Research in trouble?

Medical Leader	
Medical Expert	•
Communicator	
Advocate	•
Scholar	•
Professional	
Collaborator	
Manager	

2014 (November) - DAY 1 – Q4

You are the Director of Medical Services for a large regional hospital. Your hospital has a distinguished history of medical research and your hospital specialists have been able to access resources to support research through application to an independent community-based research fund. The hospital is affiliated to a University Clinical Teaching facility and many of your clinicians have either joint appointments with the University or honorary academic titles. This has proved to be a real benefit in the attraction and retention of good quality specialist staff.

One afternoon, you are approached by the Clinical Trials Pharmacist funded through the research foundation with concerns over a recently-approved research project to investigate the benefits of a red-wine extract in slowing the progression of cardiac disease in a randomised placebo-controlled trial in patients who have had cardiac stenting procedures performed. This trial had been approved through the jurisdictional scientific and ethical review committees

The pharmacist is especially concerned that the researchers (one of whom is a Senior Registrar completing advanced specialist training) have not yet provided any documentation that the red-wine extract (which has been imported from an overseas supplier and not licensed by your national health authority) meets appropriate pharmaceutical manufacturing standards. She also says that the stocks of the study agent have not been provided to her for appropriate storage and distribution and she has not yet been able to secure an appropriate placebo. Despite this, she has been asked to supply placebo to two patients who have already been enrolled in the trial by the Senior Registrar.

You are aware that the launch of this research was well publicised in the local media, supported by the local wine industry and that the researchers wanted to get the trial underway as soon as possible to capitalise on this publicity.

However, you can find no evidence that this trial has been formally notified to your national therapeutic products authority (such as by completion of a Clinical Trials Notification).

Questions

1. What are the issues raised by this scenario?
2. Outline your plan of action.

Guidance for Censors:

ISSUES

1. **Governance / management of a research program that appears to be in breach of appropriate standards**
2. **Credentialing / Scope of Practice – how do you ensure that your medical staff are appropriately trained in research techniques and the principles of research governance**

- First priority is the safety of the patients recruited into this trial.
- Immediately notify the investigators that recruitment into the trial is to cease immediately.
- Demand a copy of a Clinical Trials Notification form and an explanation as to why this has not been submitted previously. Candidates may be able to discuss the risks around importation of non-licensed therapeutic products into the jurisdiction.
- Notify the supervising Ethics Committee and recommend the suspension of Ethical approval pending clarification and rectification of the pharmacist's concerns.
- Open disclosure to any patients recruited into the trial as well as a review of their clinical condition by an appropriate specialist to ensure no physical harm.
- Review indemnification arrangements for institutional research and notify insurer.
- Review the research proposal as submitted for review, particularly the research credentials of the Registrar and Supervisor. Has the Registrar undertaken any orientation or training in research applications, research methodology and principles of good research governance? What are the responsibilities of the Registrar's Supervisor?
- Should your clinical staff be separately credentialed to undertake clinical research? [for example, demonstrate training in research methods, awareness of relevant national statements regarding ethical research (Australian candidates should name the National Statement on Ethical Conduct in Human Research 2007 / 2012) and New Zealand candidates, the NZ Health Consumers Code of Rights]
- Management of media and reputational risks
- What is the role of the learned College with regard to the Advanced Trainee? Does it have any standards around supervision of Advanced Trainees particularly in relation to a research project which is integral to Advanced Training?
- What systems does the organisation have to monitor research one approved and commenced?