**Good Clinical Practice Q&A**

**Do subjects who decline to participate in research need protection, as well as subjects who participate?**

In an ongoing study, funded by the National Institute of Mental Health and published in IRB: Ethics & Human Research from the Hastings Center in 2012, of what influences prisoners to decide to participate in research, authors Stiles et al. realized it was difficult to ensure that prisoners were voluntarily enrolling in their study, rather than enrolling because they were afraid of negative consequences from prison administrators if they declined. The authors stated that deception may be necessary and even ethically justified as a means for researchers to protect decliners from those who might harm them because they chose not to enroll in a study. People in need of such protections would include prisoners and others in vulnerable circumstances, such as students.

Although they believe there is great concern about protecting those who participate in research, little if any concern has been expressed in the literature about protecting individuals who were invited to participate but did not. However, there are several situations in which potential participants may experience negative consequences if they choose not to participate, for example, in the prison setting, where the power imbalance is obvious and the history of research is not a positive one.

The authors offer several options to protect decliners from possible adverse consequences. The authors concluded that deception was ethically justified to protect inmates who did not want to volunteer for their study. They protected these people by giving them the option to stay with the researchers for as long as it would take participants to complete the study. The idea was to make it difficult for corrections staff to distinguish the participants from the decliners. The authors proposed other options for protecting people who decline to volunteer for studies, including having the researchers say these people did not meet the study’s eligibility criteria. The authors also identified other populations who are vulnerable to harm if they decline to participate in research: students concerned that their grades will be affected if they don’t enroll in their professors’ studies and patients worried that the quality of their medical care will suffer if they do not enroll in their doctors’ studies.

**Source**