

Bioethical Issues behind Gene Therapy Trials

Gene therapy is a prospective therapy for curing many genetic defects by correcting the mistakes happening at gene level. It can be somatic or germline targeting either blood or bone marrow in former and eggs or sperms in latter. Ethical issues prevail with the germline gene therapy and it has not been approved yet. Similarly, the gene therapy trials need to be regulated and is governed by many bioethical issues. In US, the Department of Health and Human Services (DHHS) regulates the gene therapy clinical trials. This organization has further sub-divisions that regulate the human subjects under trials through Code of Federal Regulations (CFR) and NIH is one of them (NIH, 2016). NIH supervises the funded clinical trials from federals and makes sure the compliance of CFR along with all other guidelines. Recombinant DNA Advisory Committee (RAC) was set by NIH in 1974 to supervise genetic manipulations. RAC discusses the scientific, legal and public concerns on a clinical gene therapy trial that comes for its approval (NIH, 2016). It monitors any safety and ethical considerations due to any recombinant DNA or genetic manipulations.

Though NIH used to regulate strict rules and supervised each clinical gene therapy trial, recently a report declared that NIH has lessened the regulation of any proposed trial by special committee. The increasing proposals for gene trials and the gaining expertise in the field has evoked the need for opting a straightforward process to speed up the trials and get the outcome quick (Kaiser, 2014). The RAC will supervise only special cases involving risk factors for the society and legislator issues.

The new methodology opted by NIH is the need of the hour and should be appreciated as this policy will make the gene therapy research swift that otherwise moved with a pace of only 20% cases getting discussed. Researchers even points that like every therapy pose risks, the gene therapy trials are no more or less. As with any new development, the issues accompany and similarly with the advent of gene therapy trials the cases have been reported for some side effects. But, to combat the increasing diseases and health issues, the therapy needs to develop eventually and it is only possible through more clinical trials that will filter into most effective solutions.

References

Kaiser, J. (2014). NIH will no longer require Special Review for U.S Gene Therapy Trials. Accessed at <http://www.sciencemag.org/news/2014/05/nih-will-no-longer-require-special-review-us-gene-therapy-trials> on 22 April 2016.

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