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國立臺灣大學 115 學年度碩士班招生考試試題

科目： 臨床研究護理學

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選擇題，一題五分，共 20 題。

1. In Taiwan, which regulatory authority oversees the approval of clinical trials involving drugs?
 - A. 疾病管制署 (CDC, Centers for Disease Control)
 - B. 食品藥物管理署 (TFDA, Taiwan Food and Drug Administration)
 - C. 中央健保署 (NHIA, National Health Insurance Administration)
 - D. 研究倫理審查委員會 (IRB, Institutional Review Board)

2. Which organization typically reviews the ethical aspects of a clinical study in Taiwan?
 - A. Hospital Ethics Club
 - B. Institutional Review Board
 - C. Researcher Peer Committee
 - D. Clinical Trial Monitoring Board

3. Which historical event strongly influenced the development of modern research ethics guidelines?
 - A. World War I nursing development
 - B. The Tuskegee Syphilis Study
 - C. Discovery of antibiotics
 - D. The SARS outbreak

4. The Belmont Principle of Beneficence refers to:
 - A. Protecting participants' identities
 - B. Selecting subjects equitably
 - C. Ensuring risks are minimized and benefits maximized
 - D. Allowing participants to withdraw freely

5. Which of the following groups is most commonly considered a vulnerable population in human subjects' research?
 - A. Adults aged 65 years and older
 - B. Hospital staff
 - C. Immigrants
 - D. College students

6. Which phase of a clinical trial primarily evaluates safety and dosage?
 - A. Phase I
 - B. Phase II
 - C. Phase III
 - D. Phase IV

7. What does "adverse event (AE)" refer to in clinical research?
 - A. Only medical problems proven to be caused by the study treatment
 - B. Any unfavorable medical occurrence during study participation
 - C. Only lab-confirmed injuries
 - D. Any administrative error in study documentation

8. Which of the following is a Phase IV study purpose?
 - A. First-in-human safety testing

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- B. Efficacy testing in small groups
- C. Comparing treatment with placebo
- D. Post-marketing surveillance and long-term safety

9. In Taiwan, which professionals may serve as principal investigators in drug clinical trials?

- A. Pharmacists
- B. Nurses
- C. Dentists
- D. All of above

10. Which of the following best describes *source data*?

- A. Records or documents that are generated solely for financial or administrative auditing purposes
- B. Data summarized in final publications
- C. Data that exist only after being entered into statistical software or databases for later statistical analysis
- D. Certified copies of original records of clinical findings

11. A clinical research nurse identifies that a participant did not follow medication instructions. This is an example of:

- A. Participant withdrawal
- B. Loss to follow-up
- C. Protocol deviation
- D. Adverse event reporting error

12. Which of the following is the primary goal of clinical research?

- A. To increase hospital revenue
- B. To provide guaranteed effective treatments
- C. To generate scientific evidence for patient care
- D. To replace clinical practice guidelines

13. In Taiwan, the role of Clinical Research Nurses has expanded significantly primarily because of which of the following?

- A. A national emphasis on improving clinical research quality
- B. Decreased research funding and fewer clinical trials in the country
- C. Reduced hospital staffing that limits nurses' involvement in clinical research
- D. A decline in clinical trial participation

14. A participant states that they would like to withdraw from a clinical trial due to transportation problems. What is the *most appropriate* action for the Clinical Research Nurse to take?

- A. Record the event as an adverse event
- B. Arrange appropriate safety follow-up and documentation
- C. Report the participant to the hospital legal department for refusing participation
- D. Ask the investigator to apply strong pressure to convince the participant to remain in the study

15. A patient with lung cancer who is enrolled in a clinical trial reports new-onset shortness of breath after taking the investigational drug. The clinical research nurse places both hands on the patient's posterior chest wall and asks the patient to repeatedly say "ninety-nine." What is the nurse assessing?

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- A. Tactile fremitus
- B. Transmitted voice sounds
- C. Weber test
- D. Memory test

16. If the test above demonstrates increased tactile fremitus, which of the following is the most likely cause?

- A. Chronic obstructive pulmonary disease (COPD)
- B. Pleural effusion
- C. Infiltrating tumor
- D. Pneumonia

Please read the abstract of the following article and answer Questions 17–20:

Gale, N. K., Boland, J., Jones, C. M., & Ryall, S. (2019). "Like a nurse but not a nurse": Clinical Research Practitioners and the evolution of the clinical research delivery workforce in the NHS. *Health Research Policy and Systems*, 17(1), 88.

Background

Clinical research is increasing across the United Kingdom. Within the context of a shortage of nurses, trusts have struggled to maintain research capacity. In order to meet staffing demands, trusts have increasingly turned to Clinical Research Practitioners (CRPs) to assist in the delivery of clinical research. Initially an ad hoc workforce, the CRP role is being formalised and professionalised. This study is a close examination of the clinical research delivery workforce at one research-intensive acute trust in the United Kingdom, with a focus on the emerging CRP staff group.

Methods

The study was conducted in a large inner-city teaching hospital (acute trust) in London, United Kingdom. Data were collected between September and December 2017. Twenty-five staff were interviewed across 11 different directorates. Interviews were semi-structured with an overall focus on research staff backgrounds and roles, as well as their perceptions and experiences of careers in research. The data were managed using NVivo 11 software and analysed thematically.

Results

CRPs are drawn from a wider pool of educational and employment backgrounds than their nurse colleagues, and actively seek out work in health research. CRPs receive on-the-job training to acquire the competencies that are necessary for them to carry out their work. The CRP role, which began in an ad hoc manner, has become regularised, yet remains to be well defined, which can be a source of frustration for CRPs and those who work with them.

17. According to the abstract, what caused the medical institutions to view CRPs as an important workforce?

- A. Shortage of CRPs
- B. Poorer quality of research
- C. Government requirement
- D. Understaffing of nurses

18. What is the most likely research design of the study?

- A. Expert opinion
- B. Qualitative descriptive study
- C. Correlational study
- D. Quasi-experimental study

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19. What is the primary research aim?

- A. To explore CRPs' roles and career pathways from their own perspectives
- B. To compare CRPs' roles and career pathways between CRPs with different educational backgrounds
- C. To investigate factors influencing CRPs' roles and career pathways
- D. To understand CRPs' roles and career pathways by clinical observations

20. What conclusion is the most reasonable based on the study findings?

- A. Other healthcare providers know well about CRPs' roles
- B. There is a severe nursing shortage which threatens study quality
- C. To define CRP roles clearly may offset CRPs' work frustration
- D. CRPs with diverse educational backgrounds seek work in health research more actively

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