

Judge Limbaugh's decision addresses the rights of research participants at length, based upon federal and state law as well as the research consent forms signed by the participants. The court recognized the participants' right to discontinue participation in a study, but found that this right does not equate to "a right to control the disposition and use of the excised biological materials." Judge Limbaugh ruled that there was no donor right to redirect tissue samples to other institutions or researchers once the donation had been made; Washington University did not breach such a right because no right to reclaim or redirect samples ever existed.

The court further stated that allowing patients to redirect their tissue samples "is tantamount to a blood donor being able to dictate that his or her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man. This kind of 'selectiveness' is repugnant to any ethical code which promotes medical research to help all of mankind," wrote Judge Limbaugh. His ruling protects everyone's chance to benefit from medical research from what he characterized as "private agendas." Judge Limbaugh's formal Opinion shows that the defendant in the case, Dr. Catalona, had cast aside the rights of research participants in this way: Dr. Catalona's form and letter sent to 10,000 or more research participants soliciting them to try to redirect their tissues to him did not conform to federal regulations designed to protect the rights of research participants and was not an informed consent because it took advantage of research participants and was unlawful. The Judge wrote "the context in which this form was sent is troubling to the court. [Dr. Catalona] sent it to [research participants], many of whom were his patients and emotionally tied to him, advising them of his move, of his desire to continue his consultation/treatment practice, and then describing his need to use these samples to further his help to them. Such a communication smacks of undue influence." And, "Every expert and even Dr. Catalona testified that the letter/form did not constitute 'informed consent' pursuant to the applicable federal regulations." After examining Dr. Catalona's actions, the Judge clearly sent the message that researchers can't ignore the laws and regulations that protect research participants' rights in order to advance their private agenda.

Finally, the court noted that research participants interests are best protected when institutions house and maintain tissue repositories under the requirements of federal and state regulations. The court wrote: "A 'check and balance' system is in place to monitor the research being conducted using these materials. The safety and welfare of human subject participants is protected through a variety of legal and professional standards administered by committees of persons schooled in the fields most privy to the needs of the medical/science community."