

Elective Subject

(Academic Course 2024-2025)

Subject title: INITIATION TO CLINICAL RESEARCH IN NURSING

Code:

Subject: Elective

Responsibility Center: Faculty of Nursing, Physiotherapy and Podiatry

Credits: 3 ECTS

Number of places offered:

	Total (30% attendance)	Theory	Seminars	Practices	Others
Classroom activities	30	8	2	20	--

Course schedule: (semester, day and schedule): 1st Semester (Start in September 2024); Tuesday from 2:30 p.m. to 3:30 p.m.

STUDENT PROFILE (University degrees for which they are offered, if applicable)

Degree in Nursing

BRIEF DESCRIPTOR

Clinical research aims to generate knowledge and solve problems for its subsequent application to daily clinical practice. Clinical research nursing requires specific knowledge that is essential for the proper development of clinical research and that is the objective of this Initiation to Clinical Research in Nursing program. With the development of this subject, it is intended to provide basic tools to the student that allow them to start in clinical research.

OBJECTIVES

- Acquire basic knowledge in methodology, ethics, and legislation of clinical research.
- Train the student in the care of patients and healthy volunteers participating in clinical research.
- Develop the basic knowledge necessary to coordinate clinical trials in different therapeutic areas.
- Acquire practical skills in nursing tasks typical of research and development of clinical trials.

ACADEMIC SKILLS

Knowledge

Clinical Trial Methodology: Understanding the stages and processes involved in conducting clinical trials.

Research Ethics: Grasping the fundamental ethical principles guiding clinical research.

Good Clinical Practice: Knowing the international standards for the design, conduct, recording, and reporting of clinical trials.

Cardiopulmonary Resuscitation and Emergency Situation Management: Learning basic and advanced life support techniques.

Skills

Scheduling and Monitoring Visits and Complementary Tests: Ability to organize and manage the logistical aspects of clinical trials.

Equipment and Material Maintenance and Temperature Logging: Skill in ensuring the proper functioning and conservation of the necessary equipment in a clinical trial.

Handling, Processing, and Shipping Biological Samples: Proficiency in the proper handling of

samples for subsequent analysis.

Medication Administration and Control: Competence in managing the medication of trial participants according to established protocols.

Competencies

Active Participation in Research Meetings: Ability to effectively contribute to discussions and decisions in clinical trials.

Assessment and Management of Pharmacological Adverse Effects: Competence in identifying, evaluating, and reporting potential adverse drug effects.

Comprehensive Health Education: Skill in providing information and support to patients, addressing psychological and socio-family aspects related to their treatment.

LEARNING OUTCOMES

Knowledge

Clinical Trial Methodology: Students will be able to describe in detail the phases of a clinical trial, including design, implementation, analysis, and reporting of results.

Research Ethics: They will be capable of identifying ethical dilemmas in clinical research and applying ethical principles in decision-making.

Good Clinical Practice: They will demonstrate knowledge of good clinical practice guidelines and their application in the context of clinical research.

Cardiopulmonary Resuscitation and Emergency Situation Management: They will be able to perform basic and advanced cardiopulmonary resuscitation techniques and handle medical emergencies.

Skills

Scheduling and Monitoring Visits and Complementary Tests: Students will develop the ability to coordinate and manage patient visits and required tests in the trial.

Equipment and Material Maintenance and Temperature Logging: They will be capable of maintaining research equipment in optimal conditions and making accurate temperature logs for medication conservation.

Handling, Processing, and Shipping Biological Samples: They will acquire skills for proper handling of biological samples, ensuring their integrity and quality for analysis.

Medication Administration and Control: They will be able to administer and control medication for trial participants, ensuring protocol compliance.

Competencies

Active Participation in Research Meetings: Students will be able to effectively contribute in research meetings, offering ideas and solutions to clinical problems.

Assessment and Management of Pharmacological Adverse Effects: They will develop the competence to identify and manage adverse effects, ensuring patient safety.

Comprehensive Health Education: They will be competent in providing health education to patients, addressing their psychological and socio-family support needs, thus improving their quality of life and treatment adherence.

TEACHING ACTIVITIES (theoretical, practical, seminars, workshops, etc.)

The subject will be focus on theoretical content, in a master class format, and practical content in a clinical practice format.
It is complemented with activities in the Virtual Campus and with workshops in the clinical part.

CONTENT TOPICS

Theoretical program

Clinical trial methodology.
Research ethics.
Good clinical practices
Cardiopulmonary resuscitation and management of emergency situations.

Practical program.

It will consist of weeks of rotation supervised by the HC San Carlos Services in small group people, in the morning or afternoon, in the Clinical Research Units (Clinical Research Nursing Unit) and Nursing Consultation.

During this period, they will become familiar with the tasks of clinical research nursing in different fields, with a training program based on the following activities:

- . Participation in research meetings in the different phases of the development of a clinical trial.
- . Scheduling visits and complementary tests.
- . Maintenance of equipment and material.
- . Records of temperatures in medication storage areas.
- . Record of vital signs of trial participants.
- . Handling, processing, and shipping of biological samples.
- . Specific procedures for pharmacokinetic studies.
- . Assessment of the peripheral venous system for central venous access and care of central catheters.
- . Realization and sending of centralized electrocardiograms.
- . Administration and control of oral, intravenous, subcutaneous, or intraperitoneal medication, with special attention to the accounting of oral medication according to the trial procedures.
- . Completion of scales and questionnaires (quality of life questionnaires, pain scales, analgesic consumption, medication diaries).
- . Knowledge and management of pharmacological adverse effects.
- . Comprehensive health education aimed at cancer patients in aspects related to psychological situation and socio-family support, adherence to treatment, toxicity control and appointment management.

EVALUATION

REGULAR CONVOCATION			
EVALUATION ACTIVITY	WEIGHTING	REMARKS	MAXIMUM SCORE
Master class attendance	10%		1
Theoretical activities	10%		1
Practice activities	10%		1
Clinical practices	70%		7
EXTRAORDINARY CALL			
EVALUATION ACTIVITY	WEIGHTING	REMARKS	MAXIMUM SCORE
Theoretical test	100%		10

BIBLIOGRAPHY - INTERNET Resources

- M. Jiménez-Navarro, N. Romero-Rodríguez, F.J. Cabrera-Bueno, A. Muñoz-García.
Investigar en hospitales asistenciales: ¿lujo o necesidad? .Cardiocre, 46 (2011), pp. 125-126.
- Helsinki Declaration. Recommendations to guide physicians in biomedical research in humans [accessed 26 Mar 2012]. Available in: http://www.cnrha.msssi.gob.es/bioetica/pdf/declaracion_Helsinki.pdf
- Elizabeth Ness, RN, MS. The Role of the Clinical Trials Nurse. Center for Cancer Research, NCI [consultado Jun 2011]. Disponible en: <http://www.swog.org/Visitors/Download/Meetings/CTNrole.pdf>
- Royal College of Surgeons in Ireland [accessed 20 Mar 2012]. Disponible in: http://www.rcsi.ie/cat_course_detail.jsp?n=223&p=142&emID=60
- National Institutes of Health Clinical Center [consultado 20 Mar 2012]. Disponible in: http://clinicalcenter.nih.gov/nursing/crn/crn_2010.
- C. Mori, N. Mullen, E. Hill. Describing the role of the clinical research nurse. Research Practitioner, (2007),
- Conferencia Internacional de Armonización de los Requisitos Técnicos para el Registro de fármacos de uso en humanos. Guía ICH Tripartita y Armonizada para la Buena Práctica Médica (BPC). Ginebra; 1996.
- I. Torres, Y. Cachimalle, B. Rodríguez, A.B. Jiménez, Y. Parra.
El cumplimiento de la buena práctica de enfermería en los ensayos clínicos.
Invest Educ Enferm, 29 (2011), pp. 118-125
- A.Guerrero-Molina, G. Millán-Vázquez; C. Cruzado-Álvarez; M. Medina-Fernández. The clinical trials nurse in the hospital setting: An unknown figure. Cardiocre.2013; 48(2): 75-78.

TEACHING STAFF *(It should be indicated whether teachers have completed all their teaching dedication or not)

Teacher Responsible (coordinator): Carmen Martínez Rincón (nutrias@ucm.es)
Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.
Teaching dedication: She does not have full dedication to teaching

Teachers:

Name: Pilar Mori Vara (pmorivar@ucm.es)
Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.
Teaching dedication: She does not have full dedication to teaching

Name: Tamara Raquel Velasco Sanz (tavela01@ucm.es)
Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.
Teaching dedication: She does not have full dedication to teaching

Name: María José González Sanavia (marjgonz@ucm.es)
Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.
Teaching dedication: She does not have full dedication to teaching

Clinical faculty of the San Carlos Clinical Hospital of the Oncology Services.
Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.
Teaching dedication: She does not have full dedication to teaching.