Research Administration Training Program

Johns Hopkins University

Cohort XII

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Section 1: Program Overview

The Research Administration Training Program (RAT P) is a training program developed by Johns Hopkins University for potential research administration professionals.

The research enterprise at Johns Hopkins is in constant need of qualified administrative staff with the specialized knowledge and skills required to help manage the financial aspects of sponsored research and ensure adherence with compliance requirements. The RAT program is designed to provide people with the experience and training necessary to begin a career in research administration. The trainee should have good communication and interpersonal skills, as well as a familiarity with finance, law, contract management, or accounting transactions. It is expected that after the successful completion of this program, the trainee will have the experience and qualifications needed to apply for any number of positions that involve sponsored research administration. Successful completion of the RAT program (minimum of 15 months) adds an additional one year of relevant experience for identified jobs.

This is a full-time, fifteen-month (with the option for additional rotations up to twenty-four months) program that allows qualified candidates to work in the various offices involved in research administration during five rotations that last anywhere from two to six months. Each trainee is assigned to one of the major divisions within the university (School of Medicine, Bloomberg School of Public Health, Krieger School of Arts & Sciences, the Whiting School of Engineering and the School of Nursing) and rotates within the functional areas of those schools.

1.1 Oversight: An Executive Committee made up of the senior leaders of the university who represent research administration, business officers, and department managers oversees this Program. Current committee members are:

- Alexandra M. Albinak, Associate Vice Provost, Research Administration
- Anne Albinak, Director of Research Administration Operations, WSE
- Jim Aumiller, Sr. Associate Dean of Strategic Initiatives & Exec. Director of SSEI, WSE & UA (Chair, Executive Committee)
- Allison Benner, Associate Dean of Finance and Administration, SON
- Kevin Fogarty, Sr. Director, Finance Operations, SOM
- Paul Gasior, Sr. Director, Sponsored Projects/Accounts Receivable, UA
- Kristyn Gavrilis-Oliphant, Sr. Internal Auditor, UA
- Mary Louise Healy, Assistant Dean, KSAS
- Cindy Holstein, Administrator, Department of Biology, KSAS
- Janus Kurzmann, Associate Director, Research Administration, SON
- Jonathan Thompson, Director of Talent Acquisition, UA
- Lisa Walborn, Administrator, Department of Molecular Microbiology and Immunology, BSPH
- Thomas Burns, Assistant Dean – MGM, Research Administration, SOM

1.2 Executive Committee – The executive committee oversees the mentors assigned to the trainees. They are also responsible for the following:

- Setting rotation changes
- Overseeing the review process
- Approving the curriculum
- Setting learning expectations
- Promoting the program
- Advising trainees on possible job placement tracks

1.3 Mentors – Mentors serve as liaisons between the executive committee and the trainees. They help trainees navigate through numerous administrative issues. Mentors also work with the supervisors to make certain that learning objectives are met. Mentor responsibilities include the following:

- Managing the rotation process
- Meeting with trainees to discuss program progress
- Initiating SAP security roles
- Completing E210 time records
- Managing trainees
- Evaluating trainees
- Managing the curriculum
- Assisting with job placement

There is one mentor for each trainee. It is suggested that mentors and mentees review the *Research Administration Training Program Mentor/Mentee Toolkits*.

1.4 Supervisors – For each rotation, a trainee is assigned to a specific supervisor who specializes in a certain area. The supervisor, along with the mentor, must ensure that the learning experience of the trainee meets program expectations. These expectations are reviewed by the supervisor and mentor before each rotation begins. Supervisors are responsible for the following:

- Overseeing the trainee's work
- Evaluating the trainee's work and relaying that info to the mentor
- Participating in the learning process

Section 2: Recruitment Process

The executive committee and JHU's HR recruiters work to promote the program at JHU job fairs, during college career days, in newspapers and on-line job postings, and through word of mouth.

- Interested individuals apply on-line (http://jobs.jhu.edu).
- Selected individuals are asked to come in for an interview. These individuals are selected based on their work experience as well as college experience. The selection committee tries

- to diversify the cohort by choosing a combination of individuals with Master/Bachelor degrees and those who want a career change.
- The number of finalists depends on the number of positions funded by each school.

2.1 Hiring Process – After trainees are selected, the schools are responsible for hiring their trainees and getting them set-up.

- Position offers are extended and acceptances announced. The executive committee assigns the trainees to a school.
- Welcome letters are sent to each trainee.
- Each trainee is paired with a mentor who is experienced in research administration and can monitor the trainee's progress throughout the rotation cycles.
- Either a position is created for the trainee or the trainee is hired into a vacant position based on the home school's HR process.
- SAP roles and security access is added to the position for the first rotation assignment.
- Trainees are provided with JHED IDs, email accounts, and workplace IDs specific to their work location.
- Parking may be provided, depending on the trainee's work location.
- Each school is responsible for processing their trainee's payroll.
- Each school is responsible for providing their trainee with a laptop.
- Each school is responsible for their trainee's SAP access.

2.2 Rotation Change – With each rotation, certain administrative changes need to be made. Each rotation is associated with unique learning expectations.

- During a rotation change, each school is responsible for making the necessary adjustments to their trainee's employment information.
- Schools must change the trainee's SAP roles and security access according to the new rotation assignment.
- The trainee's workplace ID card may need to be replaced, depending on the new work location.
- Parking may need to be changed, depending on the trainee's new work location.
- Objectives and goals are shared between the mentor, supervisor, and trainee.

Section 3: Program Expectations

It is expected that each trainee will complete all five rotations set forth by the committee. To be considered for permanent employment, a trainee is required to complete two rotations. Although this is rare, it is expected, if hired permanently before the end of 15 months, to complete a "mini-rotation" in the hiring department. This "mini-rotation" would consist of working in the hiring department at the trainee's current compensation while completing any unfinished classes and working with their rotational and

hiring supervisors and their mentor to arrange a way to finish an overview of the current rotation department. At the end of the fifteen months, the trainee would be hired into the intended position with the corresponding compensation. The entire rotation cycle includes:

- Divisional Research Administration – Handles the approval and submission of proposals.
- Academic Department – Works directly with primary investigators to manage the award.
- Sponsored Projects Shared Services – Handles post award activities.
- Internal Audits – Assists members of the organization in effective discharge of their responsibilities.
- Divisional Business Office – Provides general administration and financial operations of the respective division.
- Open/Extra Rotation – Chosen according to the trainee's preference. It may be any one of the first three rotations or, depending on the trainee's wishes, it may involve special training focusing on particular skills.
  (See attached RAT P timeline)

Introduction

- JHU policies and procedures
- All basic university training
- Campus Tours

3.1 Divisional Research Administration Expectations

- Office roles and responsibilities
- Proposal review and submission
- Subawards
- Contract negotiations
- Pre-awards
- Award notifications/modifications
- Non-funding agreements
- Export controls (RPA-Barker)
- Interdivisional (RPA-Alexander)
- Model agreements
  - Clinical trial agreement
  - Model research agreement
  - Model subcontract
  - Non-disclosure agreement – unilateral and bilateral
  - Research subaward agreement
  - Letter of intent – to enter into a consortium agreement
  - Sample Adobe application
- Outgoing subawards
  - Subaward training
  - Subaward processes

        - Sample subaward agreement
        - Subaward issues
    - Notice of awards
        - Notice of award process
        - NIH grant/contract number breakdown
        - Sample NIH notice of grants (NGS)
    - Changes to ORA workflow and processes
    - Compliance
        - Compliance basics
        - General counsel guidelines
        - Contracts prime

3.2 Department Expectations

- Proposal development
    - Program announcements/opportunities
    - Budget preparation
    - Subaward
    - Statement of work
    - Biosketches
    - Current and pending support
    - Facilities
- Proposal submission
    - RPA review
    - Coeus
    - Grants.gov
    - FastLane
- Pre-award
    - Revise budget
    - Just-in-time
    - Notice of award
    - SPSS notice of account number
- Grant management
    - Reading and interpreting the NGA
    - Cost sharing and program income
    - Budget set-up
    - Subaward set-up
    - Account reconciliation and projections
    - Faculty discretionary funds
    - Progress reports
    - Close-out/final reports
    - Effort reporting

- Transactions
  - Non payroll cost transfer
  - Shopping cart
  - Travel
  - Department budget creator
  - Payroll cost transfer (eform)
  - HR/ISRs; time entry
  - Effort review and certification
  - P-Card with reconciliation
  - BW reporting
  - DGA – ISIS process for those using ISIS

3.3 Sponsored Projects Shared Services Rotation (SPSS)

- General SPSS topics
  - Controller's Office setup and procedures
  - Navigation of SAP
  - Understanding SAP terms
  - Understanding master data terms
  - Understanding basic accounting terms
  - Understanding F&A terms
  - Navigation of Oculus
  - Navigation of BW
  - How to search ECC for information
- Grant setup
  - Grant validity date
  - Create a budget
  - Add a sponsored class to a grant
  - No cost extension
  - Create an internal order
  - Create a cost share internal order
  - Create a subaward internal order
  - Create a non-payroll cost transfer
  - Add additional year funding to a grant
  - Create a grant
- Invoicing/revenue
  - Understanding billing procedures
  - Understanding letter of credit
  - Understanding deficit cash balance report
  - Invoicing
  - Bill plans
- Reporting
  - Understanding FDP/SNAP
  - Navigation of NIH Commons website

        - Navigation of Payment Management Systems website
        - Understanding federal FSR terms
        - Create a federal report
        - Create a private report
    - Transfers
        - Create a FV50
        - Create a NPCT
        - Create an Eform

3.4 Internal Audit Expectations

- Office roles and responsibilities
- Understanding risks related to sponsored funding
    - Pre-award
        - Proposal process
        - Contracting
    - Post-award
        - Award set-up
        - Allowability of sponsored expenditures
        - Effort Reporting
        - Subawards
        - Cost transfers
        - Animal care and use
        - Human subjects
- Understand processes that impact sponsored accounts including:
    - Payroll processing
        - Internal service requests
        - eforms
    - Procurement
        - Procurement card
        - Shopping cart
        - Online payments
        - Petty cash
        - Independent contractor
        - Subrecipient setup
- How to plan and conduct a research-related audit
    - Risk assessment of sponsored-related processes
    - Utilizing data to assist in the risk assessment process
    - Development of audit testing strategies that test to ensure that internal controls are adequately functioning
    - Execute audit testwork around research-related internal controls
    - Document audit testwork
    - Draft internal audit reports related to research

Other

- Utilize business warehouse to analyze sponsored accounts and transactions
- Become familiar with sponsored dashboards

3.5 Divisional Business Office

- **Continuous audit requests**
- Monitoring
- Responses
- Dashboard monitoring
- Cost share
    - Requests
    - Approval process
    - Tracking process
- Contract fee billing
- Data & report requests
    - Coeus
    - SAP
- **SAP submissions and approvals**
    - ZSRs
    - Master data requests & approvals
    - Preaward accounts
    - Check requisitions
    - Journal transfers and funding
- **COEUS submissions and approvals**
    - New users
    - New units
- **Compliance monitoring**
    - Effort Reporting
    - Deficit balances
    - Deliverables report
    - A/R Aging
    - Unallowable expenses
    - Administrative salary on grants
- Goods Receipt/Invoice Receipt Monitoring
- Control Salary
- Cost overrun monitoring and funding
- Annual budget process
    - Sponsored projections
- Monitoring non-sponsored deficits
- Capital projects
- Fixed Assets Inventory
- **Faculty**
    - Start-ups/discretionary

    - Dept salary accounts
    - Bloomberg Distinguished Professors
- **Service Center**
    - Establishment
    - Oversight
- ILabs
- Rate Schedules

Section 4: Training

While there is considerable training available through various Hopkins programs, the majority of training is accomplished on the job. This program provides hands-on experience along with formal course training in the three critical areas of research administration: pre-award, award management, and post award. The training curriculum is set by the executive committee. It consists of a combination of formal course offerings through Hopkins Learning and Development, topical sessions presented by Hopkins experts, and trainee participation in professional activities (see Curriculum section).

Section 5: Evaluation Process

The evaluation process is multi-faceted and includes all parties (the trainee, supervisor, mentor, and executive committee).

Trainee's 120-day probationary period – The first 120 days of employment is considered an introductory period for employment. The university requires an evaluation to be completed during this period. Mentors and supervisors complete this form and discuss it with their newly hired trainee(s).

Trainee's annual appraisal– This process is inherent to the trainee's assigned school. The mentor and supervisor for each trainee must complete their school's yearly annual appraisal form and discuss it with the trainee.

Trainee's program evaluation – By the end of each rotation, trainees are asked to evaluate their learning experience and offer suggestions for improvements.

Section 6: Program Monitoring

The chair of the executive committee meets regularly with the mentors, trainees, and their supervisors, and reports any findings or issues back to the executive committee. The executive committee also meets with the cohort, their supervisors, and mentors on a quarterly basis.

Section 7: Job Placement

Trainees are not guaranteed a position after their rotation cycles. However, it is the full expectation of the program that if the trainees successfully complete this training, many job opportunities will exist for them. It is both the mentors' and the executive committee's responsibility to meet with the trainees individually to discuss their goals and provide advice, discuss job opportunities, and collectively decide on a job placement track that will suit both the trainee and the institution. The trainee should be introduced to their home divisional HR representative during their third rotation. HR already works closely with current employees who are on grants that are expiring to assist with job placements. Trainees are required by JHU rules to stay in their present position for 12 months before being eligible for a self-initiated transfer and will not earn their additional year of service benefit if they do not stay in the program for 15 months. Any difficulties the trainees have with this process should be referred to the program coordinator, Dacia Jenkins (djenki35@jhu.edu).

Section 8: Program Curriculum

The curriculum detailed below separates the training into multiple components.

A. Basic University Required Training
B. Specific University Training
C. Intramural Training
D. Extramural Training
E. Other (Shadow Days, On-the-Job, Professional Skills Development)

8.1 Basic University Required Training

Basic online core e-courses are offered through Learning Solutions. These are pre-requisites to other training courses. They provide an introduction to JHU financial administration and serve as the first step to other functional areas.

- **University as a Business Organization** – This course explains the mission or purpose of the university, its organizational structure, how it operates as a business organization, and how the university fits into the overall "Johns Hopkins" family. It provides an overview of the administrative and financial structure of the university, basic financial administrative functions, and the various resources that are available.

Learning expectations:

- Differentiate between the types of business organizations.
- Describe the organizational structure of the university.
- Explain the relationship of the university to the other Hopkins entities.
- Outline the responsibilities of university administrative offices.
- Describe the basic financial administrative functions.
- Define the delegation of authority within levels of administration.
- Apply the policies on signature authority.
- State basic goals of internal control requirements and access university internal control guidelines.
- Seek and use the appropriate resources.

- **Basic Accounting Principles** – This course presents accounting principles that are applicable to the various types of business organizations. It identifies generally accepted accounting and financial reporting standards.

Learning expectations:

- Identify accounting and financial reporting standards and the standard setting bodies (e.g., GAAP, FASB, FAR, OMB).
- Explain the Financial Transaction Life Cycle and how it applies to JHU.
- Differentiate between assets and liabilities, and between revenue and expenses.
- Explain how equity/net assets relate to assets and liabilities.
- Build the accounting equation using assets, liabilities, and equity/net assets.
- Identify various classifications of expenses.
- Differentiate between non-sponsored and sponsored funds, and between direct and indirect costs.
- Locate and utilize JHU resources for additional information.

Federal Cost Principles – Many federal policies and guidelines must be followed to ensure proper grant management. They also ensure that research money is spent in a manner that complies with applicable laws and regulations. This course provides an overview of guidelines that affect the way sponsored projects are managed at JHU.

Learning expectations:

- Recognize the goal of compliance.
- Identify the criteria that allow an expense to be charged to a sponsored cost object.

Finance Overview including Chart of Accounts – Johns Hopkins uses a single system to manage all financial and administrative functions. This system is referred to as the "HopkinsOne SAP Business Suite," "HopkinsOne SAP," or just "SAP." This course takes a closer look at the organization and structure of this financial system.

Learning expectations:

- Describe the finance modules that exist within SAP.
- Describe the similarities and differences that exist among these modules.

Business Transactions – This course identifies the purpose of the university's financial reports, the types of reports generated, and how the financial transactions performed each day impact the university's financial reporting system.

Learning expectations:

- Explain how business transactions are recorded using debits and credits (double-entry accounting).
- Map financial transactions using the "T" account.
- Describe how the university "closes the books."
- Identify types of internal and external financial reports prepared by the university.
- Apply your knowledge of assets, liabilities, revenue, and expense to the university's Annual report.
- Explain the purpose of budgeting at the university.
- Explain the university's tax exemptions.
- Describe the types of audits at JHU.

SAP ECC Navigation – This program is designed to teach trainees how to navigate within the SAP WinGUI environment.

Learning expectations:

- Navigate within the WinGUI environment.
- Use the menu buttons and toolbars.
- Access transactions.
- Enter data on the transaction screens.
- Generate and manipulate reports.

8.2 Specific University Training

This training concentrates on a particular segment in the life cycle of an award (the proposal phase, award phase, managing phase, and close out phase). Learning Solutions course offerings are available as e-courses, FastFacts presentations, instructor-led sessions, and job aids. These courses may be taken by trainees during any of the rotations. For a full list of required trainings, refer to the RAT P FastTrack Curricula. Topics include:

- **Sponsored Projects**
- **Account Management**
- **HR/Payroll Administration**
- **Purchasing**
- **Accounts Payable**

8.3 Intramural Training

Additional training that compliments the basic training courses is also available. These overview sessions focus on research-related areas within the university. Meetings are prearranged during the first three rotation periods. Tentative 2021-2022 dates are below.

Seminar	*Date*	*Start Time*	*End Time*
Internal Audits	Wednesday, December 8, 2021	9:00 AM	10:30 AM
Effort Reporting/Facilities and Administration	Wednesday, January 12, 2022	9:00 AM	11:30 AM
Export Controls	Wednesday, February 9, 2022	9:00 AM	10:30 AM
Global Compliance	Wednesday, March 9, 2022	9:00 AM	10:00 AM
Hazardous Materials	Wednesday, April 13, 2022	9:00 AM	10:00 AM
Human Subjects (IRB)	Wednesday, May 11, 2022	9:00 AM	10:00 AM
Animal Facilities	Wednesday, June 8 , 2022	9:00 AM	10:30 AM
Clinical Research Training	Wednesday, July 13, 2022	9:00 AM	11:00 AM
Conflict of Interest	Wednesday, August 10, 2022	9:00 AM	10:00 AM
Funding from Corporations and Foundations	Wednesday, September 14, 2022	9:00 AM	10:00 AM
Agreements/Subagreements	Wednesday, October 12, 2022	9:00 AM	11:00 AM
Tech Transfer	Wednesday, November 9, 2022	9:00 AM	10:00 AM

Section 9: Seminars During First Rotation

9.1 Internal Audits

Description: This presentation provides a basic introduction to the Office of Hopkins Internal Audit (OHIA). Participants will learn OHIA's structure and role within the organization. Further, the audit process will be discussed including the development of the internal audit plan, how audits are conducted, and follow-up activities on outstanding audit issues. Other topics will include fraud related activities, continuous auditing, and training and education. Finally, participants will learn about the highest risk areas of the institution and audit findings commonly noted in reports.

Learning expectations:

- Identify a contact person who can provide additional information.

- Explain and discuss the topics covered in this presentation.
- Describe the role of Internal Audits and its place in research administration.
- Describe various compliance issues and how they relate to research administration.
- Describe audit plans and how they are implemented.

9.2 Effort Reporting

Description: This presentation will help participants to understand the importance of effort reporting when receiving sponsored funding. Federal and state agencies, private foundations, organizations, and industry sponsors provide significant funding to enable Johns Hopkins University to conduct research, public service, and training projects. The university's effort reporting system provides the principal means for certifying that the salaries and wages charged to, or contributed to, sponsored projects are reasonable and consistent with the portion of total professional activity committed to projects. Uniform Guidance, 2CFR part 200.319 provides guidelines for acceptable methods of documenting after-the-fact confirmation of effort provided.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the section of OMB A-21 related to effort reporting.
- Discuss the importance of effort reporting and describe how it relates to the audit of sponsored agreements.
- Describe the effort reporting process that is followed at JHU.

9.3 Facilities & Administration

Description: In this presentation, participants will learn about the F&A rate, how it is calculated, and what it represents. As part of this discussion, participants will learn about the university's DS-2 statement and its importance, as well as the various cost pools that make up the F&A rate.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe OMB A-21 and its place in research administration.
- Describe the cost pools involved in the F&A rate agreement.
- Describe the F&A rate and how it relates to covering the costs associated with sponsored agreements.
- Describe the DS-2 and how the disclosure statement impacts financial decision making.

Section 10: Seminars During Second Rotation

10.1 Export Controls

Description: This presentation covers laws, regulations, and policies that dictate how we may do business with other countries and/or their citizens. "Export control" regulations, such as the State Department's International Traffic in Arm Regulations, or the Commerce Department's Export Administration Regulations, require that we restrict access to certain tangible goods and information, which are thought to significantly contribute to national security and economic competitiveness. The Treasury Department's economic sanctions regulations require that we cut off certain foreign persons' access to finances and other resources, in order to motivate them to behave in ways that align with U.S. foreign policy and other interests. And finally, a variety of new laws/regulations/policies require that we thoroughly disclose the connections that foreign countries have to our research, in order to avoid "foreign influence" of a kind that results in the transfer of U.S.-based expertise, technology, and intellectual property to other countries in ways that undermine U.S. national security and economic competitiveness.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the Export Control office and its function.
- Explain why the Export Control office should be notified about certain sponsored agreements.
- Describe the various federal regulations related to export controls.

10.2 Global Compliance

Description: Participants will learn about global compliance. They will explore several topics that should be addressed before Johns Hopkins University faculty and staff begin any research or other sponsored and non-sponsored activities in foreign countries. There are many complexities involved in managing international activities and programs, including being compliant with U.S. and foreign laws and regulations. For example, JHU may need to formally register its presence in the foreign country (i.e., seek the permission of the host country) before opening bank accounts, signing leases, hiring employees, or signing contracts. Hiring and paying host country or third country nationals and U.S. expats also typically require special registrations, tax identification numbers, work permits, and compliance with both U.S. and host country labor and tax laws. Supplies and services in support of our activities may need to be purchased from local vendors, requiring the use of JHU purchasing and contracting terms and practices. Furthermore, working with foreign sub-recipients may require additional monitoring efforts from Baltimore. These and other considerations are discussed, as well as the role of the Office of International Business Compliance in ensuring that all of JHU's international programs remain in compliance with the myriad of laws and practices. For more

information, please go to the Office of International Business Compliance website at http://finance.jhu.edu/depts/ibc/index.html.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the payroll procedures that need to be followed when employees and nonemployees are involved in international activities.

10.3 Hazardous Materials

Description: Working in a laboratory is inherently dangerous because of the many chemical, biological, physical, and radioactive hazards. For this reason, laboratories are highly regulated work environments. Safety is directly dependent on understanding the safety measures required by regulations applicable to the participant's field of study.

1. This presentation is designed to provide participants with an overview of the following:
2. The Occupational Safety and Health regulations for worker protection
3. The Environmental Protection Agency regulations for managing hazardous materials from generation to disposal
4. The Maryland Department of the Environment, Radiological Health Program regulations for managing the use of radioactive materials and equipment
5. The Center for Disease Control and National Institutes of Health regulations applicable to the use and control of biological hazards
6. The US Department of Transportation regulations for the shipment of hazardous materials
7. The Johns Hopkins Health, Safety & Environment Division programs and policies to ensure regulatory compliance and maintain a safe work environment for faculty, staff, and students

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the regulations and governing bodies that oversee the use of hazardous materials on sponsored awards.
- Describe the procedures that staff and researchers should follow to comply with these regulations.

10.4 Animal Facilities

Description: Research Animal Resources (RAR) is Johns Hopkins' central support service for animal procurement, housing, clinical care and veterinary research support and collaboration. This

presentation will provide an overview of RAR, how we collaborate with investigators, and the importance of animals in research.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the federal regulations involved in animal research.
- Describe the policies and procedures that should be followed as part of animal research.

10.5 Human Subjects – Internal Review Board (IRB)

Description: This presentation will provide an overview of the Institutional Review Boards (IRBs), the types and number of human subjects research applications under SOM IRB review, federal regulations and institutional policies, IRB staff, and related offices/committees. Participants will gain an overall understanding of human subjects research within the SOM and the complexities of this work.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Discuss the federal regulations involved in Human Subject research.
- Discuss the policies and procedures that should be followed as part of Human Subject Research.
- Describe the different IRB offices and the makeup of the committees.
- Describe how the office interacts with COI and Research Admin process.

Section 11: Seminars During Rotations Three - Five

11.1 Clinical Research Training

Description: Clinical Research is defined as**:** *"All research that involves patients or Protected Health Information, or clinical testing or procedures, or drug/device diagnostic testing in humans or any planning/lab/clinical service in support of such clinical research."*

This orientation reviews the institutional compliance responsibilities for clinical research and the organization, and the processes and procedures used to meet those responsibilities. It includes a discussion of non-disclosure agreements, privacy and authorization for research, coordination with institutional review boards and informed consent, Medicare coverage/prospective reimbursement analyses and clinical research budgeting, contracting, the Clinical Research Management System, patient subject insurance clearance, and registration and research subject billing.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.

11.2 Conflict of Interest

Description: This presentation covers the conceptual, regulatory, and institutional aspects of financial conflicts of interest and their impact on objectivity in research, the safety of research, and perceptions of research objectivity and integrity. It addresses the historical background to this issue, including the development of close and frequent interactions between academia and industry, and the benefits and risks of these relationships. Trainees are expected to acquire a general understanding of the conceptual basis for addressing financial conflicts of interest in research. They will also gain a basic knowledge of federal regulations on conflict of interest and a general understanding of the Johns Hopkins policies and procedures for addressing financial conflicts of interest with research and in particular with sponsored projects.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe what is meant by the term Conflict of Interest and how it relates to Research Administration.

11.3 Agreements/Subagreements

Description: This presentation will provide a brief overview of contracting principles, as well as explain the meaning of common terms and clauses in both federal and private contracts as they affect the post award and departmental offices. Emphasis will be placed on assessing the importance of particular terms for a specific contract, including determining the type of contract, understanding the requirements for subcontracting, interpreting the payment terms, and managing equipment purchases, leases and maintenance. Trainees will gain an understanding of common contract terms and concepts pertaining to sponsored agreements; will better understand the importance of particular terms for specific research projects and will know the possible impact a contract may have on the university.

Learning expectations:

- Gain an understanding of common contract terms and concepts pertaining to sponsored agreements.
- Better understand the importance of particular terms for specific research projects.

- Know the possible impact a contract may have on the university.

11.4 Funding from Corporations and Foundations

Description: The Office of Foundation Relations maximizes foundation funding support to advance JHU's groundbreaking research, teaching, and outreach activities by ensuring that each University contact with a foundation is strategic and optimized. The purpose of the Corporate Relations program is to maximize corporate philanthropic support to JHU through strategic partnerships with major corporations. Foundations are tax-exempt organizations, while corporations are for-profit entities; both make awards to Johns Hopkins that include gifts, grants, and contracts.

Foundation Relations (FR) topics to be discussed include: the focus of the Foundation Relations office; how we work with faculty, major gift officers, and Research Administration staff in all of the Hopkins divisions; and key issues of mutual interest to FR and Research Administration (such as the distinction between gifts and grants, and when to involve FR in contacting foundations). Corporate Relations topics to be discussed will include: the elements of a successful corporate partnership; the focus of the JHU corporate relations program; the role of the Director of Corporate Partnerships in facilitating relationships between companies and faculty; and the importance of research administrators in all phases of these relationships.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.

11.5 Tech Transfer

Description: Our Technology Ventures Office (JHTV) manages the university's intellectual property. Each time an invention occurs in a Hopkins research laboratory, that invention is reported to our Technology Transfer Office. It is then recorded in the JHTV information system and the staff works with the inventor to understand the nature and potential of this invention. The staff then performs market and patent landscape analyses in order to develop both marketing and patenting strategies. Patents are filed and managed, first in the United States and then possibly in foreign countries. The JHTV office manages these patents throughout their prosecution and lifetime. Through the JHTV marketing efforts, the office seeks to license the inventions. Sometimes, the inventor is interested in starting a company around the technology and JHTV will help to link the inventor to business resources and to facilitate the location of funding sources. The office tracks all patent and licensing expenses for each technology case, as well as income received from licenses. Distributions of income are made to inventors, research laboratories, departments, schools, and university administration in accordance with the JHU Intellectual Property policy. The office does reporting to the sponsors of the research from which the inventions were made, to our university

administration, and to department leaders across the university. Finally, our staff works with faculty in many ways, including advising them on possible invention disclosures, providing them with relevant market and patent information, brainstorming with them on marketing strategies, providing information needed for sponsor and other reporting, and processing material transfer agreements that allow researchers to obtain materials from other institutions.

When participants visit JHTV, we introduce them to the overall role of Technology Ventures and then teach them about all of the processes described above. Technology Ventures interfaces with the other research administration functions in many ways and we help the participants to understand these relationships. It is our intention that the participants will leave the JHTV session with a general understanding of our role and function and will appreciate the business decisions that we make on behalf of our university and its faculty.

Learning expectations:

- Identify a contact person who can provide additional information.
- Explain and discuss the topics covered in this presentation.
- Describe the federal regulations that government intellectual property within sponsored agreements.
- Describe material transfers and indicate how that process works in conjunction with sponsored agreements.

11.6 Extramural Training

Trainees can learn by participating in professional activities external to the university.

National Council of University Research Administrators (NCURA) – Trainees become members, attend the annual conference, and participate in the conference workshops and sessions. The annual meeting is held in Washington, DC during the late summer of each year.

NCURA Webinars – Many webinars are hosted by JHURA and/or recorded webinars can be viewed in MyLearning.

11.7 Other Training

Shadow Days – Shadow days usually occur during the first rotation. Trainees arrange to spend a day at each of their colleague's sites and experience life in different settings.

On-the-Job Training – During each rotation, a trainee is assigned to a specific supervisor who specializes in a certain area. The supervisor, along with the mentor, must ensure that the trainee's learning experience meets program expectations.

Professional Skills Development – The Talent Management and Organization Development department offers additional Leadership, Management, and Professional Skills courses. Trainees are encouraged to take advantage of these staff development courses. The course catalog can be accessed through learning.jhu.edu.

The following are professional development course suggestions:

Living Well with Stress: Create Calm and Change Your Outlook (Virtual)

Emotional Intelligence (Virtual)

Diversity in the Workplace for Staff (Virtual)

Sparking Innovation and Creativity (Virtual)

Communicating with Tact and Professionalism (Virtual)

Mastering Your Memory

Giving and Receiving Feedback for JHU Staff

Achievement NOW - Elevate Your Success!

Unconscious Bias Training (Virtual)

Managing Multiple Priorities: The Discipline of Getting Things Done (Virtual)

Section 12: Acknowledgement

I _____ have read the RATP Program Guide which outlines the goals and expectations of the program, and my responsibilities as a cohort member.

I have familiarized myself, at least generally with the contents of this guide. By my signature below, I acknowledge, understand, accept and agree to comply with this guide provided to me by the RAT P Program Administrator. I understand this guide is not intended to cover every situation which may arise but is simply a general guide to the goals, policies, practices and expectations of the program.

_____

Employee Signature

_____

Date