

# Online Graduate Programs in Applied Clinical and Preclinical Research

Master of Applied Clinical and Preclinical Research (MACPR)

MS Pharmacology

Graduate Minor in Applied Clinical and Preclinical Research

[www.pharmacy.osu.edu/online-programs](http://www.pharmacy.osu.edu/online-programs)

## Course List

| Course #   | Course Title   | Credits | Terms Offered | Delivery Mode         | Online Programs |                 |                   |            | Other Programs |               |                |                   |
|--|--|---------|---------------|-----------------------|-----------------|-----------------|-------------------|------------|----------------|---------------|----------------|-------------------|
|  |  |         |               |                       | MACPR           | MS Pharmacology | Certificate in CP | Minor ACPR | PharmD         | BS Pharm. Sc. | MS Nursing Sc. | Global One Health |
| Research Conduct Courses                         |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| Option 1: Clinical Research Administration Focus |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| Nursing/Pharmacy 7770                            | Fundamentals of Medical Product Development and Regulation         | 3       | AU, SU        | Online                | R               |                 |                   | R1         | E              | AE            |                |                   |
| Nursing/Pharmacy 7782                            | Clinical Research Design and Methods                               | 3       | AU            | Online                | R               |                 |                   | R1         | E              | AE            | R              |                   |
| Nursing/Pharmacy 7405                            | Clinical Research Study and Site Management                        | 3       | SP            | Online                | R               |                 |                   | R1         | E              | AE            | R              |                   |
| Nursing/Pharmacy 7482                            | Principles of Quality Management for Medical Product Dev.          | 3       | SU            | Online                | R               |                 |                   |            | E              |               |                |                   |
| Option 2: Translational Pharmacology Focus       |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| BIOPHRM/NURSING/PHR 7560                         | Clinical Trials I: Design and Regulation                           | 3       | AU            | Online                |                 | R-CP            | R                 | R2         | E              |               |                |                   |
| BIOPHRM/NURSING/PHR 7561                         | Clinical Trials II: Site Management and Study Leadership           | 3       | SP            | Online                |                 | R-CP            | R                 | R2         | E              |               |                |                   |
| Pharmacy 7562                                    | Design and Management of Preclinical Studies                       | 3       | AU            | Online                |                 | R-TSP           |                   | S2         | E              |               |                |                   |
| Research Ethics Courses                          |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| Nursing 7781                                     | Responsible Conduct of Research                                    | 3       | AU, SP        | Online                | R               |                 | S1                | S1         | E              |               | R              |                   |
| Bioethics 6010                                   | Biomedical Research Ethics   | 3       | AU, SP        | Online                |                 | R               | S1                | S1         | E              |               |                |                   |
| Pharmacy 8520                                    | Research Ethics  | 1       | SU            | Face-to-face          |                 |                 |                   | S1         |                |               |                |                   |
| Vision Sc. 7960                                  | Ethics in Biomedical Research                                      | 2       | AU            | Face-to-face          |                 |                 |                   | S1         |                |               |                |                   |
| Biostatistics Courses                            |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| Pharmacy 7784                                    | Data Analysis & Interpretation for Clinical & Preclinical Research | 3       | AU            | Online                | R               | R-TSP           | S2                | S2         | E              |               |                |                   |
| PUBHBIO 6210                                     | Design and Analysis of Studies in Health Sciences I                | 3       | AU, SP, SU    | Online & Face-to-face |                 | R-CP            | S2                | S2         | E              |               |                |                   |
| PUBHBIO 6211                                     | Design and Analysis of Studies in Health Sciences II               | 3       | AU, SP        | Online & Face-to-face |                 | R-CP            |                   |            | E              |               |                |                   |
| Research Administration Courses                  |  |         |               |                       |                 |                 |                   |            |                |               |                |                   |
| Nursing 7404                                     | Project Management for Healthcare and Clinical Research            | 3       | SU            | Online                | R-CRM<br>E-RA   |                 |                   |            |                |               | R              |                   |
| Nursing 7481                                     | Data Management and Informatics in Clinical Research               | 3       | AU            | Online                | R-CRM<br>E-RA   |                 | R                 | S2         |                |               |                |                   |
| Pharmacy 7460                                    | Regulatory Strategy and Clinical Trial Reporting                   | 3       | SU            | Online                | R- RA<br>E-CRM  |                 |                   |            | E              | AE            |                |                   |

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|-------------------------------------|--|---------|---------------|---------------|-----------------|-----------------|--------------------------------|------------|----------------|---------------|----------------|-------------------|
|                                     |  |         |               |               | MACPR           | MS Pharmacology | Certificate in CB <sup>1</sup> | Minor ACPR | PharmD         | BS Pharm. Sc. | MS Nursing Sc. | Global One Health |
| Pharmacy 7570                       | Pharmaceutical Safety & Risk Management  | 3       | AU            | Online        | R-RA<br>E-CRM   |                 |                                |            | E              | AE            |                |                   |
| Pharmacy 7572                       | Global Regulation of Medical Products  | 3       | SP            | Online        | R-RA<br>E-CRM   |                 |                                |            | E              | AE            |                |                   |
| Nursing 7402/Pharmacy 5402          | Economic Evaluation of Healthcare Interventions<br>(equivalent course: PHR 5402 Intro. to Pharmacoeconomics) | 3       | AU, SP        | Online        | E-CRM           |                 |                                |            | E              | E             |                |                   |
| Pharmacology and Toxicology Courses |  |         |               |               |                 |                 |                                |            |                |               |                |                   |
| Pharmacy 5005                       | Fundamentals of Pathophysiology  | 3       | SU            | Online        | E-CRM           | R               |                                |            |                | **            |                |                   |
| HTHRHSC 5500                        | Introduction to Pathophysiology  | 4       | AU, SP        | Online        |                 | *               |                                |            |                |               |                |                   |
| BIOPHRM 5600                        | Intro. to General Pharmacology   | 3       | AU, SP, SU    | Online        |                 | R               |                                | S2         |                |               |                |                   |
| Pharmacy 5010                       | Fundamentals of Pharmacology   | 3       | SU            | Online        | R               |                 |                                | S2         |                |               |                | E                 |
| BIOPHRM/PHR/CBG 5700                | Introduction to Personalized Therapeutics & Pharmacogenomics   | 3       | SP            | Online        | E-CRM           | R-CP            |                                |            |                | **            |                |                   |
| Pharmacy 7580                       | Principles of Safety Pharmacology  | 3       | SP            | Online        | E-RA            | R-TSP           |                                |            | E              | AE            |                |                   |
| Pharmacy 7582                       | Organ System Toxicology  | 3       | AU            | Online        |                 | R               |                                | S2         | E              | AE            |                |                   |
| Pharmacy 7583                       | Advanced Organ Systems Toxicology and Risk Assessment  | 3       | SP            | Online        |                 | R-TSP           |                                |            | E              | **            |                |                   |
| Pharmacy 7584                       | Applied Pharmacokinetics & Pharmacodynamics  | 3       | SP            | Online        |                 | R               |                                | S2         |                | AE            |                |                   |
| Pharmacy 7586                       | Integrative in Vivo Modeling for Drug Development: Application for Safety and Clinical Pharmacology          | 3       | SU            | Online        |                 | R-TSP           |                                |            | E              |               |                |                   |
| Pharmacy 7588                       | Toxic Substances   | 3       | SU            | Online        |                 | R-TSP           |                                |            | E              | **            |                |                   |
| BIOPHRM 7550                        | Research Applications in Clinical Pharmacology   | 3       | SU            | Online        |                 | R-CP            |                                |            |                |               |                |                   |
| Culminating Project Course          |  |         |               |               |                 |                 |                                |            |                |               |                |                   |
| Pharmacy 7597                       | Scientific Writing: Preclinical Study Protocol & Manuscript Dev.   | 3       | AU, SP, SU    | Online        |                 | R-TSP           |                                |            | E              |               |                |                   |
| BIOPHRM 7598                        | Scientific Writing: Clinical Trial Protocol and Manuscript Dev.  | 3       | AU, SP, SU    | Online        |                 | R-CP            |                                |            | E              |               |                |                   |
| NURSING/PHR 7599                    | Culminating Project in Clinical Research   | 3       | AU, SP, SU    | Online        | R               |                 |                                |            |                |               |                |                   |

Semester abbreviations: AU = autumn semester, SP = spring semester, SU = summer term

Department abbreviations: CBG = Cancer Biology and Genetics; BIOPHRM = Biological Chemistry and Pharmacology; HTHRHSC = Health and Rehabilitation Sciences; PUBHBIO = Public Health Biostatistics

Program requirement abbreviations: R = Required, R-CRM = Required in Clinical Research Management Specialization, R-RA = Required in Regulatory Affairs Specialization, R-CP = Required in Clinical Pharmacology concentration, R-TSP = Required in Toxicology Safety Pharmacology concentration, R1 = Required in Minor Option 1, S1 = Select one ethics course, S2 = Select one elective for Minor Option 2, E = Elective, AE = Advanced Elective for BS Pharmaceutical Sciences Students

\* Acceptable substitute for PHR 5005, \*\* Pursuing approval as elective

<sup>1</sup> Proposed Graduate Certificate in Clinical Research; approval pending

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## Course Descriptions

Please note: All courses are offered online only unless otherwise specified.

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| <b>Bioethics 6010</b><br>3 credits<br>Autumn/Spring      | <b>Biomedical Research Ethics</b><br>The broad intent of this course is to highlight the importance of ethics in biomedical research and to explore how critical ethical thinking can be used to analyze personal decision-making, public regulation, and the law concerning advanced biomedical sciences/technologies and their clinical applications.<br>Prerequisites: none.  |
| <b>BIOPHRM 5600</b><br>3 credits<br>Autumn/Spring/Summer | <b>Introduction to General Pharmacology</b><br>Introductory course emphasizing the general principles of pharmacology using a systems-based and mechanism-based approach. The course provides a simple overview of the subject.<br>Prerequisites: Prior coursework in physiology.  |
| <b>BIOPHRM 7550</b><br>3 credits<br>Summer               | <b>Research Applications of Clinical Pharmacology</b><br>Application of basic and advanced concepts in pharmacology to contemporary research literature to solidify understanding of the pharmacologic principles underlying the individualization of drug therapy and contemporary drug development. Fundamentals of clinical pharmacology for the development, evaluation, and clinical use of pharmaceutical products.<br>Requirement in Clinical Pharmacology specialization.<br>Prerequisite: BIOPHRM 5600, HthRhSc 5510, PHR 5010, or other general pharmacology course; Pharmacy 7584 or other pharmacokinetics course. |
| <b>BIOPHRM 7598</b><br>3 credits<br>Autumn/Spring/Summer | <b>Scientific Writing: Clinical Trial Protocol and Manuscript Development</b><br>Best practices in scientific writing; development of an interventional clinical trial protocol (drug/device studies) and the generation of a manuscript for publication.<br>Prerequisite: Admission to the MS Pharmacology program or permission of the instructor.   |
| <b>HTHRHSC 5500</b><br>4 credits<br>Autumn/Spring        | <b>Introduction to Pathophysiology</b><br>Fundamental concepts of pathophysiology including etiology, signs, symptoms, diagnosis, treatment, and complications of major body system disorders.<br>Prerequisites: Physiology (EEOB 2520) or Physio 3102   |
| <b>Nursing 7404</b><br>3 credits<br>Summer               | <b>Project Management for Healthcare and Clinical Research</b><br>Principles of project management and strategic planning in healthcare, clinical research, and regulatory settings.<br>Prerequisite: Nursing/Pharmacy 7782.   |
| <b>Nursing 7481</b><br>3 credits<br>Autumn               | <b>Data Management and Informatics in Clinical Research</b><br>Introduction to fundamental principles of clinical research data management and informatics to include the acquisition and management of data during clinical research studies, including source data, data entry, data quality assurance, reporting, and security.<br>Prerequisite: Nursing/Pharmacy 7782.   |
| <b>Nursing 7781</b><br>3 credits<br>Spring               | <b>Responsible Conduct of Research</b><br>Concepts and policies for the responsible conduct of research (RCOR) and Institutional Review Boards, including leadership and team science.<br>Prerequisites: none.   |
| <b>Pharmacy 5005</b><br>3 credits<br>Summer              | <b>Fundamentals of Pathophysiology</b><br>This course provides a fundamental overview of human pathophysiology by comparing dysfunctional body processes to normal physiological function. Case studies will be applied to pathophysiological phenomena.<br>Prerequisites: none.   |

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| <b>Pharmacy 5010</b><br>3 credits<br>Summer | <b>Fundamentals of Pharmacology</b><br>This course presents an overview of basic principles underlying drug action including an investigation of current treatments for a variety of common diseases. In addition, this course will implement activities that emphasize the ethical aspects and implications of a variety of drug therapies.<br>Prerequisites: none.   |
| <b>Pharmacy 7460</b><br>3 credits<br>Summer | <b>Regulatory Strategy and Clinical Trial Reporting</b><br>Explores regulatory strategy in new medical product development and the roles of regulatory professionals. Scholarly and technical writing skills for regulatory professionals for new product submissions and Food and Drug Administration (FDA) Advisory Panels.<br>Prerequisite: Nursing/Pharmacy 7770.  |
| <b>Pharmacy 7562</b><br>3 credits<br>Autumn | <b>Design and Management of Preclinical Studies</b><br>Provides a fundamental overview of preclinical study design, methods, and regulation with an introduction to the clinical development process. Provides a synopsis of best practices of preclinical trial site and study management, quality and data management, and leadership in the context of preclinical and translational research endeavors.<br>Prerequisites: none.                                |
| <b>Pharmacy 7570</b><br>3 credits<br>Autumn | <b>Pharmaceutical Safety &amp; Risk Management</b><br>Comprehensive investigation of pharmacovigilance initiatives and pharmaceutical safety regulation. Pharmaceutical risk management in premarket testing and development, recognition of safety signals, post-approval experience, drug production, risk mitigation, and administration of pharmaceuticals.<br>Prerequisite: Nursing/Pharmacy 7770.  |
| <b>Pharmacy 7572</b><br>3 credits<br>Spring | <b>Global Regulation of Medical Products</b><br>Exploring legal issues related to clinical research and regulatory affairs. Examining the role of regulatory authorities, regulations and guidelines (US, EU and global) in new product development.<br>Prerequisites: Nursing/Pharmacy 7770.  |
| <b>Pharmacy 7580</b><br>3 credits<br>Spring | <b>Principles of Safety Pharmacology</b><br>Introduction to organ system studies of current experimental models, risk assessment, and regulatory guidelines for evaluating drug candidates in various organ systems.<br>Prerequisites: none.   |
| <b>Pharmacy 7582</b><br>3 credits<br>Autumn | <b>Organ System Toxicology</b><br>Principles of toxicology, physiology and pharmacology as they relate to adverse and unanticipated drug effects. Emphasis on cardiovascular, nervous, pulmonary, liver, and kidney systems.<br>Prerequisites: Open to students in MS Pharmacology program. Other students, including advanced undergraduate students, may enroll with permission of instructor. Completion of a basic pharmacology class useful but not required. |
| <b>Pharmacy 7583</b><br>3 credits<br>Spring | <b>Advanced Organ Systems Toxicology and Risk Assessment</b><br>Principles of risk assessment, toxicology, and physiology as they relate to effects of chemical and pharmacologic agents on the blood, immune, ocular, skin, reproductive, endocrine systems. Includes a review of chemical carcinogenesis, genetic, and developmental toxicity as they relate to chemical or drug exposure.<br>Prerequisite: Pharmacy 7582.                                       |

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| <b>Pharmacy 7584</b><br>3 credits<br>Spring                                      | <b>Applied Pharmacokinetics and Pharmacodynamics</b><br>Introduction to basic and advanced concepts in pharmacokinetics, pharmacodynamics, and pharmacology for clinical investigators and other research professionals participating in the conduct of clinical trials.<br>Prerequisite: Prior coursework in pharmacology recommended (ex., Pharmacy 4000, Pharmacy 4400, Pharmacy 5010, or BIOPHRM 5600)                                      |
| <b>Pharmacy 7586</b><br>3 credits<br>Summer                                      | <b>Integrative in Vivo Modeling for Drug Development: Application for Safety and Clinical Pharmacology</b><br>Evaluating drug effects and animal models for safety and toxicity assessment.<br>Prerequisite: Pharmacy 7582.   |
| <b>Pharmacy 7588</b><br>3 credits<br>Summer                                      | <b>Toxic Substances</b><br>Survey the effects of toxic substances on biological systems including the mechanism of action for major toxicants, sources of toxicants, signs and symptoms associated with intoxications, and methods of treatment. Substances presented will include those that may be encountered occupationally, environmentally, medically, and in the context of substance abuse.<br>Prerequisite: Pharmacy 7582 recommended. |
| <b>PHR 7597</b><br>3 credits<br>Autumn/Spring/Summer                             | <b>Scientific Writing: Preclinical Study Protocol and Manuscript Development</b><br>Best practices in scientific writing; development of an interventional (drug/device) safety or efficacy preclinical study protocol and the generation of a manuscript for publication.<br>Prerequisite: Admission to the MS Pharmacology program or permission of the instructor.   |
| <b>Pharmacy 7784</b><br>3 credits<br>Autumn                                      | <b>Data Analysis and Interpretation in Clinical and Preclinical Research</b><br>Introduction to the principles of biostatistical methods used in biomedical research. Analysis of clinical and preclinical research data and interpretation of statistical results in biomedical studies.<br>Prerequisite: none.  |
| <b>Pharmacy 8520</b><br>1 credit<br>Summer, 4-week Session 1<br>In-Person only   | <b>Research Ethics</b><br>Basic concepts of integrity in the process of research. This course fulfills NIH requirement for research ethics.<br>Prerequisite: none.  |
| <b>PUBHBIO 6210</b><br>3 credits<br>Autumn/Spring/Summer<br>Online and In-person | <b>Design and Analysis of Studies in the Health Sciences I</b><br>Theory and application of basic statistical concepts for design of studies in health sciences, integrated with statistical software applications.<br>Prerequisite: permission of instructor or enrolled in MACPR program.   |
| <b>PUBHBIO 6211</b><br>3 credits<br>Autumn/Spring<br>Online and In-person        | <b>Design and Analysis of Studies in the Health Sciences II</b><br>A second course in applied biostatistical methods with an emphasis on regression methods commonly used in the health sciences. The focus is on linear regression and ANOVA. Integrated with use of computer statistical packages.<br>Prerequisite: Grade of B- or above in PUBHBIO 6210  |
| <b>Nursing 7402/Pharmacy 5402</b><br>3 credits<br>Autumn, Spring                 | <b>Economic Evaluation of Healthcare Interventions / Introduction to Pharmacoeconomics</b><br>Introduction to economic evaluation of (pharmaceutical) healthcare interventions and services, including evaluating costs and health outcomes, using results to inform resource allocation, interpretation and evaluation of economic evaluations in the literature, and decision analysis in healthcare.<br>Prerequisite: none.                  |

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| <b>Nursing/Pharmacy 7405</b><br>3 credits<br>Spring                 | <b>Clinical Research Study and Site Management</b><br>Fundamental principles of clinical research operations from study site selection to study closure from the perspective of sponsors and clinical research sites including an introduction to database design, management, quality assurance and reporting for site and sponsor operations.<br>Prerequisite: Nursing/Pharmacy 7770.   |
| <b>Nursing/Pharmacy 7482</b><br>3 credits<br>Summer                 | <b>Principles of Quality Management for Medical Product Development</b><br>Concepts and application of total quality management for federal regulation of medical product development including drugs and medical devices.<br>Prerequisite: Nursing/Pharmacy 7770.  |
| <b>Nursing/Pharmacy 7599</b><br>3 credits<br>Autumn/Spring/Summer   | <b>Culminating Project in Clinical Research</b><br>The culminating project is an independent scholarly project that allows students to apply skills and competencies acquired across the master's program in clinical research. During the course, students will also complete their professional ePortfolio.<br>Prerequisite: Admission to the master's program in clinical research or permission of the instructor.  |
| <b>Nursing/Pharmacy 7770</b><br>3 credits<br>Autumn/Summer          | <b>Fundamentals of Medical Product Development and Regulation</b><br>Function of clinical research in medical product development and the regulatory process of new medical products. Laws and regulations concerning the development, testing, commercialization, and total product life cycle for medical products. Regulations governing the conduct of clinical research, including study sponsors, investigators, and Institutional Review Boards.<br>Prerequisites: none. |
| <b>Nursing/Pharmacy 7782</b><br>3 credits<br>Autumn                 | <b>Clinical Research Design and Methods</b><br>Study of research design and methods used in clinical research. Measurement issues, bias and confounding, statistical considerations, evaluation of published clinical research designs, and protocol and proposal development.<br>Prerequisites: none.  |
| <b>BIOPHRM/CBG/Pharmacy 5700</b><br>3 credit<br>Spring              | <b>Introduction to Personalized Therapeutics and Pharmacogenomics</b><br>Exploration of the trend to therapy tailored to the individual patient rather than "one drug fits all;" inter-individual differences in drug responses, with emphasis on genetic and genomic factors; ethical, regulatory and economic issues that impact drug therapies.<br>Prerequisite: Introductory biology course recommended.  |
| <b>BIOPHRM/Nursing/Pharmacy 7560</b><br>3 credits<br>Autumn         | <b>Clinical Trials I: Design and Regulation</b><br>This course provides a fundamental overview of clinical trial design, methods, and regulation with an emphasis on medical product development, clinical trial protocols, preclinical research requirements, and the appraisal of published clinical trials.<br>Prerequisite: none. Not open to students with credit for Nursing/PHR 7770.  |
| <b>BIOPHRM/Nursing/Pharmacy 7561</b><br>3 credits<br>Spring         | <b>Clinical Trials II: Site Management and Study Leadership</b><br>This course provides a fundamental overview of best practices of clinical trial study and site management, including an emphasis on data, safety, and quality management, and study team leadership.<br>Prerequisite: BIOPHRM/Nursing/Pharmacy 7560 or permission of the instructor. Not open to students with credit for NURSING/PHR 5402.  |
| <b>Vision Science 7960</b><br>2 credits<br>Autumn<br>In-Person only | <b>Ethics in Biomedical Research</b><br>Provides a general understanding of the issues surrounding the ethical conduct of science including issues related to research involving human subjects, scientific misconduct, and authorship of scientific papers. Real-life case studied will be used.<br>Prerequisite: none.  |

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