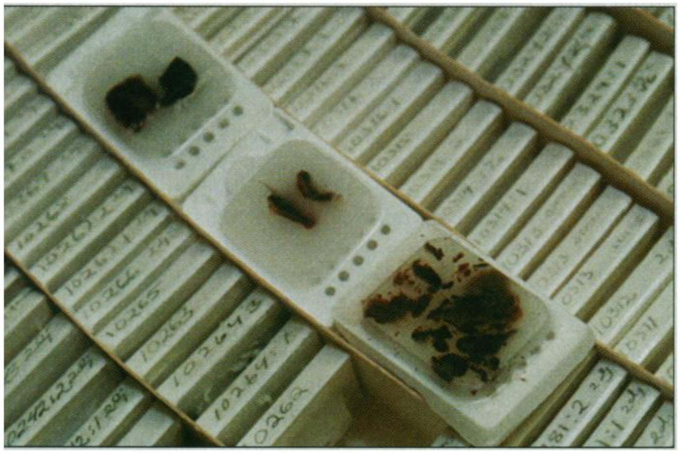
GENETIC DISEASE

Sweden Takes Steps to Protect Tissue Banks

There is growing interest among genetics researchers in Sweden's wealth of public tissue banks. Authorities are moving quickly to protect patient privacy

STOCKHOLM—Sweden and some other Nordic countries are sitting on a genomic gold mine. Their long-standing public health care systems have been quietly stockpiling unique collections of human tissue, some going back for decades. These banks hold samples of blood, sperm, fertilized eggs, umbilical cord blood, and biopsies taken during cancer treatment or medical examinations. The samples were originally stored for possible therapeutic or diagnostic uses for the patients themselves, but researchers now realize that they could contain valuable information about inherited traits that may make people susceptible to a variety of diseases. The Huddinge Hospital south of Stockholm, for example, has been storing blood samples from each newborn child in Sweden since the mid-1970s—a valuable resource for researchers needing population-wide genetic data.

When biotech companies recently started inquiring about gaining access to both samples and patient information in these banks, however, Swedish medical authorities became increasingly concerned about protecting the privacy of those who had donated the tissues. Those concerns were heightened by allegations earlier this year of a potential breach of privacy at one tissue bank. As a result, the Swedish Medical Research Council issued a new set of ethical guidelines in June that require potential users of banked tissues to acquire informed consent for every new use and place stricter safeguards on patient information. But because these guidelines are not binding on private companies that might want to set up their own tissue banks, the government has ordered the National Board of Health and Welfare to work out a proposal for a new law regulating the creation and use of tissue banks. Danish and Norwegian authorities are also looking into new legal frameworks.



Treasure trove. Sweden's health care system is continually squirreling tissue samples, like these at the University Hospital in Lund.

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The Swedish public and politicians really caught on to the privacy issue in April, when the tabloid newspaper *Aftonbladet* ran a series of articles reporting that some samples and information had already been passed on to a private company through collaboration with a researcher in Uppsala University's pathology department, which maintained a tissue bank. The newspaper also reported that the ethical committees at the hospital had not been informed that the researcher was also on the company's payroll as a consultant. This material indirectly gave the Uppsala-based company, Eurona Medical, access to the codes connecting patients to samples.

Even before the details of that arrangement hit the press, the Swedish Medical Research Council, along with several other bodies responsible for research and medical ethics, had been trying to alert politicians to the need for tighter regulations. The new ethical guidelines they have now drawn up will govern all use of tissue banks in public hospitals and research facilities, regardless of whether the proposed research is privately or publicly funded, and will be overseen by local ethics committees, which themselves come under the umbrella of the Medical Research Council's ethical advisory board.

The guidelines stipulate that the local ethical committee must approve each withdrawal, and each new use of the material should require informed consent from the donor. Gisela Dahlquist, chair of the research council's ethical advisory board, says many people seem to believe that once a blood sample and informed consent for research is collected, they are free to use the blood for any purpose. "We want to put a stop to this idea. One cannot give informed consent to something when one doesn't know what it is," she says. In addition, all tissue banks must have strict rules for how samples are stored. "The most important step is that the code key [connecting samples to individuals] shall be kept by a public agency and that private companies should only be allowed to handle unidentifiable material," says clinical physiologist Lennart Kaijser of Huddinge Hospital, who is secretary of the council's ethical advisory board.

As a model of how public tissue banks should interact with the biotech industry, researchers point to the company UmanGenomics of Umeå. Created in 1998 by Umeå University in collaboration with regional health care authorities, the company has exclusive rights to commercial use of Umeå's Medical Bank of blood samples. Since 1985, the bank has been collecting samples from almost the entire population of the isolated region of Västerbotten around their 30th, 40th, and 50th birthdays. Today it contains 100,000 samples from 60,000 individuals who have also been interviewed about their health and lifestyle. This archive can give unique insights into the environmental factors behind cardiovascular disease, often in connection with genealogical data on the patients.

Although UmanGenomics has the commercial right to use the blood bank, it remains under public authority and can still be used by university researchers. "UmanGenomics constitutes a unique model for this type of company, where the blood bank is legally separated from handling the genetic information with an ethical body in between," says Sune Rosell, director of UmanGenomics. He also points out that public involvement is ensured in three ways: All bank withdrawals have to be approved by the regional ethical committee; university and public representatives are members of the company board; and informed consent is required for each new use of the blood, even if it means advertising in the press to track down donors who are out of touch.

Ethical bodies hope the legislative proposals being worked out by the Health and Welfare Board will extend such requirements to every private company. The board is expected to complete its work next May. Dahlquist says clear rules are important to ensure that researchers and pharmaceutical companies can properly make full use of the tissue banks: "It's important that the banks can be used for valuable research and still maintain the confidence of the public." The advantages of openness have been shown by the Umeå case: Only three people have declined to participate.

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