

Managing a Research Team

Organizing, Hiring, Training, Delegating and Supervising

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Agenda

- PI responsibilities and organizing a research team
- Hiring research staff
- Effective training for research support staff
- Appropriate delegation of tasks to staff
- Successfully supervising research staff

Step 1: Organizing a research team

PI responsibilities and assessing the work to be done

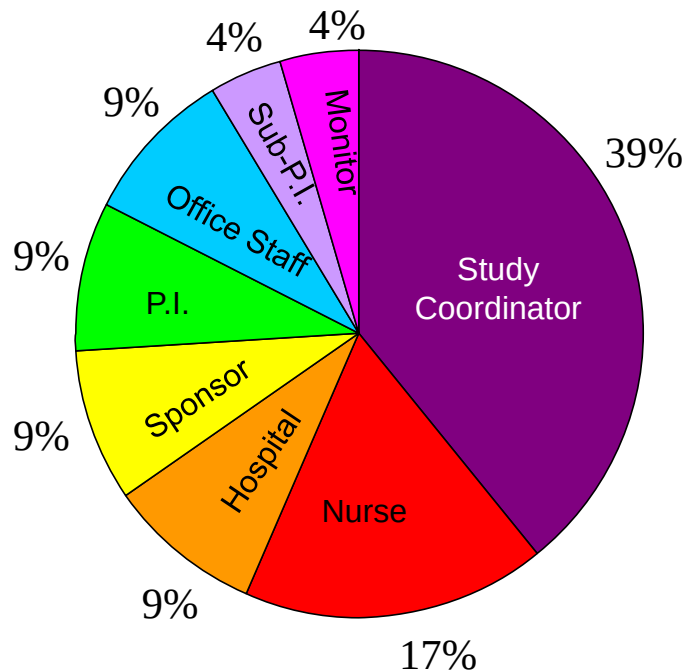
Organizing a research team

1. Know your responsibilities as the PI
2. Be ready to:
 - Delegate
 - Train
 - Supervise

Organizing a research team

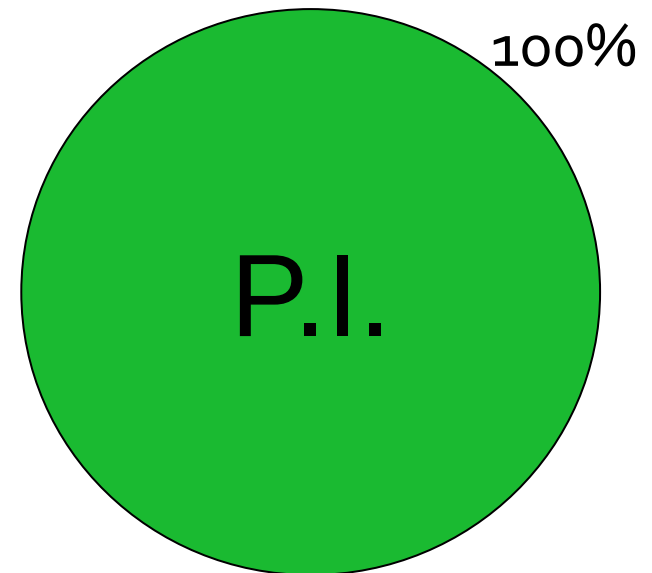
Blame for Poor Research Conduct

Investigator's Report



n (parties blamed) = 23; n (cases) = 20

FDA/IRB/Institution Position



Woollen, S.W., CDER, FDA, 2000

Organizing a research team

Investigator Responsibilities

- **Conduct** or **supervise** the investigation
- **Inform** all members of the research team about their **obligations**
- **Adhere** to the **protocol**
- **Comply** with regulatory requirements regarding **obligations** of principal investigators
- Ensure **regulatory approval (IRB, IACUC)** **requirements** are met

Organizing a research team

Investigator Responsibilities (con't)

- Maintain **accurate records**
- **Report changes** in the research activity, unanticipated **problems** and **adverse events**
- Ensure study **data** is **verifiable**
- If Human Subjects:
 - Inform **participants** about **experimental** nature of research and study **purposes**
 - Ensure an **ethical** informed **consent** process

Organizing a research team

- **Lack of knowledge** of your responsibilities may result in:
 - Study delays
 - Risk to subjects
 - Poor data
 - Frustration
 - Risk of for-cause audit



Organizing a research team

Knowledge of investigator responsibilities leads to **success**, via good:

- Delegation
- Training
- Supervision

Your research is in your team's hands!



Organizing a research team

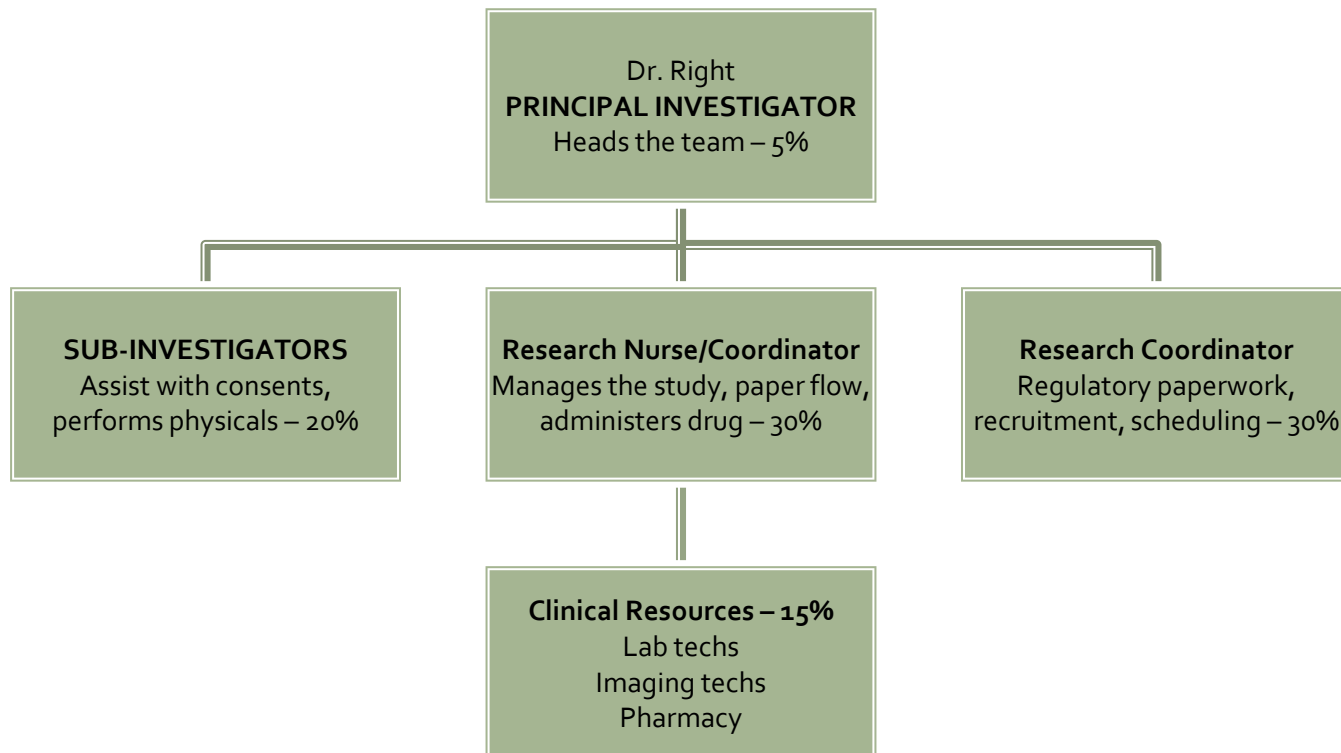
- How do you know **who** you need on your research team?
 - Analyze your project(s) and ask yourself:
 - If you were doing it, how you would do the project?
 - Identify individual tasks
 - Group tasks that flow together
 - Assess volume of tasks

If you aren't sure about anything or need ideas, seek advice from experienced colleagues.



Organizing a research team

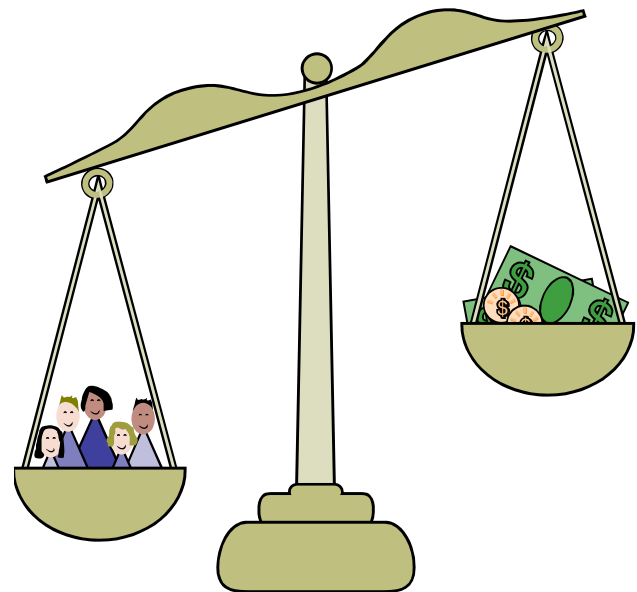
- TIP: Make an organizational chart:
 - Group tasks/roles
 - Identify the types people you need to do the tasks
 - Estimate the amount of time each type of person needs to have to do the tasks



Organizing a research team

Once you've divvied up the tasks...

- Assess time required and funding:
 - Decide what you can do yourself
 - Decide what you'll delegate



Organizing a research team

Finalize the details...ask yourself:

- What **skill sets** are needed to carry out these tasks?
- How **long** will it take **to complete** the tasks?
- How much **funding** do you have?
- How much does it **cost to hire** this team?
 - Work station + supplies!



Step 2:

Hiring research support staff

Working with UW Human Resources to find and hire your staff

Hiring research staff

Develop a job posting

- Based on analysis, determine:
 - Position title
 - Minimum necessary education
 - Minimum necessary experience
 - Pay grade and proposed pay

The screenshot shows the University of Washington's job posting page. The header includes the UW logo, "SEATTLE, WA", and navigation links like "UW HOME", "DIRECTORIES", "CALENDAR", "WAYS", "MY UW", "UW 501(c)(3)", "UW FACULTY", and a search bar. Below the header is a navigation bar with links for "Staff Jobs", "UW Medicine Jobs", "Faculty Jobs", "Library Jobs", and "Student Jobs". The main content area is titled "EMPLOYMENT AT THE UNIVERSITY OF WASHINGTON" and features a sidebar with links to "UW Employment", "Benefits & Total Comp", "Diversity", "Temporary Jobs", "Meet UW Recruiters", "Help", "Privacy/Security", and "Human Resources". The main job posting is for a "RESEARCH COORDINATOR / REGULATORY SPECIALIST" position. It includes links to "Add job to cart", "Apply for this job", and "Return to Job list". The job details are as follows:

Req #:	93830
Department:	INSTITUTE FOR TRANSLATIONAL HEALTH SCIENCES
Job Location:	Other Locations
Job Location Detail:	Health Science Center
Posting Date:	03/15/2013
Closing Info:	Closes On: 03/22/2013
Salary:	Salary is commensurate with experience and education

The posting also includes a paragraph about the University of Washington's commitment to diversity and a detailed description of the Institute for Translational Health Sciences (ITHS) and its role in improving the health research environment.

Hiring research staff

- You have many choices for research staff

- Professional

- <http://www.washington.edu/admin/hr/roles/mgr/comp/prostaff/payrolltitles/payrolltitle-list.html#Research>

- Classified

- <http://www.washington.edu/admin/hr/ocpsp/compensation/alpha.sort.files/alpha.sort.html>

Hiring research staff

PROFESSIONAL STAFF

Research

Job Code	Payroll Title	Grade	Overtime Eligible	Payroll Title Descriptor Available
1793*	APL-DEPARTMENT HEAD	13	N	
9778*	APL-FIELD ENGINEER	8	Y	
1729*	APL-FIELD ENGINEER 2	9	N	
1728*	APL-FIELD ENGINEER 3	10	N	
1765	MARINE ENGRG MANAGER	11	N	
1187	MASTER THOMPSON	11	N	
1452	MEDICAL PHYSICIST	11	N	
Job code links for Research Scientist/Engineer open the generic job description for the respective payroll title				
9691	RES SCI/ENGR - ASST	5	Y	Research Scientist/Engineer
9692	RES SCI/ENGR 1	6	Y	
1493	RES SCI/ENGR 2	7	N	
1494	RES SCI/ENGR 3	8	N	
1495	RES SCI/ENGR 4	9	N	
1497	RES SCI/ENGR-PRINCPL	11	N	
1496	RES SCI/ENGR-SR	10	N	Research Consultant
1498	RES SCI/ENGR-SR PRIN	12	N	
9685	RESEARCH CONSULTANT	5	Y	
9696	RESEARCH CONSULTANT	6	Y	
9697	RESEARCH CONSULTANT	7	Y	
1487	RESEARCH CONSULTANT	7	N	
1488	RESEARCH CONSULTANT	8	N	Research Coordinator
1489	RESEARCH CONSULTANT	9	N	
1484	RESEARCH CONSULTANT	10	N	
1483	RESEARCH CONSULTANT	11	N	
9786	RESEARCH COORDINATOR	6	Y	
1756	RESEARCH COORDINATOR	6	N	
9787	RESEARCH COORDINATOR	7	Y	Research Manager
1757	RESEARCH COORDINATOR	7	N	
1758	RESEARCH COORDINATOR	8	N	
1759	RESEARCH COORDINATOR	9	N	
1760	RESEARCH COORDINATOR	10	N	
1767	RESEARCH MANAGER	7	N	
1768	RESEARCH MANAGER	8	N	
1769	RESEARCH MANAGER	9	N	
1770	RESEARCH MANAGER	10	N	
1490	SOFTWARE ENGINEER	10	N	
1491	SOFTWARE ENGINEER	11	N	
1188	VETERINARIAN	9	N	
1192	VETERINARIAN SENIOR	10	N	
1193	VETRN SUPV	11	N	

CLASSIFIED STAFF

Job Code	Job Title	State Job Class Code Reference	Representative Group	Pay Table	Pay Range	Minimum Mo. Rate	Maximum Incremental Mo. Rate	OT Eligible
4850	RESEARCH AIDE 1	509E	Classified Non-Union	C1	31	\$2161	\$2789	Y
8527	RESEARCH AIDE 1 - BIOENGR ONLY		WFSE Campuswide	B1	31	\$2161	\$2855	Y
7851	RESEARCH AIDE 2		SEIU Local 925 Clerical Nonsupervisory	B4	37	\$2506	\$3325	Y
8528	RESEARCH AIDE 2 - BIOENGR ONLY		WFSE Campuswide	B1	37	\$2482	\$3293	Y
7030	RESEARCH ANALYST 1		SEIU Local 925 Clerical Nonsupervisory	B4	37	\$2506	\$3325	Y
8625	RESEARCH ANALYST 1		WFSE HMC	B1	37	\$2482	\$3293	Y
7031	RESEARCH ANALYST 2		SEIU Local 925 Clerical Nonsupervisory	B4	42	\$2816	\$3763	Y
7032	RESEARCH ANALYST 3		SEIU Local 925 Clerical Nonsupervisory	B4	47	\$3166	\$4255	Y
7005	RESEARCH ANALYST LEAD		SEIU Local 925 Clerical Nonsupervisory	B4	50	\$3410	\$4587	Y
4857	RESEARCH DIETITIAN 1	3111	Classified Non-Union	CA	83	\$4591	\$6568	N
4858	RESEARCH DIETITIAN 2	3111	Classified Non-Union	CA	93	\$5071	\$7257	N
7853	RESEARCH LITERATURE ANALYST		SEIU Local 925 Clerical Nonsupervisory	B4	42	\$2816	\$3763	Y
7867	RESEARCH STUDY ASSISTANT		SEIU Local 925 Clerical Nonsupervisory	B4	33	\$2289	\$3023	Y
7868	RESEARCH STUDY COORDINATOR 1		SEIU Local 925 Clerical Nonsupervisory	B4	38	\$2567	\$3410	Y
7869	RESEARCH STUDY COORDINATOR 2		SEIU Local 925 Clerical Nonsupervisory	B4	43	\$2883	\$3856	Y
7870	RESEARCH STUDY COORDINATOR LEAD		SEIU Local 925 Clerical Nonsupervisory	B4	43	\$2883	\$3856	Y
4871	RESEARCH STUDY SUPERVISOR	323P	Classified Non-Union	C1	46	\$3063	\$4014	N
7859	RESEARCH TECHNOLOGIST 1		SEIU Local 925 Research Tech BU	B4	35	\$2394	\$3166	Y
8529	RESEARCH TECHNOLOGIST 1 - BIOENGR ONLY		WFSE Campuswide	B1	35	\$2370	\$3135	Y
7860	RESEARCH TECHNOLOGIST 2		SEIU Local 925 Research Tech BU	B4	40	\$2669	\$3583	N
8530	RESEARCH TECHNOLOGIST 2 - BIOENGR ONLY		WFSE Campuswide	B1	40	\$2663	\$3549	N

Hiring research staff

- Temporary Options:

- Professional staff project appointment

<http://www.washington.edu/admin/hr/roles/mgr/hire/prostaff-temp/index.html>

- Classified direct hire temp

<http://www.washington.edu/admin/hr/roles/mgr/hire/directhire-temp/index.html>

- UW temporary staff “UTemp Staffing”

<http://www.washington.edu/admin/hr/roles/mgr/hire/utemp.html>

Hiring research staff

- Professional staff
- Complete forms:
 - Job Description
 - Research Activities Form
 - OR
 - Research Scientist/Engineer Questionnaire

HR prostaff link:

<http://www.washington.edu/admin/hr/roles/mgr/hire/prostaff/index.html>

University of Washington | Human Resources | Compensation Office

PROFESSIONAL STAFF POSITION DESCRIPTION – RESEARCH ACTIVITIES FORM

For instructions on completing this form in MS Word see: <http://www.washington.edu/admin/hr/forms/instructions.htm>
Complete this form for positions being considered for professional staff status based on involvement in research activities (e.g. Research Coordinator, Research Consultant, Research Manager). Do not use this form for Research Scientist/Engineer Series titles.
Indicate the type of responsibility and percentage of time devoted to the tasks listed below. 50% or more of the position's total percentage of time must be devoted to duties that are consistent with the criterion for professional staff exemption based on research. Percentages reflect total duties, not % FTE.

POSITION IDENTIFIERS			
Employee Name (enter "vacant" if a recruitment):	Manager's Name:	Department:	Date: mm/dd/yyyy

0.00 % = Amount of total time this position devotes to the tasks below—Not to exceed 100%

IDENTIFYING AND DEFINING RESEARCH PROBLEMS	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

DESIGNING APPROACHES OR HYPOTHESES TO BE TESTED AND METHODOLOGY TO BE USED	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

DESIGNING SPECIFIC PHASES OF RESEARCH PROJECTS	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

ANALYZING RESULTS	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

DEVELOPING CONCLUSIONS	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

PRESENTING RESEARCH RESULTS IN PUBLISHABLE FORM	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

OBTAINING RESEARCH GRANTS (DOES NOT INCLUDE GRANT RELATED FISCAL/BUDGET WORK)	
% of time	is solely responsible
% of time	provides significant contributions
% of time	provides basic input to be developed by more senior position
% of time	other, describe: _____
☐ has little or no responsibility for this task	

University of Washington | Human Resources Page 1 of 1 Compensation Office— Campus Box 359487
Revised: 05/25/11 Phone: 206-543-9404 Fax: 206-616-2372
Email: ocpsp@uw.edu

Hiring research staff

Classified staff

■ Create Job Description

1. The position's primary purpose
2. General duties
3. Any duties that make this position unique to your department
4. Lead or supervisory responsibilities
5. Required skills, knowledge, abilities, or experience
6. Desired skills, knowledge, abilities, or experience
7. Conditions of employment — Credentials required including degree(s), licenses, certificates, registrations, or other certifications that are required to perform the essential duties of the position
8. Work schedule and FTE of the position



HR classified staff link:

<http://www.washington.edu/admin/hr/roles/mgr/hire/classified/index.html>

Hiring research staff

Include in your job posting request email:

1. Appointing budget #:
2. Proposed monthly salary:
3. Payroll Title:
4. Working Title:
5. Job code (from the HR website list):
6. Type of vacancy (New, Replacement:
 - If replacement, indicate full name of person being replaced and reason for separation:
7. Provide Interview team members' full name(s), including middle initial:
8. Supervisor's full name:
9. Indicate if this position is 100% FTE (if not, indicate FTE %):
10. Work Schedule (e.g. M-F / 8-5 or Variable):
11. Job location (E.g. SLU, Harborview Medical Center, Health Science Center, UW Tower etc.):
12. Supervisory responsibility? Yes or No:
13. Will this position be funded by ARRA? Yes or No:
 - If not, indicate if it will be funded by ARRA in the future:
14. *If temporary, hourly/project appointment, provide proposed duration of the appointment (Start and End Dates):
15. Does this position include any Sensitive Security/Safety job functions? Yes or No: Yes
16. Job posting duration (1 week, 2 weeks... 4 weeks) or it could be Open Until Filled, please indicate:
17. Will the recruitment be limited or Open (open to only UW applicants or the public)?

Hiring research staff - Timeline

1. You contact your home department HR representative to request a new or replacement position be created and posted in the UWHires system. You provide all required recruitment information (forms).	Start clock
2. HR creates a new requisition in the UWHires system, which generates a requisition number, and the position is sent out for approval.	3 days
3. Central HR Recruiter will review, approve and forward to Central Compensation	2 days
4. Central Compensation reviews and approves position. You may have to change your request based on their feedback. This can take some time if they don't agree with you.	5+ days
5. The Central HR Recruiter will draft the posting, and forward it to you for final review/approval.	2 days
6. Once posted candidates are able to apply: Pro-staff resumes are forwarded to you on Tuesdays, Fridays, and the next business day after a posting closes. For classified staff, the assigned recruiter will review applicants for qualifications and forward top candidates for you to review.	Depends on length of time job is posted
7. You review applicants, conduct interviews, and proceed with reference checks	Depends on your schedule for interviews
8. When you choose your candidate, e-mail the candidate name to HR and include proposed salary amount and the start date: HR prefers that candidates start on the first day of a pay period – 1st or 16th day of the month	Depends when you finish reference checks
9. HR includes this information for the selected candidate and forwards to Central HR for review and approval	1 day
10. When the salary has been approved, HR will notify you to move forward with making an “unofficial” offer, contingent upon successful background check. Get the candidate’s date of birth for the background check.	1 day
11. With a clear background check, HR will produce a New Hire confirmation	1 day
12. After receiving the New Hire confirmation e-mail, HR will move forward with closing out the recruitment process, draft the Offer Letter, set up New Hire Orientation, etc.	2 days

Step 3:

Training the research team

Now that you've hired, you need to do onboarding and training

Training the research team

- Initial training
 1. Foundational: Know the **regulatory** landscape
 2. Institutional: Required training for **all staff** and various **research positions**
 3. Research Team: **Big-picture** scientific and project specific training, plus **task-specific** training for delegated responsibilities
- Document all trainings!
- Plan for ongoing training

Training the research team

- Time requirement for onboarding
 - Varies if internal vs. external hire
 - If internal, less time
 - If external, up to 80 hours
 - Plan training carefully to stay within your budget

*HR onboarding resource

<http://www.washington.edu/admin/hr/pod/leaders/ee-careerdev/onboarding/index.html>



Training the research team

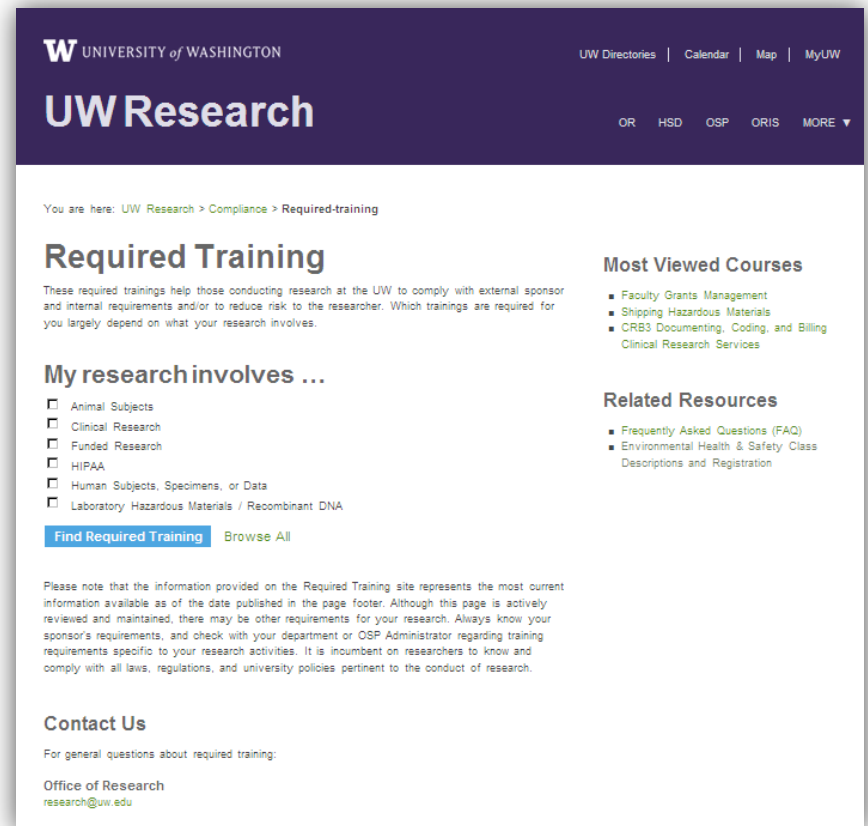
UW New Hire Onboarding

1. Human Resources Onboarding	Pre-orientation (external hire with home department HR); New employee training; Benefits orientation; Workplace Violence Prevention & Response Training; Sexual Harassment Prevention Training; General Asbestos Awareness
2. Home Department Payroll Orientation	Employee ID, UW NetID, I-9, W-4, Direct Deposit, submitting hours for payroll
3. Home Department IT System Support	Work station, access to servers, email
4. Campus Transportation	Buses, parking, shuttle system
5. Workstation Orientation	Badges, phones, keys, access cards
6. Home Department Orientation	Organizational chart, online staff directory, departmental SOPs
7. Study Team Orientation	Add biosketch, CV, license to research files; assign a “buddy”
8. UW Medicine IT Support	If employee needs access to EMR or Epic

Training the research team

UW Research Training

- Centralized Training:
<http://www.washington.edu/research/compliance/required-training/>
- **Funded Research** –
General and specific to
SoM, NSF, PHS
- **Laboratory**
- **Animal**
- **Human**



The screenshot shows the 'UW Research' website. The header is dark blue with the University of Washington logo and navigation links: 'UW Directories | Calendar | Map | MyUW'. Below the header, the 'UW Research' title is prominent, followed by a secondary navigation bar with links: 'OR | HSD | OSP | ORIS | MORE ▾'. The main content area has a breadcrumb trail: 'You are here: UW Research > Compliance > Required-training'. The section is titled 'Required Training' and includes a paragraph explaining that these trainings help researchers comply with external sponsor and internal requirements. Below this, a section titled 'My research involves ...' lists categories with checkboxes: 'Animal Subjects', 'Clinical Research', 'Funded Research', 'HIPAA', 'Human Subjects, Specimens, or Data', and 'Laboratory Hazardous Materials / Recombinant DNA'. There are two buttons: 'Find Required Training' (highlighted in blue) and 'Browse All'. To the right, under 'Most Viewed Courses', are links for 'Faculty Grants Management', 'Shipping Hazardous Materials', and 'CRB3 Documenting, Coding, and Billing Clinical Research Services'. Below that, 'Related Resources' includes 'Frequently Asked Questions (FAQ)' and 'Environmental Health & Safety Class Descriptions and Registration'. A disclaimer paragraph is present, followed by a 'Contact Us' section with the text 'For general questions about required training:' and the contact information 'Office of Research' and 'research@uw.edu'.

Training the research team

- **Laboratory Research**

<http://www.ehs.washington.edu/psotrain/corsdesc.shtm>

1. Biosafety Training
2. Biosecurity and Biosafety Training
3. Bloodborne Pathogens Training for Researchers
4. Laser Safety Training
5. Managing Laboratory Chemicals
6. Radiation Safety Training
7. Respiratory Protection and Mask Fitting
8. Shipping Hazardous Materials

Training the research team

■ Animal Research

- Animal Use Training Program (online and in-person training requirements)

<https://depts.washington.edu/auts/requirements.html>

- Many of the laboratory trainings also apply



Training the research team

■ Human Subjects Research

- Protection of Human Subjects – CITI General, NIH, DoN
- HIPAA
- Many of the Laboratory Trainings apply
- Clinical Research Budget Billing (CRBB)
- Coding for clinical research
- Epic training
- Electronic Medical Records access
- Institution-specific credentialing UWMC - <http://www.uwmedicine.org/patient-care/locations/uwmc/about/pages/credentialing.aspx>
 - Seattle Childrens – contact Home Department HR
- Mentorship on working with IRB, Radiation Safety Committee, Radioactive Drug Research Committee
- CPR



UW Medicine
COMPLIANCE



Training the research team

■ Project Specific Training

1. Big picture for all projects
2. Role-based training
 - How to interact with other types of members of team
3. Task-based training
 - Assess competency
 - Document in employee file
- Give feedback at 90-day review



Training the research team

■ Ongoing Training

- Grow your team members
- Budget for ongoing training
- Add team to existing training list-serves
- Find out what additional training is necessary at 1:1 meetings and annual reviews



Step 4:

Delegating tasks

Quick Case Study:

In a comparison study of probiotics versus dietary changes to treat metabolic syndrome, the Principal Investigator hired a dietitian to conduct most of the study procedures, including:

- recruiting participants
- conducting the informed consent process
- preparing meals for the dietary change arm
- dispensing tablets for the probiotics arm
- administering food diaries
- surveying participants about adverse events

Which of the responsibilities listed above should not have been delegated to the dietitian? Why?

Delegating tasks

- Ensure that tasks are delegated to those who are qualified by...
 - Education
 - Training
 - Experience
- Assess competency



Delegating tasks

Document delegated tasks

- Give the team member a written description
- Maintain a list of those to whom tasks are delegated
 - Describe the delegated tasks
 - Identify the dates of involvement in the study
- Keep records of qualifying training

 **ITHS**
Institute of Translational Health Sciences

ITHS Research Resources
Signature List & Delegation of Responsibility Log

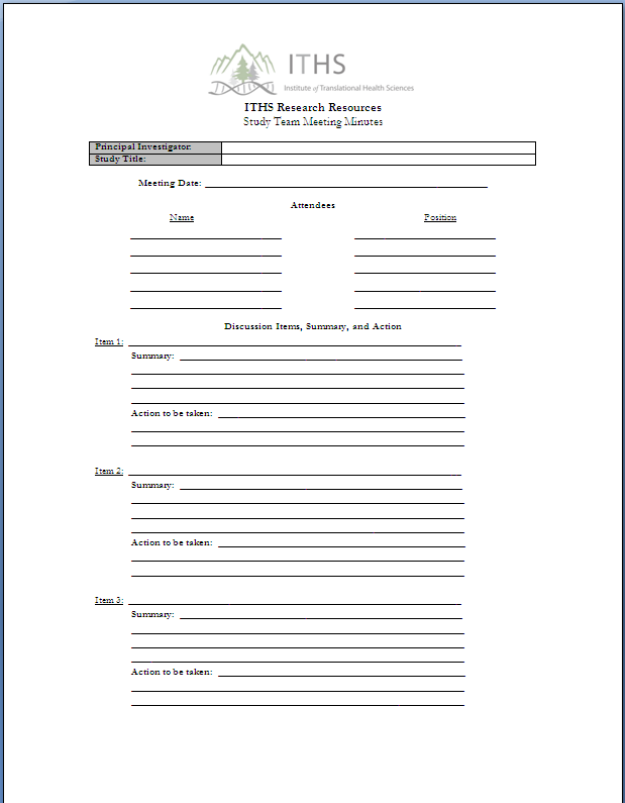
Principal Investigator:							
Study Title:							
Note: Update this log in a timely manner as new personnel are added and/or study roles change.							
#	Staff Member Name	Staff Member Title ("co-investigator," "research coordinator," "data manager," etc.)	Staff Member Signature	Initials	Delegated Study Tasks (See key below)	Start Date	End Date
1							
2							
3							
4							
5							
6							
7							
8							
9							
PI Signature: _____							
Delegated Study Task Key - Add or delete tasks as necessary to fit your study							
1. Obtain consent	5. Dispense study drug/device	9. Submit and maintain IRB docs	13. Randomization	17. Staff education			
2. Obtain medical history	6. Complete CRFs	10. Data monitoring	14. Blood draw	18. Data analysis			
3. Perform physical exam	7. Handle CRF queries	11. Safety monitoring	15. Blood storage	19. Other			
4. Assess eligibility criteria	8. Maintain regulatory docs	12. Advertising	16. Questionnaires	20. Other			

Step 5: Supervising

Keeping an open line of communication

Supervising

- Develop and nurture an open line of communication
- Stick to regular meeting schedule and agenda
 - Review basic science and clinical issues
 - Update staff on any changes to the protocol or other procedures – give them the big picture
 - Individual reports on study progress
 - Adverse events
 - Deviations/violations



The form is titled "ITHS Research Resources Study Team Meeting Minutes". It includes a header with the ITHS logo and name. Below the header, there are fields for "Principal Investigator" and "Study Title". A "Meeting Date" field is also present. The "Attendees" section is a table with columns for "Name" and "Position". Below this, there are three sections for "Discussion Items, Summary, and Action", each labeled "Item 1", "Item 2", and "Item 3". Each item section has a "Summary" field and an "Action to be taken" field.

ITHS
Institute of Translational Health Sciences

ITHS Research Resources
Study Team Meeting Minutes

Principal Investigator: _____
Study Title: _____

Meeting Date: _____

Name	Position
_____	_____
_____	_____
_____	_____
_____	_____

Discussion Items, Summary, and Action

Item 1: _____
Summary: _____

Action to be taken: _____

Item 2: _____
Summary: _____

Action to be taken: _____

Item 3: _____
Summary: _____

Action to be taken: _____

Supervising

QA PROCESSES: SELF-AUDITING



Participant Records Checklist

Research Subject ID#	INFORMED CONSENT	
Was consent obtained prior to beginning any study procedures? (ICH GCP 3.2.12, 5.10.4.4; 21 CFR 312.60) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
SUBJECT SELECTION CRITERIA		
Did the subject meet the inclusion/exclusion criteria of the current approved protocol at time of enrollment? (ICH GCP 5.10.4.0) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
DOCUMENTATION AND VERIFICATION OF PROTOCOL COMPLIANCE		
Were all study intervention/procedures administered according to the IRB- and ITHS- approved protocol and consent in the timeline specified? (ICH GCP 3.2.13, 5.10.4.0; 21 CFR 312.60) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
If NO, did missed procedures have reasons documented? (ICH GCP 4.8.0, 5.10.4.m.1) ☐ N/A ☐ Yes ☐ No		
If considered violations, were they reported to the IRB? (ICH GCP 4.8.4, 5.10.4.0) ☐ N/A ☐ Yes ☐ No		
Was data required by the protocol reported accurately on the CRFs and consistent with the source documents? (ICH GCP 5.10.4.m.2; 21 CFR 312.62(b)) ☐ N/A ☐ Yes ☐ No	REVIEW NOTES: _____	
Were adverse events, concomitant medications, and intercurrent illnesses reported in accordance with the protocol? (ICH GCP 5.10.4.m.3; 21 CFR 312.62(b)) ☐ N/A ☐ Yes ☐ No	REVIEW NOTES: _____	
Was any research related activity (e.g., specimen or data collection, procedure or intervention, etc.) conducted for a research purpose that was not specified in the approved consent and protocol? (ICH GCP 4.8.2) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
Were all source documents and other study records accurate, complete, kept up-to-date, and maintained? (ICH GCP 5.10.4.k; 21 CFR 312.62(b)) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
Were there any data entry errors, omissions, or illegibility in the study documents? (ICH GCP 5.10.4.k) ☐ Yes ☐ No ☐ See notes	REVIEW NOTES: _____	
If YES, were appropriate corrections made? ☐ N/A ☐ Yes ☐ No		
If the participant withdrew, was this reported and explained in the participant's record? (ICH GCP 5.10.4.m.5) ☐ N/A ☐ Yes ☐ No	REVIEW NOTES: _____	

Participant Records Checklist Page 1 of 2

Quality Assurance Review Sheet for Informed Consent

Principal Investigator: _____				
Study Title / Number: _____				
Conducted by: _____			On: _____	
Name: _____			Date: _____	
Informed Consent QA Review Criteria	Yes	No	N/A	Comments
1. Did the patient sign and date the correct version of the IRB-approved consent form prior to eligibility and enrollment procedures being conducted? If NO: - Notify the PI and document the discovery in a note to file, placed in the research chart. ☐ ☐ ☐ - Obtain a signed consent form at the next available opportunity. ☐ ☐ ☐ - If not already reported to the IRB, report it within 10 working days.				
2. Did the member of the research team sign and date the patient's consent form? If NO: - Notify the PI and document the discovery in a note to file, placed in the research chart. ☐ ☐ ☐ - Obtain a signed consent form from both parties at the next available opportunity. - If not already reported to the IRB, report it within 10 working days.				
3. Do the dates of the patient's and investigator's signatures match? If NO: - If the reason is explained on the consent form, no action required. - If no reason is cited on the consent form, ascertain the reason for the discrepancy. ☐ ☐ ☐ - If the discrepancy cannot be explained, document the discovery in a note to file, placed in the research chart. - If not already reported to the IRB, report it within 10 working days.				
5. Is a copy of the HIPAA authorization in the research file? If NO: - Check the patient's medical record. If it cannot be located, document the discovery in a note to file, placed in the research chart. ☐ ☐ ☐ - Obtain a new HIPAA authorization at the next available opportunity. - If not already reported to the IRB, report it within 10 working days.				

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Supervising

Consider using Standard Operating Procedures or a Protocol-Specific User Manual

Version X, Effective Date: 1/1/2020	Version X, dated 1/1/2020 - Approved																
Documenting, Resolving, and Reporting Protocol Deviations and Violations Procedure PURPOSE: To describe the process of documenting, resolving, and reporting protocol deviations and violations. POLICY: According to federal regulations and ICH Good Clinical Practice guidelines, a research team should not implement any deviation from the IRB-approved research plan without documented approval from the sponsor and IRB, except where necessary to eliminate an immediate hazard to research participants. The research team should document and explain any deviation from the approved research plan. If the deviation is done to eliminate an immediate hazard to research participants, research team should document and explain the deviation to the sponsor, IRB, and, if applicable, regulatory authorities. DEFINITIONS: The University of Washington's Human Subjects Division provides the following applicable definitions: 1. A protocol violation is an event or incident that occurs off protocol, without the permission of the sponsor, which has a significant or potentially significant impact on subjects. Example: A follow-up letter to a subject participating in a study on illegal drug use is sent to the wrong address. The person who received the letter by mistake opens. The letter clearly identifies the subject by name and the content of the letter provides information that the subject is an illegal drug user. The subject's loss of confidentiality significantly impacts the subject in a negative way because the subject could then be reported to the police for illegal drug use. 2. A protocol deviation is an event or incident that occurs off protocol, with or without the permission of the sponsor, but has minor or no impact on subjects. Example: Follow-up study visit occurred 1 day out of the "window of time" described in the protocol, but was due to the subject's inability to travel long distance during inclement weather, but had minor or no impact on the safety of the subject. PROCEDURE: 1. Identification: If an event occurs outside of the IRB-approved research plan and meets one of the two above definitions, identify the event as a protocol deviation or violation. 2. Documentation: Record the event immediately in the participating clinician's and the regulatory files on the Protocol Deviation Log, including the following information: a. Date of event	b. Description of the event including involved participant's study ID, reasons/contributing factors for the event c. Description of resolution of the event including the date, action taken to minimize harm (drawn to the participant's), maintain data integrity, and prevent recurrence (i.e., changes to research procedures, consent forms, recruitment materials). d. Date reported to sponsor (if applicable) e. Date reported to IRB f. Action required by sponsor and/or IRB (state "none" if no action required) 3. Reporting: Notify the sponsor of the event (if necessary) within ten working days of learning of the event. Complete the IRB's Modification Form with accompanying Supplemental Form: Report of Other Problems (document K-324) and submit to the IRB within ten working days. a. NOTE: If complete resolution of the event takes more than ten working days from learning of the event, reporting can be done prior to resolution. If reporting the event without resolution, the first report is the initial report, and a follow-up report is submitted upon resolution. REFERENCES: • 45 CFR 46.103(c)(4)(ii) • 21 CFR 312.61 • ICH GCP 4.5.2-4.5.4 • University of Washington Facility Handbook, Volume 4, Part 2, Chapter 2, Section 5.5 • UW Human Subjects Division Form "Report of Other Problems," document K-324 • IRB Research Responder Protocol Deviation Log <table border="1"><tr><td>Author name:</td><td></td><td>Date:</td><td></td></tr><tr><td>Author signature:</td><td></td><td>Date:</td><td></td></tr><tr><td>Authorizing signature:</td><td></td><td>Date:</td><td></td></tr><tr><td colspan="4">Replace previous version dated:</td></tr></table>	Author name:		Date:		Author signature:		Date:		Authorizing signature:		Date:		Replace previous version dated:			
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Summary

Managing a Research Team

- Think through your **budget** and what you can realistically do yourself
- Make wise decisions about **who** you choose to support your projects
- **Document** training and assess **competency**
- Keep an open line of **communication**
- Give **feedback**

Questions?

