

# Clinical Investigation (CLIV)

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Course information contained within the Bulletin is accurate at the time of publication in June 2026 but is subject to change. For the most up-to-date course information, please refer to the Course Catalog.

## **CLIV 8101. Leveraging Artificial Intelligence Approaches to Scientific Research and Writing. 3 Credit Hours.**

This is a required course in both the masters and certificate in Clinical Investigation programs providing the practical, responsible and ethical framework for the use of artificial intelligence (AI). Students will learn to apply AI to scientific literature searches, preparation of scientific articles and research proposals. Through a variety of assignments and discussions students will gain experience with this specific application of AI and understand its strengths and weaknesses in scientific writing and research.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may not be repeated for additional credits.

## **CLIV 8102. Research Applications for Biostatistics and Data Science. 3 Credit Hours.**

This course provides foundational training in biostatistics, study design, data science, and modern machine learning methods utilizing clinical data sets. The emphasis is on statistical methods, reasoning, interpretation, reproducibility, and clinical decision relevance, rather than mathematical derivation or algorithm development. Students will participate in critical evaluation of published quantitative analyses in journal articles, conduct common statistical analyses using clinical datasets, and understand the appropriate and responsible use of machine learning and artificial intelligence in healthcare research.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may not be repeated for additional credits.

## **CLIV 8103. Clinical Data: Operations, Origins and Ownership. 1 Credit Hour.**

This is a survey seminar-style course providing a foundation for understanding the origins, structure, quality, governance, and regulatory context of clinical data used for research purposes. You will learn the vocabulary and frameworks necessary to evaluate clinical data sources, appreciate how clinical operations shape research data, and understand the factors involved in designing compliant approaches for identifying, allocating, protecting, and sharing research datasets.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may not be repeated for additional credits.

## **CLIV 8201. Ethics and Health Justice in Clinical Trials. 3 Credit Hours.**

This course equips students with the ethical frameworks, practical tools, and justice-oriented perspectives needed to design, conduct, evaluate, and oversee clinical trials responsibly. Moving beyond compliance-based ethics, the course emphasizes how power, inequality, structural injustice, and historical context shape research practices, participant experiences, and the social value of clinical trials. Students will learn to identify ethical risks, navigate real-world dilemmas, and integrate principles of equity and justice into clinical research decision-making.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may not be repeated for additional credits.

## **CLIV 8501. Clinical Investigation Journal Discussion. 1 Credit Hour.**

Students will present current clinical investigations, reporting gene therapy, biological, or small molecule therapeutic outcomes. Critical appraisal will include an evaluation of methodological rigor, interpretation of results and conclusions, and an assessment of the potential impact of funding sources on the study. Students will present their thesis research project at least once during the semester. Following the journal and research presentation, all students will participate in an informal discussion.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may be repeated for additional credit.

**CLIV 9991. Clinical Investigation Certificate Capstone. 2 Credit Hours.**

The Clinical Investigation Certificate Capstone project has MD/DO, medical and graduate students and other matriculants apply their analytical, ethical, and scientific foundational knowledge by proposing a clinical trial. Students will prepare sections of an FDA Investigational New Drug application, i.e., the Introductory Statement, General Investigation Plan, and the Protocol. The plan will be conceived of and developed by the student with the assistance of a faculty mentor and follow the current FDA template. The student will submit the written document and deliver an oral presentation on their proposed trial for their grade.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may not be repeated for additional credits.

**Pre-requisites:** Minimum grade of B in CLIV 8101, CLIV 8102, and CLIV 8201.

**CLIV 9996. Masters Thesis Research. 7 to 9 Credit Hours.**

Thesis research is the culminating event in the Master's in Clinical Investigation program. Students will be embedded in ongoing clinical trial research conducted at the Temple University Health System. Students may register for up to 9 credits of thesis research. From their participation students are expected to understand all aspects of the trial including patient enrollment, data collection and analysis and the interpretation of outcomes. The student will write and defend a thesis.

**Level Registration Restrictions:** May not be enrolled in one of the following Levels: Undergraduate.

**Repeatability:** This course may be repeated for additional credit.