

JOB DESCRIPTION

TITLE: Administrative Secretary

POSITION INFORMATION: Assists in the proper functioning of an office by maintaining files, scheduling appointments, registering for education courses, acting as a receptionist, typing, preparing reports, conducting correspondence, collecting fees, distributing information, data entry, coordinating activities. Provides administrative support to the Director in the daily operations.

REPRESENTATIVE DUTIES:

1. **File Maintenance.** Maintains office research files that are of a confidential nature and subject to audit by regulatory agencies. Creates new files and labels. Performs routine filing and file retrieval.
2. **Appointment Scheduling.** Schedules various appointments for office personnel. Registers faculty and staff for education courses.
3. **Reception.** Receives incoming calls for office personnel. Records messages or responds to caller with routine information. Refers caller to appropriate personnel. Serves as a contact person for other employees or the outside public.
4. **Typing.** Types and proofreads letters. Performs simple data recording and may transcribe material. Assist with receipt and data-entry using Microsoft Access database.
5. **Report Preparation.** Verifies education requirements and prepares education reports. Prepares staff meeting minutes.
6. **Correspondence.** Generates monthly first & second reminder notices and quarterly batch letters. Performs routine follow-up correspondence. Receives responses and updates database.
7. **Collect Fees.** Assists the Director with the collection of IRB fees. Use PeopleSoft software for posting deposits.
8. **Information Distribution.** Distributes various forms of information to office personnel such as mail, or newsletters. Delivers completed packages and research materials. Delivers deposits.
9. **Activity Coordination.** Plans and coordinates the compilation of weekly board meeting materials. Assist with the coordination and preparation of education materials for education sessions.
10. **As Needed.** Performs related duties as assigned to successfully fulfill the function of the position.

REQUIREMENTS:

Education: High School Diploma or GED

Experience: 36 months secretarial experience.

Preferred: Experience in Microsoft Office and People Soft. Secretarial experience in a University setting. Attention to details, excellent communication and organizational skills are essential to this position.

KNOWLEDGE/ SKILLS/ ABILITIES/ AND OTHER CHARACTERISTICS:

1. Ability to type 50 wpm with 90% accuracy
2. Ability to spell 20 out of 25 words correctly
3. Ability to lift 10 to 15 pounds on a regular basis

JOB DESCRIPTION

TITLE: Administrative Secretary

POSITION INFORMATION: Provides assistance in the proper functioning of the Institutional Review Board by maintaining files, scheduling appointments, registering for education courses, acting as a receptionist, typing, preparing reports, conducting correspondence, creating vouchers for payment, creating invoices for sponsor fees, distributing information, data entry, coordinating activities. Provides administrative support to the Director and Assistant Director in the daily operations. Provides assistance to the Education Coordinator with education activities.

REPRESENTATIVE DUTIES:

1. **File Maintenance.** Maintains office research files that are of a confidential nature and subject to audit by regulatory agencies. Performs routine filing and file retrieval. Maintains IRB staff files, IRB Member files and service agreements, and assists with maintaining education files.
2. **Appointment Scheduling.** Schedules various appointments for office personnel. Registers faculty and staff for education courses.
3. **Reception.** Provides back-up assistance to the receptionist. Receives incoming calls for office personnel. Records messages or responds to caller with routine information. Refers caller to appropriate personnel. Serves as a contact person for other employees or the outside public.
4. **Typing.** Types and proofreads letters. Performs simple data recording and may transcribe material. Assist with receipt and data-entry using Microsoft Access database. Creates education certificates.
5. **Report Preparation.** Verifies education requirements and prepares education reports. Prepares weekly reports for Director.
6. **Correspondence.** Generates monthly and quarterly batch letters. Performs routine follow-up correspondence. Receives responses and updates database.
7. **Office Management.** Monitors and orders supplies for the office and for training events. Orders food and beverages for meetings and training events. Prepares service unit and motor pool requests. Receives invoices from vendors, creates vouchers for payment using PeopleSoft. Creates invoices and payment vouchers for community members. Collects IRB staff time sheets.
8. **Information Distribution.** Distributes various forms of information to office personnel such as mail, or newsletters.
9. **Activity Coordination.** Assist with the coordination and preparation of education materials for education sessions. Arranges video-conferencing with TV services for meetings and training events. Schedules meetings and conference calls. Creates and distributes invoices for IRB fees, monitors for payment, sends collection letters, maintains electronic and paper copies.
10. **As Needed.** Performs related duties as assigned to successfully fulfill the function of the position.

REQUIREMENTS:

Education: High School Diploma or GED

Experience: 36 months secretarial experience.

Preferred: Experience in Microsoft Office and People Soft. Secretarial experience in a University setting. Attention to details, excellent communication and organizational skills are essential to this position.

KNOWLEDGE/ SKILLS/ ABILITIES/ AND OTHER CHARACTERISTICS:

1. Ability to type 50 wpm with 90% accuracy
2. Ability to spell 20 out of 25 words correctly
3. Ability to lift 10 to 15 pounds on a regular basis

JOB DESCRIPTION

TITLE: Assistant Director, Office for Human Research Participant Protection (HRPP)

Position Information: Responsible for assisting the Director in the coordination and management of the OUHSC comprehensive program for the protection of human participants in research, including ensuring that the functions, operations and services of the Institutional Review Board (IRB) are in compliance with federal and state regulations governing human research. Responsible for Assisting the Director in the implementation and conduct of the Education and Quality Improvement programs for the protection of human participants in research.

REPRESENTATIVE DUTIES:

1. **HRPP/IRB Office Operations.** Assists the Director with management of the HRPP/IRB Office operations. Serves as a non-voting member of the IRB providing guidance and consistency to the IRB Chairs with the management of the IRB meetings. Assists the Director by attending IRB meetings and for ensuring that the meetings are conducted and meeting minutes are documented in compliance with federal regulations. Monitoring of items on meeting agenda that require follow up to assure that necessary actions are taken. Screens research applications to determine Investigator initiated projects and the need to submit to the FDA for IND/IDEs. Coordinates this activity with the Associate Vice President for Clinical Research. Assigns research applications to an appropriate IRB. Oversees the Applications for Continuing Review including notifying Investigators, receipt of applications, through completion of the review.
2. **Management and Supervision.** Supervises the work of six IRB Administrators by monitoring their progress and providing timely feedback in their performance. Provides assistance and training to the IRB Administrators. Advises the IRB Administrators on policies and IRB regulations in the processing of IRB submissions. Responsible for the oversight of the IRB Administrators in the development of the minutes for IRB meetings ensuring compliance with federal guidelines and IRB policy. Responsible for the oversight of the IRB Administrators in the development of correspondence to Principal Investigators regarding IRB decisions.
3. **IRB Liaison.** Acts as the primary IRB liaison with research coordinators and faculty, providing technical assistance and guidance on human research participant protection. Acts as a liaison between the IRB Chair, IRB members and Investigators. Acts as the liaison with the GCRC Advisory Committee (GAC).
4. **Technical Assistance.** Provides technical assistance and feedback to research coordinators and Principal Investigators engaged in research involving human participants. Coordinates with research coordinators and Principal Investigators regarding the ongoing IRB review required to assure compliance with federal regulations, state law, and university and IRB policies and procedures. Reviews IRB submissions for regulatory compliance and provides feedback to the Principal Investigators. Reviews all Emergency Use applications for appropriateness and coordinates review with the IRB Chair.
6. **Policies and Procedures.** Assists the Director with the development and implementation of IRB Policies and Procedures (SOPs) that comply with federal regulations, guidance documents, and state laws. Monitors IRB staff, IRB members, faculty and research staff for adherence with IRB SOPs. Maintains library resources of IRB rules, regulations, and guidance documents. Proposes revised IRB SOPs in responses to changes in federal regulations, guidance documents, and state laws.
7. **Education and Quality Improvement.** Assists the Director with the development of the comprehensive curriculum for training in human research participant protection, GCP, investigator responsibilities, IRB and regulatory reporting. Conducts IRB workshops and individual training for Investigators and staff. Attends education programs, remains current on federal and state legislation, and incorporates all relevant information into curriculum. Assists the Director with the management and conduct of the Quality Improvement Program for OUHSC Human Participants Research Protocols. Assists the Director in the conduct of Quality Improvement audits.
8. **As Needed.** Perform various duties as needed to successfully fulfill the function of the position.

REQUIREMENTS:

Supervision: Supervises IRB Administrators.

Supervision Received: Receives general supervision from the Director, Office for Human Research Participant Protection.

Experience: Requires at least 5 years experience in IRB or clinical research and/or patient care. Two years experience with MicroSoft Word, Outlook, Excel, and Access.

Other: Successful completion of the IRB Professionals Certification Exam Eligibility will be required after 2.5 years of service.

Preferred: R.N. with Bachelor's degree or higher, professional degree in a health care field, or Certified IRB Professional (CIP). Excellent oral and written communications skills. Ability to interact professionally with MDs and PhDs. Ability to interpret and apply complex federal and University policies and procedures. Ability to maintain professional standards under routine conditions of severe and nonnegotiable time constraints.

JOB DESCRIPTION

TITLE: Business Analyst

Position Information: Responsible for participating in the planning, design, development, training and support of the information systems utilized to support the core organizational functions and business processes of the OUHSC Institutional Review Board (OUHSC IRB). This includes gathering and analyzing data in support of business cases, proposed projects, and systems requirements; data analysis and report development; and functional and technical support, including research into systems issues, complete with causes and possible solutions.

Responsible for applying communication, analytical, and problem-solving skills to assist the OUHSC IRB in meeting assurance of compliance with all federal guidelines and requirements. Strong analytical and interpersonal skills are essential.

REPRESENTATIVE DUTIES:

1. Technical Assistance.

- Identify probable causes and possible solutions to system issues. Meet with Director, Assistant Director, systems owners, and end users to help define and document business and operations requirements and systems goals.
- Collaborate with the department core users, end users and Information Technology in the planning, design, development and deployment of new applications, and enhancements to existing IRB applications.
- Provide user support in use of the system. Prepare formal presentation of new system functions and reports.
- Assist the Director to provide analysis, design and development reports for the core users and end users of the system.
- Provide application documentation and training to users for all modified and new systems including associated policies and procedures.

2. **Quality Control.** Provide data quality control, including data analysis and clean-up, and data fixes. Coordinate and perform in-depth tests, including end-user reviews, for modified and new systems, and other post-implementation support.

3. **System Maintenance.** Perform IRB project management duties as functional team lead on development and implementation projects.

4. Education.

- Maintain knowledge on developments in technology, techniques of analysis and design, query, reporting and data management tools.
- Develop and maintain comprehensive knowledge of the department's information assets.
- Maintain knowledge on developments in technology, techniques of analysis and design, query, reporting and data management tools.

- Develop and maintain comprehensive knowledge and ensure compliance of the Information Technology policies and procedures for application development and production support.

5. As Needed. Performs various duties as needed to successfully fulfill the function of the position.

REQUIREMENTS

Supervision: None

Supervision Received: Receives general supervision from the Director, Office for Human Research Participant Protection.

Experience: Requires at least 5 years experience in systems analysis and operation systems.

Other: Requires at least 5 years experience with Access, Excel, MicroSoft Word, and Outlook.

JOB DESCRIPTION

TITLE: Director, Human Research Participant Protection

FUNCTIONS:

1. Coordinates and manages the OUHSC comprehensive program for the protection of human participants in research.
2. Manages the function, office operations, and services of the Institutional Review Board (IRB), ensuring compliance with federal and state regulations governing human participant research.
3. Develops, coordinates and conducts education on the protection of human participants in research.

REPRESENTATIVE DUTIES:

A. Development, implementation and management of IRB policies and procedures that comply with all federal and state laws and regulations.

Essential – 10%

1. Maintains library resources of IRB rules and regulations.
2. Revises and updates OUHSC IRB policies, procedures and guidelines in responses to changes in federal and state regulations.
3. Maintains and revises as needed the IRB rosters, and the OUHSC Federal Wide Assurance with the Office for Human Research Protection (OHRP).

B. Provides consultative services and guidance to faculty and research staff regarding protection of human participants in research.

Essential – 10%

1. Consults with faculty Principal Investigators on IRB applications, protocols, and informed consent documents, to assure compliance with federal, state and university policies, regulations, and guidelines.

C. Operations management and direction of the OUHSC IRB

Essential – 50%

1. Serves as ex-officio member of the IRB.
2. Coordinates all incoming IRB work, with appropriate delegation to IRB staff, Determines if new submissions meet guidelines for exempt or expedited review, forwards to Board Chair of Full Committee as needed, and delegates for appropriate staff action.
3. Reviews and edits letters to principal investigators communicating IRB decisions.
4. Liaison between the IRB Chair, committee members and investigators.

5. Monitoring of items on meeting agenda that require follow up (approvable pending, deferred, etc.) to assure that necessary actions are taken, delegating appropriately as necessary to IRB staff.

D. Interactions with Internal Committees, and with External Agencies and Organizations.

Essential – 10%

1. Serves as primary contact with the OHRP for the OUHSC Federal Wide Assurance (FWA). Works with faculty investigators, OUHSC administration, and OHRP representatives to assure University compliance with the FWA and other applicable regulations.
2. Coordinates IRB matters between the University and federal agencies (OHRP, FDA), Oklahoma Health Center Organizations (OUMC, VAMC, OMRF, DMEI), pharmaceutical or other sponsors of research, regional research coordinators (SWOG, POG, GOG), and other affiliated institutions.
3. Serves as a member of the GCRC Advisory Committee (GAC) and coordinates all IRB related matters between GAC and IRB.
4. Liaison between Institutional Biosafety Committee, Radiation Safety Committee, and the VA Research and Development Committee.

E. Develops comprehensive curriculum for training in human research participant protection, good clinical practice (GCP), investigator responsibilities, IRB, and regulatory reporting, offered regularly.

Essential – 20%

1. Provides instruction as part of above programs.
2. Record keeping of researcher and research staff training and certification
3. Attends education programs, remains current on federal and state legislation, and incorporates all relevant information into curriculum.
4. Liaison with Graduate College re: education requirements for federally funded research and other sponsored research.
5. Obtains CME, CEU accreditation for programs.

F. Performs other duties related to human research participant protection as assigned by the Director of Compliance.

SUPERVISION OF OTHERS:

Supervises the Assistant Director, Business Analyst, Education Coordinator, Quality Improvement Coordinator, 6.5 IRB Administrators, 1 administrative secretary, and 1 staff secretary.

SUPERVISION RECEIVED:

Receives general supervision from the Director of Compliance.

MINIMUM QUALIFICATIONS:

- A. Bachelor's Degree (equivalent experience) plus three years in University research administration, with experience directly related to human participant research required.
- B. Knowledge of the federal regulations for the protection of human participants.
- C. Excellent organizational and oral/written communication skills.
- D. Well developed supervisory and leadership skills.
- E. Ability to interact professionally with MDs and PHDs.
- F. Ability to interpret and apply University policies and procedures.
- G. Ability to maintain professional standards under routine conditions of demanding time constraints.

JOB DESCRIPTION

TITLE: Director, Human Research Participant Protection

FUNCTIONS:

1. Coordinates and manages the OU-Norman comprehensive program for the protection of human participants in research.
2. Manages the function, office operations, and services of the Institutional Review Board (IRB), ensuring compliance with federal and state regulations governing human participant research.
3. Develops, coordinates and conducts education on the protection of human participants in research.

REPRESENTATIVE DUTIES:

A. Development, implementation and management of IRB policies and procedures that comply with all federal and state laws and regulations.

Essential – 10%

1. Maintains library resources of IRB rules and regulations.
2. Revises and updates OU-Norman IRB policies, procedures and guidelines in responses to changes in federal and state regulations.
3. Maintains and revises as needed the IRB rosters, and the OU-Norman Federal Wide Assurance with the Office for Human Research Protection (OHRP).

B. Provides consultative services and guidance to faculty and research staff regarding protection of human subjects in research.

Essential – 10%

1. Consults with faculty Principal Investigators on IRB applications, protocols, and informed consent documents, to assure compliance with federal, state and university policies, regulations, and guidelines.

C. Operations management and direction of the OU-Norman IRB

Essential – 50%

1. Serves as ex-officio member of the IRB.
2. Coordinates all incoming IRB work, with appropriate delegation to IRB staff, Determines if new submissions meet guidelines for exempt or expedited review, forwards to Board Chair of Full Committee as needed, and delegates for appropriate staff action.
3. Reviews and edits letters to principal investigators communicating IRB decisions.
4. Liaison between the IRB Chair, committee members and investigators.

5. Monitoring of items on meeting agenda that require follow up (approvable pending, deferred, etc.) to assure that necessary actions are taken, delegating appropriately as necessary to IRB staff.

D. Interactions with Internal Committees, and with External Agencies and Organizations.

Essential – 10%

1. Serves as primary contact with the OHRP for the OU-Norman Federal Wide Assurance (FWA). Works with faculty investigators, OU-Norman administration, and OHRP representatives to assure University compliance with FWA and other applicable regulations.
2. Coordinates IRB matters between the University and federal agencies and other affiliated institutions.
3. Liaison between Institutional Biosafety Committee, Radiation Safety Committee, and the RSO.

E. Develops comprehensive curriculum for training in human research participant protection, GCP, investigator responsibilities, IRB, and regulatory reporting, offered regularly.

Essential – 20%

1. Provides instruction as part of above programs.
2. Record keeping of researcher and research staff training and certification
3. Attends education programs, remains current on federal and state legislation, and incorporates all relevant information into curriculum.
4. Liaise with Graduate College re: education requirements for federally funded research and other sponsored research.
5. Obtains CEU accreditation for programs.

F. Performs other duties related to human research participant protection as assigned by the Director of Compliance.

SUPERVISION OF OTHERS:

Supervises one IRB Coordinator and one student .

SUPERVISION RECEIVED:

Receives general supervision from the Director of Compliance.

MINIMUM QUALIFICATIONS:

- A. Bachelor's Degree (equivalent experience) plus three years in University research administration, with experience directly related to human subjects research required.
- B. Knowledge of the federal regulations for the protection of human subjects.
- C. Excellent organizational and oral/written communication skills.
- D. Well developed supervisory and leadership skills.
- E. Ability to interact professionally with MDs and PHDs.
- F. Ability to interpret and apply University policies and procedures.
- G. Ability to maintain professional standards under routine conditions of demanding time constraints.

JOB DESCRIPTION

TITLE: Education Coordinator, Office of Human Research Participant Protection

FUNCTIONS:

1. Responsible for assisting the Director in the development, coordination, and implementation of the OUHSC comprehensive education program for the protection of human participants in research, GCP, investigator responsibilities, IRB and regulatory reporting.
2. Responsible for assuring that all components of the education program are in strict compliance with federal and state regulations and Institutional policies governing human research.
3. Assists the Director in the development and maintenance of the education program library utilizing current resources and media available for training.
4. Assists the Director in determining that all yearly certification requirements have been met by all faculty and staff engaged in research involving human subjects.
5. Responsible for the development and implementation of educational materials (manual for faculty and staff, newsletters, web updates, announcements).

REPRESENTATIVE DUTIES

A. Assists the Director with the development of the comprehensive curriculum for training in human research participant protection, GCP, investigator responsibilities, IRB and regulatory reporting, offered regularly.

Essential – 60%

- 1) Develops comprehensive curriculum on issues related to the use of human subjects in research for: Investigators, Study Coordinators, IRB Members, IRB Administrative Staff, General Research Community including Oklahoma City, Norman and Tulsa Campuses and Affiliate Institutions
 - a) Provides instruction as part of above program.
 - b) Maintains record keeping of educational activities and certification.
 - c) Assures that educational certifications have been met prior to the initiation of research involving human subjects.
- 2) Attends education programs, remains current on federal and state legislation, and incorporates all relevant information into curriculum.
- 3) Obtains CME, CEU accreditation for programs.
- 4) Provides current information to IRB Members and IRB Administrative Staff regarding national and regional educational opportunities such as PRIMR, ARENA.

B. Assists the Director with the development of the Human Research Participant Protection educational materials.

Essential – 35%

- 1) Revises and updates OUHSC IRB policies and procedures in responses to changes in federal and state regulations.

- 2) Maintains library of IRB rules, regulations, current literature and resources.
 - 3) Develops and maintains faculty staff manual on human research participant protection.
 - 4) Develops quarterly newsletter, web updates and announcements.
- C. Performs other duties as assigned.
Essential – 5%

SUPERVISION RECEIVED:

Receives general supervision from the Director, Human Research Participant Protection.

MINIMUM QUALIFICATIONS:

- A. B.S. degree or higher preferred, or professional degree in education or a health care field such as Pharmacy or Nursing), with at least 2 years experience in clinical research, patient care, and/or research administration.
- B. Excellent oral and written communication skills.
- C. Excellent organizational skills
- D. Ability to interact professionally with MDs and PhDs.
- E. Ability to interpret and apply complex federal and University policies and procedures.
- F. Ability to maintain professional standards under routine conditions of severe and nonnegotiable time constraints.

JOB DESCRIPTION

TITLE: Institutional Review Board (IRB) Administrator

Position Information: Provides administrative support to the Institutional Review Board by assisting with submission and review coordination. Provides technical assistance to investigators involved in human subjects research. Provides recommendations for improving the IRB review process.

REPRESENTATIVE DUTIES:

1. **Submission Assistance.** Assists investigators with the application submission process. Interprets and advises investigators on applicable policies, procedures, guidelines, federal regulations, and other compliance related requirements. Answers various questions and may guide investigators through some processes.
2. **Application Screening:** Screens research study applications to determine completeness and accuracy. Determines if studies meet review criteria for “exempt”, “expedited”, or full board by reviewing the IRB application, protocol and consent forms, ensuring they receive appropriate review according to federal regulations. Screens revised applications and resubmissions, reviews changes, and if acceptable, forwards to IRB Chairperson for final approval.
3. **Administrative Assistance.** Establishes record of incoming mail into IRB database. Distributes exempt and expedited studies to IRB Chairperson for review. Coordinates with principal investigators for preparation of material for board meetings. Generates correspondence on behalf of Director, Assistant Director, and/or IRB Chairpersons. Stamps consent forms appropriately. Distributes correspondence to Investigators.
4. **Review Coordination.** Act as a liaison between the IRB, the IRB Chairperson, Investigators, Office of Research Administration (ORA), Radiation Safety Office and the Institutional Bio-safety Committee. Responsible for following up with investigators to ensure they are aware of time limits and deadlines. Coordinates and schedules monthly reviews and annual review reports with the IRB.
5. **Meeting Coordination.** Coordinates meetings for the Institutional Review Boards. Creates agenda, and ensures there is an appropriate composition of members to make quorum according to federal regulations. Ensures proper procedures are followed. Creates board letters with instructions for corrections based on deliberations at the meeting. Takes minutes, prepares written draft, and distributes to the IRB Chairperson as required.
6. **Process Improvement.** Makes recommendations for streamlining IRB review process such as the revision of applications and consent forms, investigator notification, prior categorization and assignment of application submitted for board review.
7. **As Needed.** Perform various duties as needed to successfully fulfill the function of the position.

REQUIREMENTS:

Education: Bachelor’s Degree in a Health Care field, or related field; will accept 48 months of equivalent experience in lieu of a Bachelor’s degree.

Experience: Twelve months experience in any combination of the following areas, IRB administration, grant and contract administration, clinical and/or laboratory research experience, communication or education fields.

Other: Successful completion of the IRB Professionals Certification Exam Eligibility will be required after 2.5 years of service.

Preferred: Two years IRB, research administration or clinical research experience. Certified IRB Professional (CIP).

JOB DESCRIPTION

I. TITLE: Research Programs Coordinator, Human Research Participant Protection

II. FUNCTIONS:

1. Responsible for assisting the Director in the development, implementation, and management of the OUHSC Quality Improvement Program for the protection of human participants in research.
2. Responsible for monitoring the informed consent process, conducting audits of clinical research protocols and IRB records for adherence to federal, state regulations, IRB and institutional guidelines governing human research.

III. REPRESENTATIVE DUTIES

A. Responsible for the development, implementation and management of the OUHSC Quality Improvement Program for the protection of human participants in research.
Essential – 5%

1. Responsible for maintaining up-to-date information regarding federal regulations, ethical considerations, and IRB policies related to the use of human participants in research.
2. Revises and updates IRB Quality Improvement policies and procedures in response to changes in federal and state regulations and IRB and institutional guidelines. Maintains audit forms, questionnaires and reporting forms, utilized during the audit process and implements revisions as necessary.
3. Attends education programs, remains current on federal and state legislation, and incorporates all relevant information into the program.

B. Assists the Director in the conduct of Quality Improvement audits of investigator sites.
Essential – 40%

1. Responsible for performing quality improvement initiatives and clinical study audits of IRB approved protocols. Responsible for conducting for cause audits of investigator sites on a case-by-case basis as determined by the Institutional Review Board (IRB) or IRB Chair, Vice Chair Committee.
2. Responsibilities include performing queries of the IRB database for random selection of protocols identified for quality improvement audits, generating written audit notification to investigators, scheduling audits; and communicating with research staff of all levels.
3. Responsibilities include reviewing IRB correspondence; reviewing research records, medical records for audit data; preparing audit reports and presenting audit findings at the IRB Chair, Vice Chair Meetings.

C. Responsible for monitoring the informed consent process as requested by the IRB Executive Committee or on randomly chosen protocols
Essential – 15%

1. Responsibilities include reviewing the designated research protocol, interviewing a member of the research team, observing the informed consent

discussion, interviewing the research participant, preparing a written report and presenting audit findings to the IRB Executive Committee.

D. Assists the Director in the conduct of Quality Improvement audits of the IRB records.

Essential – 30%

1. Performs queries of the IRB database for random selection of protocols identified for audits.
2. Conducts review of IRB protocol files and corresponding minutes and board member rosters.
3. Develops reports of audit results for submission to the Director.

D. Assists the Director in the maintenance of correspondence, records and audit results developed during audits.

Essential – 10%

1. Maintains reports, electronic records, and audit findings of audits conducted.
2. Maintains correspondence to investigator and investigator responses.

E. Performs other duties as assigned.

Essential – 5%

IV. SUPERVISION RECEIVED:

Receives general supervision from the Director, Human Research Participant Protection.

V. MINIMUM QUALIFICATIONS:

- A. R.N. with Bachelor's degree or higher preferred, or professional degree in a health care field (e.g. pharmacy), with at least 5 years experience in clinical research and/or patient care.
- B. Excellent organizational skills.
- C. Excellent oral and written communication skills.
- D. Ability to interact professionally with MDs and PhDs.
- E. Ability to interpret and apply complex federal and University policies and procedures.
- F. Ability to maintain professional standards under routine conditions of severe and nonnegotiable time constraints.

This position may evolve to include monitoring and auditing other areas that fall within the purview of the Office of Compliance.

JOB DESCRIPTION

TITLE: Student Assistant

Position Information: Responsible for providing assistance to the Human Research Participant Protection Program. This position requires reliability and excellent customer service and communication skills. Strong attention to detail and organizational skills. Excellent interpersonal skills and ability to work with all levels of professionals.

REPRESENTATIVE DUTIES

- 1. File Maintenance.** Assist with filing, file retrieval, and creation of new files.
- 2. Communication.** Assists the IRB office with routine copying, faxing and phone coverage. Provides information and assistance to researchers as needed. Assists the IRB office with contacting investigators as needed.
- 3. Package Preparation.** Prepares packages for the IRB meetings and delivers packages to IRB members.
- 4. As Needed.** Performs other duties as assigned.

REQUIREMENTS

Education: Must be currently enrolled at the University of Oklahoma, either OKC or Norman Campus, and have a valid driver's license.

Experience: Two years experience with MicroSoft Word, Outlook, Excel, and Access.

Preferred: Work experience in an office setting.