Every cancer patient is distinctive, with their own genetic fingerprint and their own response to treatment. To researchers working to develop better, more tailored cancer treatments, those differences can be crucially relevant.

To help ensure such important data can be included in research studies, Yale Cancer Center and Smilow Cancer Hospital have instituted a new umbrella consent protocol. This will smooth the way for patients at Smilow Cancer Hospital and the Smilow Cancer Hospital Care Centers to make their unique contributions to the research process.

“We’re asking patients in advance for permission to use leftover blood samples and specimens to help us further cancer research,” explained Maureen Major Campos, RN, MS, Director, Patient Services for Smilow Cancer Hospital’s Ambulatory Clinics. “No additional biopsies or labs are required. This will give us great insight into cancer and how we treat it.”

Typically, when researchers need to seek patients’ consent to use clinical information and tissue samples as part of a research question for their study, they need to approach patients in advance, one at a time. Umbrella consent, on the other hand, gives patients the opportunity to agree to participate in research studies universally, allowing their de-identified, relevant clinical and laboratory information to be included in a variety of studies. The process saves time and energy for both researchers and patients, and it ensures that patients who are eligible for a particular study don’t get left out.

Having both patient samples and background medical information in hand “will allow us to ask questions which we never really could ask before,” said Edward Kaftan, PhD, Assistant Director for Translational Research Administration. Dr. Kaftan works to help bring basic scientists and clinicians together to translate lab discoveries swiftly into advances in patient care.

“A new therapy—either a new regimen or a new drug itself—could eventually evolve out of information that was gathered through this umbrella consent process,” Lajos Pusztai, MD, DPhil, Professor Professor of Medicine (Medical Oncology) and Principal Investigator of the protocol explained. “The possibilities,” he added, “are almost endless in terms of the health impact it could have for cancer patients.”

In the planning stages since 2015, the full consent process was approved in July 2019 by the Institutional Review Board (IRB) at Yale University, which carefully reviews the ethics of all proposed research protocols. It is expected to roll out to all 15 of the Smilow Cancer Hospital Care Centers by early 2020. Smilow is the only cancer hospital in Connecticut to offer this broad consent option.

It’s important to understand that patients agreeing to the umbrella consent are not signing up to participate in a
clinical trial. A trial involves the testing of a specific intervention, such as a new drug. Rather, umbrella consent allows researchers, both within and beyond Yale, to study excess tissue such as blood or biopsy materials from patients who are already having those materials collected as part of their care, as well as de-identified information from their medical records. This information strengthens present-day and future studies that rely on examining multiple patients’ cancer data and outcomes, such as comparing how patients with differing genetics respond to the same standard-of-care treatment.

For example, a newly diagnosed cancer patient will undergo blood tests as part of their routine care. Once all those tests are completed, some blood is typically left over. Normally, that blood is safely discarded. But if patients agree to the umbrella consent, researchers may use the blood for future research studies. Similarly, under umbrella consent, researchers may examine surgically excised tumor tissue once pathologists have finished analyzing it for diagnosis.

All data collected are kept strictly anonymous. Any protected health information that could be used to identify a patient—including name, date of birth, Social Security number, and medical record number, is stripped away from tissue samples and information in the medical record—reflecting Yale’s commitment to patient privacy in accordance with federal law.

Researchers interested in analyzing patient data covered under the umbrella consent will need to submit a query through the IRB to obtain prior approval for their research protocol. Once approved, data analysts will then send researchers information for those patients that meet the study’s inclusion criteria — again, stripped of all patients’ personal identifying information.

For example, if a researcher has an IRB approved protocol to study the genetics of multiple myeloma using bone marrow samples from 50 patients with the disease, they would request de-identified information and leftover tissue samples for patients fitting their criteria.

Alternatively, if the researcher is interested in the blood pressure of multiple myeloma patients, an application can be submitted to access and study de-identified medical records of those who signed the umbrella consent in the past.

Patients have the option to opt out of the umbrella consent after signing, or to speak with their physicians first to learn more about the process. Their decision will not in any way affect the care they receive. Currently, registration staff are reaching out to consent new patients during their first appointment at Smilow. The umbrella consent is first introduced during their initial phone call for appointment scheduling, and is finalized as part of their check-in process. As of late 2019, 624 patients have agreed to participate. Front-desk staff, nurses, and other staff are trained to answer questions patients may have.

“Our goal is to ensure that the support providers in all of our clinics will also be able to talk to our patients about the process, and answer their questions,” Ms. Major Campos said. “The implications for this are really huge.”

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