

Penn-developed online informed consent tool could boost number of patients in cancer clinical trials

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A new multimedia informed consent tool accessed via the Internet may make it easier for cancer patients to understand and feel comfortable enrolling in clinical trials, according a study conducted by researchers in the Perelman School of Medicine at the University of Pennsylvania that will be presented at the American Society for Radiation Oncology's (ASTRO) 53rd Annual Meeting. The research group points to the tool as a potential way to buoy the low percentage of adult cancer patients who participate in clinical trials, which hovers between 2 and 4 percent nationwide.

"We know that the [informed consent](#) process can be confusing and tedious for [cancer patients](#), who are asked to read many documents and understand a tremendous amount of information in a short amount of time – often when they are already frightened, tired, and vulnerable due to their illness," said senior author James Metz, MD, an associate professor and vice chair of the clinical division in Penn Medicine's department of [Radiation Oncology](#). "We believe our tool can make that process easier for patients and their families, as well as for clinicians, who often struggle to accrue enough patients to complete trials."

The Penn researchers developed an Internet-based multimedia informed consent resource (housed on Penn Medicine's cancer web site, OncoLink, www.oncolink.org) which contained a video version of a trial principle investigator talking through the traditional informed consent

process for proton therapy [clinical trials](#), as well as a PDF of the written informed consent. The tool allows patients to stop, start, and replay the video as many times as they would like, as well as to play it for family members or other support people who may not be able to be present for the appointment in which the information is initially discussed. This video component may be especially helpful for patients with literacy issues, or to those who speak English only as a second language. Providing a PDF of the written materials also allows patients to take their time understanding the protocol, its potential risks and benefits, and other important information.

Among 23 health professionals -- research coordinators, radiation oncologists, research nurses and others -- surveyed about their experiences with the new tool, 94 percent reported they were pleased with the information presented in the online resource. Seventy five percent said they thought the resource would expedite the informed consent process, and 88 percent think it will "greatly enhance" the process for the patient. Seventy five percent of respondents said they would like to have similar multimedia content created for their trials in the future.

Proton therapy research, in particular, represents an opportunity to improve the informed consent process, since the modality is new and therefore many not be well understood by the public at a time when doctors are increasingly studying its use. After piloting the multimedia informed consent tool with health professionals, the research team put it into practice as an adjunct to the standard informed consent process for [patients](#) receiving treatment at Penn's Roberts Proton Therapy Center. They plan to further study the tool's utility via patient satisfaction surveys and evaluation of impact on patient accrual for clinical trials.

Provided by University of Pennsylvania School of Medicine

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