一、美國有學術研究單位已宣佈正式開始首例針對某神經性疾病應用人體胚胎幹細胞進行移植治療之臨床試驗與研究。若您是在台灣執行此類型研究的臨床研究護理師，請回答下列問題：

(1) 請您依「臨床試驗與分期」的概念，說明其應屬於第幾期的臨床試驗？(5%)

(2) 從我國政府、計劃主持人及臨床研究護理師的角度，闡述此試驗案可能應關注的內容包括哪些 (10%)？其立論依據為何 (5%)？

二、請您就護理專業角色發展的觀點，試著回答下列問題：

(1) 說明護理人員拓展「臨床研究護理師」進階實務角色的可能性及將教育程度提升至碩士層級的必要性與理由為何？ (10%)

(2) 臨床研究護理師應提升的「進階實務護理 (advanced practice nursing )」能力有哪些？ (10%)

(3) 您個人認為「臨床研究護理師」在發展護理專業進階角色時，所遭遇到的瓶頸或困境為何，並請提出適切可行之因應方法與解決策略。 (10%)

三、請闡述「實驗設計法(experimental design)」所必須具備的三個特點，並加以說明之；並請您舉出某一「護理研究案例」它是如何來運作此三特點。 (20%)

四、針對臨床試驗受試者之照護，請比較分析「臨床研究護理師」與「臨床護理師」各自所扮演的角色功能之異同點。 (15%)

五、請將下列這段英文敘述逐字翻譯成中文，以忠實呈現其意涵。 (15%)

Federal regulations and ethical principles require every research participant be fully informed of the basic elements of the research study prior to enrollment. Obtaining informed consent is a difficult task. The CPHS approved Consent Form contain the elements needed to ensure informed consent. However obtaining informed consent consists of more than just the Form – it is a process and an ongoing dialog with the potential participant.

The CPHS is introducing a tool to assist in the consent process. The tool is an evaluation procedure designed to enhance the communication between researcher and potential participant. The tool is referred to as "Informed Consent Evaluation Feedback Tool" (ICE FT). The ICE FT is a simple list of questions which include the basic elements of informed consent. The ICE FT can be used *during* the consent process in order to evaluate the level of understanding of the potential research participant.

Using the ICE FT, the researcher can evaluate, in real time, the level of understanding of the potential participant. The participant should not enroll in the research study until both the researcher and the participant are confident of his/her understanding of the basic elements of the informed consent.

In addition, the ICE FT can be used as a recording mechanism that can document the discussions that took place. For example, the researcher can take notes on the ICE FT and the completed ICE FT can become part of the study record. It can also be used as a source of reference as the participant proceeds in the study.

試題隨卷繳回