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The Margin of Moral Duty of Human Being to Participate in Biomedical Research

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ABSTRACT

The existing paradigm of biomedical research ethics, based on respecting the free and informed consent of the research participant, originates from the famous Nuremberg Trial (1947), where the Nazi doctors were convicted of killing and torturing prisoners using medical experiments in German Concentration Camps during World War II. Since the second half of the 20th century, several international instruments have been developed to protect the rights of persons involved in research, considering the voluntariness of participation. Nevertheless, scientific community started to discuss the moral basis of mandatory human participation in biomedical research. Even today, some scholars argue that biomedical research creates public goods in the form of health, safety, and knowledge enjoyed almost by all members of society. The moral duty to participate in research is due to the need for public participation in producing public goods. Others suggest that human beings have a moral obligation to take some risks to help others. So, the moral duty to participate in biomedical research relies on the principles of justice, beneficence, etc. Considering the importance of this issue for research ethics, this article discusses the doctrines and theories, including public goods, free-riding, and beneficence, to set the margin of the moral duty of human beings to participate in biomedical research.

INTRODUCTION

The history of the protection of the rights of human beings involved in biomedical research starts with the *Nuremberg Code (1947)*[1] – recognized as one of the most critical documents in the history of biomedical research ethics.[2] The first article of the Code declares the voluntary involvement of participants in medical research based on informed consent.[3] The Code provides for the right of the research subject to withdraw the consent as well.

In 1964, the World Medical Association *(WMA)* adopted the Declaration on the Ethical Principles for Medical Research Involving Human Subjects *(Helsinki Declaration),*[4] the primary addressee of which was the medical staff. According to Article 4 of the declaration, the doctor is responsible for protecting and improving the rights, health, and well-being of those involved in medical research. The 1966 International Covenant on Civil and Political Rights underlined the importance of informed and free consent of research subjects.[5] So, today, Good Clinical Practice *(GCP)* relies on respect for the autonomy of the human subject.[6]

In parallel with the formation of international instruments for the protection of the rights of those involved in biomedical research, in the 60s of the 20th century, the scientific community started to discuss the moral basis of mandatory participation of human beings in biomedical research. Certain representatives of the medical field *(Walsh McDermott, Louis Lasagna, and Leon Eisenberg*) advocated the idea of mandatory human participation in research.[7] They argued that the results of biomedical research created public goods in the form of health, safety, and knowledge consumed almost by all members of society.[8] In their view, the obligation to participate in research was due to the need for public participation in the production of public goods.[9] This view, along with other scholars, was challenged by the German philosopher *Hans Jonas*.[10] For *Jonas*, *"the moral pull exerted by the desire to have public goods was counterbalanced by far more powerful moral force of respect for individual autonomy."* Besides, it was still controversial for him that health, safety, and knowledge were public goods.

Another consideration supporting the idea of mandatory participation in biomedical research

1 The Nuremberg Code was adopted in August 1947 at a trial in Nuremberg (Germany), also known as the Doctors Trial. Nazi doctors were convicted of killing and torturing prisoners using medical experiments in German Concentration Camps during World War II at the Nuremberg Trials. A tribunal investigating World War II crimes has set the standard for the need for voluntary, informed consent by people involved in medical experiments. *See further:* International Military Tribunal (1950), Trials of war criminals before the Nuremberg Military Tribunals under Control Council law no.10, *Washington, D.C.: Government Printing Office, in* Shuster, E., 1997. Fifty Years Later: The Significance of the Nuremberg Code, *The New England Journal of Medicine, 337(20),* p. 1436.

2 Annas, G. J., Grodin, M. A., 1992. The Nazi doctors and the Nuremberg Code: human rights in human experimentation, *New York: Oxford University Press,* p. 227-39. Annas, G. J., Grodin, M. A., 1996. Legacies of Nuremberg: medical ethics and human rights, *JAMA, 276,* p. 1682-3, *in* Shuster, E., 1997. p. 1436.

3 According to article 1 of the Nuremberg Code, the voluntary consent of the human subject is required for conducting a medical examination *("The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent. should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion…"), See.* The Nuremberg Code, 1996. *British Medical Journal, No 7070, Volume: 313,* p. 1448. *See further:* Sade, R. M., 2017. Controversies in Clinical Research Ethics, *The Journal of Law, Medicine and Ethics, 45(3),* p. 292.

4 In 1964, at 18the General Assembly of the World Medical Association in Helsinki, the Declaration of Ethical Principles for Medical Research Involving Human Subjects was adopted, *available at:* < https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects> [Last *Seen* 15.07.2022].

5 *See.* Article 7, *available at:* <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights> [Last *Seen* 15.07.2022].

6 Guideline for Good Clinical Practice (GCP) E6(R2), International Council for Harmonisation of Technical Require-ments for Registration of Pharmaceuticals for Human Use, EMA/CHMP/ICH, 2017.

7 Mcdermott, W., 1967. The changing mores of biomedical research, *Annals of Internal Medicine, 67(7),* p.39-42, *in* Caplan, A. L., 1984. Is There a Duty to Serve as a Subject in Biomedical Research?, *IRB: Ethics and Human Research, 6(5),* p. 2.

8 Ibid.

9 Caplan, A. L., 1984. p. 2.

10 Ramsey, P., 1970. The Patient as Person, *New Haven: Yale University Press.* Rutstein, D. D., 1969. The ethical design of human experiments, *Daedalus, 98,* p. 523-541. Jonas, H., 1969. Philosophical reflections on experimenting with human subjects, *Daedalus, 98,* p. 219-247, *in* Caplan, A. L., 1984. p. 2.

derived from the doctrine of the social contract between generations.[11] Proponents of this doctrine considered that each previous generation produced public goods by participating in biomedical research enjoyed by each subsequent generation. Consequently, under the principle of reciprocity, society was morally indebted to the previous generation, which they could repay by producing public goods for future generations.[12] Not surprisingly, opponents challenged this doctrine.

The debate over the moral basis for mandatory human participation in biomedical research is still relevant. Since the 2000s, scholars *(Harris, Rhodes, and Evans)* have published several works.[13] These authors relying on the principles of *Justice* and *Beneficence*, argue for the existence of the moral duty to participate in biomedical research. They assume that almost all members of society enjoy the public goods generated from biomedical research. They set examples of not only active *(medical care, medications)* but passive forms of use of public goods like herd immunity resulting from vaccination. The proponents of mandatory human participation in biomedical research argue that the use of public goods without reciprocal contribution is unjust behavior, also referred to as "free-riding".[14] Thus, the general idea of *Justice* and *Beneficence* requires that the members of society redistribute the risk and burden of participation in research between themselves.[15] Other scholars *(Sharp, Yarborough, Wachbroit, Wasserman, Rennie)* have criticized the proponents for not discussing the issue in depth based on counterarguments.[16] The relevance of the present issue for biomedical research ethics stipulates an in-depth analysis of scientific discourse. Accordingly, the following chapters will consider the doctrines and theories of *Public Good*, *Beneficence*, *Free-riding*, and *Contract Theory* concerning the research subject.

PUBLIC GOOD

Scholars supporting the existence of the moral duty to participate in biomedical research assume that knowledge and experience generated from biomedical research are what economists call a *public good*.[17] According to *Paul Samuelson*, *"public good is a good which all enjoy in common in the sense that each individual's consumption of such a good leads to no subtractions from any other individual's consumption of that good..."*.[18] In the modern economy, *goods* are usually defined as public goods if they are both non-rivalrous and non-excludable.[19] According to *Reiss*, national defense is a paradigmatic example of a public good.[20] Typical

11 Jonas, H., 1969. p. 219-247, *in* Caplan, A. L., 1984. p. 2.

12 Caplan, A. L., 1984. p. 2.

13 Evans, H. M., 2004. Should patients be allowed to veto their participation in clinical research?, *Journal of Medical Ethics, 30(2).* Harris, J.,2005. Scientific Research is a Moral Duty, *Journal of Medical Ethics, 31(4).* Rhodes, R., 2005. Rethinking Research Ethics, *The American Journal of Bioethics, 5(1)*. Rhodes, R., 2005. Response to Commentators on "Rethinking Research Ethics", *The American Journal of Bioethics, 5(1).* Rhodes, R., 2008. In Defence of the Duty to Participate in Biomedical Research, *The American Journal of Bioethics, 8(10).* Rhodes, R., 2017.When is Participation in Research a Moral Duty?, *The Journal of Law, Medicine and Ethics, 45(3).*

14 Rhodes, R., 2005. Rethinking Research Ethics, *Am J Bioeth,* 5(1), *in* De Melo-Martín, I., 2008. p. 28. *Comp.* Rennie, S., 2011. p. 42.

15 Ibid.

16 Sharp, R. R., Yarborough, M., 2005. Additional Thoughts on Rethinking Research Ethics, *The American Journal of Bioethics, 5(1).* Wachbroit, R., Wasserman, D., 2005. Research Participation: Are We Su bject to a Du ty?, *The American Journal of Bioethics, 5(1).* De Melo-Martín, I., 2008. A duty to Participate in Research: Does Social Context Matter?, *T he American J ournal o f Bioethics, 8(10).* Rennie, S., 2011. Viewing Research Participation as a Moral Obligation: In Whose Interests?, *Hasting Center Report, 41(2).* Yarborough, M., 2017. Why There Is No Obligation To Participate I n Clinical Research, *T he J ournal o f Law, Medicine and Ethics, 45(3).*

17 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. The Obligation to Participate in Bi omedical Research, *The Journal of the American Medical Association, 302(1),* p. 3. Seiler, C., 2018. Can there be a moral obligation to participate i n biomedical research?, *Eur J C lin Invest., 48(e12896),* p. 2.

18 Samuelson, Paul A., 1954. The Pure Theory of Public Expenditure, *The Review of Economics and Statistics, 36(4),* p. 387, *in* Reiss, J., 2021 (Fall). Public Goods, *The Stanford Encyclopedia of Philosophy,* Edward, N. Zalta (ed.), *available at:* <https://plato.stanford.edu/archives/fall2021/entries/public-goods/> [Last *See*n 15.07.2022].

19 Rivalrous and excludable goods are called private goods. Food, clothes and flats are paradigmatic examples of private goods. *See.* Reiss, J., 2021 (Fall). *available at:* <https://plato.stanford.edu/archives/fall2021/entries/public-goods/> [Last *See*n 15.07.2022].

20 "... A corollary of the non-excludability characteristic is that there are limitations to consumers' consumption decisions regarding the public good, if it is produced. Individuals might have different preferences for t he level of security provided by national defense, b ut o nce nation-

examples of public goods are fresh air and electoral democracy as well.[21] It does not matter who creates the public good, the private or the public sector.[22]

According to *Schaefer et al.*, there is a significant difficulty in generating public goods itself. As a rule, there is no incentive for a person to contribute to a public good even if the beneficence is greater than the burden.[23] In addition, denying an individual to benefit from a public good no matter how much or how little he has contributed himself is impossible. That makes public goods deficit.[24] To overcome the problem, society sometimes uses coercive measures.[25] An example of public compulsion is the requirement to equip vehicles with a catalytic convector to ensure air purity.[26] In some cases, the community uses a positive incentive method to ensure the public good, such as administering influenza vaccination to develop herd immunity.[27] In other cases, people get involved in generating public goods because they believe they should do so.[28] For instance, many people vote not because they think their vote will radically change the outcome but because they believe they should support the electoral democracy.[29]

Unlike national security or electoral democracy, the answer to whether biomedical research produces a public good is unclear and much more ambiguous. For a valid conclusion, it is essential to analyze biomedical research from the public good's perspective. Once public good is produced, no one can be excluded from benefiting from it. Indeed, biomedical research may lead to improvements in treatment methods or medications. Though, their availability is limited. *Rennie* points out that millions of people in developing countries still suffer from diseases those effective treatment methods researchers discovered years ago.[30] *Sharp* and *Yarborough* indicate limited public access to health services due to high costs.[31] *De Melo-Martín* points to the social contexts for restricting the use of results of biomedical research as well.[32]

It is noteworthy that *Rosamond Rhodes* – one of the proponents of mandatory human participation in biomedical research, speaks about the unfair distribution of medical resources in the United States.[33] Though, as she explains, limited access to medical services is irrelevant to mandatory human participation in research. *Rhodes* believes that participation in biomedical research should be encouraged in parallel with supporting access to medical care. However, *Rennie* argues that the public good argument can not be strong until everyone has access to the benefits of biomedical research.

Besides limited access to the benefits of biomedical research, scientists consider the factor of ineffective and failed research. According to *Sharp* and *Yarborough*, much biomedical research fails to cure human diseases. This fact strengthens skepticism about the social value of biomedical research.[34] As scholars argue, studies ended in indefinite or unsuccessful results can fall into the ineffective studies category.[35] According to *Schaefer et al.*, the publicly available research's negative consequences are the public good, as the results of the ineffectiveness of the treatment method or substance may be helpful for other studies.[36] Proponents of mandatory human partic-

al defense is in place, they will consume the level that has been produced, not more or less of it. One cannot "opt out" of the consumption of a public good. Similarly, while everyone might like clean air, individuals will differ in their degree of tolerance of pollution. But once "clean air" has been produced, consumers must consume it independently of their preferences". *See.* Reiss, J., 2021 (Fall). *available at:* <https://plato.stanford.edu/archives/fall2021/entries/public-goods/> [Last *See*n 15.07.2022].

21 Head, J. G. & Shoup, C. S., 1969. Public Goods, Private Goods, and Ambiguous Goods, *The Economic Journal, 79(315),* p. 567–572*, in* Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3. Rennie, S., 2011. p. 42.

22 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3.

23 Olson, M.,1965. The Logic of Collective A ction, *Cambridge, MA: Harvard University Press, in* Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3. Samuelson,

24 P. A., 1955. Diagrammatic exposition of a the-ory of public expenditure, *The Review of Economics and Statistics, 37(4),* p. 350–356, *in* Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3.

25 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3.

26 Ibid.

27 Ibid.

28 Ibid.

29 Ibid.

30 Rennie, S., 2011. p. 43.

31 Sharp, R. R. & Yarborough, M., 2005. p. 41.

32 De Melo-Martín, I., 2008. p. 32.

33 Rhodes, R., 2005. *Response to Commentators on "Rethinking Research Ethics",* The American Journal of Bioethics, 5(1), p.17. Rhodes, R., 2008. p. 38.

34 Sharp, R. R. & Yarborough, M., 2005. p. 40.

35 Ibid.

36 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 8.

ipation in biomedical research argue that one person's use of the knowledge made public does not deprive others of using it.[37] Moreover, they point to the inadmissibility of restricting public use of the knowledge gained from research.[38] However, publicly available results being a public good is controversial. Just publicity of information cannot be a public good, though it may facilitate subsequent research and thus be helpful.

Sharp and *Yarborough* focus on biomedical research beneficiaries. People who are skeptical about the social value of biomedical research think that the principal beneficiaries of biomedical research are those involved in developing, manufacturing, and distributing medical products and services.[39] As *Sharp* and *Yarborough* argue, research benefits may be considered relatively limited contributions to the public good as they are available only through a distributional network that cannot be separated from the interests of particular individuals and corporate entities.[40]

Another consideration is about "me-too" drugs. As *David Wendler* explains, "these are drugs identical in all clinically relevant respects to approved drugs already in use and the development of a me-too drug offers the potential to redistribute market share without increasing overall health and well-being."[41] Rennie argues that most research focuses on the production of me-too drugs.[42] This is why there is a strong skepticism about the ideal goals of maximizing population involvement in biomedical research.[43]

Despite the many obstacles to concluding that biomedical research produces a public good, it must be taken into account that biomedical research has significantly contributed to developing public health and reducing infections or diseases. Proponents of mandatory human participation in biomedical research point out that the knowledge gained from biomedical research made it possible to eradicate polio infections over the past century and discover and develop new surgical and other life-saving techniques.[44] Besides, studies have shown the effectiveness of several medical interventions, significantly reducing morbidity and mortality.[45]

Furthermore, *Reiss* argues that "individuals benefit from a healthy population in various ways. For example, the fewer individuals are infected with a contagious disease, the less likely it is that any given (currently healthy) infects him – or herself. These benefits obtain in a non-excludable and non-rivalrous manner. A healthier population is also more likely to be productive, making public health analogous to education."[46] However, a small portion of biomedical research focuses on eradicating infections or improving public health. Considering limited access to health services and medications, producing me-too drugs, and failed and industry-sponsored research, biomedical research does not produce a public good in its classical sense.

BENEFICENCE

Another critical argument supporting mandatory human participation in biomedical research derives from the principle of benefitting others.[47] Some scholars argue that every member of society is responsible for preventing significant harm within a reasonable risk.[48] For instance, various diseases affect both patients and those around them. Biomedical research makes it possible to cure the disease in turn.[49] The principle of beneficence requires engaging in research to alleviate another person's suffering.[50] Thus, a person who refuses

37 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3, *comp.* Seiler, C., 2018. p. 2.

38 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3.

39 Sharp, R. R. & Yarborough, M., 2005. p. 41, *comp.* Rennie, S., 2011. p. 43.

40 Sharp, R. R. & Yarborough, M., 2005. p. 41.

41 Wendler, D., 2021 (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *See*n 15.07.2022].

42 Rennie, S., 2011. p. 43.

43 Ibid.

44 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3.

45 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 3. De Melo-Mart n, I., 2008. p. 28.

46 Reiss, J., 2021 (Fall). *available at:* <https://plato.stanford.edu/archives/fall2021/entries/public-goods/> [Last *See*n 15.07.2022].

47 Rennie, S., 2011. p. 41-42, *comp.* Barry, B., 1995. Justice as impartiality, *Oxford: Clarendon Press,* p. 228*, in* Harris, J., 2005. p. 242.

48 Harris, J., 2005., *in* De Melo-Martín, I., 2008. p. 28.

49 Ibid.

50 Ibid. *See further:* „... Because biomedical research offers our best chance for achieving that end, and because we cannot will an end without also willing the necessary means to achieve it, we are duty-bound to participate in

to participate in biomedical research is indifferent to the suffering and pain experienced by another person and undeservedly and unfairly benefits from past studies in which participants have taken risks.[51] As Wendler argues, medical research inevitably exposes research participants to some risks for the benefit of other or future patients that brings us to the central ethical challenge – when is it ethically permissible to expose participants to risks of harm for the benefit of others?[52]

Proponents of mandatory human participation in research explain that there is *prima facie,* not an absolute, obligation to participate in biomedical research.[53] P*rima facie* obligation exists as long as there are no grounds excluding it.[54] According to *Schaefer et al.,* one should break a promise to meet a friend to take care of his sick child.[55] Like this, if biomedical research violates one's religious belief about bodily integrity, then the obligation to participate in biomedical research might be overridden.[56]

Rhodes emphasizes the nature of a moral obligation. She argues that if an action is morally obligatory, the person in case of non-performance is the addressee of negative moral attitudes like criticism, reprimand, and accusation.[57] Otherwise, there should be any legitimate excuse.[58] Herewith, *Rennie* clarifies the distinction between morally obligatory and morally permissible actions. He states, "there is no blameworthiness attached to the failure to perform morally permissible actions, though other disapproving attitudes may be warranted".[59]

Rennie is interested in transforming action into a moral obligation. He argues that there are some moral reasons to act or not. Besides, "moral reasons in favor of action are necessary, but not sufficient, to make that action morally obligatory."[60] For instance, a person may have a good reason to help homeless people voluntarily after work instead of going to the gym and exercising. Although volunteering has an excellent moral basis, going to the gym is not blameworthy. As *Rennie* suggests, for an action to be morally obligatory, social expectations must support those reasons and give them force.[61] For clarity, *Rennie* points to *Susan Wolf's* argument that there may be a good moral reason to volunteer at a rape crisis center or avoid eating food of animal origin. Though, there is no (or not yet) sufficient social expectation that would transform that action into a moral obligation.[62]

Considering the above arguments, we can conclude that although participating in medical research may benefit others, the risks and burdens associated with biomedical research preclude social expectations that would make research participation morally binding.

FREE-RIDING

As mentioned earlier, testing new drugs and medical interventions in humans poses risks to the research participants, no matter how many laboratory and animal tests precede it.[63] According to *Rhodes,* each of us benefits from medical research. Hence, a person who benefits from research but does not participate in it and therefore does not pose a particular risk is a *free rider. John Harris* explains in the same way. "Where I benefit from research but refuse to participate in it, I am clearly acting unfairly in some sense. I am free-riding on the back of the contribution of others."[64]

research ". , Rhodes, R., 2008. p. 37-38.

51 Rennie, S., 2011. p. 42.

52 Wendler, D., 2021 (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-re-search/> [Last *See*n 15.07.2022].

53 Ross, W. D., 2002. The Right and the Good, *Oxford: Clarendon Press, in* Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 4.

54 Schaefer, G. O., Emanuel, E. J., & Wertheimer, A., 2009. p. 4.

55 Ibid.

56 Ibid.

57 Rhodes, R., 2017. p. 319.

58 Ibid.

59 Rennie, S., 2011. p. 41.

60 Rennie, S., 2011. p. 42, *comp.* „Being a free rider is, however, unfair and people always have a moral reason not to act unfairly. This moral reason is probably enough to justify a n enforceable obligation bu t we do no t have to use compulsion as a strategy of first resort", *See*. Harris, J., 2005. p. 243.

61 Rennie, S., 2011. p. 42.

62 Wolf, S., Moral Obligations a nd S ocial Commands, *in* Metaphysics and the Good: Themes from the Philosophy of Robert Merrihew Adams, 2009. *Oxford University Press,* p. 343-367, *in* Rennie, S., 2011. p. 42.

63 Wendler, D., 2021 (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-re-search/> [Last *See*n 15.07.2022].

64 Harris, J., 1999. The principles of medical ethics and medical research, *Cad. Saúde Pública, Rio de Janeiro, 15 (sup.*

As *Wachbroit* and *Wasserman* propose, merely benefiting is not morally objectionable, so further arguments are necessary.[65] The authors point to the principle of division of labor and, consequently, risk redistribution. In their view, each of us takes advantage of the risks posed by firefighters, although this does not oblige us all to become firefighters. Indeed, there is always the likelihood that some individuals will reap more benefits for the less risk they incur.

Alternative contribution is one of the main counterarguments of the moral basis for mandatory human participation in biomedical research.[66] *Rennie* wonders if it is possible to avoid being a *free rider* without personal involvement in the study. So, he offers an experiment in which a person donates a part of a hospital for research purposes, sponsors young researchers, or contributes to research by paying taxes. So, a person is not a *free rider* in its literal sense because he directly contributes to the research or in the form of taxes.[67]

Wachbroit and *Wasserman* discuss the need for participation in research in kind. As Rhodes suggests, a person who enjoys the benefits of diabetes research can fulfill a moral obligation by engaging in genetic research. Accordingly, if a diabetic patient can avoid being a free rider by participating in genetic research, why can't the same be said in the case of teaching something?[68] "Dispute is narrowly confined to the question of whether we must contribute our bodies as well as our money. Because of the impossibility of medical advances without humans subjecting themselves to study, we have to give more than just our cash," – argues *Rhodes.*[69]

Rennie makes another assumption: the number of subjects willing to participate in biomedical research is enough or surplus. In that case, the moral basis for participating in the study is as weak as when requesting a blood donation when there is no blood shortage. *Rennie* argues that mandatory human participation in biomedical research rests on a somewhat *utilitarian assumption* – if more people volunteer for research, more discoveries will lead to significant social benefits. So, from the utilitarian perspective, biomedical research ought to be expanded as far as possible to maximize potential benefits, in which case there will never be enough research participants.[70]

For *Rennie,* one might test the soundness of the utilitarian approach by empirical facts. In particular, the practical management of biomedical research and implementation of its results should be evaluated. Besides, we should take into consideration the moral basis for mandatory participation in research – *the public good argument,* according to which biomedical research significantly improves public health.[71] According to *Rennie,* most research focuses on producing me-too drugs, or most of the funds raised for research focus on the diseases afflicting a small portion of the world's population. That creates a strong skepticism about the ideal goal of maximizing population involvement in biomedical research.[72] Also, statistics show that the majority of industry-funded research results are favorable to research sponsors, or adverse research outcomes are unknown to physicians and patients. Also, statistics show that the majority of industry-funded research results are favorable to research sponsors,[73] or adverse research outcomes are unknown to physicians and patients.[74]

Despite *Rennie's* arguments, there is no doubt that the development of medicine depends on discoveries made through biomedical research. However, the moral duty to participate in biomedical research associated with personal risks and burdens should also be analyzed from the perspective of individual freedom and contract theory.

1):7-13, p. 12.

65 Wachbroit, R., Wasserman, D., 2005. p. 48.

66 Rennie, S., 2011. p. 42.

67 Brassington, I., 2007. John Harris' Argument for a Duty to Research, *Bioethics, 21(3),* p. 160-68, *in* Rennie, S., 2011. p. 42, *comp.* De Melo-Martín, I., 2008. p. 29.

68 Wachbroit, R., Wasserman, D., 2005. p. 49.

69 Rhodes, R., 2005. Response to Commentators on "Rethinking Research Ethics", *The American Journal of Bioethics, 5(1), W15-W18,* p. 17.

70 Rennie, S., 2011. p. 43.

71 Ibid.

72 Ibid.

73 Bekelman, J. E., Li Y., Gross, P. C., 2003.Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review, *Journal of the American Medical Association, 289,* p. 454-65, *in* Rennie, S., 2011. p. 43.

74 Rennie, S., 2011. p. 43.

CONTRACT THEORY

Some scholars link mandatory human participation in biomedical research with *Contract Theory*. In particular, as *David Wendler* explains, "at least all individuals who have access to medical care have benefited from the efforts of previous research participants in the form of effective vaccines and better medical treatments. One might try to argue that these benefits obligate us to participate in clinical research when it's our turn."[75] Nevertheless, as *Wendler* argues, these are the future patients who will benefit from the current participation in clinical research. So, "if we incur an obligation for the benefits due to previous research studies, we presumably are obligated to the patients who participated in those studies, an obligation we cannot discharge by participating in current studies."[76]

For some scientists, it is conceptually wrong to deem the altruistic merits of previous generations as a *debt*.[77] They consider it quite enough to express gratitude for the *gift*.[78] Herewith, *Arthur L. Caplan,* the professor of bioethics, considered it too naive to deem participation in medical research only as altruism.[79] For clarity, he brought attention to coercion, deception, or compensation for participation in the studies. Besides, according to *Wendler,* contract theory does not work in case of the very first clinical trials since the participants had never benefited from previous clinical research.[80]

Alternatively, one might argue that we are obliged to participate in research, not for the benefits we receive from the efforts of previous participants, but to the social system in which we live and that research is part of it.[81] In particular, we have to do our part because of the many benefits we have received as a result of living within the social system.[82] As Wendler argues, the first challenge for this position is to clarify why the mere enjoyment of benefits, without some prospective agreement to respond in kind, obligates individuals to benefit others. For instance, if you did something nice for me yesterday without my invitation or knowledge, why am I obliged to give you a good turn today? This question is much more critical in case of pediatric research.[83] According to Wendler, children benefit from previous research studies as usual, but typically do so unknowingly, so, the case of pediatric research makes it complicated to justify mandatory participation in research based on contractualist grounds. "Contract theories have difficulties with those groups, such as children, who do not accept in any meaningful way the benefits of the social system under which they live" – argues *Gauthier.*[84] Thus, *contract theory* fails to provide sufficiently strong arguments to justify the idea of a moral duty to participate in research in kind.

CONCLUSION

Scientists supporting mandatory human participation in biomedical research rely on the doctrines of *public good* and *free-riding,* the principle of *beneficence*, and the *contract theory.* According to the proponents, almost all members of society enjoy the public good of health services generated from biomedical research, which creates so-called duty to make our part. However, as already discussed, considering the limited access to health services and medications, producing me-too drugs, and failed and industry-sponsored studies, biomedical research does not produce a public

75 Wendler, D., 2021 (Winter). The Ethics of Clinical Research, *The Stanford Encyclopedia of Philosophy,* Edward, N. Zalta (ed.), *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *Seen* 15.07.2022].

76 Ibid.

77 Simmons, A. J., 1979. Moral Principles and Political Obligations, *Princeton University Press, in:* Caplan, A. L., 1984. p. 3.

78 Ibid.

79 Ibid.

80 Wendler, D., 2021 (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *Seen* 15.07.2022].

81 Brock, D. W., 1994. "Ethical issues in exposing children to risks in research," Chapter 3 (pp. 81–101) of Grodin and Glantz (eds.), Children as Research Subjects, *New York: Oxford University Press, in* Wendler, D., 2021. (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *Seen* 15.07.2022].

82 Wendler, D., 2021. (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *Seen* 15.07.2022].

83 Ibid.

84 Gauthier, D., 1990. Morals by Agreement, *Oxford: Clarendon Press, in* Wendler, D., 2021. (Winter). *available at:* <https://plato.stanford.edu/archives/win2021/entries/clinical-research/> [Last *Seen* 15.07.2022].

good in its classical sense. So, as *Rennie* argues, the public good argument cannot be sufficiently strong until everyone has access to the benefits of biomedical research. Besides, although participating in medical research may benefit others, the risks and burdens associated with biomedical research preclude social expectations that would make participation in biomedical research morally binding. As for the contract theory, it fails to provide solid arguments for the example of pediatric studies and the example of the earliest studies.

To summarize the issue, one might ask how the existing *status quo* will change if participation in research is morally binding. In particular, if participation in biomedical research is a moral duty, would participation be a real choice? Would it still make sense to get *informed consent* from a research participant? Would it still be appropriate *(as is now commonly part of the consent process)* to tell participants that they can leave a study at any time? How might the ethics review of research change if participation becomes morally obligatory? – these are questions to which there are still no reasonable answers. When it comes to changing the existing moral paradigm of participation in research, we need to consider one more issue – whose interests it is. Furthermore, as *Rennie* suggests, the moral status of research participation cannot be separated from its history. Nazi experimentation and abuses, at least in part, consolidated the view that participation in research should not be obligatory in order to protect research participants from exploitation by more powerful stakeholders.[85]

In any case, scholars supporting the changes must present credible evidence that the change will bring more benefits than burdens when discussing transforming the *status quo* of biomedical research ethics. Suppose a new paradigm, where participation in biomedical research is morally binding, leads to negative consequences. In that case, it will be an additional reason not to change the existing moral status. So, the ball is in the court of the proponents of mandatory human participation in biomedical research. It is their turn.

85 Rennie S., *Viewing Research Participation as a Moral Obligation: In Whose Interests?,* Hasting Center Report, 41(2), 2011, 46.

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