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Contact: Jim Newman 503 494-8231, newmanj@ohsu.edu

Are Some Cancer Patients Involved in Clinical Trials Too Optimistic? Why?

PORTLAND, Ore. – Optimism is healthy for any person battling cancer and taking part in a clinical trial. But if a person is unrealistically optimistic, is it a problem? New research published this week in the journal *IRB: Ethics & Human Research* focuses on this issue. Oregon Health & Science University took part in the newly published research along with investigators from Columbia University, The University of Chicago, The University of Arizona, Beth Israel Comprehensive Cancer Center (Manhattan) and the National Institutes of Health.

“Our research, which was funded by the NCI, focused on gaining greater insight into why some study subjects participating in early phase cancer trials report high expectations for therapeutic benefit,” explained **Lynn Jansen, R.N., Ph.D.**, the Madeline Brill Nelson Chair of Ethics Education in the OHSU Center for Ethics in Health Care and a member of the OHSU Knight Cancer Institute.

“This is an ethically important question that reaches to the heart of informed consent. Informed consent is the process to help ensure that patients understand the benefits/risks of the research they are taking part in and are able to accurately apply that information to themselves. Reports of high expectations for therapeutic benefit are particularly troubling in phase I clinical trials, which are aimed at determining whether a treatment is safe. Later stages determine the therapy’s effectiveness.”

Because cancer is such a complex disease, the chances of improvement or recovery from a therapy in the early stages of a cancer trial are relatively small, yet several studies have shown that subjects strongly believe the experimental agent being tested in these trials will assist them. The persistence of these high expectations has led many to worry about whether something has gone wrong in the informed consent process.

This research provides preliminary data to suggest that these reported high expectations may actually be the result of a psychological bias (known as unrealistic optimism) that distorts the way people apply information about risks and benefits to themselves.

To conduct the research, investigators surveyed 72 cancer study subjects taking part in Phase I, Phase I/II and Phase II clinical trials in New York State in 2008 and 2009. When the results were examined, it was determined that a significant number of study subjects said that they were above average in two areas: their chances of experiencing a health benefit from participating in the trial and their chances of having their cancer controlled from participating in the trial. They also thought that they were below average in their chances of experiencing a health problem from participating in the trial.

When there are no known factors that might make some individuals more or less susceptible to risk or benefit – such as participation in an early phase oncology trial - an individual's claim that he/she is more likely to receive benefit than others enrolled in the same trial and less likely to experience a health problem provides direct evidence that he/she is unrealistically optimistic about these events.

Importantly, these expectations were not significantly related to a misunderstanding on the part of subjects about the nature and purpose of the trial in which they were participating. Instead, high expectations for benefit were linked to the way in which the study subjects themselves processed this information

“Our next step is to gain a better understanding of where this unrealistic optimism comes from,” added Jansen. “Once we can figure that out, we will have a better idea of how to help subjects more clearly appreciate the risks and benefits associated with research and this will improve the informed consent process.

About OHSU

Oregon Health & Science University is the state’s only health and research university, and only academic health center. As Portland's largest employer and the fourth largest in Oregon (excluding government), OHSU's size contributes to its ability to provide many services and community support activities not found anywhere else in the state. It serves more than 184,000 patients, and is a conduit for learning for more than 3,900 students and trainees. OHSU is the source of more than 200 community outreach programs that bring health and education services to each county in the state.

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