I. Course Information

Title: Patient Specimen Methods
Course No.: 
Prerequisites: None

II. Instructor Information

Course Coordinator: Lilith Reeves, Associate Professor of Pediatrics, Cincinnati Children’s Research Foundation, 3333 Burnet Ave., Phone: (513) 636-3468, Fax: (513) 636-1330, e-mail: lilith.reeves@cchmc.org. Office hours: TBD

Course content is as follows:

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<thead>
<tr>
<th>Hours</th>
<th>Topic</th>
<th>Content</th>
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| 1     | Applicable Regulations | Provide/discuss CAP regulations  
|       |       | Provide reference to CLIA regulations  
|       |       | Compare to GLP/GMP regulations |
| 1     | Sample documentation | Receive and process Phase I Gene Transfer IND specimen (if available) or, alternatively, receive and process a clinical sample with discussion of applicable considerations. |
| 2     | SOP requirements | Discuss requisite components of an SOP.  
|       |       | Perform assay per Approved SOP  
|       |       | Provide reference to NCCLS SOP standards |
| 4     | Audits | Perform assay & report audit with QA  
|       |       | Perform laboratory internal audit with QA  
|       |       | Review internal audit response with QA |
| 2     | Controls | Review:  
|       |       | Validation requirements for (GCP & GMP)  
|       |       | Assay standards (GCP)  
|       |       | Assay controls (GCP)  
|       |       | Proficiency testing (GCP)  
|       |       | Instrument calibrations (GCP & GMP)  
|       |       | Reagent/Raw Material QC (GCP & GMP) |

III. Catalog Description

A critical component of translational research is to use human subject specimens to drive laboratory research that may impact ongoing clinical research or lead to a new clinical trial. Therefore, it is essential for translational researchers to understand the steps required for collecting, handling, storing, and allocating patient material for study in Good Clinical Practices (GCP) and HIPAA-compliant fashion. This is a hands-on course in which students will spend time in the CCHMC the Translational Trials Development Support Laboratory using GCP and will be introduced to Good Manufacturing Practice (GMP) and Good Laboratory
GLP). Practical knowledge of using the web-based biologic sample tracking system developed at CCHMC will also be covered. Knowledge of how clinical material for safety and efficacy testing must be handled, assayed and reported will aid students in designing translational research trials. Experience in disease-specific assays can be sought from the clinical labs on a case-by-case basis, to total no more than 2-4 hours.

IV. Course Mission
This course is designed to give the student hand-on, real-world practical experience with the laboratory handling and study of human specimens in the context of clinical trials.

V. Course Objectives
At the end of the course, students will:
- Appreciate the complexity of tracking and storing patient specimens
- Understand the basic outlines and purposes of Standard Operating Procedures
- Know about the various federal agencies that regulate clinical laboratories and work in support of the multiple phases of translational research
- Be familiar with methods of quality control and quality assurance

VI. Teaching Methods
Teaching will be conducted in a “preceptorship-like” setting with 1-2 students and 1 faculty member. While a portion of the time will be spent in a small-group discussion setting, many of the sessions will be “hands-on” in the laboratory.

VII. Assessment
A sign-in sheet will be used to document participation in each session.

VIII. Grading Policies
Grading will be pass/fail based on participation. Each student must complete all sessions to pass.

IX. Course Schedule
This course is offered in the winter quarter. Dates and times are to be arranged with Ms. Reeves at the beginning of the quarter.

X. Texts/Resources
College of American Pathologists/Clinical Laboratory Improvement Act: Accessed Via /wwwn.cdc.gov/clia/