procedures, screening, etc. and is done either with sponsor representative (if required) or primary coordinator of trial

\*\* Consent process includes: determination that I/E criteria met, interaction with subject/family, and documentation of process