

ROCHESTER COMMON COURSE OUTLINE

Course discipline/number/title: BIOL 1200: Introduction to the Clinical/Research Laboratory

Α. **CATALOG DESCRIPTION**

- 1. Credits: 2
- 2. Hours/Week: 2
- 3. Prerequisites (Course discipline/number): None
- 4. Other requirements: None
- 5. MnTC Goals (if any): NA
- Β. **COURSE DESCRIPTION:** This course is for students currently employed in or ultimately seeking employment in a clinical or research laboratory with a health care focus. This course is specifically designed for students in the Biotechnology and Laboratory Science programs at RCTC. The goal of this course is to familiarize the student with key confidentiality, documentation, and safety issues encountered when working with patient samples in a clinical or research laboratory.

DATE LAST REVISED (Month, year): March, 2025 C.

D. **OUTLINE OF MAJOR CONTENT AREAS:**

- 1. The role of biomedical technologist
 - a) Clinical lab
 - b) Research lab
 - c) General job descriptions and boundaries of positions
- 2. Patient rights and confidentiality
 - a) History of human subject research
 - i. Nuremberg code
 - ii. Helsinki Declaration
 - iii. Belmont Report
 - iv. Office of Human Research Protection (OHRP)
 - b) Patient Bill of Rights
 - i. Informed consent
 - ii. Institutional Review Boards (IRB)
 - c) Patient confidentiality
 - i. HIPPA-Security Rule
 - ii. Documentation and record keeping of patient information
 - d) Legal ramifications of a patient's rights or confidentiality breach.
- 3. Collecting and Testing Biospecimens
 - a) Proper specimen labeling and handling
 - i. Biosafety and infectious control
 - ii. Methods of quality assurance and quality control
 - iii. Proper documentation requirements
 - b) Use of Microsoft Excel for data entry and management

Ε. LEARNING OUTCOMES (GENERAL): The student will be able to:

- 1. Describe the general role of the clinical and research biotechnologist in a biomedical setting.
- 2. Paraphrase the international and national laws and guidelines regarding the inclusion of human subjects in clinical trials.
- 3. Summarize correct and legal documentation of patient information
- 4. Articulate general legal and biomedical institutional requirements for long-term record maintenance and data storage.
- 5. Identify the unique risks of handling potentially infectious biological material and how to minimize exposure to infectious agents.
- 6. Describe and be able to apply industry specific quality assurance practices in handling patient samples.
- 7. Identify the need for the uses of quality control standards in biomedical assays and know how to determine standards for a given assay.
- Demonstrate use of Microsoft Excel for basic data entry, organization, storage and retrieval of data. 8.



F. LEARNING OUTCOMES (MNTC): NA

- G. METHODS FOR EVALUATION OF STUDENT LEARNING: Methods may include but are not limited to:
 - 1. Lecture exams, quizzes and assignments on general concepts.
 - 2. Analysis of case studies involving patient confidentiality and personal conduct issues.
- RCTC CORE OUTCOME(S). This course contributes to meeting the following RCTC Core Outcome(s):
 Critical Thinking. Students will think systematically and explore information thoroughly before accepting or formulating a position or conclusion.
- I. SPECIAL INFORMATION (if any): None