# A Population of Addiction

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Scientific research takes pride in the multitude of new, modern medical advancements through pharmaceutical, surgical, and therapeutic interventions. However, one of the most prominent issues in today's population is not the development of new life-saving drugs, but rather the abuse of already established medications. Healthcare has reached the point to which physicians are forced to over-prescribe medications, especially powerful opioids and pain supplements. In turn, America is experiencing the effects of rising addiction cases in patients. Unfortunately, because the epidemic is so new, there is little previous research on the best form of treatment for these suffering patients. In addition, it is not known how patients who are addicted to such serious medications will react to clinical trials aiming to research their disorder. In this paper, I plan to analyze the ethical implications of having research subjects who are actively on mind-altering drugs at the time of study consent and throughout participation. I believe that as long as the processes of consent are comprehensive, the patient is fully aware of what he or she is agreeing to, and there is an open, reciprocal relationship between the investigator and the participant, the study is justified to work with drug-addicted subjects.

This past summer I interned for a public health research organization working on a new clinical trial. This trial was testing a new treatment plan for patients suffering from an opioid use disorder in low-income areas. I worked alongside the patients throughout the program, and collected data on their progress in order to learn how to help their addictions in a comprehensive way. The patients generally seemed appreciative for our help. However, at times some were agitated by our frequent, mandatory visits and use of biological samples even though they consented to all aspects of the study at the beginning of the research period. Many participants would also fail to show up to required visits or check-ins and therefore relinquish their participation in the study without completing the full treatment.

This experience raised a few fundamental questions about a participant's full and true consent. In order to be a part of an addiction study, a participant is assumed to be currently using the medication or supplement that the investigator is researching. However, how can a participant consent if these drugs have the ability to alter states of consciousness, modify memories, or force patients to make regretful decisions at the time of being actively under the influence?

In the *Belmont Report*, which summarizes the basic ethical principles of conducting a research study, it mentions the following concerning participant consent: "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" (Ryan et. al. 6). Respect for persons addresses the basic principle of protecting the rights of human subjects. This emphasis on the participant's capability of consent is important in studies including addicted participants. If being under the effects of drugs is the subject's normal state of function, then it can be concluded that this is the state they make many other decisions concerning their lives. The report also includes the responsibility of the researcher to keep the participant as comfortable and informed as possible with the study's work. The report stresses that, "It is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information" (Ryan et. al. 7). Therefore, if the subject is under the influence of drugs, it is the researcher's job to adapt its consent policy to be most beneficial, and informative to the participant under these circumstances. As evident in previous research with addicted subjects, "[investigators] found support for previously reported components of the therapeutic misconception, as well as for two core concepts that differentially influence comprehension of informed consent information for the drug users in our study" (Fisher et. al 2).

This research compared patients sober and on addictive drugs and their understanding of research. It pleads for studies to provide extra safeguards against any misunderstandings. An example of an improvement to this primary stage would be a comprehension quiz at the end of a consent packet to make sure the participant understands all the prevalent information. An additional method could utilize a form of continuous consent that must be re-signed once a month to make sure the subject has not forgotten and important risks or benefits to the study process. These processes will not only allow the patient to feel more comfortable and aware, but will also let the researcher continue the study itself without any ethical hesitation.

The Belmont Report also comments specifically on volunteers whose comprehension is limited. It has been proposed that for patients with serious limitations, a third party should be involved in consent: "Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm" (Ryan et. al. 7). Although this point is a fair rebuttal for those with significant limitations, this does not seem relevant for subjects under the influence of opioids. If the participants are still able to live independently while on the drug, a third party would not be needed to sign additional consent. In addition, these studies could not have a serious enough risk for a third party to be involved as IRB guidelines would not allow this.

The biggest issue of a study including drug addiction research is the vulnerability of the participants. They are able to be a part of the project because they are addicted to a debilitating drug or medication. The need for quick and efficient help can make any form of benefit or reward more valuable as the situation is dire. This can lead participants to consent to studies because they think it is the only option, and do not fully pay attention to risks. As the Belmont

Report warns, “inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable” (Ryan et. al. 8). With this information, researchers should make sure to make known to the patient all treatment services available, and direct them to other help centers if they refuse a trial.

In addition, the relationship between the researcher and patient must be positive and supportive. There are levels of trust for drug populations, as many Americans who are using drugs such as opioids may not be buying them legally. The patient can also easily begin buying legally and transition to other methods of use and stronger medications such as heroine. If the investigator shames the participant or considers legal action against them, then the participants are not in a safe research environment. If careful consideration of subjects is ensured from the beginning, then the methods of consent and the relationship between the subjects and the teams should be respectful and trustworthy.

As evident in drug statistics, wide ranges of individuals are seen in affected by this epidemic. Although there are trends, there is no one race, class, or gender that is solely the addicted population. Stated in *Addiction Research Ethics and the Belmont Principles: Do Drug Users Have a Different Moral Voice?*, “the life situations of individuals who use illegal drugs on a regular basis combined with the socio-ecological context in which addiction science is conducted often raise unique and unexpected conflicts between different ethical principles” (Fisher). Every patient entering the study will have a different story. It is important to not only respect the person, but also try to cater to the participant in an individualized way while still keeping the integrity of a standardized study.

From the above examples, it is clear that although studies involving opioid addicts can be very effective, this subject group should have a careful set of precautions built into research

guidelines for their benefit. The participants should have as clear a consent process as they are capable, as well as an honest relationship with the research staff in case of any questions or concerns. It is evident from previous research that this population is vulnerable. Therefore further ethical study is recommended while the population finds out more about this epidemic, and the people who suffer from addiction everyday.

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