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## Pittsburgh-based tech firm clarifies approval process

By The Tribune-Review Thursday, September 10, 2009  
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### About the writer

The Tribune-Review can be reached [online](#) or at 412-321-6460.

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The president of a Pittsburgh-based high-tech firm developing cancer diagnostic tests says waivers and exemptions allowed the company to collect and review medical records of some 300 cancer patients whose tumors were tested by the company.

Precision Therapeutics' Sean McDonald said the waivers were granted by review panels at Magee-Womens Hospital, Pittsburgh, and eight other institutions around the country that participated in a five-year study, results of which were published in 2006.

"It was a completely legitimate study. The study did not require patient consent," he said.

McDonald made the comments in response to a Tribune-Review story saying that Precision may have violated federal rules by failing to obtain proper informed consent.

One institution, the Cooper Hospital in Camden, N.J., according to Sharon Kim, a Precision official, required that consent be obtained from patients whose records were being reviewed.

The waivers and exemptions, McDonald said in an interview, allowed the company to review the patient records without informing the patients or seeking their permission. He said the patients had signed consent forms authorizing the original tests on their tumors.

In a prior interview and in a series of emails, McDonald and another Precision official repeatedly stated that the company obtained consent from patients.

McDonald said the waivers and exemptions from the consent requirement were obtained under the provisions of federal regulations covering medical records from which personal identifiers had been removed. He said the company used the services of an independent company to remove personal identifiers.

Kim provided copies of letters for the study from Magee and other health facilities, including the Dartmouth-Hitchcock Medical Center, authorizing both the study and the waiver.

Kim and McDonald said the company study was "in full compliance" with federal regulations.

The study, which was published in 2006, covered the testing of tumor samples on about 300 patients over five years ending in 2002.

South Side-based Precision markets a product called ChemoFx, which is used by some physicians to determine which chemotherapy is likely to work best on an individual tumor.

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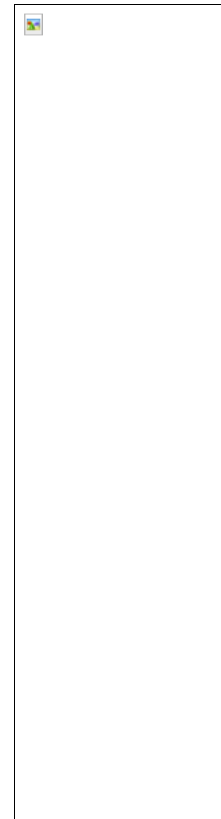
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