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Administrative Medicine Part II Fellowship Examination 2010

Q3 You are the Clinical Service Coordinator (Medical Stream) and Chair of the Hospital Research Ethics Committee of a large metropolitan hospital with a strong research reputation.

You are approached by the Committee's secretary who tells you that she has heard from informal channels that the Department of Urology has successfully solicited a donation from an anonymous donor to install a new Veridex machine in their Department. The Veridex machine is leading edge technology which can detect and count circulating tumour cells which in turn can guide therapy and prognosis. This is the first machine of its type in Hong Kong. The secretary said the only vendor of the machine has lent the machine to the department for trial and that the Urologists are using blood samples taken for other routine testing and submitting them to testing on this machine without patient consent.

What ethical and clinical governance issues arise in this scenario and how would you manage them?



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Q3 Key Points

For Examiner

Introduction

Clinical governance
Research ethics

Clinical governance

Introduction of new technology – completed appropriately? Justification, expected outcomes, costs, complications, balance, reporting?

Research Ethics

Protect patients, protect investigators
Levels of need for informed consent – basis for each level
Screening vs diagnosis
Costs associated, balance

Approach

Fact finding – is the rumour true?
What governance process was followed?
Meet with people who now need to submit ethics proposal and explain the issues....