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Washington University Human Research Protection Office training manual: Expedited reviewer specialist

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WASHINGTON UNIVERSITY HUMAN RESEARCH PROTECTION OFFICE TRAINING MANUAL

EXPEDITED REVIEW SPECIALIST

Developed by Sarah Fowler-Dixon, PhD, CIP in consultation with Martha F. Jones, MA, CIP; Jeanne Velders, RN, JD, CIP and Jen Bass-Patino, MA.

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Training Instructions:

- This document is to be used to train individuals in the position(s) indicated. If any items remain in this document that are no longer applicable, the Trainer should mark them as "Not Applicable (NA)" and ask that this document be updated. Supplemental materials may need to be developed. The quiz will be provided to the Trainer for administration.

- The trainer should have knowledge of all areas covered in this document and be able to obtain additional resources if necessary. The trainer should have a Master's Degree or above, be a Certified IRB Professional (CIP) with IRB review, human subjects research, and administrative experience, having a minimum of 4 years cumulative experience in human subjects research and/or IRB review.

- Materials can be covered concurrently. And, to help with understanding, it would be best if information is not covered in isolation. For example, it might be helpful to learn about the regulations as one reviews already approved protocols and learns what the workflow is within the office.

- The material in the Level 1 should be covered before advancing to Level 2 If this is being used for re-training purposes, based on the individual's knowledge, experience and comfort level material may not be covered or not covered as thoroughly (as long as both the employee and trainer are comfortable with the employee's grasp of the topic/information).
- For each item listed, both the employee and trainer must sign off. This ensures that there must be a dialogue between the employee and trainer. The same is true for assessments. If there is a disagreement, or the trainer feels that the employee needs improvement, a plan for improvement must be agreed to by both the employee and trainer and carried out within the specified timeframe.

- The trainer is ultimately responsible for having all material covered and completes the Assessment portions of this document with the employee. The trainer may ask others to assist in the process by covering material in this document with the employee, if /when that occurs the person who meets with the employee initials in the area marked "met with" and the trainer verifies with the employee that he/she has not only covered the material but he/she understands the material and needs no further instruction.

- If training is delegated, it should be done by the Trainer to those selected should be established in their position and either be trained on how to present the information to the new employee or already be performing job functions in accordance with current IRB internal procedures. Trainers are powerful, select them wisely.

- Trainees should be told that material in this document will need to be read many times over the course of their career in human subjects research and protections.

OVERVIEW INFORMATION FOR WASHINGTON UNIVERSITY EMPLOYEES

OVERVIEW

FIRST MORNING OF EMPLOYMENT

OVERVIEW - TO BE COMPLETED THE FIRST MORNING OF EMPLOYMENT-NEW EMPLOYEES – WITH THE MANAGER OF OPERATIONS	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	

• Learns the University telephone exchanges: 935 (Danforth); 286, 362, 454, 747 (Medical School)
 	
• Learns the University website URLs: www. (used by Danforth); http:// (used by medical school)
 	
• Familiarizes oneself with the computer sign on and standard office software installed that will need to be used for the job function:
  • Microsoft Office,
  • Outlook for e-mails,
  • Internet Explorer and Mozilla Firefox, etc.
  • If any programs are unfamiliar or new employee is rusty, schedule a training session for given software or go to the CIT website and print down the appropriate Quick Reference Guide. CIT website: http://citservices.wusm.wustl.edu/Pages/Welcome.aspx. CIT HelpDesk for IRB is Central IT on the Medical School campus at 362-7798.
 	
• Name your computer. Open a Word document, go to the Office Button on the top left of your document, go to Word Options at the bottom right of the pop-up screen, type in your name and initials under Personalize Your Copy of Microsoft.
 	
• Registers oneself for Research News, http://researchnews.wustl.edu, and selects, amongst other options, human subjects research to receive notification.
 	
• Signs the IRB Assurance Form. (Copies are kept with New Member Training materials.)
 	
• Get acquainted with office:
  • Office tour to locate supplies
  • Ordering supplies
  • Orientation to use of the copier/scanners
  • Demonstration as to use of copier/scanners from Manager, Operations.
  • Manager Operations, goes over Safety Plan,
  • Manager Operations goes over how to access suite and building after hours.
 	
• Conference Room use
  • Lunch
  • Committee meetings
  • Other meetings
  • Scheduling on IRB conference room calendar
  • Locking the doors
  • Where key is kept.
  • Clean-up
• Schedule a session with Manager, Operations to go over general tools available to the office,				

• Access and use of office calendar • Access and use of the Conference Room calendar • Access and use of shared contact mailing lists • Location and use of IRB committee membership lists • Any other inboxes needed • Review Use of Employee Self-Serve for time reporting and payroll (https://research.wustl.edu/Pages/ResearchGateway.aspx) • Go over the Absence Request Procedure and Absence Request Form • Kitchen Etiquette: • Use of the refrigerator, ice machine, microwave • Cleaning up after oneself; no dirty dishes in the sink • Office leftovers • Marking your food • Making and cleaning up the coffee and coffee pot • Eating in the Conference Room –when this is possible; cleaning up after oneself • Kitchen clean-up list • Birthday treats list • Front Door • No receptionist • Answering when Deb Aumer is not available • Ask for WU ID • Suite Access • Use of an access code or WU ID to enter suite • Pass code for the alarm system • Turning off your lights at night • Opening the office if you are the first to arrive • Turn on the lights • Wake up the copiers by touching the screens • Make a pot of coffee • Closing the office when you are the last person to leave • Turn off all the lights. • Check all the doors to make certain they are locked • Throw out any old coffee and turn off the coffee maker • Copies go "to sleep" on their own • Leave through the front door; set the alarm and leave through the doors • Maintenance Problems • Report any maintenance problems to the Manager, Operations				

EMAIL AND PHONE - TO BE COMPLETED THE FIRST MORNING OF EMPLOYMENT-NEW EMPLOYEES – WITH THE MANAGER OF OPERATIONS	**INITIALS**			**TRAINER VERIFIES**
	Employee	Met With	Date	
Go over e-mail account and usage. Set up E-mail signature line with: Signature (optional); name; title; office address; direct phone line; fax number (see example below); *Sarah* Sarah Fowler-Dixon, PhD Education Specialist Washington University in St. Louis Human Research Protection Office (IRB) 22 N. Euclid Ave., Ste. 233 St. Louis, MO 63108 314-633-7456 314-367-3041 (fax) **The materials in this email are private and may contain Protected Healthcare Information. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying, distribution, or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.**				
Go over telephone use/etiquette/voicemail. Set up office voicemail and e-mail out of office e-mail notification using standard office language: ***Primary phone message***: "Hi, you have reached [name] in the Human Research Protection Office. I am either on the phone or away from my desk. Please leave your name and number and I will return your call as soon as possible. Thank you." ***Alternate message***: "Hi, you have reached [name] in the Human Research Protection Office. I am currently out of the office and will return on [Monday, November 30]. Please leave your name and number and I will return your call as soon as possible. If you need immediate assistance, please contact** [Deb Aumer at 633-7440]. Thank you." ** [Your manager or designated person in the office during your absence; confirm with your manager and back-up person.] Directions to change phone message: Press "Message" on your phone Enter password (passwords are reset to 1111); followed by # 8 – to change mailbox options 2 – to record or select personal greeting 1 – to record greeting 1 – for Primary or 2 – Alternate ***Out of office e-mail***: "Hi, I am currently out of the office until [December 28]. If you need immediate assistance, please contact **[Name of Person at 633-XXX or e-mail address.]. Thank you. ** [Your manager or designated person in the office during your absence; confirm with your manager and back-up person.]				

OVERVIEW

FIRST WEEK OF EMPLOYMENT

OVERVIEW - TO BE COMPLETED THE FIRST WEEK OF EMPLOYMENT-NEW EMPLOYEES – WITH THE MANAGER OF OPERATIONS	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	

• Attends Human Resources (HR) new employee orientation session. IRB Manager, Operations will assist in scheduling a session.
Date of Session Scheduled: _____
 	
• Reads/Reviews Employee Handbook, in particular policies pertaining to Equal Opportunity, Harassment, Abusive Conduct, Drugs and Alcohol, Family Medical Leave Act, and inclement weather policy. Employee handbook can be found on the HR website at: http://medschoolhr.wustl.edu/. Signs the Employee Handbook Acknowledgement Form that is placed in the employees HR file.
 	
• Parking information:
  • Obtain a parking location and/or U Pass information (http://parking.wustl.edu) with the assistance of the Manager, Operations.
  • Learn about parking options on-campus and off-campus in the Central West End
  • If parking on-campus, complete the necessary paperwork to do a payroll deduction.
  • Learn about the WE CAR use
  • Identify the Office Parking Liaison who sends notices of road and parking closures
  • Should have parking paperwork for on-campus parking.
  • Go over the IRB Parking Policy for parking in the lot under the building.
 	
• Reviews maps of the Medical School campus found at: http://www.wustl.edu/community/visitors/maps/index.html to familiarize oneself with the campus and building names. Using the maps, locate the WUSTL Libraries, http://library.wustl.edu/, (Olin on Danforth, Becker Memorial Library on Medical School, http://becker.wustl.edu/) and WUSTL Bookstores, http://www.wustl.edu/about/campusstores/. The Athletic Complex is on Danforth. You may visit the library and bookstore on the medical campus to see their exact location and reference to other facilities on campus.
 	
• Obtain Identification badge from the security desk outside Becker Medical Library. Hours of operation are Monday-Friday 9:00 am to 3:30 pm. From the Manager, Operations obtain the Washington University School of Medicine Identification/Access Control Request (Badge) Form
 	
• Find out your Employee Identification Number (EMPLID): _____
 	
• Completes Environmental Health & Safety (EH &S) clerical/administrative training.
 	
• Reviews University Benefit information. New Benefit eligible employees must enroll within the first thirty-one (31) days of employment eligibility. This is reviewed at HR orientation and can also be found on the HR website at: http://medschoolhr.wustl.edu/ under Benefits.
 	
• Reviews Human Resources Professional Development opportunities: Learning and Development (http://hr.wustl.edu/career_development/Pages/CourseCatalog.aspx), Tuition Assistance (http://medschoolhr.wustl.edu/medadmin/hr/hrweb.nsf/WV/9362D0A1E6CC728986257218006CF024?OpenDocument), Computer Training (http://becker.wustl.edu/classes/index.html).				

• Confirms TB Test – follow up with Employee Health				

• Greeted by Manager/trainer who will show him/her the assigned workspace, introduce new employee to other staff members, and provide new employee with this Orientation/Competency checklist. Includes conversation on terms of employment (employment program/orientation period/salary), work schedule & breaks/overtime, time and leave reporting/paydays, maintenance of accruals, requesting time off, job duties and performance expectations, performance appraisals.
 	
• Schedule of meetings with Manager/trainer established to discuss progress and orientation/competency checklist items
  • Month one: Daily one-on-one meetings are established. Attendance at regular staff and team meetings mandatory.
  • Month two: Bi-weekly one-on-one meetings are established. Attendance at regular staff and team meetings mandatory.
  • Month three: Weekly one-on-one meetings are established. Attendance at regular staff and team meetings mandatory.
  • Month four and beyond: One-on-one meetings are scheduled as needed. Attendance at regular staff and team meetings mandatory.
 	
• Meets with HRPO Executive Director to discuss function of the department, IRB organizational chart; IRB's role within the WU research enterprise; departmental mission, vision and goals; expected office decorum and professionalism. Included is a discussion of how the IRB is perceived.
 	
• With your manager, go over the workflow charts.
 	
• Familiarizes oneself with the office shared folders and locate the IRB Reference Library (a file containing articles pertaining to human subjects research topics).
 	
• Review material provided on the HRPO website, http://hrpohome.wustl.edu and Vice Chancellor for Research website, http://research.wustl.edu. Know what information is provided on each website and familiarize yourself with the various research offices' names and functions.
 	
• Reads and completes the University Code of Conduct found at: http://universitycompliance.wustl.edu/codeofconduct/Pages/default.aspx
 	
• Completes mandatory HIPAA training assigned by HIPAA Liaison. (UserID, password, and location of training provided by Liaison.)
 	
• Contacts IT at 314-935-5707 to obtain WUSTL Key. (need EMPLID to develop WUSTL Key)
 	
• Schedule a one hour session with a myIRB administrator to go over myIRB administrative functions for your position, where to find and/or store information, and system questions. Date session scheduled _____				

OVERVIEW MYIRB ELECTRONIC SUBMISSION TRAINING

FIRST MONTH OF EMPLOYMENT

OVERVIEW - TO BE COMPLETED THE FIRST MONTH OF EMPLOYMENT-- WITH MYIRB ADMINISTRATOR	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	

• Attend myIRB training sessions. Register through the IRB website under myIRB.
  • New Project Training session date attended_____
  • REF/Legacy Training session date attended _____				

• In the trainees 'draft folder, prepare a mock submission in myIRB to help familiarize you with the system. DO NOT SUBMIT.				

OVERVIEW AND MYIRB COMPETENCY ASSESSMENT

OVERVIEW COMPETENCY ASSESSMENT - TRAINER COMPLETES WITH EMPLOYEE	NEEDS IMPROVEMENT	SATISFACTORY	INITIALS		DATE
			Employee	Trainer	
Able to navigate the myIRB system					
Familiar with office procedures					
Adheres to IRB office procedures, e.g. absence requests, copier use, office hours, etc.					
Able to use any required additional software needed for position, e.g. Microsoft Word, Outlook, Internet Explorer, etc.					
Able to understand and integrate new information, whether guidance, policy or office procedures into current work flow, when needed					
Is aware of and adheres to WU Human Resource policies.					

Non-IRB Offerings

Completed throughout the fiscal year

HUMAN RESEARCH PROTECTION PROGRAM TRAINING – NON-IRB OFFERINGS OBJECTIVES ARE TO GET A FEEL FOR THE ENTIRE WU RESEARCH ENTERPRISE AND TO LEARN HOW OTHERS OUTSIDE THE OFFICE COMMUNICATE WITH ONE ANOTHER.	**INITIALS**			**TRAINER VERIFIES**
	Employee	Trainer	Date	
Attends two to three free WU sessions, offered by offices other than IRB, that relate to some aspect of the submission, review, or conduct of human subjects research, e.g. Grand Rounds, Brown Bag, PERCSS (RCR) session, Departmental specific offering (Biotech 21, Genomics, CIDER, ClinPortal and caTissue, etc). Some of these sessions are advertised on Research News at http//researchnews.wustl.edu, some events are advertised on the WU Medicine homepage at http:/medicine.wustl.edu, some in the Record that comes electronically, some on the Vice Chancellor for Research page at http://research.wustl.edu under Resources, others can be found within departmental advertising. You can do a search for calendars of events on the WU School of Medicine or Danforth campus websites. Date and Name of Session: Date and Name of Session: Date and Name of Session:				

LEVEL 1 TRAINING
HUMAN SUBJECTS ORIENTATION
Level 1 should be completed in the first 6 – 9 months of training

Level 1 Human Subjects Foundation

First 2 weeks of employment

HUMAN SUBJECTS FOUNDATION THIS INFORMATION SHOULD BE READ BY THE TRAINEE SO THAT EVERYONE HAS SEEN THE FOUNDATION MATERIAL. INITIALS AND DATE INDICATE THAT THE MATERIALS HAVE BEEN READ. CAN BE COMPLETED CONCURRENTLY WITH IRB REVIEWER ORIENTATION. HOWEVER, THIS SECTION SHOULD BE COMPLETED IN THE FIRST 2 WEEKS OF EMPLOYMENT.	**INITIALS**		**DATE**	**DATE RE-READ**
	Employee	Trainer		
Completes IRB member level CITI training track. Access and directions found on the IRB homepage under CITI at http://hrpohome.wustl.edu. Learns the HHS Expedited and Exempt Categories. On the OHRP website, read information pertaining to Federal Regulations, both HHS and FDA, http://www.hhs.gov/ohrp/humansubjects/index.html • 45 CFR 46 • 21 CFR 50 • 21 CFR 56 • 21 CFR 312/314 • 21 CFR 812/814 • Read the IRB Policies and Procedures found under Policies on the IRB homepage at http://Hrpohome.wustl.edu • Read all IRB published guidelines found on the Guidelines page at http://Hrpohome.wustl.edu. • Read the following research policies on the Vice Chancellor for Research website at http://research.wustl.edu/PoliciesGuidelines/Pages/WUSTLPoliciesGuidelines.aspx - Clinical Trial Registration: Letter from the Vice Chancellor for Research to Faculty; Clinical Trial Registration FAQ - Code of Conduct - Environmental Health & Safety, Policies and Procedures - HIPAA: Policy numbers 11 minimum necessary; 13 uses or disclosures of protected health information without verbal or written authorization; 15 use of disclosure of protected health information in research; 17 security measures required to comply with privacy policies - Human Embryonic Stem Cell Research Guidelines - Human Research Education Policy - Human Research Participant Protection, Institutional Statement of Commitment - Intellectual Property Policy - Investigational Drug/Device Accountability Policy & Sample Logs • Read the Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation Standards at: http://www.aahrpp.org/www.aspx?PageID=316. • Meet with Manager/Trainer to go over hierarchy of regulations, state statues, federal guidance, and institutional guidance. When does one trump the other?				

Level 1 Assessment 1 Quiz

LEVEL 1 ASSESSMENT 1 - Satisfactory completion requires 70% or better on a quiz

Basic understanding of the following documents and their contents is tested

- HHS Expedited and Exempt Categories.
- 45 CFR 46
- 21 CFR 50
- 21 CFR 56
- 21 CFR 312/314
- 21 CFR 812/814
- IRB Policies and Procedures

- IRB published guidelines found on the Guidelines

- Vice Chancellor for Research policies
  - Clinical Trial Registration: Letter from the Vice Chancellor for Research to Faculty; Clinical Trial Registration FAQ
  - Code of Conduct
  - Environmental Health & Safety, Policies and Procedures
  - HIPAA: Policy numbers 11 minimum necessary; 13 uses or disclosures of protected health information without verbal or written authorization; 15 use of disclosure of protected health information in research; 17 security measures required to comply with privacy policies
  - Human Embryonic Stem Cell Research Guidelines
  - Human Research Education Policy
  - Human Research Participant Protection, Institutional Statement of Commitment
  - Intellectual Property Policy
  - Investigational Drug/Device Accountability Policy & Sample Log

ASSESSMENT – based on a passing score of 70%	NEEDS IMPROVEMENT	SATISFACTORY	DATE

Level 1 – CRITERIA FOR REVIEW: RISKS, MONITORING

IN SOME AREAS THERE IS REFERENCE INFORMATION THAT MUST FIRST BE READ BY THE TRAINEE BEFORE A STUDY CAN BE SCREENED OR REVIEWED TO SEE HOW THIS CRITERION IS APPLIED. THIS CAN BE DONE AS A CLASS OR IN A GROUP SETTING WITH STANDARD MOCK STUDIES. THIS CAN ALSO BE DONE IN AN INTENSIVE 3 WEEK TRAINING PROGRAM. WHEN SCREENING OR REVIEWING A STUDY, THE TRAINEE SHOULD CHECK OFF THE AREAS COVERED. THE NUMBER OF STUDIES THAT NEED TO BE SCREENED AND REVIEWED DEPENDS ON THE ISSUES IN EACH STUDY AND THE COMFORT LEVEL OF THE TRAINEE. ONCE EACH AREA HAS BEEN SCREEN/REVIEWED THE RESPECTIVE CRITERION WILL BE COMPLETE.				
STEP 1 – READ THE INFORMATION **STEP 2 – FIND AN EXPEDITED STUDY AND DISCUSS IT PER THE APPLICABLE CRITERIA BELOW WITH YOUR TRAINER.** **STEP 3 – FIND AN EXEMPT STUDY. WHAT APPLIES? DISCUSS WITH TRAINER.**	**READ MATERIALS THAT ADDRESS A GIVEN AREA**	**EXPEDITED STUDY**	**EXEMPT**	**DATE RE-READ MATERIAL**
Risks are Minimized • Review the Assessing Risk Guideline on the IRB website under Biomedical Guidelines, Risk & Data Monitoring Guidelines at http://Hrpohome.wustl.edu/study_team/guidelines.aspx • See myIRB Section VI (Participants) Section VII (Project Description) and Section VIII (Risks)				
Risks are Reasonable • Read the Belmont Report found on the OHRP website at: http://www.hhs.gov/ohrp/humansubjects/index.html • Read the IRB Policies and Procedures on Unanticipated Problems found under Policies in the IRB website in the Policies and Procedures document at http://Hrpohome.wustl.edu/study_team/policies.aspx • On the OHRP website, review "Reviewing and Reporting Unanticipated Problems Involving Risks to others and Adverse Events; Withdrawal of Subjects from Research" at http://www.hhs.gov/ohrp/policy/investigators/index.html • See myIRB Section VIII (Risks) and Section IX (Benefits)				
The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants • On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html, review the guidelines found under **For Investigators** groups documents that will be of particular interest to research investigators, such as how to handle subject withdrawal from a protocol, how to assess unanticipated problems and adverse events that may occur during the conduct of research, and the general responsibilities of research investigators • On the IRB website, under Risk & Data Monitoring Guidance, review the Data Monitoring guideline. • See myIRB Section VIII (Risks)				

Level 1 Assessment 2 Quiz

LEVEL 1 ASSESSMENT 2 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following elements of approvability are tested • Risks are Minimized • Risks are Reasonable • Provision for monitoring the data collected to ensure the safety of participants			
ASSESSMENT – based on a passing score of 70%	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 1 – CRITERIA FOR REVIEW: AND PARTICIPANT SELECTION, RECRUITMENT AND CONSENT

IN SOME AREAS THERE IS REFERENCE INFORMATION THAT MUST FIRST BE READ BY THE TRAINEE BEFORE A STUDY CAN BE SCREENED OR REVIEWED TO SEE HOW THIS CRITERION IS APPLIED. THIS CAN BE DONE AS A CLASS OR IN A GROUP SETTING WITH STANDARD MOCK STUDIES. THIS CAN ALSO BE DONE IN AN INTENSIVE 3 WEEK TRAINING PROGRAM. WHEN SCREENING OR REVIEWING A STUDY, THE TRAINEE SHOULD CHECK OFF THE AREAS COVERED. THE NUMBER OF STUDIES THAT NEED TO BE SCREENED AND REVIEWED DEPENDS ON THE ISSUES IN EACH STUDY AND THE COMFORT LEVEL OF THE TRAINEE. ONCE EACH AREA HAS BEEN SCREEN/REVIEWED THE RESPECTIVE CRITERION WILL BE COMPLETE.				
STEP 1 – READ THE INFORMATION **STEP 2 – FIND AN EXPEDITED STUDY AND DISCUSS IT PER THE APPLICABLE CRITERIA BELOW WITH YOUR TRAINER.** **STEP 3 – FIND AN EXEMPT STUDY. WHAT APPLIES? DISCUSS WITH TRAINER.**	**READ MATERIALS THAT ADDRESS A GIVEN AREA**	**EXPEDITED STUDY**	**EXEMPT STUDY**	**DATE RE-READ MATERIAL**
Participant Selection is Equitable • On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html review the guidelines found under the **Vulnerable Populations** includes guidance addressing vulnerable groups such as children, prisoners, and subjects for whom a certificate of confidentiality may offer appropriate additional protections • Review 45 CFR 46, subparts B, C, and D http://www.hhs.gov/ohrp/humansubjects/index.html • Review 21 CFR 50 subpart D http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1 • See myIRB Section VI (Participants) and Section VII.D (Recruitment and Consent)				
Recruitment methods are fair, appropriate, and designed to allow to ensure equitable selection of subjects • Review the FDA Recruiting Study Subjects – Information Sheet at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm • Review OHRP guidance Research Participants – Employees in the Workplace With your manager, discuss the following Recruitment issues:				

• What does the IRB need to see • What should be in an advertisement; what is an acceptable ad • Use of SS# to recruit or follow-up • Use of Facebook and such • Use of commercial groups to recruit Recruitment vs. engagement in the study				
Payment arrangements are fair, honest, and appropriately designed to allow for the equitable selection of participants and to fulfill the regulatory requirements for consent • On the FDA website, review Payment to Research Subjects – information sheet athttp://www.fda.gov/RegulatoryInformation/Guidances/ucm122046.htm				
The Consent Process provides sufficient protections to participants such that additional oversight is not required. • On the IRB website review Guidelines listed under Vulnerable Populations: Third Party Consent Guidelines, Vulnerable Population – Healthy, Students, and Employees, and Wards of the State. • On the IRB website review the Subject Pools guidance for Olin School of Business and Psychology Department. • On the IRB website review the Legal Age to Consent (outside of Missouri) guideline • See myIRB Sections VI (Participants) and Section VII.D (Recruitment and Consent)				
For HHS-supported multicenter clinical trials, the IRB should receive and review a copy of the HHS-approved sample informed consent document(s) and the complete HHS-approved protocol, if they exist. • Only pertains to NIH studies where a sample consent is provided. • With the assistance of your manager, locate a study that has a sample consent form to review. • Review OHRP "Guidance on Written IRB Procedures" http://www.hhs.gov/ohrp/policy/irbgd107.html • Review the CTEP, DCTD and NCI Investigator's Handbook for Cancer research regarding this topic found under 7.3 Informed Consent on page 45 at http://ctep.cancer.gov/investigatorResources/docs/InvestigatorHandbook.pdf which states "Individual institutions may make minor changes to model informed consent forms. However, the informed consent document's originator must approve any changes in risks or alternative procedures." • Review OHRP guidance "Institutional Review Board of Protocol and Informed Consent Changes" found on the OHRP website at: http://www.hhs.gov/ohrp/policy/consent/nci200870929.html • Read and familiarize yourself the WU myIRB consent template found within the myIRB system.				
Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR) • On the IRB website, review the Consent Guidance and Missouri Statutes included in that guidance document. • On the IRB website, review the, taxable income and waiver of consent guidelines. • On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html, review the **Informed Consent** groups documents that address autonomy and consent issues. • See myIRB Sections VII.D (Recruitment and Consent), Secdtion IV.2-19 (Waiver of Consent and Waiver of Elements of Consent), Section VII.D16 (Waiver of Documentation of Consent)				

Is it appropriate to allow the inclusion of adult subjects who do not have the ability to consent for themselves? • On the IRB website review Guidelines listed under Vulnerable Populations: Cognitive Impairment • On the IRB website, review the Assent guideline • See myIRB Sections VI.25 – VI.31 (Decisionally impaired participants) and VII.D (Recruitment and Consent)				
Informed Consent will be appropriately documented. • Review the OHRP Informed Consent Checklist at: http://www.hhs.gov/ohrp/policy/consentckls.html • See myIRB Sections VII.D (Recruitment and Consent), IV. 3 (Waiver of Informed Consent or Waiver of Authorization), VII.D16 (Waiver of Documentation of Consent) With your manager discuss the following Consent issues: • Non English speaking populations and consent • Short form consent and its use • Alteration or elimination of consent elements • Mandatory vs. optional elements of consent, when • Debriefing documents, when appropriate • Appropriate consent language • Collection of SS# when payments are made to research participants				

Level 1 Assessment 3 Quiz

LEVEL 1 ASSESSMENT 3 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following elements of approvability are tested • Participant selection is equitable • Recruitment methods are fair, appropriate, and designed to allow to ensure equitable selection of subjects • Payment arrangements are fair, honest, and appropriately designed • Consent Process provides sufficient protections to participants such that additional oversight is not required • Information provided in the WU consent document is consistent with the DHHS approved sample consent document • Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR) • Is it appropriate to allow the inclusion of adult subjects who do not have the ability to consent for themselves? • Informed Consent will be appropriately documented.			
ASSESSMENT – based on a passing score of 70%	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 1 – CRITERIA FOR REVIEW: PRIVACY, CONFIDENTIALITY, VULNERABLE POPULATIONS

IN SOME AREAS THERE IS REFERENCE INFORMATION THAT MUST FIRST BE READ BY THE TRAINEE BEFORE A STUDY CAN BE SCREENED OR REVIEWED TO SEE HOW THIS CRITERION IS APPLIED. THIS CAN BE DONE AS A CLASS OR IN A GROUP SETTING WITH STANDARD MOCK STUDIES. THIS CAN ALSO BE DONE IN AN INTENSIVE 3 WEEK TRAINING PROGRAM. WHEN SCREENING OR REVIEWING A STUDY, THE TRAINEE SHOULD CHECK OFF THE AREAS COVERED. THE NUMBER OF STUDIES THAT NEED TO BE SCREENED AND REVIEWED DEPENDS ON THE ISSUES IN EACH STUDY AND THE COMFORT LEVEL OF THE TRAINEE. ONCE EACH AREA HAS BEEN SCREEN/REVIEWED THE RESPECTIVE CRITERION WILL BE COMPLETE.				
STEP 1 – READ THE INFORMATION **STEP 2 – FIND AN EXPEDITED STUDY AND DISCUSS IT PER THE APPLICABLE CRITERIA BELOW WITH YOUR TRAINER.** **STEP 3 – FIND AN EXEMPT STUDY. WHAT APPLIES? DISCUSS WITH TRAINER.**	**READ MATERIALS THAT ADDRESS A GIVEN AREA**	**EXPEDITED STUDY**	**EXEMPT STUDY**	**DATE RE-READ MATERIAL**
There are adequate provisions to protect the privacy interests of participants. • Review the IRB guidance on Guidelines for reviewing studies involving genetic research. • See myIRB Sections X (Privacy and Confidentiality), Section VII.C (Genetic Research) and Section XII (Future Research)				

There are adequate provisions to maintain the confidentiality of data.
• Read HI-TECH addition to the HIPAA Regulations found on the HHS website at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/enforcementrule/hitechenforcementifr.html
• Review the Confidentiality Guidelines on the IRB website under Confidentiality guidelines: Certificate of Confidentiality, Maintenance of Confidentiality, NIH Certificate of Confidentiality Guideline & Other Information, FDA application
• Computer Security
  • Who is responsible
  • What is needed to satisfy IRB review
  • Who to contact with questions – WU HIPAA Security Officer
  • Which databases/systems are considered secure and WU approved for use: RedCap, secure USB drives issued by HIPAA security liaisons; secure FTP maintained by the School of Business, SharePoint sites, BJC, SLCH, and WU e-mails, sites behind WU firewalls, SurveyMonkey (although information may be identifiable if obtained through SurveyMonkey).
  • Non-secure devices include Android phones; IPads; The Cloud; Google
  • Review Laptop Security, Encryption Security, Polices and Procedures at Network Security Office homepage: http://nso.wustl.edu/Services/Pages/default.aspx
• See myIRB Sections X (Privacy and Confidentiality), Section VII.C (Genetic Research) and Section XII (Future Research)				

When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or pregnant women, additional safeguards have been included in the study to protect the rights and welfare of these participants. • See myIRB Sections VI (Participants) and VII.D (Recruitment and Consent) With your manager, discuss the types of Populations seen at WU: • Healthy volunteers • Those with the condition under study				

• Not healthy but not with the condition under study • Students • Employees • Decisionally impaired • Terminally ill • Critically ill • Minors • Emancipated Minors • Wards of the State				

Level 1 Assessment 4 Quiz

LEVEL 1 ASSESSMENT 4 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following elements of approvability are tested • Provisions to protect the privacy interests of participants • Adequate provisions to maintain the confidentiality of data • When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or pregnant women, additional safeguards have been included in the study to protect the rights and welfare of these participants			
ASSESSMENT – based on a passing score of 70%	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 1 – FDA: IND, IDE and the Difference between HHS and FDA Regulations

IN SOME AREAS THERE IS REFERENCE INFORMATION THAT MUST FIRST BE READ BY THE TRAINEE BEFORE A STUDY CAN BE SCREENED OR REVIEWED TO SEE HOW THIS CRITERION IS APPLIED. This can be done as a class or in a group setting with standard mock studies. This can also be done in an intensive 3 week training program. When screening or reviewing a study, the trainee should check off the areas covered. The number of studies that need to be screened and reviewed depends on the issues in each study and the comfort level of the trainee. Once each area has been screen/reviewed the respective criterion will be complete.				
Step 1 – read the information **Step 2 – find an expedited study and discuss it per the applicable criteria below with your trainer.** **Step 3 – Find an Exempt study. What applies? Discuss with trainer.**	**Read materials that address a given area**	**Expedited Study**	**Exempt Study**	**Date re-read material**
IND Determination • See myIRB Section VII.B 1 – 8 On the FDA website, read information pertaining to investigational drugs and devices, http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/InvestigationalNewDrugINDorDeviceExemptionIDEProcess/default.htm • FDA Investigational New Drug application information: http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/InvestigationalNewDrugINDorDeviceExemptionIDEProcess/ucm094309.htm • Investigational New Drug number required vs. not • Review the FDA Combined products guidance documents: http://www.fda.gov/RegulatoryInformation/Guidances/ucm122047.htm				
IDE Determination • See myIRB Section VII.B 20-26 On the FDA website, read information pertaining to investigational drugs and devices, http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/InvestigationalNewDrugINDorDeviceExemptionIDEProcess/default.htm • FDA Investigational Device Exemption information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm - Definitions and Acronyms; Approval Process; Responsibilities; Application; Reports; IRB: Informed Consent; Financial Disclosure; Early/Expanded Access; Enforcement of Good Clinical Practice Regulations; Import/Export of Investigational devices; FAQ about IDE; IDE related topics; IDE guidance • Significant vs. Non-significant Risk Devices vs. Exempt Devices • General Device Advice FDA page is: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm				

Difference between HHS and FDA regulations • Re-read 45 CFR 46 with all its subparts • Re-read 21 CFR 50 with its subparts • Review the chart that outlines the differences between FDA and HHS regulations found on the FDA website at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/educationalmaterials/ucm112910.htm. • Discuss the difference and the application of each regulation your train/manager.				

Level 1 Assessment 5 Quiz

LEVEL 1 ASSESSMENT 5 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following elements of approvability are tested • IND determinations • 21 CFR 312 and 21 CFR 314 • IDE determinations • 21 CFR 812 and 21 CFR 814			
ASSESSMENT – based on a passing score of 70%	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 1 – Other Review Considerations: Conflict of Interest, Multi-Site Research, Grant, Research Design and Assurance

In some areas there is reference information that must first be read by the trainee before a study can be screened or reviewed to see how this criterion is applied. This can be done as a class or in a group setting with standard mock studies. This can also be done in an intensive 3 week training program. When screening or reviewing a study, the trainee should check off the areas covered. The number of studies that need to be screened and reviewed depends on the issues in each study and the comfort level of the trainee. Once each area has been screen/reviewed the respective criterion will be complete.				
Step 1 – read the information **Step 2 – find an expedited study and discuss it per the applicable criteria below with your trainer.** **Step 3 – Find an Exempt study. What applies? Discuss with trainer.**	**Read materials that address a given area**	**Expedited Study**	**Exempt Study**	**Date re-read material**
Conflict of Interest • Read the Conflicts of Interest: Conflict of Interest Policy; Conflict of Interest and Clinical Research Policy on the Vice Chancellor for Research website at http://research.wustl.edu/PoliciesGuidelines/Pages/WUSTLPoliciesGuidelines.aspx • Review the Personal Conflict of Interest guideline on the IRB website under http://Hrpohome.wustl.edu/reviewers/reviewing_guidance.aspx • On the OHRP website under Investigators review the Financial Conflict of Interest Policy from HHS at http://www.hhs.gov/ohrp/policy/index.html.				
The study has an adequate plan to manage information and communication for multi-site research when WU is the lead site or provides study-wide services. • On the OHRP website, review IRBs and Assurances at: http://www.hhs.gov/ohrp/assurances/index.html • On the IRB website under Community Engaged Research (CEnR) Program, under WU Researchers, review Obtaining and Assurance and Requesting WU as the IRB of Record. • See myIRB Section VIIA 10-17 (Basic Project Information)				

If the study is funded by NIH or another federal agency, and WU is the prime awardee site, is the grant consistent with the protocol?
 	
With your manager go over the following to determine what it is, when it is used, and what IRB/IRB does with the document, if anything.
• Grant –
  • In addition to the above questions, review the various grant mechanisms on the NIH website at: http://grants.nih.gov/grants/funding/funding_program.htm
  • Of those listed on a grant who is considered engaged in human subjects research and needs to be listed on IRB submissions
• Contract
• Subcontract
• Gift
• Fee for Service				

The Research Design has Scientific or Scholarly Validity:				

• On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html review the guidance listed under **Protocol Review** groups information addressing the categories and criteria for approval of human subjects research under the HHS regulations, including guidance on exempt and expedited review determinations and continuing review. • On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html review the guidance listed under **Checklists & Decision Trees** groups decision charts and checklists that have been developed for the IRB community. • On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html review the guidance listed under **Biological Materials & Data** groups OHRP's guidance addressing issues such as research using human subjects data and biological samples, and application of the Genetic Information Nondiscrimination Act (GINA) in research. • Read the Declaration of Helsinki (World Medical Association www.wma.net, specific URL: http://www.wma.net/en/20activities/10ethics/10helsinki/) • Read the Nuremberg Code (Office of Human Subjects Protection, http://ohsr.od.nih.gov/guidelines/nuremberg.html) • On the IRB website, review the Local Research Review (outside of the US) • Read basic information about study designs: http://hsl.lib.umn.edu/biomed/help/understanding-research-study-designs; http://galton.uchicago.edu/~thisted/courses/315/lectures/0297.pdf • See myIRB Section I.7, I.8 (Project Summary and Research Question), Section VII.E (Methods), IX.2 (Benefits to Society) and XI. (Data Analysis)				

Assurances
• On the OHRP website, http://www.hhs.gov/ohrp/policy/index.html, review the guidelines pertaining to **Institutional Issues** groups documents that will be of particular concern to institutions, such as management of an IRB and conduct of IRB meetings, determination of institutional-level engagement in human subjects research, and institutional reporting requirements.
• On the OHRP website, http://www.hhs.gov/ohrp/assurances/index.html, read information about Assurances (FWA, IIA, IAA)
• With your manager, discuss Engagement in a research study
  • OHRP guidance on engagement
  • Federalwide Assurance
  • Individual Investigator Agreement
  • IRB authorization Agreement
  • Individual Volunteer Agreement
  • WU-SLU umbrella agreement
  • Human subjects education needed
  • HIPAA training/implications
  • Letter of agreement vs. Code access agreement vs. e-mail of agreement
  • Data use agreement – what is this and when does this change engagement in the study?				

Level 1 Assessment 6 Quiz

LEVEL 1 ASSESSMENT 6 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following elements of approvability are tested • Conflict of interest • Adequate plan to manage information and communication for multi-site research when WU is the lead site or provides study-wide services • Grants and other funding mechanisms • Research Design has Scientific or Scholarly Validity • Assurances			
ASSESSMENT – based on a passing score of 70%	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 1 New Member Training

NEW MEMBER TRAINING (NMT)	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	

• Attend a New Member Training session
• Observe 2 – 3 committee meetings just to see how the members interact with one another
  • Note what the IRB Chair for the meeting does or does not do.
  • Note what the Administrative Representative does or does not do.
 	
• Discuss meeting dynamics with your Manager/trainer, Coordinator for that meeting, and possibly the Executive Chair.				

Level 1 REVIEWER FORMS

REVIEWER FORMS – TRAINEE SHOULD GO OVER THE REVIEWER FORMS TO FAMILIARIZE HIM/HERSELF WITH THE FORMS AND WHAT IS INCLUDED IN EACH.	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	
After completing the Criteria for Review, go over the Reviewer Forms to see how they would be used in conjunction with the Criteria and with studies under review. Discuss any questions with the trainer. • New Protocol Submission • Continuing Review Submission • Modifications • Unanticipated Problem • Pregnant women • Neonates (non-viable or of uncertain viability) • Children • Prisoners • Deception				

LEVEL 2
APPLICATION OF INFORMATION TO EXPEDITED REVIEWER DUTIES

Level 2 Procedure Overview

PROCEDURE OVERVIEW – THIS IS TO ORIENT YOU TO THE SPECIFIC PROCEDURES YOU WILL USE AS AN EXPEDITED REVIEWER.	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	
• The trainee will review the procedure outline located here: G:\Policies and Procedures\Procedures Date completed: • The trainee will meet with the trainer to discuss and answer questions.				

Level 2 myIRB Electronic Application Guide and Reviewing

SCREENING AND MYIRB APPLICATION GUIDE TRAINING – THIS IS TO ORIENT YOU TO THE SCREENING PROCESS AND USE OF THE MYIRB APPLICATION GUIDE THE EXPECTED TIMELINE FOR REACHING PLACEMENT INTO ROTATION (STEP 3) ON ALL SUBMISSIONS IS 6 MONTHS.	INITIALS			TRAINER VERIFIES
	Employee	Met With	Date	
• The trainer will review purpose and goals of the myIRB application guide with the trainee. • The trainer and trainee will step through the process of a recently approved, pre-selected study or a mock study specifically designed for training purposes. • **Reviews preselected Expedited Protocols for each category** (employee looks at approved studies for all components: submission, reviewer notes, correspondence, IRB determinations) if available, for components, content, and review. (Behavioral and Biomedical) Provide IRB # for each protocol reviewed. • Category 1 protocol reviewed: Biomedical _____ Behavioral _____ • Category 2 protocol reviewed: Biomedical _____ Behavioral _____ • Category 3 protocol reviewed: Biomedical _____ Behavioral _____ • Category 4 protocol reviewed: Biomedical _____ Behavioral _____ • Category 5 protocol reviewed: Biomedical _____ Behavioral _____ • Category 6 protocol reviewed: Biomedical _____ Behavioral _____ • Category 7 protocol reviewed: Biomedical _____ Behavioral _____ • Category 8 protocol reviewed: Biomedical _____ Behavioral _____ • Category 9 protocol reviewed: Biomedical _____ Behavioral _____ • Combined categories reviewed: _____ • Combined categories reviewed: _____ • See Level 3 Intermediate Level for more types of studies. • **Reviews Non-human protocols** for each category (employee looks at approved studies for all components: submission, reviewer notes, correspondence, IRB determinations), if available, for components, content, and review. (Behavioral and Biomedical) Provide IRB # for each protocol reviewed. 1. Non-human protocol reviewed: _____ 2. Non-human protocol reviewed: _____ 3. Non-human protocol reviewed: _____ 4. Non-human protocol reviewed: _____ 5. Non-human protocol reviewed: _____				

6. Non-human protocol reviewed: _____ 7. Non-human protocol reviewed: _____ 8. Non-human protocol reviewed: _____ 9. Non-human protocol reviewed: _____ 10. Non-human protocol reviewed: _____ • **Reviews preselected Exempt protocols** for each category (employee looks at approved studies for all components: submission, reviewer notes, correspondence, IRB determinations), if available, for components, content, and review. (Behavioral and Biomedical) Provide IRB # for each protocol reviewed. • Category 1 protocol reviewed: Biomedical _____ Behavioral _____ • Category 2 protocol reviewed: Biomedical _____ Behavioral _____ • Category 3 protocol reviewed: Biomedical _____ Behavioral _____ • Category 4 protocol reviewed: Biomedical _____ Behavioral _____ • Category 5 protocol reviewed: Biomedical _____ Behavioral _____ • Category 6 protocol reviewed: Biomedical _____ Behavioral _____ • Combined categories reviewed: _____ • Combined categories reviewed: _____ • **Reviews Modifications:** Employee looks at approved studies for all components: submission, reviewer notes, correspondence, IRB determinations) at least 5 different preselected approved modifications (includes notifications that are submitted as modifications) for components, content, and review. (Mixture of Behavioral and Biomedical studies) Provide IRB # for each protocol reviewed. • Modification Type: _____ IRB number: _____ • Modification Type: _____ IRB number: _____ • Modification Type: _____ IRB number: _____ • Modification Type: _____ IRB number: _____ • Modification Type: _____ IRB number: _____ • **Reviews Renewals and Renewals with Modifications:** Employee looks at approved studies for all components: submission, reviewer notes, correspondence, IRB determinations) at least 5 different preselected approved renewals or renewal/modifications for components, content, and review. (Mixture of Behavioral and Biomedical studies) Provide IRB # for each protocol reviewed. • Renewal Type: _____ IRB number: _____ • Renewal Type: _____ IRB number: _____ • Renewal/Modification Type: _____ IRB number: _____ • Renewal/Modification Type: _____ IRB number: _____ • Renewal/Modification Type: _____ IRB number: _____				

Level 2 Contingency Training

CONTINGENCY TRAINING– THIS CAN BE DONE WITH THE REVIEWS ABOVE. THE TRAINER WILL SHOW THE TRAINEE WHERE CONTINGENCIES ARE WRITTEN, DURING THE REVIEW PROCESS, IN THE MYIRB SYSTEM. THEN THE FOLLOWING STEPS WILL BE FOLLOWED FOR EACH REVIEW TYPE ABOVE. STUDIES COMPLETED CAN BE MARKED BELOW OR ABOVE IN THE PREVIOUS SECTION. NUMBER OF STUDIES COMPLETED BEFORE THE TRAINEE GOES TO THE NEXT STEP IS DEPENDENT ON TRAINEE UNDERSTANDING AND COMFORT LEVEL.
Step 1-The trainer and trainee will review a submission together looking for contingencies that may be asked of the study team. Contingencies are written into the my IRB system and sent to the investigator. • Expedited Study IRB number(s): • Non-Human study IRB number (s): • Exempt Study IRB number (s): • Modification IRB number (s): • Renewal IRB number (s): • Renewal/Modification IRB number (s): Step 2 -The trainee will review a submission and then meet with the trainer to review questions prior to sending to the research team. If there are no questions, the trainee will meet with the trainee to review the continuing review to prior to sending for scheduling. • Expedited Study IRB number(s): • Non-Human study IRB number (s): • Exempt Study IRB number (s): • Modification IRB number (s): • Renewal IRB number (s): • Renewal/Modification IRB number (s):

Level 2 Assessment 1 Mock Protocol

A MOCK OR PRE-SELECTED PROTOCOL IS USED TO ASSESS THE EXPEDITED REVIEWER'S ABILITIES.			
ASSESSMENT	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 2 Placed into Rotation

CONTINGENCY TRAINING: PLACED INTO ROTATION – Once Step 3 is reached the trainee will be placed into rotation
Step 3- The trainee will continue to review assigned submissions, write contingencies (if necessary) and send such to the research team. The trainer will be available for questions as needed.

Level 2 Assessment 2 Placed into Rotation

AREA NEEDING IMPROVEMENT (SPECIFY)	PLAN FOR IMPROVEMENT	DEADLINE	NOT SATISFACTORY	SATISFACTORY	INITIALS		DATE
					Employee	Trainer	

LEVEL 3 INTERMEDIATE TRAINING

TO BE COMPLETED AFTER THE FIRST 9 MONTHS OF EMPLOYMENT UP TO 48 MONTHS OF EMPLOYMENT.

Level 3 Community Engaged Research, International Studies, Psychology

	INITIALS		
	Employee	Trainer	Date
Community Engaged Research Studies, include St. Louis Community/ University Health Research Partnership grant background/information, IRB process for handling CEnR studies, FWA/IIA/IAA issues, human subjects education training issues, engagement of sites, methodology used, various types of CEnR studies such as HealthStreet, WU PAARC. IRB numbers: _____			
Review and discuss an **International Study** including consent, translated consents, qualified translators, local context review, ethics committee/government approvals Embargos, international FWAs. IRB number: _____			
Psychology protocol, include consent document, debriefing documents, protocol/submission, Experimetrix, psychology pool information, terminology, coercion/undue influence and how handled, recruitment methods. IRB number: _____			

Level 3 Assessment 1 Mock Protocol

A MOCK OR PRE-SELECTED PROTOCOL IS USED TO ASSESS THE EXPEDITED REVIEWER'S ABILITIES.			
ASSESSMENT	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 3 Industry Sponsored, NCI Cooperative Group, CIRB Reviewed

	INITIALS		
	Employee	Trainer	Date
Review and discuss an **Industry sponsored protocol**, include investigator's brochure, device pamphlet, consent document, protocol, MedWatch reporting document., terminology, FDA regulation and what that means, reporting requirements, IRB number: _____			
Review and discuss a **NCI cooperative group protocol** include sample NIH consent document, protocol, reporting requirements, toxicity requirements for determining adverse/serious adverse events, notifications, how cooperative groups function, funding mechanisms. IRB number: _____			
CIRB reviewed studies, what this means, what is looked for, what is CIRB and how can use it. https://www.ncicirb.org/			

Level 3 Assessment 2 Mock Protocol

A MOCK OR PRE-SELECTED PROTOCOL IS USED TO ASSESS THE EXPEDITED REVIEWER'S ABILITIES.			
ASSESSMENT	**NEEDS IMPROVEMENT**	**SATISFACTORY**	**DATE**

Level 3 Humanitarian Use Device, Emergency Use, Single Patient Treatment

	Initials			Date Re-Read
	Employee	Trainer	Date	
Review and discuss a **Humanitarian Use Device study**, what are they, why are they reviewed by the IRB, what should be submitted for review, what types of consent are acceptable, when does a HUD become an investigational device and need an investigational device exemption, how to make modifications to a HUD. Discuss off-label use of the HUD. HUD information is available from the FDA at: http://www.fda.gov/downloads/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/UCM283504.pdf IRB number: _____				
Review and discuss the **Emergency Use** of an investigational drug or device. Review IRB procedures. FDA information can be found at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm.				
Review and discuss **Single Patient Treatment with an Investigational Drug or Device.** FDA information can be found at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm				

Level 3 Assessment 3 Mock Protocol

A MOCK OR PRE-SELECTED PROTOCOL IS USED TO ASSESS THE EXPEDITED REVIEWER'S ABILITIES.			
ASSESSMENT	**Needs Improvement**	**Satisfactory**	**Date**

Level 3 Genomics or GWAS, Not Engaged Determinations

	Initials			Date re-Read
	Employee	Trainer	Date	
Review and Discuss a **Genomics or GWAS** study. Review a brief guide to Genomics from the National Human Genome Research Institute at http://www.genome.gov/18016863. Review IRB guidelines and procedures				
Review Not-Engaged Determinations that come into the IRB. • Read the OHRP Guidance on Engagement: http://www.hhs.gov/ohrp/policy/engage08.html • Read the NIH Decision Trees: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html • Case studies/case reports. On the HRPO website under Guidance at http://hrpohome.wustl.edu/study_team/guidelines/casestudyguideline.rtf • Training Grants • Overall approvals • Quality assurance projects • Program evaluations				

Level 3 Assessment 4 Mock Protocol

A MOCK OR PRE-SELECTED PROTOCOL IS USED TO ASSESS THE EXPEDITED REVIEWER'S ABILITIES.			
ASSESSMENT	**Needs Improvement**	**Satisfactory**	**Date**

Level 3 Distinguish the Difference, Department of Education and Department of Defense

	INITIALS			DATE RE-READ
	Employee	Trainer	Date	
Distinguishing the Difference. You should already be familiar with the terms below. If not, take time to review each term. Once you have learned the definition and use for each term, it is time to learn how they are different from one another and to learn which the clinical terms are and which the research terms are. As these terms are often interchanged but have different meanings, the goal is to tell them apart, know when a submitter is really referring to the research term and what that research term entails. A discussion regarding each should take place with the Manager/Trainer • Source Document vs. IRB submission material • Clinical chart/record/document vs. Research chart/record/document • Clinical consent vs. Research consent • HIPAA training vs. Human Subjects Research Training vs. Responsible Conduct of Research Training vs. Environmental Health and Safety Training • Clinical terminology vs. Regulatory/research terminology • Investigator's point of view vs. IRB point of view • Research participant vs. third party vs. no third party vs proxy consent • Exempt 2 vs. Expedited 7 • Exempt 4 vs. Expedited 5 • PI collects data/specimens vs. wants access to data specimens and was collaborator vs. wants access and was not collaborator • Wavier of consent vs. Waiver of authorization vs. partial waiver of authorization • Non human vs. human subjects research vs. exempt • Modification vs new study • Expedited review vs. referral to full board • New study is needed vs a modification to an existing study • QA/QI vs Research				
Department of Education (DoE) regulations relevant to human subjects research. http://www2.ed.gov/policy/fund/reg/edgarReg/edgar.pdf • Education Department General Administrative Regulations (EDGAR) 34 CFR Parts 76 (Participation of Students Enrolled in Private Schools); 97 (Protection of Human Subjects); 98 (Student Rights in Research, Experimental Programs and Testing); 99 (Family Educational Rights and Privacy), • Family Educational Rights and Privacy Act (FERPA); http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html • Protection of Pupil Rights Amendment (PPRA), http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html				
Department of Defense (DoD) regulations relevant to human subjects research • DoD and OUSD (P &R) Specific and Unique Requirements, http://fhp.osd.mil/pdfs/HRPP_laws_regulations_policies.pdf				

Level 3 Assessment 7 Quiz

LEVEL 3 ASSESSMENT 7 - Satisfactory completion requires 70% or better on a quiz

- Understanding of the following and being able to distinguish between the two often confused items:
  - Source Document vs. IRB submission material
  - Clinical chart/record/document vs. Research chart/record/document
  - Clinical consent vs. Research consent
  - HIPAA training vs. Human Subjects Research Training vs. Responsible Conduct of Research Training vs. Environmental Health and Safety Training
  - Clinical terminology vs. Regulatory/research terminology
  - Investigator's point of view vs. IRB point of view
  - Research participant vs. third party vs. no third party vs proxy consent
  - Exempt 2 vs. Expedited 7
  - Exempt 4 vs. Expedited 5
  - PI collects data/specimens vs. wants access to data specimens and was collaborator vs. wants access and was not collaborator
  - Wavier of consent vs. Waiver of authorization vs. partial waiver of authorization
  - Non human vs. human subjects research vs. exempt
  - Modification vs new study
  - Expedited review vs. referral to full board
  - New study is needed vs a modification to an existing study
  - QA/QI vs Research

- 34 CFR Parts 76
- Family Educational Rights and Privacy Act (FERPA)
- Protection of Pupil Rights Amendment (PPRA
- DoD and OUSD (P &R) Specific and Unique Requirements

ASSESSMENT – based on a passing score of 70%	NEEDS IMPROVEMENT	SATISFACTORY	DATE

Level 3 Social Media, HIPAA Issues, How WU HRPP Works Together

	Initials			Date re-read
	Employee	Trainer	Date	
Uses of Social Media for research purposes • Read the Washington University Social Media Guidelines issued by Medial Public Affairs at: http://medschool.wustl.edu/policies/social_media_guidelines				
HIPAA Issues • Business Associate Agreement – who handles this? • Data Use agreement • What is the covered entity at WU? • When does HIPAA apply to a study? • Can parts of a study be HIPAA governed and others not? E.g. Departments that live in and out of covered entity: Social Work, Institute for Public Health, Surgery • How to know that the hardware/software proposed in a study for data collection is HIPAA compliant, if applicable.				
What are the various research offices at WU and how do they work together?				

Level 3 Assessment 8 Quiz

Level 3 Assessment 8 - Satisfactory completion requires 70% or better on a quiz			
Understanding of the following as it pertains to human subjects research • WU Social Media guideline • HIPAA Issues • How the WU Human Research Protection Program (HRPP) works together.			
ASSESSMENT – based on a passing score of 70%	**Needs improvement**	**Satisfactory**	**Date**

Level 3 On-Call: questions by phone

ANSWERING GENERAL QUESTIONS BY PHONE (ON-CALL) - INITIALS AND DATE INDICATE THAT DISCUSSION HAS TAKEN PLACE.	**INITIALS**		
	Employee	Trainer	Date
• Step 1 - Phone calls taken with Manager/Trainer (within first month of hire) • Step 2 - Phone calls taken with direction from Manager/Trainer based on comfort level/knowledge of employee (should begin no later than second month of hire) • Step 3 - Phone calls taken independently. Employee may refer to Manager/Trainer if he/she has questions or needs assistance. (should begin no later than third month of hire)			

Level 3 SWAT: office hours

ANSWERING QUESTIONS FOR GENERAL QUESTIONS – OFFICE HOURS AND SWAT- INITIALS AND DATE INDICATE THAT DISCUSSION HAS TAKEN PLACE.	**INITIALS**		
	Employee	Trainer	Date
• Read all HRPO/IRB Guidance Documents on the website and/or all At-A-Glance documents, if available. • Step 1: Face-to-face meeting with investigators done in conjunction with Manager/Trainer (within first month of hire) • Step 2: Face-to-face meeting with investigators with direction from Manager/Trainer based on comfort level/knowledge of employee (should begin no later than second month of hire) • Step 3: Face-to-face meetings done independently. Employee may refer to Manager/Trainer if he/she has questions or needs assistance. (should begin no later than third month of hire)			

Level 3 Assessment Answering Questions

AREA NEEDING IMPROVEMENT (SPECIFY)	**PLAN FOR IMPROVEMENT**	**DEADLINE**	**NOT SATISFACTORY**	**SATISFACTORY**	**INITIALS**		**DATE**
					Employee	Trainer	

Level 3 Re-Read Material in Levels 1 and 3. Mark the date the materials were re-read in the space provided in each applicable section.

Additional Reference Materials (if desired, these may have to be purchased at the employee's expense):

- Designing Clinical Research, third edition by Steven B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady, and Thomas Newman, Lippincott Williams & Wilkins (ISBN-13: 978-0-7817-8210-4), www.lww.com

- Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams, Jossey-Bass (ISBN: 0-7879-6570-7), www.josseybass.com

- Clinical Research Resources: Training and Guidance for Regulatory Compliance series, www.clinicalresources.com

- The Cartoon Guide to Statistics by Larry Gonick and Woollcott Smith, July 14, 1993, Harper Collins (ISBN: 0-06-273102-5). Also available on www.amazon.com.

- How to Lie with Statistics by Darrell Huff and Irving Geis, 1992, W.W. Norton & Company, Inc (ISBN 978-0-393-31072-6). Also available at www.amazo.com

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