



Optional Subject of DEGREE (Academic year 2023-2024)

Name SUBJECT: INITIATION TO CLINICAL RESEARCH IN NURSING

Code:

Type of subject (character): OPTIONAL

Center responsible: FACULTY OF NURSING, PHYSIOTHERAPY AND PODIATRY

Credits: 3

Number of places offered: 30

	Total (32%)	Toorie	Practices	Outros
Face-to-face hours	30 h	8 h	20 h	2 h

Proposed calendar and schedule: Group A: 1st Semester (Start in September 2023); Group B: 2nd Semester (Starting in February 2024), Tuesday from 2:30 p.m. to 3:30 p.m.

Student profile (Degrees offered, if any): 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.

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COMPETENCES

Understands the role of the coordinating nurse in a clinical trial.

- Recognizes clinical situations that require the intervention of the research team.
- Prepares, manages, and develops clinical trials at a basic level, in any area of knowledge.

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- Knows the different research studies and the role of the nurse or coordinator of clinical trials.
- Interprets the results of a clinical trial.
- Knows the ethical, regulatory, and good clinical practice standards in clinical trials.
- Knows the role of the clinical trial coordinator.
- Handles data, biological samples, and medication from a clinical trial.
- Manages the recruitment and visits of participants in clinical trials.
- Identifies emergency situations that require the intervention of the research team.
- Organize and plan, together with the trial coordinator, its development in pathologies under study.

LEARNING OUTCOMES

At the end of the course, the student will be able to:

- 1. Know the main clinical research designs.
- 2. Use strategies that facilitate the care of volunteer patients who participate in clinical research studies.
- 3. Identify the main problems and difficulties when coordinating a clinical trial.
- 4. Properly handle the biological samples and the medication of a clinical trial.
- 5. Identify emergency situations that occur in a clinical trial

TEACHING ACTIVITIES (theoretical, practical, seminars, workshops, etc.)
The subject will be developed through master classes and practical seminars in hospital clinical
services.

AGENDA/ CONTENTS

Theoretical program

Clinical trial methodology.

Research ethics.

Good clinical practices

Coordination of clinical trials

Cardiopulmonary resuscitation and management of emergency situations.

Practical program.

It will consist of three weeks of rotation supervised by the HC San Carlos Services in small groups of three 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

In the evaluation of the subject the following points will be considered:

- 1. The student will develop different theoretical-practical activities that will be detailed in the virtual campus and that will be related to what is taught in the theoretical classes. The completion of these activities will constitute 40% of the final grade.
- 2. Assistance to practical seminars. Attendance at practical seminars is mandatory and will constitute 60% of the final grade. The lack of attendance at practical seminars must be duly justified.
- 3. To pass the subject it will be necessary to obtain a grade of equal to or greater than five in the theoretical activities and to have completed the practical seminars.

Bibliografía:

M. Jiménez-Navarro, N. Romero-Rodriguez, F.J. Cabrera-Bueno, A. Muñoz-García.

Investigar en hospitales asistenciales: ¿lujo o necesidad?.

Cardiocore, 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

ein: 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\iot\iot\end{black}emID=60

National Institutes of Health Clinical Center [consultado 20 Mar 2012]. Disponible inn: http://clinicalcenter.nih.gov/nursing/crn/crn 2010.html

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 Farmacéuticos 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 clínical trials nurse in the hospital setting: An unknown figure. Cardiocore.2013; 48(2): 75-78.

TEACHING STAFF* (It must be indicated if the teaching staff has already completed all their teaching dedication or not)

Responsible teacher:

Name: Carmen Martínez Rincón (nutrias@ucm.es) (She does not have full dedication to teaching)

Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.

Other teachers:

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

Name: Tamara Raquel Velasco Sanz (tavela01@ucm.es) (She does not have full dedication to teaching)

Department: Department of Nursing. Faculty of Nursing, Physiotherapy and Podiatry.

Name: María José González Sanavia (marjgonz@ucm.es) (She does not have full dedication to

teaching)

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Clinical faculty of the San Carlos Clinical Hospital of the Oncology and Cardiovascular Services.