

TRANSCCOMM

THE TRANSCCELL NEWSLETTER

October / 2016 / VOL. 10

BIORIGHTS- AN EXAGGERATION OR NECESSITY



There is so much information on the internet regarding biorights. The most concise information I found was an article in the Boston Globe dated October 10, 2016.

It seems that people are no longer willing to allow or provide specimens to labs without being financially compensated, given a full medical workup of the findings, or granted control over how their specimens will be used in research or even which research the specimens will be used in. Also, as seen in the 2010 bestseller “The Immortal Life of Henrietta Lacks”, what happens in the event that the specimen outlives the donor and there is no consent to use that specimen? It seems the majority of the time, no consent is given at all whether the person is alive or dead.

It’s difficult to come to a clear conclusion on what is “right” and what is “wrong”. It’s complicated. As with most issues of this nature, we are walking a fine line of ethics. A precarious line.

First I think it’s important to determine who is the owner of the specimen. In my opinion, the specimen belongs to the donor. Initially. But . . . Is there a transfer of ownership of that specimen once it is given to the lab? Or is the transfer of ownership only once a consent has been signed? Or is the transfer of ownership only upon payment for that specimen? In my opinion, the transfer of ownership is when the specimen is given WITH a signed consent.



Anand Soorneedi, M.Sc, MS, MA
Process Scientist Transcell Biologics

With regards to consent, this should be done during any collection of any sample. Whether through a scheduled medical appointment/test or during a specific collection designated for research. I am a bit surprised that this has even been an issue. So consent in regards to specimens is something that I feel should be just a part of those consents. In the event of post mortem collection of a specimen, there are several options for obtaining consent. Perhaps, as in the US, people can simply register as organ donors and/or consent can be given by a family member at the time of organ donation in the event the donation takes place prior to death. In situations where people have “left their bodies to science” I don’t think any additional consent is necessary – consent has already been given.

Then the transfer of ownership of the specimen transfers to the lab and should be used at will unless there is a specific notation of where, what, when and how the specimen can be used.

Many donors request a full medical workup of what is found during the research. I think that is the right thing to do. Especially in cases where the BRCA gene and other significant findings are uncovered. In some instances, the specimen may lead to advances in medicine directly related to the actual specimen that was given. That to me is mind blowing! In the words of my inner geek – science is so cool!

A more difficult determination is whether people should be compensated for their specimen donations. Why not? After all, it does belong to the donor until ownership has been transferred. And when a specimen is taken during a surgical/medical procedure, the donor does pay the cost of that procedure. And let us not forget the amount of revenue these samples can produce. Biological samples will generate up to \$23 Billion by 2018 for research/medical/pharmaceutical organizations. \$23 Billion! Why shouldn’t the donor reap a bit of the reward?

My answer to this is, are we missing it? In the name of “big business” have we lost sight of the “big picture”? Have we gone from science for the greater good to science for the sake of a buck? My answer is a resounding and sad - yes!

For me personally, if I can do something to contribute to the greater good – whether alive or dead – then by all means yes. If it means a life can be saved; if it means another person can spend another day with their loved ones or have a greater quality of life, then yes. I do not need to know how, what, when or why. I just need to know that I did all I could to benefit my fellow beings. It does not matter if the specimen is used before or after I die.

In this edition of Transcomm, we have tried to encompass the opinions on biorights held by people from various walks of life. Happy reading!

Biorights should be redefined as the right to know the details of the research for which the sample is sourced to know the prospects of the research being done to know the profile of the sample by the donor only and cannot be a source of financing mechanism to alleviate poverty or convolute the purpose of research. Also, technically, even the regulatory bodies in Bioethics and Biorights domain have to be well informed in terms of the type of samples that are being collected and used for what kind of research rather than coming up with blanket policy covering all the contexts, which would compromise the sanctity and the power of research.

As a researcher, I believe informed Consents with details for samples where extraction has to be done from a living donor with tracking system in place is a civilized approach maintaining an all time scientific and medical inviolability. Paying the subjects/donors of the samples for research is a malpractice according to me, that could by itself lead to disastrous situations in the long run. Also, the truth that no sample collected has any value in research or development of any technology for human application, unless it is processed and the required material



S Dravida, PhD
Transcell Biologics, Hyderabad.

either genetic or cells are harvested and stored which involves investment in infrastructure suitable and for processing and cryopreservation is to be disseminated. Again, the term research defines that it is experimental and standardization with only 10-15% of probability of success in building the hypothesis. So, where is the exploitation of the donor of the sample that is assumed and monetary benefit is debated? The donors are doing no favor to the research that is undertaken by the pharma or any company or institute doing medical research in contributing towards either understanding the basic sciences or applications to treat diseases of mankind. More so, it is an option given to the eligible donors and whosoever believes with conviction that the research on their samples would help solving medical problems if not in their lifetime at least for the human race would participate voluntarily with no monetary expectation from the recipients.

Science and research in medicine is an art of soluble for sure while social value orientation promotes donation of samples. The movement of Biorights emphasizing on monetary benefits to the donor of the sample could trickle down as trade violating the right to human integrity in countries like India where there is no ecosystem connecting researchers, institutes, hospitals and patient population. The closest analogy of the situations is Commercial Surrogacy in India, which had sparked debate in the society that is disjointed at the grass root level.

To provide the necessary biological products like blood and blood components including Bone marrow to meet the need of the patients or researchers, the volunteer donors are encouraged or motivated to participate in the program at their understanding level.

I personally feel that every individual has a right to decide to help others by donating their biological samples and donors may be given the confidence of keeping their records, assured.

Donors of biological material have a right to be informed of its possible uses and of potential commercial spin-offs;

The right to control the biological material taken from a donor ceases at the time of donation. Donors cannot claim rights of “ownership” in biological material; and the recipient has the right to commercial exploitation of any products developed from the processing of biological material received, in accordance with current legislation. Typically, patients who consent to the use of their tissue for biomedical research do so with the expectation that the donated tissue will be used to further scientific knowledge and to enhance the health and well-being of other patients.

The tissue is given by the patient as a gift, on the assumption that it will be used in good faith for the medical benefit of others. Patients’ perceptions of such donations might be very different if it is known that commercial profits are a potential objective of the research to be conducted. Patients, therefore, cannot provide fully informed consent to the use of their organs or tissues in clinical research unless potential commercial applications of the tissue and its products are disclosed.

Physicians or the Pharmaceuticals contemplating the commercial use of human tissue should abide by the following guidelines:

1. Informed consent must be obtained from patients for the use of organs or tissues in clinical research.
2. Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials.
3. Human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material.
4. Profits from the commercial use of human tissue and its products may be shared with patients, in accordance with lawful contractual agreements.



Nedunchezian, PhD, PGMS.
Ncare Solutions, Hyderabad, India

My opinion is where organs or samples are being collected by the Companies or Research Institutes for research purposes, in the event of commercial success of such research, it would be justified that some portion of the proceeds or the commercial benefits accrued by the Companies be contributed to a Fund. This Fund could be used for extending some pecuniary advantage to the donors or their families or used for the benefit of the patient population at large.



Ravi Prasad Pisupati, LLM
Tempus Law Associates, Hyderabad.

Research and Development is never funded adequately to the needs of the population and donations are the major source of its continuance. The new era of promising research involving stem cells, bone marrow cells to name a few are revolutionising the treatment options for the needy and offering hope for a range of diseases without any cure, so far. Due to existing laws and resistance from people with ethical considerations, most of these research activities are going at a slow pace. However, there are lots of entrepreneurs trialing self-funded research with the help of donors. It is an undisputed fact that these will lead to saving lives at the end of the day.



Ravi Nyayapati
Australia

The argument that people or MNCs involved in the research would/may make millions after finding a cure for any disease and hence donors get some money for their participation is ridiculous. This would be an insult to the generosity of the donor, if there is a monetary consideration. Donation of Organs, Stem cells, blood and plasma to name a few are helping many needy in the world giving humanity a ray of hope. We need to understand that research is not just a means of making money but a passion for people who value life.

Paying the donors has previously had negative consequences across the globe. Till the 90s Blood donors were paid in India and it became one of the most flourishing businesses that had to be abolished. Every new step has always been viewed with suspicion, but we need to be practical and optimistic, I feel.

My son was diagnosed with Stargardt's Macular Dystrophy, a juvenile form of Macular Degeneration at the age of 18 in 2013. There is no known cure for it and a number of clinical trials are underway throughout the world using different protocols. Stem cell therapy and Gene therapy are the two new strategies that are proposed to give hope to my son. He chose to participate in a stem cell therapy case study with Transcell Biologics Pvt. Ltd in Hyderabad for the last 2 years. He is hopeful that the degeneration would stop and he would be in a position to get a cure for his condition soon! This is only possible if research is continued in finding cures for diseases and genetic conditions. Donors are very important in providing healthy stem cells and Bone marrow cells. Creating controversies would only delay results for people who badly need cure.

These issues need to be taken up as a social responsibility and more participation is needed from people and entrepreneurs. Profits are not the only means of research and people who talk about paying donors need to realize that a quality life is more important than money. Hope common sense prevails!

Biorights is a movement that was initiated with an intent to enhance control and provide financial incentives to participants of research for their biological contributions.



Sanjana Kareti, MBBS
Junior research fellow, Transcell Biologics

At first, it only seems fair that the subjects benefit financially for providing their personal genetic/ biological data in the form of blood samples, saliva etc. Some companies develop patents for financial gains. Some collect these samples only to be stored and sold later to researchers. It feels reasonable to demand a share in the profits being made.

Existing norms demand that participants have access to the following information- the purpose of the study, how patient information will be used in the study, the risks that he/she could face and most importantly that they consent to it, having understood the implications.

An enhanced control, however, would mean complete disclosure of all the information gleaned from the participants' sample during the study and any additional information that was intentionally sought from it.

Health and human resources and 15 other federal agencies have proposed a controversial new requirement of patients' permission to study biological material such as blood, pieces of tumor and other left over tissue from routine or surgical procedures even if researchers are unaware of the donors' identity.

Proposal of such advances have made researchers anxious as many feel that it would stifle growth and drastically slow down medical research. Offering money as incentive can significantly reduce the number of subjects that can be studied. It may be nearly impossible to solicit patients for consent without adequate resources and information offered by healthcare centers that provide samples. It would be unfair to those that have struggled to bring about real change rather than merely seeking commercial gains and have relied solely on the beneficence of people for the same.

Can we strike a balance? Is there a solution that can ease the anxiety on both sides?

Here are a few suggestions that could be considered-

Standardization : Developing an understanding on how much and when the information on the results of the study has to be revealed is crucial. This can only happen through dialogue and by addressing issues on both sides to reach a compromise.

At collecting centers, patients could be made aware that their samples could potentially be used in research and that they can consent for the same. Contact information of those willing can be documented making it easy to reach them when required.

Educating patients further on how their contribution has helped for the advancement of a study or in making a cutting edge discovery will only serve as a motivation for many more to join in.

Alleviating misconceptions about misuse of biological data can also make a huge difference.

Now a days “Biobanks” are a major business segments across the world. Biobanks refers to the repository that collects stores and distributes human biological materials including blood, plasma, saliva, purified DNA and other biospecimens. Lot of centres do sell the material for commercial purposes or sublease the repository for further research or monetary gains where the patient does not get any benefit from the ongoing business.

Whenever the business comes into research, people’s expectations also increases and they would start demanding for compensation. Probably this is single most important reason for the “Biorights”. Every biological specimen is collected after an informed consent. If some on volunteers to donate the sample, I personally feel that there is no need to compensate for the patient or subject provided the company or organization does only research work and there is no commercial element. If someone collects the sample for the commercial purpose, it is judicious to compensate the respective patient or subject. Coming to royalties from the ongoing research, there should be strict understanding and guidelines between the governments or controlling authorities, research companies and public.



Ramesh Teegala
MS (BHU); MCh(AIIMS), MBA (HCS)

Angel Investor , Nagendra Bandaru, echoes the opinion of “No cash” for donating samples for research that may have commercialization potential. He also strongly believes that community participation from patients, donors volunteering the samples donation (that would not hurt them) to the research and development towards the discoveries and innovations in drugs development should not be of business interest, which is instant gratification only. The focus and hope could be more towards the final objective that is for larger good. He also suggests Clinicians crucial role in this altruistic movement connecting the context.



Nagendra Bandaru, LLM, MIM



Social Networking
TranScell Biologics is now live on Facebook and Twitter.

Please like us on
Facebook – TranScell Biologics
and follow us on **Twitter @ TranScellhyd**

Please do visit our Blog Page
<http://transcellhyd.wordpress.com>

Contact Us



TRANSCCELL BIOLOGICS PVT. LTD.
Aleap Industrial Pvt. Ltd.
Plot No : 64, Road No : 5
Gajularamaram
Hyderabad – 50090 India
+91 8985000888

www.transcell.in