

**REGULATORY AFFAIRS Specialization**

**Sample Plans of Study**

**AUTUMN ENTRY – Full-time 12-Month Plan**

Please note: 12-month plan of study is only available to students entering the program in autumn semester.

Year 1 – Autumn		Year 1 – Spring		Year 1 – Summer (12-week term)	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical Product Development and Regulation	3	NURSING 7781: Responsible Conduct of Research	3	PHR 5010: Fundamentals of Pharmacology [1]	3
NURSING/PHR 7782: Clinical Research Design and Methods	3	NURSING/PHR 7405: Clinical Research Study and Site Management	3	NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev.	3
PHR 7784: Data Analysis and Interpretation in Clinical Research	3	<i>PHR 7580: Principles of Safety Pharmacology [2]</i>	3	PHR 7460: Regulatory Strategy and Writing for Medical Product Dev.	3
PHR 7570: Pharmaceutical Safety and Risk Management	3	PHR 7572: Global Regulation of Medical Products	3	NURSING/PHR 7599: Culminating Project in Clinical Research	3
	12		12		12

**AUTUMN ENTRY – Part-time 24-Month Plan**

Year 1 – Autumn		Year 1 – Spring		Year 1 – Summer (12-week term)	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical Product Development and Regulation	3	NURSING 7781: Responsible Conduct of Research	3	PHR 5010: Fundamentals of Pharmacology [1]	3
NURSING/PHR 7782: Clinical Research Design and Methods	3	NURSING/PHR 7405: Clinical Research Study and Site Management	3	NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev.	3
	6		6		6
Year 2 – Autumn		Year 2 – Spring		Year 2 – Summer (12-week term)	
Course	credits	Course	credits	Course	credits
PHR 7784: Data Analysis and Interpretation in Clinical Research	3	<i>PHR 7580: Principles of Safety Pharmacology [2]</i>	3	PHR 7460: Regulatory Strategy and Writing for Medical Product Dev.	3
PHR 7570: Pharmaceutical Safety and Risk Management	3	PHR 7572: Global Regulation of Medical Products	3	NURSING/PHR 7599: Culminating Project in Clinical Research	3
	6		6		6

The MACPR degree requires a minimum of 36 credits. Adjustments may be made to the sample plans of study as follows:

[1] Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) may substitute one of the following courses:

- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- NURSING 7404: Project Management for Healthcare and Clinical Research (3 credits, summer term)
- Or elective below [2]

[2] *Electives in italics.* May substitute one of the following electives:

- Nursing 7481: Data Management and Informatics in Clinical Research (3 credits, spring semester)
- HTHRHS 5500: Introduction to Pathophysiology (4 credits, autumn and spring semesters)
- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

**REGULATORY AFFAIRS Specialization**

**Sample Plans of Study**

**SPRING ENTRY – Part-time 24-Month Plan**

Year 1 – Spring		Year 1 – Summer (12-week term)		Year 1 – Autumn	
Course	credits	Course	credits	Course	credits
NURSING 7781: Responsible Conduct of Research	3	NURSING/PHR 7770: Fund. of Medical Product Development and Regulation	3	NURSING/PHR 7782: Clinical Research Design and Methods	3
<i>PHR 7580: Principles of Safety Pharmacology [2]</i>	3	PHR 5010: Fundamentals of Pharmacology [1]	3	PHR 7784: Data Analysis and Interpretation in Clinical Research	3
	6		6		6
Year 2 – Spring		Year 2 – Summer (12-week term)		Year 2 – Autumn	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7405: Clinical Research Study and Site Management	3	NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev.	3	PHR 7570: Pharmaceutical Safety and Risk Management	3
PHR 7572: Global Regulation of Medical Products	3	PHR 7460: Regulatory Strategy and Writing for Medical Product Dev.	3	NURSING/PHR 7599: Culminating Project in Clinical Research	3
	6		6		6

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[1] Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) may substitute one of the following courses:

- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- NURSING 7404: Project Management for Healthcare and Clinical Research (3 credits, summer term)
- Or elective below [2]

[2] *Electives in italics.* May substitute one of the following electives:

- Nursing 7481: Data Management and Informatics in Clinical Research (3 credits, spring semester)
- HTHRHSC 5500: Introduction to Pathophysiology (4 credits, autumn and spring semesters)
- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

**REGULATORY AFFAIRS Specialization**

**Sample Plans of Study**

**SUMMER ENTRY – Part-time 24-Month Plan**

Year 1 – Summer (12-week term)		Year 1 – Autumn		Year 1 – Spring	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical Product Development and Regulation	3	NURSING/PHR 7782: Clinical Research Design and Methods	3	NURSING 7781: Responsible Conduct of Research	3
PHR 5010: Fundamentals of Pharmacology [1]	3	PHR 7784: Data Analysis and Interpretation in Clinical Research	3	NURSING/PHR 7405: Clinical Research Study and Site Management	3
	6		6		6
Year 2 – Summer (12-week term)		Year 2 – Autumn		Year 2 – Spring	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev.	3	PHR 7570: Pharmaceutical Safety and Risk Management	3	PHR 7572: Global Regulation of Medical Products	3
PHR 7460: Regulatory Strategy and Writing for Medical Product Dev.	3	NURSING/PHR 7599: Culminating Project in Clinical Research	3	<i>PHR 7580: Principles of Safety Pharmacology [2]</i>	3
	6		6		6

The MACPR degree requires a minimum of 36 credits. Adjustments may be made to the sample plans of study as follows:

[1] Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BPS graduates) may substitute one of the following courses:

- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- NURSING 7404: Project Management for Healthcare and Clinical Research (3 credits, summer term)
- Or elective below [2]

[2] *Electives in italics.* May substitute one of the following electives:

- Nursing 7481: Data Management and Informatics in Clinical Research (3 credits, spring semester)
- HTRHSC 5500: Introduction to Pathophysiology (4 credits, autumn and spring semesters)
- PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)