Oversight of biohacking when the stakes are high: Ethics police or FBI?

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ABSTRACT

Biohackers should fall within the scope of research ethics boards, known as the "ethics police," regardless of FBI involvement in reeling them in if they break the law. It may even be argued that the bioethical principles, often discussed in research ethics, may align with the goals of biohackers. Both bioethicists and biohackers argue that equitable access and justice should be pursued, however, the means by which this is achieved differs greatly. Bioethicist and journalist, Alex Pearlman, is leading a project to help biohackers set-up their own norms. This paper argues that ethical conduct of biohackers falls within the broad scope of research ethics, with special consideration of practical implications and recommendations.

Biohacking refers to any form of optimizing or improving one's body or mind and is part of synthetic biology and the DIY (do-it-yourself) community.

Keywords: biohacking, research ethics, CRISPR, WHO, scientific centralization, open science

INTRODUCTION

A gap exists in the scholarly field of research ethics in which the conduct of biohackers (often in their garages) is dismissed as a non-scientific phenomenon.[1] Bio-hacks like ex-NASA scientist Josiah Zayner's attempts to make muscles grow bigger by using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)-Cas9 system to disrupt the myostatin gene, with himself as research subject, did not pass through any of the usual institutionalised ethical gatekeepers.[2] Some argue biohacking, which includes the unauthorized or unethical exploitation or altering of genetic material experimentally, is against the law and therefore has nothing to do with research ethics nor IRBs.[3] In 2009, the US Federal Bureau of Investigation (FBI) joined forces with unusual allies:[4] biohackers. The FBI did this by hosting them at the International Genetically Engineered Machine Competition (iGEM) with the goal of educating and building a network between the U.S. Government and the biohacking community.[5]

Biohackers should fall within the scope of research ethics boards, known as the "ethics police,"[6] regardless of FBI involvement in reeling them in if they break the law. It may even be argued that the bioethical

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principles, often discussed in research ethics, may align with the goals of biohackers. Both bioethicists and biohackers argue that equitable access and justice should be pursued, however, the means by which this is achieved differs greatly. Bioethicist and journalist, Alex Pearlman, is leading a project to help biohackers set-up their own norms.[7] This paper argues that ethical conduct of biohackers falls within the broad scope of research ethics, with special consideration of practical implications and recommendations.

Biohacking refers to any form of optimising or improving one's body or mind and is part of synthetic biology and the DIY (do-it-yourself) community.[8] The human augmentation market is estimated to grow to $2.3 billion by 2025.[9] Considering these numbers, biohacking is not an irritating fad, it is a distinct trend. Social phenomena do not exist in isolation; they are influenced by cultural and political values.[10] Their conduct implies a general disregard for authoritative powers and a desperate attempt to democratize science[11] and the clinical applications thereof, making it accessible for all. The conduct of biohackers should be considered scientific research. Biohacking forms part of general scientific inquiry and consequently falls within the Ethos of Science.[12]

Although biohackers generally operate in the privacy of their homes or online, many first gathered in 2003 for iGEM at Massachusetts Institute for Technology.[13] In 2011, 165 teams took part in the competition, and in 2012 a High School and Entrepreneurship Division were added.[14] The projects ranged from "…rainbow pigmented bacteria and banana smelling bacteria to an arsenic biosensor."[15] Today, communities such as Biobricks offer online education and training, and Genspace (NYC) offers a community biolab.[16]

II. Background: Shifting paradigm

Scientific inquiry is indebted to Greek Philosophers such as Socrates, Plato and Aristotle, who used reason rather than myths and stories to explain the world around them. Today, the academic publishing industry is worth billions, driven by the exponential accumulation of data.[17] Research, includes all basic, applied, and demonstrated research.[18] Research records such as progress reports, journal articles, and laboratory records make up the facts resulting from scientific inquiry.

During the development of science there was a shift from open science (consider the Wright brothers who produced the first successful airplane), to a centralized institutionalization of science. Furthermore, the foundations upon which ethical scientific research were built are a "…complex of values and norms which is held to be binding on the man of science."[19] The norms that guide research practices are communalism, universalism, disinterestedness and organized skepticism.[20] Stehr differentiates between social and cognitive norms of science, identifying a split between scientific ideas and scientific practice.[21] These developments inevitably came with a strong drive toward monetization. Consequently, both in biohacking and mainstream science, it would be prudent to keep in mind the possibility that objectivity of facts could be duly influenced. This is an evolving process by which science, society and economic factors determine research and its clinical application, *i.e.,* what is eventually brought to market.[22]

The oversight of research and clinical application of CRISPR-Cas9, the bacterial immune defense system[23] which can be used to easily and cost-effectively edit any genome has been disparate and controversial. In 2015, one of the lead scientists in the discovery, Jennifer Doudna, called for a temporary moratorium on the use of CRISPR for clinical human gene editing until further research.[24] It should have been understood that clinical application of CRISPR in germline cells, which are heritable changes in human sperm or egg cells, should not proceed anywhere in the world. Yet, subsequent events suggest this was insufficient. In 2018, He Jiankui, exploited this grey area when he edited heritable changes into human

embryos, and two baby girls were born. He Jiankui claimed that he had CRISPR edited these children's genome by targeting the CCR5 gene to make them resistant to HIV, knowing their father was HIV positive. This, however, was a violation and ethical breach as there are much safer and more efficient ways to prevent acquiring HIV during the process of in vitro fertilization. Even though somatic cell gene editing research as well as germline research is considered ethically acceptable, it is not acceptable to transplant any gene edited cells into a person's uterus.[25] In reaction, a well-established group of 18 scientists from seven countries called for a global moratorium against making genetically altered children.[26] This example of one scientist's exploitation of unclear oversight, resulting in the altering of the gene pool of humanity with CRISPR technology, is a reminder that the stakes are high.

Additionally, the National Academy of Medicine and National Academy of Sciences and the United Kingdom's Royal Society and others formed the 2019 International Commission on the Clinical Use of Human Germline Genome Editing to set-up new, more stringent, and clearer recommendations, which may be binding in the future.[27] The World Health Organization (WHO) also formed the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing in 2019 to provide a comprehensive report that avoids ambiguity.[28] It is anticipated that this report will be released in the summer of 2020.

The constraints that govern mainstream institutions are mostly responsible for biohackers' untraditional methods of conducting research. The strenuous process of passing through ethical gatekeepers enshrined by academic institutions[29] also sparks biohacking. These rules and regulations can discourage scientific inquiry, slow down discoveries, and make it more difficult to bring much-needed solutions to those with diseases. By working against open science, too many rules are a constraint. Yet without ethics oversight, biohacking would continue unchecked, possibly risking safety. The difference between research by professional scientists and biohackers is that biohackers can do things which are prohibited through mainstream science.[30] Experimentation without any oversight may lead to risks outweighing benefits. Biohacking without respect to ethics is not aligned with the WHO's guidelines of scientific integrity.[31] Some argue that wide acceptance of CRISPR-Cas9 technology, could follow suit of the personal computer.[32] People were skeptical about personal computers in their homes, and today everyone has a smart phone in their hand - generally unregulated, used by the public as they see fit.

III. Scope of Research Ethics

The scope of research ethics spans an infinite and diverse field of inquiry.[33] Legally binding documents such as Nuremberg code,[34] Declaration of Helsinki[35] and Belmont report[36] help govern inevitable research involving humans by requiring informed consent and IRB/REC approval. The Declaration of Helsinki by World Medical Association[37] states that "the primary purpose of medical research is to generate new knowledge, however that this may never take priority over the rights and interests of individual research subject."[38] Medical research, involving human subjects "must conform to generally accepted scientific principles and be based on thorough knowledge of the scientific literature, other sources of relevant sources of information and adequate laboratory and as appropriate, animal experimentation."[39] "The design and performance of each research study involving human subjects must also be clearly described and justified in a research protocol."[40]

Biohackers usually do not have formally approved protocols and this lack of clarity is further highlighted when biohackers exercise their right to autonomy and self-informed consent by "enrolling" themselves as research participants in their own experiments, bypassing the role of IRBs. IRB's main imperatives are to

ensure scientific relevance, quality and integrity of the study, that the interests of all potentially affected parties are considered and that adequate risk-benefit assessments are done.[41] These standards for the research ethics review system[42] function within a systemized approach. This implies that all research with human participants is "presumptively subject to IRB oversight" and also forms part of larger research participant protection programmes that ensure effective training and efficient functioning.

Under WHO's[43] systemized approach, biohacking forms part of the broad scope of research ethics and is within the ethos of a person of science's norms.[44] Biohackers promote the norm of communalism as scientists rely on past science, basing their search for new discoveries on meaningful data.[45] Even unconventional research cannot be conducted without building on previous discoveries. Biohackers are part of the broadly defined scientific community.

An alternative suggestion is for biohackers to self-govern. Some argue for the institutionalisation of biohackers, which may speak to the norm of universalism, on networks such as diybio.org, promoting self-governance of biohackers collectively. Alex Pearlman, a bioethicist and journalist, wants to help develop a set of norms distinct to biohackers. There is an urgency to establish a framework for systematically evaluating the risks and dangers of biological engineering.[46]

It can be argued that biohackers are not violating the bioethical principles as they are self-informed and autonomous. They are exercising their respect for their autonomous decisions, by choosing to elect themselves as the research participant, *i.e.,* promoting the principle of distributive justice and beneficence. However, if they do germline editing, it holds risks and consequences for humanity that already are strongly governed by bioethical standards. Biohackers should not be exempt from well-defined principles merely because they claim to operate based on other principles. Within structural scientific communities, researchers cannot claim that autonomy allows them to violate Helsinki standards.

The field of research ethics should adapt to the paradigm shift of biohackers making important scientific discoveries. An attempt to engage instead of passing the buck to the FBI would lead to collaboration to develop ethical framework and give biohackers bright-line guidance. Some might argue that the FBI's oversight is sufficient as a policing power. However, the FBI chooses to involve itself in the actual act of biohacking by hosting iGEM. Bringing biohacking into the scope of research ethics would address the ethical conduct of biohackers within research ethics, engaging the biohackers in the process of creating a systemic ethical framework.

IV. Practical considerations

Opposing critics might argue that to consider biohackers as part of the scope of research opens up an array of complexities. Some assert that IRB's are already overworked and that there is no capacity for reasonable oversight of biohackers. However, the stakes are too high to not rise to the challenge of implementing a system of oversight.

Some also argue that, for now, biohackers are not conducting research of consequence. Sloppy experiments done in kitchens do not amount to precise measurement of scientific outcomes. Even if adequate empirical data could be collected it is likely that their research design would have a n=1 hypotheses, which is insignificant ($p<0.05$). Yet, the Chinese twins and other experiments show both an active field and the promise of new preventions and cures. As biohackers make more consequential discoveries, an organized ethical oversight is warranted.

Conclusion

Research ethics has not addressed the conundrum of ethical conduct of biohackers sufficiently. Biohackers indicate a paradigm shift from a centralized power back to decentralisation with a strong focus on the democratization of science. While biohackers can lead to more accessible research and push science forward, the new paradigm calls for oversight in forming an ethical framework to which they must adhere. Biohackers themselves should be invited to engage with the traditional scientific sphere to help frame the ethical guidelines and to represent their viewpoints and their scientific goals.

Better considerations should be made as to how research can be made more accessible for all. Bioethicists and IRB specialists can investigate how treatments for curative diseases can be brought to market in a more time efficient yet safe way. A balanced approach would hold biohackers accountable to ethical standards while addressing their concerns of scientific freedom and market-based accessibility to new discoveries. Biohackers should be empowered to continue hacking in garages and basements with the hopes of a lucrative and scientifically valid discovery, albeit one that is ethically achieved.

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