REQUIRED COMPETENCY AREAS, GOALS, AND OBJECTIVES FOR POSTGRADUATE YEAR TWO (PGY2) INVESTIGATIONAL DRUGS AND RESEARCH PHARMACY RESIDENCIES

Introduction

The PGY2 Investigational Drugs and Research pharmacy residency program offers the opportunity to develop clinical, analytical, teaching, and leadership skills required to support clinical trials research. The program encompasses the fields of clinical research, medication safety, leadership, regulatory compliance, and quality assurance and is designed to develop expert skills in pharmacists' provision of care for patients enrolled in clinical trials. Upon completion the resident will have expertise in clinical trial design and conduct, pharmacy operations and clinical services for the research enterprise, and investigational drug service pharmacy leadership within an interprofessional environment.

The Investigational Drugs and Reseach competency areas, goals, and objectives are to be used in conjunction with the *ASHP Accreditation Standard for Postgraduate Year Two (PGY2) Pharmacy Residency Programs.* The first five competency areas described herein are required to be included in all programs, and the others are elective. Programs may add one or more required additional competency areas from the elective competency area choices to meet program-specific needs. Programs selecting an additional competency area are not required to include all of the goals and objectives in that competency area. In addition to the potential additional competency areas described in this document, programs are free to create their own unique competency areas with associated goals and objectives based on the specific needs of their program. Each of the objectives associated with the goals encompassed by the program's selected program competency areas (required and additional) must be taught and evaluated at least once during the residency year. Elective competency area(s) may also be selected for specific residents when creating their residency development plan.

Each of the objectives listed in this document has been classified according to educational taxonomy (cognitive, affective, or psychomotor) and level of learning. An explanation of the taxonomies is available elsewhere.[1]

Competency areas for PGY1 residencies are available on the ASHP website. PGY2 competency areas, goals, and objectives in Investigational Drugs and Research pharmacy are differentiated from those from PGY1 by specialization and the expectation of PGY2 residents for greater work competence and proficiency.

Definitions

Competency Areas: Categories of the residency graduates' capabilities.

Competency areas are classified into one of three categories:

[1] Bloom, B., Englehart, M. Furst, E., Hill, W., & Krathwohl, D. (1956). *Taxonomy of educational objectives: The classification of educational goals. Handbook I: Cognitive domain*. New York, Toronto: Longmans, Green.

Required: Five competency areas are required (all programs must include them and all their associated goals and objectives).

Additional (for program): Competency area(s) that residency programs may choose to use (in addition to the five required areas) to meet program-specific program needs. Additional competency areas also include those developed by individual programs.

Elective (for specific residents): Competency area(s) or specific goals and objectives within the competency area(s) selected optionally for specific resident(s).

Educational Goals (Goal): Broad statement of abilities.

Educational Objectives: Observable, measurable statements describing what residents will be able to do as a result of participating in the residency program.

Criteria: Examples that describe competent performance of educational objectives. Since the criteria are examples, they are not all required but are intended to be used to give feedback to residents on how well they are doing and how they can improve on the skill described in educational objectives while they engage in an activity.

Activities: The Standard requires that learning activities be specified for each educational objective in learning experience descriptions. Activities are what residents will do to learn and practice the skills described in objectives. Activities are the answer to the question, "What can residents do in the context of this learning experience that will provide the kind of experiences necessary to achieve the educational objective?" (Compare and contrast activities with criteria by referring to the definition of criteria immediately above.) Specified activities should match the Bloom's Taxonomy learning level stated in parentheses before each objective.
Example:
Objective R1.1.2: (Applying) Interact effectively with patients, family members, and caregivers.
Learning activity: Provide education to patients regarding proper medication use and administration, adherence, and possible adverse drug effects for all new medications initiated during clinic appointments.
Criteria:

- Interactions are respectful and collaborative.
- Uses effective communication skills.
- Shows empathy.
- Empowers patients to take responsibility for their health.
- Demonstrates cultural competence.

Competency Area R1: Patient Care

Goal R1.1: In collaboration with the health care team, provide comprehensive medication management to research participants following a consistent patient care process.

Objective R1.1.1: (Applying) Interact effectively with research teams and clinical care teams to manage medication therapy for research participants.

Criteria:

- Demonstrates cooperative, collaborative, communicative, and respectful interactions.
- Demonstrates skills in consensus building, negotiation, and conflict management.
- Demonstrates advocacy for the patient.
- Contributes pharmacotherapy knowledge and patient care skills as an essential member of the healthcare team.

Objective R1.1.2: (Applying) Interact effectively with research participants, family members, and caregivers.

Criteria:

- Ensures adherence to the research protocol, including maintaining study blinds as appropriate.
- Interactions are respectful and collaborative.
- Maintains accuracy and confidentiality of patients' protected health information.
- Employs excellent (e.g., clear, concise, accurate, verbal and written) communication skills.
- Exhibits empathy.
- Empowers patients, family members, and caregivers regarding the patient's well-being and health outcomes.
- Demonstrates cultural competence.
- Communicates with family members to obtain patient information when patients are unable to provide the information.

Objective R1.1.3: (Analyzing) Collect information on which to base safe and effective medication therapy for research participants.

Criteria:

- Collects and organizes information in an efficient manner.
- Collects relevant information about the investigational product and standard of care medication therapy, including:
    - Researching documents, including previous clinical trial participation.
    - History of present illness.
    - Relevant health data that may include past medical history, health and wellness information, biometric test results, and physical assessment findings.
    - Social history.
    - Medication history; including prescription, non-prescription, illicit, recreational, and non-traditional therapies, other dietary supplements, immunizations, and allergies.
    - Patient assessment, including, but not limited to: physiologic monitoring, laboratory values, microbiology results, diagnostic imaging, procedural results, and scoring systems (e.g., RASS, CAM-ICU).
    - Pharmacogenomics and pharmacogenetic information, if available.
    - Adverse drug reactions.
    - Medication adherence and persistence.

    - Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care.
- Selects sources of information that are most reliably available, including electronic and face-to-face.
- Ensures recording system is functional for subsequent problem solving and decision making.
- Clarifies information as needed.
- Displays understanding of limitations of information in health records. Poses questions as needed.

Objective R1.1.4: (Analyzing) Analyze and assess information on which to base a participant's eligibilty for a clinical trial.
Criteria:
- Explains the study rationale, design, objectives, and endpoints.
- Adheres to the inclusion and exclusion criteria of the clinical trial protocol.
- Identifies lifestyles or other factors that may impact enrollment in the trial.
- Evaluates concomitant and prohibited medications as outlined in the clinical trial protocol.

Objective R1.1.5: (Analyzing) Analyze and assess information on which to base adherence to the research protocol for participants enrolled in a clinical trial.
Criteria:
- Identifies investigational product and standard of care medication therapy problems, including:
    - Adverse drug or device-related events or the potential for such events.
    - Clinically significant drug–drug, drug–disease, drug–nutrient, drug–DNA test interaction, drug–laboratory test interaction, or the potential for such interactions.
    - Use of harmful social, recreational, nonprescription, nontraditional, or other medication therapies.
    - Problems arising from the financial barriers that impact protocol compliance.
    - Participant lacks understanding of investigational product or standard of care medication therapy.
    - Participant not adhering to investigational product or standard of care medication regimen and root cause (e.g., knowledge, recall, motivation, financial, system).
    - Laboratory monitoring needed.
    - Discrepancy between prescribed investigational product, standard of care medications, and the established care plan for the patient.

Objective R1.1.6: (Creating) Design or redesign safe and effective patient-centered therapeutic regimens and monitoring plans (care plans) for research participants.
Criteria:
- Specifies evidence-based, measurable, achievable therapeutic goals that include consideration of:
    - Relevant patient-specific information, including culture and preferences.
    - The goals of other interprofessional team members.
    - The patient's disease state(s).
    - Medication-specific information.
    - Best evidence, including clinical guidelines and the most recent literature.
    - Interpretation of new literature for application to patient care.
    - Ethical issues involved in the patient's care.
    - Quality-of-life issues specific to the patient.
    - End of life issues, when needed.
    - Integration of all the above factors influencing the setting of goals.
- Designs/redesigns standard of care regimens that:

- Are appropriate for the disease states being treated and compliant with the research protocol.
- Reflect:
  - Clinical experience.
  - The therapeutic goals established for the patient.
  - The patient's and caregiver's specific needs.
  - Consideration of:
    - Any pertinent pharmacogenomic or pharmacogenetic factors.
    - Best medical evidence.
    - Pertinent ethical issues.
    - Pharmacoeconomic components (patient, medical, and systems resources).
    - Patient preferences, culture, and/or language differences.
    - Patient-specific factors, including physical, mental, emotional, and financial factors that might impact adherence to the regimen.
- Adhere to the health system's medication-use policies.
- Follow applicable ethical standards.
- Address wellness promotion and lifestyle modification.
- Support the organization's formulary or the formulary of the participant healthcare coverage.
- Address medication-related problems and optimize medication therapy.
- Engage the patient through education, empowerment, and promotion of self-management.

- Designs/redesigns monitoring plans that:
  - Comply with the research protocol.
  - Evaluate achievement of therapeutic goals.
  - Ensure adequate and timely follow-up.
  - Establish parameters that measure therapeutic goal achievement or protocol endpoints.
  - Reflect consideration of best evidence.
  - Select the most reliable source for each parameter measurement.
  - Have correct value ranges selected for the patient.
  - Have parameters that measure efficacy.
  - Have parameters that measure potential adverse drug events.
  - Have parameters that are cost-effective.
  - Have obtainable measurements of the parameters specified.
  - Reflect consideration of compliance.
  - Anticipate future drug-related problems.
  - Ensure a strategy for verification of investigational product returns by an ambulatory patient.
  - Reflect preference and needs of the patient, when applicable.
  - Represent the highest level of patient care.
  - Reflect the requirements of monitoring for the research protocol.

Objective R1.1.7: (Applying) Ensure implementation of protocol specific monitoring plans for participants enrolled in clinical trials by taking appropriate follow-up actions.

Criteria:

- Collaborates with members of the healthcare team, research team and communicates participants' regimens and associated monitoring plans.
  - Poses questions as needed. Recommendation is persuasive.
  - Communication conveys expertise and complete understanding of the protocol.
  - Presentation of recommendation accords participant's right to refuse treatment.
  - If participant refuses treatment, pharmacist exhibits responsible professional behavior.
  - Creates an atmosphere of collaboration.

    - Skillfully defuses negative reactions.
    - Communication is assertive but not aggressive.
    - Where the participant has been directly involved in the design of the plans, communication reflects previous collaboration clearly.
- Ensures monitoring plan is implemented effectively for the participant, including ensuring that the:
    - Therapy corresponds with the assigned treatment plan.
    - Therapy is initiated at the correct time (investigational product treatment plan corresponds with the protocol).
    - Medication orders are clear and concise.
    - Activity complies with research protocol and with the health system's policies and procedures.
    - Tests correspond with the monitoring plan and the clinical trial protocol.
    - Tests are ordered and performed in a timely manner.
- Takes appropriate action based on analysis of monitoring results.
- Initiates, modifies, discontinues, or administers standard of care medication therapy as authorized.
- Responds to notifications and alerts in electronic medical records and other information systems that support medication ordering processes (based on factors such as weight, age, gender, comorbid conditions, drug interactions, renal function, and hepatic function).
- Provides thorough and accurate education to participants and caregivers, including information on medication therapy, adverse effects, compliance, appropriate use, handling and storage, and medication administration.
- Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration.
- Participates in follow-up care as indicated in the protocol to achieve protocol objectives and endpoints.

Objective R1.1.8: (Applying) For research participants, document direct patient care activities.
Criteria:

- Selects direct patient care activities for documentation.
- Communicates accurate and concise drug therapy recommendations to healthcare professionals representing different disciplines.
- Documents patient/caregiver communication and all relevant direct patient care activities in a timely manner.
- Follows the health system's policies and procedures for documentation, including requirements that entries be signed, dated, timed, legible, and concise.
- Complies with study protocol requirements for documentation.
- Does not violate masking or blinding of the study documentation, if applicable.

Objective R1.1.9: (Applying) Demonstrate responsibility to research participants.
Criteria:

- Triages patient care activities.
- Plans prospectively.
- Conducts all steps of the medication management process.
- Assumes responsibility for investigational product and medication therapy outcomes.
- Actively works to identify the potential for significant medication-related problems.
- Actively pursues all significant existing and potential investigational product and medication-related problems, until satisfactory resolution is obtained.
- Ensures appropriate transitions of care.
- Helps participants navigate the health care system.

- Informs participants how to obtain their investigational product and standard of care medications in accordance with the research protocol.
- Determines barriers to participant compliance and makes adjustments.
- Abides by the confidentiality requirements of the research protocol.

Goal R1.2: Ensure continuity of care during research participant transitions between care settings.

Objective R1.2.1: (Applying) Manage transitions of care for research participants.
Criteria:
- Participates in obtaining or validating a thorough and accurate medication history.
- Participates in thorough medication reconciliation when necessary.
- Follows up on identified drug-related problems, additional monitoring, and education in a timely and caring manner.
- Participates in medication education as allowed by the research protocol.
- Provides accurate and timely follow-up information when participants transfer to another facility, level of care, pharmacist, or provider.
- Participates in a participant's transition between standard of care and research study.
- Follows up with participants in a timely and caring manner.
- Takes effective steps to help avoid unnecessary hospital admissions and/or readmissions.
- Provides information to other pharmacists in transitions to mitigate medication therapy problems.
- Communicates effectively with the research team and other health care providers.

Goal R1.3: Manage and facilitate delivery of investigational products to support safe and effective drug therapy for research participants.

Objective R1.3.1: (Applying) Prepare and dispense investigational products according to the protocol, following best practices and the local organization's policies and procedures.
Criteria:
- Accurately interprets the study design, research documents, and the participant's treatment assignment prior to preparing the investigational product.
    - Identifying, clarifying, verifing, and correcting any investigational product and medication order errors.
    - Considering complete patient-specific information.
    - Identifying existing or potential drug therapy problems.
    - Determining an appropriate solution to an identified problem.
    - Securing consensus from the research team for modifications to therapy and according to the protocol.
    - Ensuring that the solution is implemented.
    - Maintain the blind if applicable.
- Prepares investigational product and standard of care medication according to the protocol or supplemental documents and follows the organization's policies and procedures and applicable professional standards, including:
    - When required, accurately calibrating equipment.
    - Ensuring intravenous solutions are correctly concentrated when necessary, without incompatibilities; stable; and stored according to manufacturer's recommendations.
    - Adhering to appropriate safety and quality assurance practices.

    - Preparing labels that conform to the research protocol, state and federal regulations.
    - Ensuring that all necessary and appropriate ancillary labels are utilized.
    - Inspecting the final medication before dispensing for accuracy.
    - Completing the required documentation.
    - Destroying or retaining the investigational packaging, if applicable.
- When dispensing investigational products:
    - Follows the research protocol procedures.
    - Follows the organizations policies and procedures.
    - Ensures the participant receives the investigational product(s) as ordered.
    - Ensures the integrity of investigational product dispensed.
    - Provides any necessary written and/or verbal counseling for the patient and support/education for relevant interdisciplinary staff (e.g., nursing, respiratory therapy).
    - Ensures the participant receives the investigational product and standard of care medication(s) on time.
    - Maintains the integrity of the protocol blinding procedure, if applicable.
    - Validates participant treatment assignment as necessary to dispense the medication.
- Maintains accuracy and confidentiality of participants' protected health information.
- Obtains agreement on modifications to standard of care medication orders when acting in the absence of, or outside, an approved protocol or collaborative agreement.
- References literature resources to ensure use of proper practices regarding compatibility, fluid overload, and concentrations.

Objective R1.3.2: (Applying) Manage aspects of the medication-use process related to formulary management for research participants.
Criteria:
- Follows standard of care procedures at the institution with regard to the necessities of the research protocol.
- Follows established procedures regarding exceptions to the formulary, if applicable, in compliance with policy.
- Ensures non-formulary medications are evaluated, dispensed, administered, and monitored in a manner that ensures patient safety.
- Manages drug shortage situations and identifies solutions with regard to the limits of the clinical trial.
- Communicates with the research team members.

Objective R1.3.3: (Applying) Utilize available clinical decision support when verifying and dispensing investigational medications.
Criteria:
- Identifies available technology at the institution.
- Utilizes relevant technology to aid in decision-making and increase safety.
- Assesses information from clinical decision support systems accurately.
- Confirms accuracy of the decision support technology as needed.
- Utilizes available technology for randomization, investigational product allocation, and inventory management accurately.

Objective R1.3.4: (Applying) Facilitate aspects of the medication-use process for research participants.
Criteria:
- Demonstrates commitment to medication safety.

- Prioritizes workload and organizes workflow.
- Validates accuracy of investigational products dispensed, including correct patient identification, medication, dosage form, label, dose, number of doses, and expiration dates; and proper repackaging and relabeling medications, including compounded medications (sterile and nonsterile).
- Promotes safe and effective drug use on a day-to-day basis.

Competency Area R2: Advancing Practice and Improving Patient Care

Goal R2.1: Manage the medication-use processes for investigational drug services, as applicable to the organization.

Objective R2.1.1: (Creating) Prepare or revise a drug class review, monograph, treatment guideline, or protocol related to care of research patients, including proposals for medication-safety technology improvements.

Criteria:

- Displays objectivity.
- Synthesizes information from the available literature.
- Applies evidenced-based principles.
- Consults relevant sources.
- Considers medication-use safety and resource utilization.
- Uses the appropriate format.
- Communicates any changes in medication formulary, medication usage, or other procedures to appropriate parties.
- Demonstrates assertiveness and timeliness in presenting pharmacy concerns, solutions, and interests to internal and external stakeholders.
- Makes proposals for medication-safety technology improvements, when necessary.

Objective R2.1.2: (Analyzing) Make optimization recommendations to and/or collaborate with other disciplines to perform requisite build in available technology and automation systems as applicable for inventory control, prescribing, order processing, verification, dispensing, administration and clinical documentation of investigational medications.

Criteria:

- Participates in the institution's process to create electronic orders and documentation to support clinical trials research in compliance with the protocol, oganizational policies and procedures.
- Reviews each component of the medication use process (i.e., inventory control, prescribing, order processing, verification, dispensing, administration and clinical documentation) to assure appropriateness of information in electronic health records for research participants.
- Develops a protocol-specific medication order template or other protocol specific requirements to meet electronic health record needs.
- Serves as a subject matter expert on the considerations for successful integration of investigational medications into the health-system formulary.
- Participate in quality assurance activities to optimize the build process of adding or revising information in electronic systems.

Objective R2.1.3: (Evaluating) Participate in a medication-use evaluation related to care of research participants.

Criteria:

- Develops criteria for use by applying evidence-based principles.
- Demonstrates a systematic approach to gathering data.
- Accurately analyzes data gathered.
- Demonstrates assertiveness in presenting pharmacy concerns, solutions, and interests to internal and external stakeholders.
- Implements approved changes, as applicable.

Objective R2.1.4: (Applying) Participate in the review of medication event reporting and monitoring related to care for research participants.

Criteria:

- Identifies and evaluates medication events reportable to the institutional review board (IRB).
- Evaluates medication events reportable to the sponsor and/or investigator.
- Utilizes available technology and automation that supports a safe medication-use process.
- Accurately determines, investigates, reports, tracks, and trends adverse drug events, medication errors, and efficacy concerns using accepted institutional resources and programs.
- Communicates directly with the principal investigator, research team, pharmacy team and other necessary team members.
- Distinguishes adverse drug events (ADEs) and serious ADEs.
- Utilizes the Investigator's Brochure and protocol as a reference for reported adverse events and toxicities.
- Describes the definitions of adverse events and the adverse drug reporting requirements of the protocol.
- Collaborates with the appropriate healthcare providers to create a corrective action/prevention action (CAPA) plan.

Objective R2.1.5: (Analyzing) Identify opportunities for improvement of the medication-use system related to care of research participants.

Criteria:

- Identifies problems and opportunities for improvement and analyzes relevant background data.
- Evaluates data generated by health information technology or automated systems to identify opportunities for improvement.
- Utilizes best practices to identify opportunities for improvements.
- Makes medication-use policy recommendations based on a review of practice standards and other evidence (e.g., FDA Code of Federal Regulation, International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, and other research related standards).

Goal R2.2: Demonstrate ability to conduct a quality improvement or research project.

Ideally, objectives R2.2.1-R2.2.6 will be addressed through residents working on one quality improvement or research project; however, if this is not possible, all objectives must be addressed by the end of the residency year and can be addressed through work on more than one initiative.

Objective R2.2.1: (Analyzing) Identify and/or demonstrate understanding of a specific project topic for a pharmacy quality improvement or research project.

Criteria:

- Identifies problems and opportunities for quality improvement or research projects.
- Conducts a comprehensive literature search and draws pertinent conclusions.
- Determines an appropriate research question or topic for a practice-related project of significance to patient care that can realistically be addressed in the desired time frame.
- Uses best practices or evidence-based principles to identify opportunities for improvements.
- Accurately evaluates, or assists in the evaluation of, data generated by health information technology or automated systems to identify opportunities for improvement.

Objective R2.2.2: (Creating) Develop a plan for a pharmacy quality improvement or research project.

Criteria:

- Develops specific aims, selects an appropriate study design, and develops study methods to answer the research question(s).
- Applies safety design practices (e.g., standardization, simplification, human factors training, lean principles, FOCUS-PDCA, other process improvement or research methodologies) properly and accurately.
- Plan for improvement includes reviews and approvals required by department and/or organization, and addresses the concerns of all stakeholders.
- Applies evidence-based and/or basic pharmacoecomic principles, if needed.
- Develops a sound research or quality improvement question that can be realistically addressed in the desired time frame.
- Develops a feasible design for a prospective or retrospective clinical or outcomes analysis project that considers who or what will be affected by the project.
- Identifies and obtains necessary approvals, (e.g., IRB, funding) for a practice-related project.
- Acts in accordance with the ethics of research on human subjects, if applicable.
- Implements the project as specified in its design.
- Plan design is practical to implement and is expected to remedy or minimize the identified challenge or deficiency.

Objective R2.2.3: (Evaluating) Collect and evaluate data for a pharmacy quality improvement or research project.

Criteria:

- Collects the appropriate types of data as required by project design.
- Utilizes electronic data and information from internal information databases, external online databases, Internet resources, and other sources of decision support, as applicable.
- Utilizes methods for analyzing data in a prospective and retrospective clinical, humanistic, and/or economic outcomes analysis.
- Develops and follows a research or project timeline.
- Correctly identifies need(s) for additional modifications to the project.
- Applies results of a prospective or retrospective clinical, humanistic, and/or economic outcomes analysis to internal business decisions and modifications to a customer's formulary or benefit design.
- Uses continuous quality improvement (CQI) principles to assess the success of the implemented change, if applicable.
- Considers the impact of the limitations of the project or research design on the interpretation of results.
- Develops a plan to address opportunities for additional changes.

Objective R2.2.4: (Applying) Implement a pharmacy quality improvement or research project.
Criteria:

- Plan is based on relevant data.
- Effectively presents plan (e.g., accurately recommends or contributes to recommendation for operational change, formulary addition or deletion, implementation of medication guideline or restriction, or treatment protocol implementation) to appropriate audience.
- Demonstrates assertiveness in presenting pharmacy concerns, solutions, and interests to external stakeholders.
- Gains necessary commitment and approval for implementation.
- Follows established timeline and milestones.
- Effectively communicates any changes in medication formulary, medication usage, or other procedures to appropriate parties.
- Outcome of change is evaluated accurately and fully.

Objective R2.2.5: (Evaluating) Assess changes or need to make changes as a result of a quality improvement or research project.
Criteria:

- Evaluate data and/or outcome of the project accurately and fully.
- Includes operational, clinical, economic, and humanistic outcomes of patient care.
- Uses continuous quality improvement (CQI) principles to assess the success of the implementated change, if applicable.
- Correctly identifies need(s) for additional modifications or changes.
- Accurately assesses the impact of the project, including its sustainability (if applicable).
- Develops a plan to address opportunities for additional changes.

Objective R2.2.6: (Creating) Effectively develop and present, orally and in writing, a final project report suitable for publication related to a quality improvement or research project at a local, regional, or national conference (the presentation may be virtual).
Criteria:

- Reports outcome of change accurately to stakeholder(s) and policy-making bodies, according to departmental and/or organizational processes.
- Includes implications for changes for the improvement in pharmacy practice in the report.
- Utilizes an accepted manuscript style in the report, suitable for publication in professional literature.
- Oral presentations to audiences within the department, organization, and/or to external audiences use effective communication and presentation skills and tools (e.g., handouts, slides) to convey points successfully.

Competency Area R3: Research Protocols and Regulations

Goal R3.1: Serve as an authoritative resource on the optimal use of investigational products used in clinical research.

Objective R3.1.1: (Applying) Actively participate in the development of a clinical trial protocol.
Criteria:

- Collaborates with the principal investigator to determine study objectives and the section of protocol to be developed.
- Describes drug study designs and the format of the clinical trial protocol.
- Develops complete and accurate medication information section for a protocol including the investigational product dosing plan, based on information provided in the investigator's brochure or known pharmacokinetic parameters, if applicable.
- Reviews all sections of the protocol which refer to the investigational product for consistency, accuracy, and feasibility.
- Utilizes outcomes from pharmacokinetic and pharmacodynamic trials, if applicable.
- Determines the source for the investigational product.

Objective R3.1.2: (Applying) Effectively serve as a resource to the research team and institution staff for drug information questions related to medications, including the investigational product, used with clinical trial participants.
Criteria:
- Develops complete and accurate medication information section for a protocol.
- Educates pertinent pharmacy personnel and other clinical staff on clinical research study.
- Responses consider institutional policies and procedures.
- Responses are evidence-based and consider the standards of care/clinical care for the patient.
- Responses are concise, applicable, comprehensive.
- Responses are made in a timely manner.

Objective R3.1.3: (Analyzing) Assess the drug approval process and identify opportunities for pharmacist involvement.
Criteria:
- Describes the drug approval process from preclinical to the postmarketing phase.
- Describes clinical trial phases.
- Participates in the investigational new drug application (IND) process.
- Participates in the development of a chemistry, manufacturing, control sheet for an IND application.
- Identifies the FDA structure correctly and the Centers that evaluate investigational products.
- Identifies the different types of drug applications that can be submitted to the FDA.

Objective R3.1.4: (Applying) Participate or demonstrate understanding of methods to obtain funding for clinical trials.
Criteria:
- Compares and contrasts different sources of funding.
- Identifies viable means of obtaining funding and the related application processes accurately.
- Participates in the creation of a grant application.

Goal R3.2: Demonstrate ability to assess the feasibility of research protocols for the organization.

Objective R3.2.1: (Evaluating) Accurately assess the organization resources and the feasibility of the research protocol for the institution.
Criteria:
- Determines the requirements for pharmacy support from the institutional review board submission to termination of the clinical trial.

- Describes the requirements for drug preparation and storage in context to the pharmacy processes, available pharmacy equipment, staff education and training, and facility limitations.
- Prepares and participates in a site feasibility visit for the clinical trial.
- Considers appropriate institutional and regulatory policies and procedures.
- Explains the specific requirements for the implementation of a clinical trial.
- Compares the research protocol and the institution standards of care.

Objective R3.2.2: (Understanding) Describe the role of the investigational drug service in the coordination of a multi-center research protocol.

- Describes differences in the relevant research regulations between the various centers involved in the clinical trial.
- Identifies criteria for assessing feasibility of multi-site distribution of investigational drug products.
- Identify the role of investigational drug services as a coordinating center for multi-site services.

Objective R3.2.3: (Applying) Participate in a sponsor site visit to the organization as the pharmacy representative for the research team.

Criteria:

- Prepares adequately for the site visit and is able to answer pharmacy related questions.
- Accurately answers questions and acts as a representative of the institution.
- Properly documents and communicates visit outcomes with relevant research team members and to the investigational drug service pharmacy team.

Goal R3.3: Serve as an authoritative source to the institutional review board (IRB) to ensure the safety of human subjects.

Objective R3.3.1: (Applying) Participate in IRB's review and evaluation of a research protocol.

Criteria:

- Describes the role and responsibilities of the IRB to protect the rights, safety, and well-being of human subjects.
- Follows IRB institutional procedures and guidelines while reviewing and evaluating a research protocol.
- Attends an IRB meeting(s).
- Explains the process to determine when an IND/IDE is needed.
- Follows IRB documentation requirements.
- Accurately identifies elements of a risk versus benefit assessment, utilized when evaluating a study protocol.
- Demonstrates knowledge of the accreditation standards and process for IRBs.
- Examines the various forms of IRB communication to the principal investigator.
- Participates in IRB compliance monitoring procedures and reporting to the FDA.
- Participates in the contracting and financial processes conducted by the OHSR.
- Demonstrates understanding of the IRB requirements and process for protocol submission, approval and continuing review.
- Demonstrates knowledge of the accreditation standards and process for IRBs.

Objective R3.3.2: (Applying) Participate in the consent process for a participant enrolling in a clinical trial.

Criteria:

- Explains the required elements of informed consent documentation.
- Identifies medication related information required in the consent process.
- Participates effectively in the process for consenting a participant.
- Uses effective communication skills.
- Demonstrates cultural competence.

Objective R3.3.3: (Applying) Demonstrate adherence to the ethical standards for the conduct of research.
Criteria:
- Follows IRB's ethical standards and how it is incorporated into research project evaluation.
- Participates in IRB's process to ensure the safety of participants.
- Demonstrates knowledge of the historical codes of ethics and regulations that guide ethical clinical research (e.g., Nuremberg Code, Declaraion of Helsinki, Belmont report, U.S. Common Rule).
- Applies Good Clinical Practice (GCP).

Goal R3.4: Demonstrate the ability to evaluate the federal, state, and institution regulations as it pertains to clinical trials.

Objective R3.4.1: (Evaluating) Assess clinical trial adherence to federal and state regulations, accreditation standards, and institutional policies.
Criteria:
- Identifies relevant federal and state regulations, accreditation standards, and institutional policies accurately.
- Explains the relevant regulations and their implications for investigational product use and pharmacy services.
- Identifies areas of noncompliance with the regulations (e.g., USP, BDA, ISMP, ASHP).

Competency Area R4: Leadership and Management

Goal R4.1: Demonstrate leadership skills for successful self-development in the provision of care for research participants.

Objective R4.1.1: (Applying) Demonstrate personal, interpersonal, and teamwork skills critical for effective leadership in the provision of care for research participants.
Criteria:
- Demonstrates effective time management.
- Manages conflict effectively.
- Demonstrates effective negotiation skills.
- Demonstrates ability to lead interprofessional teams.
- Uses effective communication skills and styles.
- Demonstrates understanding of perspectives of various health care professionals.
- Expresses benefits of personal profession-wide leadership and advocacy.
- Provides leadership in patient care related services, including interprofessional teams, code blue, and rapid response teams.

Objective R4.1.2: (Applying) Apply a process of ongoing self-evaluation and personal performance improvement in the provision of care for research participants.
Criteria:

- Summarizes own strengths and areas for improvement (in knowledge, values, qualities, skills, and behaviors) accurately.
- Uses a self-evaluation process for developing professional direction, goals, and plans.
- Engages in self-evaluation of progress on specified goals and plans.
- Demonstrates ability to use and incorporate constructive feedback from others.
- Uses principles of continuous professional development (CPD) planning (reflect, plan, act, evaluate, record/review).

Goal R4.2: Demonstrate management skills in the provision of care for research participants.

Objective R4.2.1: (Applying) Contribute to departmental planning.
Criteria:

- Identifies and helps develop plans related to factors that influence departmental planning, including:
  - Financial management of services to support clinical trials research.
  - Accreditation, legal, regulatory, and safety requirements.
  - Facilities design for dedicated pharmacy space to support clinical trial research.
  - The organization's political and decision-making structure.
  - Expansion of services and growth in patient volumes.
  - Strategic decisions which impact research (affiliations, collaborations, networks).
- Explains the potential impact of factors on departmental planning.
- Participates in the strategic planning process.

Objective R4.2.2: (Understanding) Explain the elements of the pharmacy enterprise related to investigational drug services and their relationship to the health care system.
Criteria:

- Identifies appropriate stakeholders to communicate updateds on trends and changes within pharmacy and health care.
- Correctly identifies changes to laws and regulations (e.g., value-based purchasing, consumer-driven health care, reimbursement models) related to medication use.
- Considers internal and external quality metrics (e.g., FDA-mandated Risk Evaluation and Mitigation Strategy) and how they are developed, abstracted, reported, and used.
- Describes the governance of the health care system and leadership roles.

Objective R4.2.3: (Applying) Contribute to investigational drug services departmental management.
Criteria:

- Helps identify and define significant departmental needs.
  - Manpower/staffing.
  - Staff scheduling and contingencies.
  - Staff qualifications.
  - Assesses and develops educational opportunities for investigational drug service line staff.
- Helps develop plans that address departmental needs.
  - Orientation.
  - Training and supervision.
  - Effectively participate in, or evaluate, strategic plan.
  - Develops a plan for the implementation and new use of technology to improve services.

- Participates effectively on committees or informal work groups to complete group projects, tasks, or goals.
- Participates effectively in implementing changes, using change management and quality improvement best practices and tools, consistent with team, departmental, and organizational goals.
- Participates in the creation and review of policies and standard operating procedures.

Objective R4.2.4: (Applying) Manage one's own investigational drug service practice effectively.
Criteria:

- Reviews and interprets the most recent primary literature.
- Evaluates clinical practice activities for potential contributions to scholarship.
- Accurately assesses successes and areas for improvement (e.g., a need for staffing projects or education) in managing one's own practice.
- Makes accurate, criteria-based assessments of one's own ability to perform practice tasks.
- Regularly integrates new learning into subsequent performances of a task until expectiations are met.
- Routinely seeks applicable learning opportunities when performance does not meet expectations.
- Demonstrates effective workload and time-management skills.
- Assumes responsibility for personal work quality and improvement.
- Is well prepared to fulfill responsibilities (e.g., patient care, projects, management, meetings).
- Sets and meets realistic goals and timelines.
- Demonstrates awareness of own values, motivations, and emotions.
- Demonstrates enthusiasm, self-motivation, and a "can-do" approach.
- Strives to maintain a healthy work–life balance.
- Works collaboratively within the organization's political and decision-making structure.
- Demonstrates pride in and commitment to the profession through appearance, personal conduct, planning to pursue board certification, and pharmacy association membership activities.
- Demonstrates personal commitment to and adheres to organizational and departmental policies and procedures.

Goal R4.3: Demonstrate skills in the financial management and budgeting to conduct clinical trials.

Objective R4.3.1: (Analyzing) Identify opportunities for improvement and/or demonstrate understanding of the budgeting process of a clinical trial and the distribution of funds.
Criteria:

- Identifies the elements included in a budget for the entire clinical trial.
- Describes the utilization of funding, including where and how the budget is used.
- Identifies required documentation and reporting for the clinical trial budget.

Objective R4.3.2: (Applying) Participate in the clinical trial appraisal process and effectively design a budget for pharmacy services to support a clinical trial.
Criteria:

- Accurately identifies the elements included in a pharmacy budget for a clinical trial.
- Develops a pharmacy budget based on the requirements of the protocol.
- Communicates the budget with relevant research team members accurately.
- Describes the process for generating clinical trial bills and the electronic transfer of funds.

Objective R4.3.3: (Applying) Develop an appropriate financial management plan for a selected aspect of the investigational drug service pharmacy budget.
Criteria:

- Explains the components of a financial management plan.
- Explains investigational drug service pharmacy's financial performance within the context of the broader pharmacy department.
- Justifies new services using return on investment (ROI) analyses.

Competency Area R5: Teaching, Education, and Dissemination of Knowledge

Goal R5.1: Provide effective clinical trial and medication education to participants, caregivers, health care professionals, students, and the public (individuals and groups).

Objective R5.1.1: (Applying) Design effective educational activities related to care of research participants.
Criteria:

- Defines educational needs with regard to target audience (e.g., individual versus group) and learning level (e.g., health care professional versus patient).
- Selects topics of significance to investigational drug services as outlined in the appendix.
- Defines educational objectives that are specific, measurable, at a relevant learning level (e.g., applying, creating, evaluating), and address the audiences' defined learning needs.
- Plans use of teaching strategies that match learner needs, including active learning (e.g., patient cases, polling).
- Selects content that is relevant, thorough, evidence based (using primary literature where appropriate), and timely and reflects best practices.
- Includes accurate citations and relevant references and adheres to applicable copyright laws.

Objective R5.1.2: (Applying) Use effective presentation and teaching skills to deliver education related to care of research participants.
Criteria:

- Demonstrates rapport with learners.
- Captures and maintains learner/audience interest throughout the presentation.
- Implements planned teaching strategies effectively.
- Effectively facilitates audience participation, active learning, and engagement in various settings (e.g., small or large group, distance learning).
- Presents at appropriate rate and volume and without exhibiting poor speaker habits (e.g., excessive use of "um" and other interjections).
- Body language, movement, and expressions enhance presentations.
- Summarizes important points at appropriate times throughout presentations.
- Transitions smoothly between concepts.
- Uses audio-visual aids and handouts to support learning activities effectively.
- Documents education to dispensing pharmacy.

Objective R5.1.3: (Applying) Use effective written communication to disseminate knowledge related to care of research participants.

Criteria:

- Writes in a manner that is easily understandable and free of errors.
- Demonstrates thorough understanding of the topic.
- Notes appropriate citations and references.
- Includes critical evaluation of the literature and knowledge advancements or a summary of what is currently known on the topic.
- Develops and uses tables, graphs, and figures to enhance reader's understanding of the topic when appropriate.
- Writes at a level appropriate for the target readership (e.g., physicians, pharmacists, other health care professionals, patients, the public).
- Creates one's own work and does not engage in plagiarism.

Objective R5.1.4: (Applying) Appropriately assess effectiveness of education related to care of research participants.

Criteria:

- Selects assessment method (e.g., written or verbal assessment or self-assessment questions, case with case-based questions, learner demonstration of new skill) that matches activity.
- Provides timely, constructive, and criteria-based feedback to learner.
- If used, assessment questions are written in a clear, concise format that reflects best practices for test item construction.
- Determines how well learning objectives were met.
- Plans for follow-up educational activities to enhance or support learning and (if applicable) ensure that goals were met.
- Identifies ways to improve education-related skills.
- Obtains and reviews feedback from learners and others to improve effectiveness as an educator.

Goal R5.2: Effectively employ appropriate preceptor roles when engaged in teaching students, pharmacy technicians, or fellow health care professionals about care of research participants and investigational drug services.

Objective R5.2.1: (Analyzing) When engaged in teaching related to care of research participants and investigational drug services, select a preceptor role that meets learners' educational needs.

Criteria:

- Identifies which preceptor role is applicable for the situation (direct instruction, modeling, coaching, facilitating).
    - Selects direct instruction when learners need background content.
    - Selects modeling when learners have sufficient background knowledge to understand the skill being modeled.
    - Selects coaching when learners are prepared to perform a skill under supervision.
    - Selects facilitating when learners have performed a skill satisfactorily under supervision.

Objective R5.2.2: (Applying) Effectively employ preceptor roles, as appropriate, when instructing, modeling, coaching, or facilitating skills related to care of research participants and investigational drug services.

Criteria:

- Accurately assesses the learner's skill level to determine the appropriate preceptor role for providing practice-based teaching.

- Instructs students, technicians, or others as appropriate.
- Models skills, including “thinking out loud,” so learners can “observe” critical-thinking skills.
- Coaches, including effective use of verbal guidance, feedback, and questioning, as needed.
- Facilitates, when appropriate, by allowing learner independence and using indirect monitoring of performance.

ELECTIVE COMPETENCY AREAS, GOALS, AND OBJECTIVES FOR POSTGRADUATE YEAR TWO (PGY2) INVESTIGATIONAL DRUGS AND RESEARCH PHARMACY RESIDENCIES

Competency Area E1: Academia

Goal E1.1: Demonstrate understanding of key elements of the academic environment and faculty roles within it.

Objective E1.1.1: (Understanding) Demonstrates understanding of key elements of the academic environment and faculty roles within it.
Criteria:

- Accurately describes variations in the expectations of different colleges/schools of pharmacy for teaching, practice, research, and service, including public versus private colleges/schools of pharmacy and relationships between scholarly activity and teaching, practice, research and service.
- Accurately describes the academic environment, including how the decisions by university and college administration impact the faculty and how outside forces (e.g., change in the profession, funding source, accreditation requirements) that impact administrator and faculty roles.
- Describes faculty roles and responsibilities.
- Describes the types and ranks of faculty appointments, including the various types of appointments (e.g., non-tenure, tenure-track, and tenured faculty), various ranks of faculty (e.g., instructor, assistant professor, associate professor, full professor), and the role and implications of part-time and adjunct faculty as schools continue to expand and faculty shortages occur, and promotion and tenure process for each type of appointment, including types of activities that are considered in the promotion process and for tenure.
- Explains the role and influence of faculty in the academic environment, including faculty in governance structure (e.g., the faculty senate, committee service) and faculty related to teaching, practice, research, and service roles (e.g., curriculum development, committee service).
- Identifies resources available to help develop academic skills, including the role of academic-related professional organizations (e.g., AACP) and other resources to help develop teaching skills and a teaching philosophy.
- Identifies and describes ways that faculty maintain balance in their roles.
- Describes typical affiliation agreements between a college of pharmacy and a practice site (e.g., health system, hospital, clinic, retail pharmacy).

Goal E1.2: Exercise case-based and other teaching skills essential to pharmacy faculty.

Objective E1.2.1: (Applying) Develop and deliver cases for workshops and exercises for laboratory experiences.
Criteria:

- Identifies the appropriate level of case-based teachings for small group instruction.
- Identifies appropriate exercises for laboratory experiences.
- Provides appropriate and timely feedback to improve performance.

Objective E1.2.2: (Evaluating) Compare and contrast methods to prevent and respond to academic and profession dishonesty and adhere to copyright laws.
Criteria:

- Evaluates physical and attitudinal methods to prevent academic dishonesty.
- Describes methods of responding to incidents of academic dishonesty.
- Explains the role of academic honor committees in cases of academic dishonesty.
- Identifies examples and methods to address unprofessional behavior in learners.
- Describes copyright regulations as related to reproducing materials for teaching purposes.
- Describes copyright regulations as related to linking and citing on-line materials.

Goal E1.3: Develops and practices a philosophy of teaching.

Objective E1.3.1: (Creating) Develop or update a teaching philosophy statement.
Criteria:

- Teaching philosophy includes:
  - Self-reflection on personal beliefs about teaching and learning;
  - Identification of attitudes, values, and beliefs about teaching and learning; and,
  - Illustrates personal beliefs on practice and how these beliefs and experiences are incorporated in a classroom or experiential setting with trainees.
  - If updating, reflect on how one's philosophy has changed.

Objective E1.3.2: (Creating) Prepare a practice-based teaching activity.
Criteria:

- Develops learning objectives using active verbs and measureable outcomes.
- Plans teaching strategies appropriate for the learning objectives.
- Uses materials that are appropriate for the target audience.
- Organizes teaching materials logically.
- Plans relevant assessment techniques.
- When used, develops examination questions that are logical, well-written, and test the learners' knowledge rather than their test-taking abilities.
- Participates in a systematic evaluation of assessment strategies (e.g., post-exam statistical analysis) when appropriate.
- Ensures activity is consistent with learning objectives in course syllabus.

Objective E1.3.3: (Applying) Deliver a practice-based educational activity, including didactic or experiential teaching, or facilitation.
Criteria:

- Incorporates at least one active learning strategy in didactic experiences appropriate for the topic.
- Uses effective skills in facilitating small and large groups.
- For experiential activities:
  - Organizes student activities (e.g., student calendar);
  - Effectively facilitates topic discussions and learning activities within the allotted time;
  - Effectively develops and evaluates learner assignments (e.g., journal clubs, presentations, SOAP notes);
  - Effectively assesses student performance; and,
  - Provides constructive feedback.

Objective E1.3.4: (Creating) Effectively document one's teaching philosophy, skills, and experiences in a teaching portfolio.
Criteria:

- Portfolio includes:
  - A statement describing one's teaching philosophy;
  - Curriculum vitae;
  - Teaching materials including slides and other handouts for each teaching experience;
  - Documented self-reflections on one's teaching experiences and skills, including strengths, areas for improvement, and plans for working on the areas for improvement;
  - Peer/faculty evaluations; and,
  - Student/learner evaluations.

Competency Area E2: Initiating an Investigational Drug Service

Goal E2.1: Develop a proposal for a new investigational drug service or expansion of existing service(s).

Objective E2.1.1: (Creating) Write a proposal for an investigational drug service or expansion of existing service(s).
Criteria:

- Writes a proposal to meet a perceived need of the health system and its patients, including metrics and/or other evidence to substantiate the need for the service, and specific goals/outcomes to be achieved by implementing the service.
- Considers financial and human resource requirements necessary for the new service.
- Writes a proposal that is clear and persuasive, written at an appropriate level for presentation to senior leadership, and which utilizes standard business plan structure and content.

Objective E2.1.2: (Creating) Present a proposal for a new investigational drug service or expansion of existing service(s).
Criteria:

- Identifies appropriate concerned entities and stakeholders as audience for presentation, and develops an agenda to ensure effective use of allotted time.
- Uses effective presentation skills to ensure the delivery is clear and persuasive, and at an appropriate level for presentation to senior leadership.
- Develops appropriate visual aids and documents to enhance the presentation.

Objective E2.1.3: (Applying) Implement a new investigational drug service or expansion of existing service(s).
Criteria:

- Identifies and employs selected strategies for implementing the new service, including standard project management tools and processes.
- Communicates progress of implementation to stakeholders.
- Demonstrates knowledge of change management during the implementation process.
- Adapts implementation strategy as needed in response to information received during the implementation process

Objective E2.1.4: (Applying) Assess a new investigational drug service or expansion of existing service(s).
Criteria:

- Identifies objective and measurable outcomes and criteria for assessment of impact and/or success of the new service.
- Recommends a process for continuous quality improvement of the new service.
- Communicates outcomes to stakeholders and senior leadership.

Competency Area E3: Publishing

Goal E3.1: Write and submit for publication pertinent scholarly content on investigational drug service-related topics.

Objective E3.1.1: (Creating) Write an article for a publication on an investigational drug service-related topic.
Criteria:

- Selects appropriate publication for submission of article.
- Writes in a style appropriate for the audience of the publication (e.g., health care professional and/or the public).

Objective E3.1.2: (Applying) Submit an article on an investigational drug service-related topic for a peer-reviewed publication.
Criteria:

- Formats article suitable for publication.
- Follows appropriate submission procedures.
- Effectively addresses reviewer comments, if appropriate.

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The effective date for implementation of these educational outcomes, goals and objectives is July 1, 2020.

APPENDIX

Statement on Rationale for No Appendix: Due to the highly dynamic nature of the fields of Investigational Drugs and Research (IDR), healthcare information technology, the emergence of new therapeutic modalities, and the evolving regulatory compliance landscape, an Appendix of specific scenarios would quickly become outdated and not applicable for the life of the document. Therefore, the Competency Areas, Goals, and Objectives (CAGOs) for Postgraduate Year Two (PGY2) IDR pharmacy residencies do not include an Appendix. The level of knowledge, understanding, and experience in all core areas or relevant issues in the field of investigational drugs and research expected of graduates of PGY2 IDR programs has been incorporated into the CAGOs listed above. Provided below is an optional list of related topics which can serve as the basis for discussions and specific learning activities.

Key Investigational Drugs and Research Pharmacy Residency Topic References

The topics listed below may be incorporated into the program content in order to develop a well-rounded PGY2 IDR pharmacy resident. Any of these topics, beyond what is required in the Competency Areas, Goals and Objectives for the residency are not required, however, you may want to include them in your program design in order to provide comprehensive training for the residents across a spectrum of research concepts, regulatory requirements, performance measures, information technology, and leadership principles.

Concepts in Clinical Research • Clinical trial designs • Phases of clinical trials • Randomization • Participant recruitment • Informed Consent process • Investigator responsibilities • Ethics/protection of human subjects • Investigational drug masking (blinding) procedures • Placebo formulations • Confidentiality • Data management and recordkeeping	**Research Compliance & Quality** • Performance Measures (metrics), Implementation and Evaluation • Association for the Accreditation of Human Research Protection Programs (AAHRPP) • FDA inspections • Internal auditing procedures • External auditing (monitors) • Adverse event reporting and analysis • Best practice standard • Data Safety Monitoring • Developing Standard Operating Procedures	**Regulations** • Code of Federal Regulations • FDA Drug Approval Processes • USP Chapter <797> • USP Chapter <800> • USP Chapter <795> • Office of Human Research Protections • The Joint Commission • IRB Role and Responsibilities • International shipping • State Board of Pharmacy • Institutional policies and guidelines • FDA Guidance Document
Medication Use Policy • Drug Information and Literature Evaluation • Study Design • Statistics • Pharmacy and Therapeutics (P&T) Committees	**Financial Management** • Pharmacy budgets/billings to support clinical trials • Pharmacy cost center budget • Cost Containment Strategies • Sources of funding research	**Pharmacoeconomics & Pharmacoepidemiology** • Comparative Effective Research • Pharmacoeconomic Evaluation Techniques • Cost-Effective Analysis (CEA)

• Compendia and knowledge bases • Formulary management • Biosimilars		• Cost-Utility Analysis • Pharmacoeconomics • Patient Reported Outcomes • Research Project
Technology • Electronic Health Record • Electronic prescribing • Clinical decision support • Building investigational drugs into electronic systems • Software to support protocol management and investigational product inventory • Barcode technology • Interactive Response Technology • Clinical Research Management System (CRMS) • Use of automation for drug preparation	**Leadership** • Strategic planning • Health system/network management of IDS • Staffing models • Human Resources • Business plan development • Medication use process • Pharmacy collaboration (outpatient, homecare and specialty pharmacies) • Coordinating Center Role • Practice Advancement (services and staff)	**Personalized Medicine** • Precision Medicine • Pharmacogenomics • Gene therapy • Cellular-based therapies