

Can a Patient Edit their Consent Form before Signing?

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Category: Informed Consent

Ethical Dilemma

A patient is handed a consent form to allow their tissue samples to be used for current and future research. However, before signing the final page, the patient has one request: they would like to *edit* the form before finalizing their agreement to participate. The patient does not want to give up ownership of their tissue, but still very much wants to participate. The patient would like to write, “*I retain ownership of all tissue*” on the hard copy form of consent and then sign it. Confused about the legality and permissibility of the patient editing the consent form, the research coordinator requests a research ethics consult.

Expert Opinion

While patients do have the right to decide whether or not to participate in research and whether to donate bodily tissue for research, the right to ownership and control over the use of that tissue no longer exists once it leaves the patient’s body.¹ This standard has been set by a number of court cases. *Moore v. Regents of California* (1990) confirmed that while proper informed consent is necessary for research, a person’s donated tissue and cells are not considered to be their property. A more recent case, *Greenberg v. Miami* (2003), further solidified the ruling of *Moore v. California*. A young patient with Canavan, a rare genetic disease, donated extensive samples that aided research that ultimately resulted in the development of a prenatal test to screen for the disease.² If patients retained ownership and control of their samples, the court argued, this would erroneously “give each donor complete control over how medical research is used and who benefits from that research.”³

Here, the emphasis should be placed on obtaining proper informed consent that makes patients aware of their participation in and contribution to research. Moreover, patients should be made cognizant of the fact that they do not own tissue that is taken either for clinical or research purposes. In addition, they must be aware that they will not financially profit from potential products produced by the research. The AMA Code of Medical Ethics mandates that the financial interests and potential commercial profit must be disclosed to the patient prior to their agreement to participate.⁴ When supplied with this knowledge and engaged in a thorough discussion aimed to identify specific preferences and goals, a patient may arrive at a decision that is both more informed and concordant with their specific desires. If the inability to control how their tissue and information is used, and the fact that others may eventually profit from the advances made through the research with their tissue is not concordant with the patients’ views, the patient should not sign the tissue banking consent.

In sum, the patient may not edit the consent to state that he or she retains ownership of the tissue. The patient should be reapproached and made aware that they do not own their tissue that has been extracted nor will they profit from research with it, but they can still donate it to research if they so choose. The choice is theirs.

¹ Schleiter, Kristin. Donors retain no rights to donated tissue. *Virtual Mentor*, 2009; 11(8): 621-625.

² *Ibid.*

³ Andrews L. Who owns your body? A patient's perspective on *Washington University v. Catalona*. *J Law Med Ethics*. 2006;34(2):398-407.

⁴ American Medical Association. Opinion 2.08. Commercial use of human tissue. *Code of Medical Ethics*. Chicago, IL: American Medical Association. 2007