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Absence of legislation and technology to protect patients' biomedical specimens and genetic information

Analysis from stored human specimens in biomedical research can provide valuable knowledge that can be applied to disease prevention and production of medical treatment. However, the idea of "acquisition of specimens" has created controversy. In some cases, people think that this acquisition impacts individual rights. In the US, there are many ethical issues related to the use of human specimens for research. For instance, some believe that Henrietta Lacks' rights were violated when her cells were taken in 1951 and distributed worldwide to many researchers without her consent or her family's knowledge. However, at that time, there was a regular process by which a medical professional could collect, study, store, transfer, or dispose his or her patients' tissue from surgical removal of a specified part of the body without the patient's awareness for future research. It took more than a thirty year process for the Lacks family to realize their rights. Unfortunately, today, there are still few laws that can protect her and other patients' biomedical specimens and tissues from being stored or distributed for any purpose, including the use for denial of insurance or employment, and it is therefore important for governments to reconsider laws in the context of ownership of research specimens and patients' privacy.

Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*, writes to emphasize the problem of ownership of excised tissue. "Today most Americans have their tissue on file somewhere. When you go to the doctor for a routine blood test or to have a mole removed…the stuff you leave behind doesn't always get thrown out. Doctors, hospitals, and laboratories keep it" (315). Doctors and industrial scientists conduct research on a patients' tissues collected and archived in the laboratories without outlining to the patient and his or her family the rights of ownership of the biomedical specimens, patient data, or research results. According to Gillian Haddow et al, who wrote the research on the creation of DNA databases "Tackling Community Concerns about Commercialization and Genetic Research: A Modest Interdisciplinary Proposal," the law is ambiguous concerning who has ownership of tissues, and this has caused many arguments and lawsuits. Moreover, in situation of commercial purposes, Haddow argues that it can create uncertainty among potential purchasers of the tissue who desire to produce commercial products from someone's tissues.

According to Devid Peloquin's presentation topic Specimen Science: Ethics and Policy Implications, the Common Rule requires "Research involving human subjects that is funded by one of 18 federal departments and agencies, generally require IRB [institutional review boards] review of research and informed consent of subject." Nevertheless, the Common Rule does not address the question of who owns human tissue specimens used in research.

It is a fact that today, when the courts are asked to adjudicate the question of ownership of human tissue samples used for any research purposes, they will follow two published judgements as case laws. In the case of *Moore v the University of California,* the California Supreme Court determined that, although the excised cells initially belonged to an individual, when they were removed, individuals do not retain rights of ownership of excised tissue used to

develop new products. In the 2003 case of *Greenberg et al v Miami Children's Hospital,* the judge adopted the reasoning used in the Moore case, although the difference between Greenberg and Moore was the acquisition of specimens. Greenberg el al donated their tissues voluntarily and knowingly for use in research, and their tissues were not collected surreptitiously during medical treatment. According to Jennifer Girod and Katherine Drabiak, who wrote the article "A Proposal for Comprehensive Biobank Research Laws to Promote Translational Medicine in Indiana," "Greenberg also implicitly rejected the equity concern of ensuring that specimen donors can benefit or obtain access to any research discoveries resulting from their donations" (227) From this, Greenberg did not satisfy with a court' decision that he had no right on his excised tissues even though he had created an agreement which controled what research should happen on his tissue.

It is obvious that the Lacks Case, Moore Case, Greenberg Case and other cases such as Canavan and Catalona, all involved lawsuits concerning claims of private ownership of human specimens used in research. However, in none of these cases did courts decide that the tissues' provider had any ownership to their excised tissue, but the courts gave precedence to informed consent instead. Nevertheless, in terms of informed consent, Rina Hakimian, JD, MPH and David Korn, MD, author of "Ownership and Use of Tissue Specimens for Research," highlight that consent forms do not always address directly the issue of tissue ownership either by the individual who is the source of the specimen, the research participants, or the institution conducting research. Hakimian and Korn note that the situation reflects the lack of clarification concerning ownership rights. To date, there are no federal laws to establish individual ownership rights in excised human tissue specimens used for research or other purposes.

Another issue is patient privacy. Karen J. Maschke's speech topic on *Specimen Science: Ethics and Policy Implications* at Harvard Law School claims that "Traditional research ethics [and] framework/human research protections [are] inadequate for research with biospecimens and associated data because biobanks may involve" sharing bio-specimens and associated data with many investigators, including from commercial entities by lack of broad consent for future unspecified research. Collected tissues are always accompanied by clinical information containing specified patient identifiers, while human tissue specimens are a unique and irreplaceable research raw material. Furthermore, the advent of affordable whole genome technologies which increases the identifiability of specimens and genomic data in research databases has been questioned concerning patients' privacy. As a consequence, people have started to fear that genetic information can be used as a basis for discrimination in health care insurance, employment and education.

Unfortunately, only a few statutes address genetic information collected during clinical tests and genetic research, restricting its disclosures and forbidding its use to deny insurance, employment and academic acceptance. For instance, Cathleen D. Zick et al, contributors of "Genetic Testing for Alzheimer's Disease and its Impact on Insurance Purchasing Behavior," state that "Genetic testing has the potential to create adverse selection in an insurance market." In a test of almost 150 "cognitively normal individuals participating in a randomized clinical trial of genetic testing for Alzheimer's disease," administered by Cathleen D. Zick et al, "those who tested positive were 5.76 times more likely to have altered their long-term care insurance than individuals who did not receive APOE [Apolipoprotein E] genotype disclosure." Therefore, if our genetic testing for Alzheimer's disease or any other disease is published openly, it tends to cause adverse selection in the long-term care insurance market. In the circumstance of

employment, *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, the employer conducted employment entrance exams by evaluations from genetic testing whether the potential employee had any genetic unhealthy conditions or not. Sadly, some states in the US lack federal protections against unauthorized disclosures of individual's genetic information to employers and insurance companies (Girod and Drabiak 247).

Clearly, many causes of these lawsuits involved a lack of information regarding consent. Rebecca Skloot says that, "Today, if doctors want to gather tissues from patients strictly for research purposes – as in Henrietta's case – they are required to get informed consent. But storing tissues from diagnostic procedures like, say, mole biopsies, and using them in future research doesn't require such consent" (317). Although there are many ethical codes and guidelines such as the Nuremberg code and the Common Rule which require doctors to inform patients if their tissue samples will be used in research or making some profits, these are not laws which require many doctors to explain exactly what will be done with their patients' tissues. As the solution, researching on human specimens should have a better system to inform the patient about information regarding ownership and retention of excised tissue. Following are the lists which laboratorians and researchers should do before conducting research on human tissue specimens.

In order to do research on human tissue specimens, first, laboratorians and researchers should understand and be in compliance with state and federal laws. Second, they should give a quality consent form to their patients. Then, they inform research participants as much as possible about how their specimens will be used. Finally, if new studies are undertaken on specimens, consent forms should be obtained for each new study.

There is a good example in which Baruch Blumberg had professional consent to use Ted

Slavin's antibodies for hepatitis B research. Ted Slavin, who needed money for basic survival, was notified that his cells had potential to use them in research and commercialization. He finally saw the light at the end of the tunnel. He created an agreement by which he was able to control his tissues before his tissues would be in researchers' hands. Therefore, many patients might have the same question as Rebecca Skloot has: "How much science should be obligated (ethically and legally) to put people in the position to do the same as Slavin" (326). However, it is clear in laws that it is illegal to sell human organs and tissues for transplants or medical treatment. The laws concerning the regulation should be reconsidered to allow an individual to receive some kind of benefit from his or her cells. As a consequence, Skloot has given Lori Andrew's opinion, who denotes work undertaken without charge on biological ownership cases, that giving a person property rights in their tissues "would slow down research because people might withhold access for money" (324). When some scientists and researchers disagree to give patients' rights over their tissue, money can persuade people to investigate whether they have any potential to have special tissues which are valuable for research or not. Moreover, there should be some institutional control over that profit from any product developed using human tissue. For example, laws should give ownership over the tissues to an intermediary or a third party to control or divide profits which might come after the research result. This way patients will not need to watch closely on what is happening with their cells or tissues and be confident that they will get some benefits from the research. Moreover, we know it is impossible that an individual is able to track all research activities. Having this law can answer the question as to who has ownership over tissues.

The most obvious factor influencing an individual's privacy is when excised tissues are not intended for a single purpose. Genetic samples and information are usually preserved in

some research database for future research studies. In this way, the benefits of medical knowledge derived from tissue research potentially accrue. However, many patients' concerns on the disclosure of genetic information to third parties will discriminate against a person or a member of the person's family on the basis of genetic analysis, genetic information, or genetic propensity. "Computing Ethics Big Data Analytics and Revision of the Common Rule" research by Jacob Metcal supports that traditional research ethics such as the Common Rule has "given the emergence of big data analytics." Since "the Common Rule has typically not been applied to the core disciplines of big data (computing, mathematics, and statistics) because these disciplines are assumed to be conducting research on systems, not people", Metcal suggests that the Common Rule should be revised to protect "the information [which] is recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to researchers and most risky to subjects." As to legal protection, according to Jennifer Girod and Katherine Drabiak, "Alaska is currently the only state to have a law that defines the actual DNA sample as the 'exclusive property' of an individual" (236). The question is why other states do not enact laws as Alaska has. The law can minimize the possibility of using one's genetic information as the basis for privacy threats and discrimination. The rule is defensible to protect patients' privacy.

The United States is a country that prides itself on property rights. It has been questioned as to who owns human tissue specimens? As studies on genetic material become more prevalent, the frequency of lawsuits is increasing. In most cases such as the Moore Case and the Greenberg Case involving excised tissue for clinical purposes and tissue donated for research, courts have decided that patients and research participants do not retain ownership rights over the excised tissues. However, this needs to change. Although, in the last decade, the evolving of regulations

has imposed limits on the ability of researchers to use tissue specimens, some states in the US still lack comparable regulations. Laws should be created specifically to protect the privacy of tissue donors and to limit uses of specimens. Finally, as the guardians of tissue obtained during treatment and surgery, we need to reconsider the laws to answer the question: Who should have ownership over the tissue.

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