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Human Research Protection Office clinical research coordinator training manual

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CLINICAL RESEARCH COORDINATOR ORIENTATION MANUAL

Human Research Protection Office

School of Medicine Liaison Group Subcommittee on Coordinator Training

INSTRUCTIONS

1. This manual is a guide for orienting/training clinical research coordinators in human subjects research and may be altered to meet specific needs. Optional sign-off columns and evaluation points may also be added or removed along with any additional information that may need to be obtained or added.
    a. Hyperlinks may be accessed by moving the cursor over the link and pressing "Ctrl"+ double right click on the mouse.

2. Training is ideally done under the direction of a trainer within the department, division, or area.

3. If done alone and additional assistance is needed, you are welcome to contact any of the following individuals/areas:

Office/Area	Name	Contact Information
Allergy/Immunology	Tarisa Mantia	tmantia@wustl.edu (314-996-8339)
Cardiovascular	Kim Striler	kstriler@wustl.edu (314-747-4452)
Cardiothoracic Surgery	Jennifer Bell	Jennifer.bell@wustl.edu (314-747-6969)
General Surgery	Kristin Geile	geile@wustl.edu (314-286-1506)
Neurology	Rachel Karbarski	karbarskir@wustl.edu (314-362-3282)
Pediatrics	Ann Desai	anndesai@wustl.edu (314 747-5527)
Human Research Protection Office	Sarah Fowler-Dixon	sfowler-dixon@wustl.edu (314-747-6861)

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OVERVIEW OF WASHINGTON UNIVERSITY

	DIRECTIONS/LINKS
1. Start date and time	Obtain start date and time to report to work
2. Parking	Obtain a parking pass from Parking Services https://facilities.med.wustl.edu/parking-transportation/parking/ or Access parking from https://one.wustl.edu/ , search Parking.
3. Washington University School of Medicine (WUSM) Handbook	Review the WUSM Employee Handbook: http://hr.wustl.edu/policies/Pages/default.aspx Select "Cancel" once site is accessed and the information should pull up.
4. WU Badge(s)	Obtain a badge from WU Protective Services located in Olin Residence Hall
5. Time Reporting	Submit time using HRMS system accessible through https://one.wustl.edu/ with your WUSTL Key. Search Time Reporting.
6. WUSTL KEY	This is your unique userID and passwords for most WU electronic systems. Call 314-935-5707 for set-up or assistance. To reset your WUSTL Key, go to https://one.wustl.edu/ and search WUSTL Key.
7. Department Policies	Review any dress codes, absence policies, etc. specific to the area you are working in.
8. Human Resources New Employee Orientation	Attend a New Employee Orientation http://hr.med.wustl.edu/LearningandDevelopment/Pages/NewEmployeeOrientation.aspx
9. Emergency response	Learn the Emergency Response system at WU: 314-362-4357 on medical school campus or 911 on West County, South County, or St. Peters campus
10. 10 Digit Dialing – Medical Campus	All 10 digits have to be dialed when calling from the Medical School campus.

The above activities were completed.	Signatures	Date
Trainer's Signature and Date		
Trainee's Signature and Date		

GENERAL OFFICE INFORMATION

	DIRECTIONS/LINKS
1. Department Username and Password (example: PCF Username and Password for Pediatrics)	
2. Email address	
3. Electronic Systems- Drives, Folders, EMRs	
4. Printer(s)	
5. Phone/Voicemail Instructions	
6. Long Distance Code	
7. Copy Code	
8. Orient to restroom, cafeteria, vending machines	
9. Orient to office space, furniture, computer, phone, office supplies, ordering office supplies	
10. Provide keys	
11. Access to appropriate shared drive	
12. Scrubs Access and SIS (as applicable) Contact BJH Perioperative Services at 314-362-5584for information.	
13. Assign direct co-worker as mentor; introduce co-workers, identify resources within office	
14. Review attendance policy, reporting illness, absences, scheduling vacation time, computer use, passwords, personal email and internet usage	
15. Tour of Operating Rooms/Patient Floors/Clinic areas where will frequent	
16. Order business cards	
17. Order lab coat(s)	
18. Create curriculum vitae (CV) adding current position, Washington University affiliation/address	Print, sign and date on page. Save in shared drive and print and place in central binder
19. Provide copy of license (as applicable).	Print for central binder, scan for shared drive license file
20. Review Department Organization Chart	

The above activities were completed.	Signatures	Date
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Trainee's Signature and Date		

REQUIRED EMPLOYEE COMPLIANCE TRAINING

	DIRECTIONS/LINKS
Complete the following in Learn@Work • Compliance Profile • HIPAA • Physician Billing • EH&S • Code of Conduct • CITI • ePARS	https://learnatwork.wustl.edu/ Learn@Work can be accessed in One at https://one.wustl.edu/ using your WUSTL Key.
Clinical Skills Fair (WU-annually)	

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Trainee's Signature and Date		

AREA SPECIFIC COMPLIANCE RESOURCES

	DIRECTIONS/LINKS
1. Billing Matrix Training	Obtain valid credentials. http://research.wustl.edu/ComplianceAreas/clinical/billing/Pages/BillingMatrixFAQ.aspx Access Billing Matrix at: http://wumatrix2.wusm.wustl.edu/ (This takes you to the log-in page for the Billing Matix.) Or at https://one.wustl.edu/, search Billing Matrix
2. Environmental Health and Safety Training page	http://ehs.wustl.edu/training/Pages/default.aspx
3. Office of University Compliance Code of Conduct	http://universitycompliance.wustl.edu/codeofconduct/Pages/default.aspx or at https://one.wustl.edu/ , search code of Conduct
4. Human Research Protection Office - HRPO CITI training Education/ Human Studies	Required Initial Training. Education "Biomedical Research Team member" or those conducting biomedical research. Print and save your certificate of completion as this will be needed. http://hrpo.wustl.edu/education/human-subjects-education or at https://one.wustl.edu/ , search CITI Initial.
5. Office of Physician Billing	Main Page: http://opbc.wustl.edu • Compliance Education: https://opbc.wustl.edu/CE/Pages/default.aspx • Annual Billing and Compliance Education: https://opbc.wustl.edu/CE/Pages/AnnualBillingComplianceEducation.aspx
6. School of Medicine OpenSpecimen (lab/sample) training	https://ehs.wustl.edu/training/Pages/default.aspx

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Trainee's Signature and Date		

STUDY SPECIFIC TRAINING

Review this section with your trainer or other member of the research team.

	DIRECTIONS/LINKS
1. Review computer shared drives and how to access research files/folders stored on these drives	
2. Review job description and additional training requirements	
3. Review open and enrolling study protocols and essential documents	
4. Arrange protocol training for open studies	
5. Add as study team member to myIRB for active trials	
6. Notify sponsors of new study team member and provide contact information	
7. Meet regularly with employee to answer questions and review progress	
8. Establish performance goals for the year	
9. Feasibility assessment to conduct the study (applicable for experienced personnel or individuals solely responsible for all study aspects)	
10. Contract and Budget	
11. Research Protocol • IRB Approval • Elements/Parts of Protocol • Compliance/Adherence REQUIRED • Deviations	
12. Monitoring/Oversight • Reptrax for monitor and access to pharmacy • Investigator Meeting • Visits: PSSV, SIV, IMV, COV • Visit Reports • Audits	

Assessment Area	**Satisfactory**	**Needs Improvement**	**Plan for Improvement**

The above activities were completed	Signatures	Date
Trainer's Signature and Date		

STUDY SPECIFIC TRAINING (con'd)

Review this section with your trainer or other member of the research team.

	DIRECTIONS/LINKS
13. Study Set-up • Other departments/disciplines/vendors (i.e. lab, pharmacy, radiology, equipment vendors, central reading centers, etc) - Logistics, credentials, etc • Equipment – calibration and maintenance records • Trial Master File (Regulatory Binder, Essential Documents) & update during trial • Data Collection Tools for protocol adherence (source doc worksheets, logs, etc.) • Trainings	
14. Investigational Product Management • Records: receipt, inventory, storage, dispensing, accountability, return/destroy • Randomization codes/Emergency codes • Compliance calculations	
15. Study Supplies Management	
16. Subjects • Recruitment • Scheduling Logistics • Informed Consent • Inclusion/Exclusion • Screening/Enrollment Logs • Source Documents	

Assessment Area	**Satisfactory**	**Needs Improvement**	**Plan for Improvement**

The above activities were completed	Signatures	Date
Trainer's Signature and Date		
Trainee's Signature and Date		

STUDY SPECIFIC TRAINING (con'd)

Review this section with your trainer or other member of the research team.

	DIRECTIONS/LINKS
17. Subject Visits • Day/Time requirements • Procedures: order of &/or time requirements and follow protocol instructions for performing procedures	
18. Timely review of study data (lab/test/radiology results) and communication with Investigator	
19. Case Report Forms (CRFs)/ Electronic Case Report Forms (eCRFs)	
20. Adverse Event (AE) Reporting including Serious Adverse Events (SAEs)	
21. Data Queries	
22. Payments if applicable	
23. Documents • Communications – email, phone • Notes to File • Record Retention	

Assessment Area	**Satisfactory**	**Needs Improvement**	**Plan for Improvement**

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Trainee's Signature and Date		

RESOURCES FOR JOB FUNCTIONS

	DIRECTIONS/LINKS
1. Clinical Research at WUSTL • Billing Matrix • Clinicaltrials.gov. How to register a study. • Forms Library. Case Report Forms, Regulatory Binder Lists. • Roles and Responsibilities document.	http://research.wustl.edu The Billing Matrix can also be accessed in One at https://one.wustl.edu/, search Billing Matrix.
2. myIRB information under FAQ.	http://HRPO.wustl.edu or https://myirb.wusm.wustl.edu/ or HRPO FAQ and myIRB can be accessed through https://one.wustl.edu/ , search HRPO to go to the HRPO website.
3. CITI Clinical Research Coordinator Course in Learn@Work.	http://learnatwork.wustl.edu. Learn@Work can be accessed through https://one.wustl.edu/ .
4. Necessary Elements in Fundamentals of Human Subject Research on the HRPO website and in Learn@Work.	3 day course. Optional. There is a cost. Offered two times per year. http://hrpo.wustl.edu/education/conferences-series-workshops/necessary-elements-1/ or http://learnatwork.wustl.edu. Learn@Work can be accessed through https://one.wustl.edu/ .
5. Research Career Development Program (formerly Brown Bag Sessions) in Learn@Work	http://learnatwork.wustl.edu. Learn@Work can be accessed through One.wustl.edu.
6. Research Programs available WU University College	http://ucollege.wustl.edu/students/prospective
7. Subscribe to Research News.	To receive information on human subjects education, policy and development updates. http://researchnews.wustl.edu/
8. Schedule and attend HRPO myIRB orientation, training sessions under Education.	http://hrpo.wustl.edu,
9. Standard Operating Procedures (SOP) examples at:	https://research.wustl.edu/ComplianceAreas/clinical/Research_forms/Pages/SOP-Library.aspx
10. Financial Management Resource Guide under Resources and Training	https://financialservices.wustl.edu/ or search Financial Services in One at https://one.wustl.edu/
11. Financial Management Series classes (STAR)	Offered 2-3 times per year – listed on the Office of the Vice Chancellor of Research (OVCR) Education Calendar http://research.wustl.edu/events/Pages/UpcomingEvents.aspx or in Learn@Work https://learnatwork.wustl.edu/ , browse for STAR

RESOURCES FOR JOB FUNCTIONS (con'd)

12. Review Research Resource Forms Library at:	http://research.wustl.edu/ComplianceAreas/clinical/Research_forms/Pages/default.aspx
13. Electronic medical record systems related to patient records (Clindesk, Touchworks/Allscripts, IDX, Compass, OTTR, KIDDOS, Wellsoft, HMED)	Attend training if offered, as required.
14. Research record systems related to research participant records (CIDER, ClinPortal) as required.	Attend training if offered.
15. Recruitment Resource: Volunteers for Health	https://ccs.wustl.edu/
16. Recruitment Resource: Institute of Clinical and Translational Services (ICTS)	http://icts.wustl.edu/
17. Recruitment Resource: WU PAARC	http://icts.wustl.edu/icts-researchers/icts-cores/find-services/by-core-name/washington-university-pediatric-adolescent-ambulatory-research-consortium-wu-paarc
18. CCS and CARs services (all-inclusive paid and free)	https://ccs.wustl.edu/
19. Contracts and CTA (required)	https://ccs.wustl.edu/
20. OnCore Clinical Trial Management System	https://oncore.wustl.edu/login/
21. RedCap – Research Electronic Datacapture	https://redcap.wustl.edu/redcap/srvrs/
22. Qualtrics	For instructions and use: https://provost.wustl.edu/resources/
23. Financial Conflicts of Interest	Financial conflicts of interest need to be on file and disclosed for all engaged members of the study team. See the WUSTL Vice Chancellor for Research website at: http://research.wustl.edu/compliancеareas/coi/guidanceandprocedures/financialdisclosureprocedures/Pages/default.aspx
24. Sunshine Act and Open Payments Program Under the Sunshine Act, physicians' financial conflicts of interest with pharmaceutical companies are posted publically on the Centers for Medicare and Medicaid (CMS) website. CMS is responsible for administering the Sunshine Act and named it the Open Payments Program.	For more information on the Sunshine Act See CMS website at: https://www.cms.gov/openpayments/ For a specific doctor's payment, see the CMS Open Payments website at: https://openpaymentsdata.cms.gov/

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OVERVIEW OF RESEARCH AT WASHINGTON UNIVERSITY

	DIRECTIONS/LINKS
1. WU Compliance Guide	www.ComplianceGuide.wustl.edu
2. Research Gateway	https://one.wustl.edu/
3. Broad WU roles and responsibilities	http://www.wustl.edu/policies/
4. Large list of research policies at WU	http://research.wustl.edu/PoliciesGuidelines/Pages/WUSTLPoliciesGuidelines.aspx
5. CRC SELF ASSESSMENT TOOL from CCS	To be used 3-6 months in the role
6. IRB Fees in the Research Toolkit	https://hrpo.wustl.edu/research-toolkit/fees/
7. Cancer research: Siteman Cancer Center	https://siteman.wustl.edu/

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ADDITIONAL RESOURCES (This is just a listing of useful websites.)

	DIRECTIONS/LINKS
1. ACRP professional organization (certification/membership)	http://www.acrpnet.org/
2. Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
3. Clinical Trials.gov	https://clinicaltrials.gov/
4. Code of Federal Regulations	http://www.ecfr.gov/
5. Declaration of Helsinki	https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
6. ICH GCP Training:	Learn@Work, ACRP GCP training, search GCP at https://learnatwork.wustl.edu/ NDAT Clinical Trials Network training at https://gcp.nihtraining.com/
7. Office of Research Integrity	https://ori.hhs.gov/
8. SOCRA professional organization	https://www.socra.org/
9. Title 21 The Food and Drug Administration	www.fda.gov
10. Title 45 Health and Human Services	www.hhs.gov

ACRONYMS AND ABBREVIATIONS

A	
AAHRPP	Association for the Accreditation of Human Research Protections Programs
ACRP	Association of Clinical Research Professionals
ADR	Adverse Drug Reaction
AE	Adverse Event
ATTC	Addiction Technology Transfer Center
C	
CE	Covered Entity
CDA	Confidentiality Disclosure Agreement
CFR	Code of Federal Regulations
CIDER	Clinical Investigational Data Exploration Repository
CITI	Collaborative IRB Training Initiative (Human Subjects Education) U of Miami
COI	Conflict of Interest
COV	Close Out Visit
CPA	Cooperative Project Assurance
CR	Common Rule
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Clinical Research Organization/Contract Research Organization
CRC	Clinical Research Coordinator
CTA	Clinical Trial Agreement
CV	Curriculum Vitae (resume)
D	
DHEW	Department of Health, Education and Welfare (no longer exists)
DHHS	Department of Health and Human Services (replaced DHEW)
DIA	Drug Information Association
DMC	Data Monitoring Committee
DoD	Department of Defense
DoDD	Department of Defense Directive
DoE	Department of Education
DOE	Department of Energy
DOJ	Department of Justice
DRC	Disclosure Review Committee
DSMB	Data Safety Monitoring Board
E	
EC	Ethics Committee
ECOG	Eastern Co-operative Oncology Group
ED	Emergency Department
EH&S	Environmental Health & Safety
EPA	Environmental Protection Agency

ACRONYMS AND ABBREVIATIONS (con'd)

F	
FD	Financial Disclosure
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FIS	Financial Information System
FWA	Federal Wide Assurance
G	
GCP	Good Clinical Practice
GOG	Gynecologic Oncology Group
GMP	Good Manufacturing Practice
H	
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health Maintenance Organization
HPA	Human Protections Administrator
HRP	Human Research Protections
HRPP	Human Research Protection Program
HRPO	Human Research Protection Office
HRMS	Human Resources Management System
HSR	Health Services Research
HUD	Humanitarian Use Device
I	
IAA	IRB Authorization Agreement
IACUC	Institutional Animal Care and Use Committee
IB	Investigator's Brochure
IBC	Institutional Biohazard Committee
ICF	Individual Consent Form or Institutional Consent Form
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals
ICH-GCP	International Conference on Harmonization/Good Clinical Practice
ICTS	Institute of Clinical and Translation Sciences
IDE	Investigational Device Exemption
IEC	Institutional Ethics Committee/Independent Ethics Committee
IIA	Individual Investigator Agreement
IMV	Interim Monitoring Visit
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
J	
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JIT	Just in Time (procedure)
L	
LCME	Liaison Committee for Medical Education
Learn@Work	Learning Management System for Washington University
LTF	Subjects Lost to Follow-up

ACRONYMS AND ABBREVIATIONS (con'd)

M	
ML	Medical License
MPA	Multiple Projects Assurance
MSO	Medical Staff Office
N	
NAIM	National Association of IRB Managers
NCPHSBBR	National Commission for the Protection of Human Subject of Biomedical and Behavioral Research
NBAC	National Bioethics Advisory Commission
NCQA	National Committee for Quality Assurance
NDA	New Drug Application
NHRPAC	National Human Research Protections Advisory Committee
NIA	Nonaffiliated Investigator Agreement
NIH	National Institute of Heath
NIJ	National Institute of Justice
NSF	National Science Foundation
NSR	Non-significant Risk
O	
OGC	Office of General Council
OHRP	Office of Human Research Protections (formerly OPRR)
OPRE	Office of Planning, Research & Evaluation
OPRR	Office of Protection from Research Risks
ORA	Office of Regulatory Affairs
ORCA	Office of Research Compliance and Assurance
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
OVCR	Office of the Vice Chancellor of Research
P	
PARC	Protocol Adherence Review Committee
PI	Principal Investigator
PHI	Private Healthcare Information/Public Health Information/Protected Health Information
PHS	Public Health Service (USPHS United States Public Health Service)
PMA	Pre-Market Approval
POG	Pediatric Oncology Group
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Q	
QA	Quality Assurance
QI	Quality Improvement

ACRONYMS AND ABBREVIATIONS (con'd)

R	
RAPS	Regulatory Affairs Professional Society
RCO	Regulatory Compliance Officer
RDRC	Radioactive Drug Research Committee
REB	Research Ethics Board
RCT	Randomized Control Trial
RCR	Responsible Conduct of Research
RTOG	Radiation Therapy Oncology Group
S	
SAE	Serious Adverse Event
SAR	Suspect Adverse Reaction
SIS	Student Information System
SIV	Site Initiation Visit
SMO	Site Management Organization
SoCRA	Society of Clinical Research Coordinators
SOP	Standard Operating Procedure
SPA	Single Project Assurance
SR	Safety Report and/or Significant Risk
SRO	Sponsored Research Office
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWOG	South West Oncology Group
V	
VA	Department of Veteran's Affairs
VPR	Vice President for Research
W	
WMA	World Medication Association
WUSTL Key	Washington University in St. Louis unique userID and password system

Developed by the Human Research Protection Office School of Medicine Liaison Group Subcommittee on Coordinator Training:

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