

## **Association of Clinical Pharmacology Units (ACPU)**

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### **Ethics Case Studies**

**David Forster, JD  
Annette Rid, MD  
Elyse I. Summers, JD**

#### **Ethics Cases, Healthy Phase 1 Subjects Case 1**

- A Phase I unit policy requires a body and luggage search for all healthy subjects. A subject complains to the IRB that this policy violates the Belmont Report Principle of Respect for Persons.

### **Ethics Cases, Healthy Phase 1 Subjects Case 1, continued**

- Is it more acceptable to use a metal detector wand rather than a body search?

### **Ethics Cases, Healthy Phase 1 Subjects Case 2**

- A subject is in a 2-week in-house Phase I study. He has an argument by phone with his girlfriend, and decides to drop out of the study a half hour before the final blood draw to go find her.
- The consent form states that all payments will be pro-rated if the subject drops out of the study.
- The unit decides to pay only half of the total sum to this subject because his reason for leaving was not compelling.

### Ethics Cases, Healthy Phase 1 Subjects Case 3

- A phase I study coordinator is doing the initial consent for a healthy subject. She has often seen him panhandling outside of a liquor store down the street.
- He states that he does not drink, and his screening blood tests are negative for alcohol. Regular alcohol use is an exclusion criteria for this study. Should she allow him to enroll?

### Ethics Cases, Healthy Phase 1 Subjects Case 4

- A phase I unit traditionally recruits subjects through newspaper and radio advertisements.
- A new recruitment specialist joins the unit, and suggests that they post fliers on telephone poles where day laborers collect to be hired by contractors and homeowners.
- She recommends that the poster be in both Spanish and English.

### **Ethics Cases, Healthy Phase 1 Subjects Case 4, continued**

- The same recruitment specialist later suggests that they post fliers in local homeless shelters.

### **Ethics Cases, Phase I Subjects with Cancer Case 1**

- A phase I study of a new chemotherapy agent is proposed for subjects with end-stage renal cancer who have failed all standard treatment with a prognosis of 6 months to live. The sponsor proposes a double blinded, randomized protocol with subjects receiving either placebo or the study agent.
- If the tumor shrinks or stays the same size, the subjects remain on their arm. If the tumor grows, the subjects are unblinded and if they are on placebo they are placed on the active agent arm.
- Is this ethical?

### Ethics Cases, Phase I Subjects with Cancer Case 2

- A phase I study of a new chemotherapy agent is proposed for pancreatic cancer. The sponsor proposes a double blind, randomized, placebo controlled study design with the new agent added on to standard chemotherapy treatment. The protocol specifies that if subjects are on the placebo arm, they cannot cross over to the active agent arm or receive the investigational drug through treatment use.

### Ethics Cases, Phase I Subjects with Cancer Case 2, continued

- The FDA has reviewed the protocol.
- The investigator asks the sponsor to change the protocol to allow the cross over of subjects on placebo, but the sponsor refuses to do so based on concerns about scientific validity and the fact that they don't want to go back to FDA.
- Should the investigator conduct the study?