

Administrative Secretary
Job Performance Standards

Task	Standard
Maintains Institutional Review Board office research files and performs routine filing of daily IRB correspondence and associated attachment, creates new files and labels.	Promptly, accurately, and efficiently files documents in correct file folders. Promptly, accurately, and efficiently files file folders in the correct order and placement in the file room.
Assists the IRB Administrators with receipt and data-entry of research projects using Microsoft access database.	Performs accurate daily data-entry of research projects.
Assists the IRB Administrators with compilation of weekly Board meeting materials and delivers completed packages to Board members.	Conscientiously and efficiently prepares and delivers board meeting packages following established departmental deadlines.
Assists the IRB Education Coordinator with preparation of education materials for routine education session.	Conscientiously and efficiently prepares education materials accurately prepared and ready for the education session the day before the session.
Assists the Director with the collection of IRB fees utilizing People Soft Software, QuickBooks and Quicken.	Provides assistance with the collection of IRB fees according to University and department guidelines.
Generation of monthly reminder notices and quarterly batch letters. Perform routine follow-up correspondence on pending files following written OUHSC IRB policies and procedures.	Prints Continuing Review reminders letters and presents to Assistant Director. Prints quarterly batch letters, pulls the corresponding files and presents to the Director for signature.
Coverage of the reception desk and incoming calls for the IRB office and other duties as needed.	Records messages accurately, provides information and assists visitors and callers as needed.
Prepares service unit requests (SURs). Creates vouchers for payment.	Accurately prepares SURs and creates vouchers according to University and department guidelines.
Monitors and orders supplies, food, and beverages for events. Schedules meetings, meeting rooms, and conference calls. Arranges video-conferencing.	Conscientiously monitors and orders supplies as needed to maintain adequate materials for office operations. Accurately schedules and confirms meetings, meeting rooms, conference calls, and video-conferencing.

Business Analyst
Job Performance Standards

Task	Standard
Meet with Director, Assistant Director, Core Users, and end users to help define and document business and operations requirements and systems goals	Efficiently define and document business and operations requirements as well as systems goals utilizing appropriate tools
Work with the Director and Assistant Director to provide analysis, design and development for core users and end users system reports	Provide analysis, design, and development of system reports with design accuracy
Coordinate and perform in-depth tests, including core user reviews as well as end user reviews, for modified and new systems, and other post-implementation support	Coordinate actions with competency when proposing enhancements or modifications to modified, new or post implementation systems
Collaborate with IRB Staff, end users, and Information Technology in the planning, design, development, and deployment of new applications, and enhancements to existing IRB applications	Evaluate request for new requirements or enhancements and incorporate into application environment meeting design specifications in a timely fashion
Provide data quality control, including data analysis, clean up, and data fixes	Provide proficient data quality control and accurately analyze, clean up, and fix data
Research system issues, identifying probable causes and possible solutions	Promptly assess requests and identify probable cause and recommend well-organized and competent solutions
Perform IRB project management duties as functional team lead on development and implementation projects	Initiate and maintain effective communication to ensure that project development and implementation occur as requested

IRB EDUCATION COORDINATOR

Task	Standards
<p>Develops, coordinates, and implements the OUHSC comprehensive education program for the protection of human participants in research, GCP, investigator responsibilities, IRB, and regulatory reporting, under the direction of the HRPP Director.</p>	<ul style="list-style-type: none"> - Proficiently develops and modifies education/certification policies to maintain current standards. - Maintains current state laws and institutional policies on the CITI web-based training site's Institutional page. - Efficiently coordinates, schedules, implements, and conducts all education programs. - Cordially and effectively assists faculty and staff regarding submission process, informed consent design, and proper use of IRB & HIPAA forms.
<p>Assures that all components of the education program are in strict compliance with federal and state regulations and Institutional policies governing human research.</p>	<p>Consistently attends yearly relevant education programs and conferences to remain current on federal and state regulations, conducts web searches regarding latest guidance, accurately incorporates relevant information into curriculum</p>
<p>Develops and maintains the education program library utilizing current resources and media available for training, under the direction of the HRPP Director.</p>	<p>Develops and consistently maintains resource center of recent reference material on federal regulations, guidance documents, articles on pertinent topics, IRB guidebooks</p>
<p>Determines all yearly certification requirements have been met by faculty and staff engaged in research involving human participants.</p>	<ul style="list-style-type: none"> - Proficiently and accurately develops and maintains database to track certification status of OUHSC faculty & staff, IRB members, and IRB staff, consistently send out notifications regarding new course announcements, requirements, deadlines. - Accurately maintains individual Investigator files
<p>Develops and implements educational materials (manual for faculty and staff, newsletters, web updates, announcements).</p>	<p>Develops and promptly updates IRB webpage, distributes e-mail newsletter announcements</p>

HRPP Director
Job Performance Standards

Task/Objective	Standard
Development, implementation, and management of IRB policies and procedures that comply with all federal and state laws and regulations.	Conscientiously develops, implements, and manages OUHSC IRB policies, procedures, and guidelines in timely response to changes in federal and state regulations.
Management of Multiple Project Assurance/Federal Wide Assurance (MPA/FWA) with the Office of Human Research Protections. Management of IRB Rosters.	Maintains current and accurate MPA/FWA and IRB Rosters; promptly notifies Office of Human Research Protections (OHRP) of changes.
Provides consultative services and guidance to faculty and research staff regarding protection of human subjects in research.	Maintains proficient communication with faculty Principal Investigators on IRB applications, protocols, and informed consent documents, to assure compliance with federal, state and university policies, regulations, and guidelines.
Operations management and direction of the OUHSC IRB.	Expertly manages the daily functions and operations of the IRB office; expertly delegates tasks to appropriate IRB staff. Provides continuous and expert guidance and education to the IRB staff.
Interacts with Internal Committees and with External Agencies and Organizations.	Initiate and maintain prompt, conscientious communication with (OHRP), Food and Drug Administration (FDA), sponsors of research, research participants, and the University as needed. Initiate and maintain prompt, conscientious communication between the IRB and other internal committees.
Development and management of a comprehensive curriculum for education in human research participant protection, GCP, investigator responsibilities, IRB, and regulatory reporting, offered regularly.	Proficiently develop and manage a quality HRPP education program. Provides expert guidance and leadership to the Education Coordinator in coordinating the daily operations of the comprehensive HRPP education program.
Development, implementation, and management of a Quality Assurance Program.	Proficiently develop, implement, and manage a Quality Assurance program. Provides expert guidance and leadership to the Assistant Director and Quality Assurance Coordinator in coordinating the daily functions of the Quality Assurance Program.

HRPP Assistant Director
Job Performance Standards

Task/Objective	Standard
Assists the Director with the development, implementation and management of IRB policies and procedures that comply with all federal and state regulations.	Conscientiously assists the Director in the development, implementation and management of OUHSC IRB policies, procedures, and guidelines in timely response to changes in federal and state regulations. Maintains current and accurate records of IRB actions.
Provides assistance in the operations, management and direction of OUHSC IRB.	Proficiently manages the daily functions of the IRB office. Uses sound judgment in decision making and planning. Provides accurate and timely guidance to the IRB staff in the performance of their duties. Proficiently supervises the IRB Coordinators by monitoring their progress and providing timely feedback in their performance.
Assists the Director with the development and implementation of a comprehensive curriculum for training in human research participant protection, GCP, investigator responsibilities, IRB and regulatory reporting, offered regularly.	Conscientiously assists the Director with the development of the OUHSC HRPP education program. Produces accurate educational materials for use in the IRB workshops and seminars by extensively researching the guidance documents and regulations.
Assists the Director with the development and implementation of a Quality Assurance Program.	Proficiently conducts audits of research projects as needed. Pays close attention to detail and effectively coordinates with the research team. Provides accurate and thorough audit results and conclusions.
Provides Technical Assistance to nurse study coordinators and Principal Investigators engaged in Research Involving Human Subjects.	Expertly provides individual training and assistance to nurse study coordinators and Principal Investigators. Successfully handles difficult situations with ease.

IRB Administrator
Job Performance Standards

Task	Standard
Coordinates meetings for Institutional Review Boards	Efficiently coordinates IRB meetings in accordance with federal regulations and institutional guidelines.
Acts as a liaison between the Institutional Review Board, the Chair, Investigators and other offices.	Effectively communicates with other offices and committees to facilitate timely review and approval of research.
Responsible for following up with investigators on pending items.	Promptly and effectively communicates with Investigators on all pending items in accordance with departmental guidelines and timeframes.
Establishes record of incoming mail into the IRB database.	Promptly, accurately and efficiently performs data entry of all incoming documents and effectively communicates with investigative team for needed items.
Prepares letters and minutes.	Provides prompt and accurate written correspondence for distribution to investigators. Proficiently and accurately develops minutes in accordance with departmental guidelines and timeframes.
Review applications submitted to the Institutional Review Board.	Review submissions for accuracy and completeness according to department guidelines.

**Quality Improvement
Research Programs Coordinator
May 19, 2004**

Task	Standard
<p>Develops, coordinates, and implements the OUHSC comprehensive Quality Assurance Program for the protection of human participants in research under the direction of the HRPP Director.</p>	<p>Proficiently revises and updates IRB Quality Assurance policies and procedures related to human research protections.</p> <p>Effectively maintains audit forms, questionnaires and reporting forms utilized during the audit process.</p> <p>Consistently attends yearly relevant education programs and conferences to remain current on federal and state regulations.</p>
<p>Responsible for performing quality improvement initiatives and clinical study audits of IRB approved protocols.</p>	<p>Efficiently coordinates, schedules, implements, and conducts all quality assurance audits of investigator sites.</p> <p>Professionally and effectively communicates with investigative staff throughout the audit process.</p> <p>Accurately maintains records of such communications.</p> <p>Expertly reviews records for audit.</p> <p>Expertly and accurately develops audit reports and proficiently presents audit findings.</p>
<p>Responsible for developing reports for identification of selected protocols for audits.</p>	<p>Accurately performs queries of the database for selection of protocols for audits.</p>
<p>Assists the Director in the conduct of Quality Assurance audits of IRB Records.</p>	<p>Effectively and efficiently conducts internal review of IRB protocol files and corresponding minutes and board member rosters.</p>
<p>Assists the Director in the maintenance of correspondence, records, and audit results developed during the audits.</p>	<p>Proficiently and accurately develops and maintains reports, electronic records, and audit findings conducted.</p> <p>Accurately maintains individual audit files.</p> <p>Accurately maintains correspondence to investigator and investigator responses.</p>

Student Assistant
Job Performance Standards

Task	Standard
Maintains Institutional Review Board office research files and performs routine filing of daily IRB correspondence and associated attachment, creates new files and labels.	Promptly, accurately, and efficiently files documents in correct file folders. Promptly, accurately, and efficiently files file folders in the correct order and placement in the file cabinets.
Assists the IRB office with routine copying and faxing.	Promptly and accurately copies and faxes items as needed.
Assists the IRB Administrator with compilation of Board meeting materials and delivers completed packages to Board members.	Conscientiously and efficiently prepares and delivers board meeting packages following established departmental deadlines.
Coverage of the reception desk and incoming calls for the IRB office and other duties as needed.	Records messages accurately, provides information and assists visitors and callers as needed.