

Conserving Culture: CBPR as a Framework for Group Research

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Recent research emphasizing shared genetic traits among members of a population has caused human subjects researchers to reexamine ethical standards surrounding interactions with groups. Specifically, the *Havasupai v. Arizona Board of Regents* case, in which researchers from Arizona State University (ASU) took blood samples from members of the Havasupai under the pretext of looking into their high incidence of diabetes, only to use these samples for research that stigmatized the tribe, drew a lot of attention to research misconduct between researchers and Native American tribes. In response to this, numerous reforms relating to beneficence, justice, and respect for persons were proposed among the research ethics community. Of these proposals, the only one that truly prevents future ethical problems, particularly in cases when scientific values conflict with cultural beliefs, is Community Based Participatory Research (CBPR), which successfully mends past breaches of trust between tribes and researchers by opening a channel of communication between the two. Additionally, despite claims to the contrary, CBPR can be successfully applied to larger, non-isolated groups that share a socially identifiable trait to prevent future ethical breaches.

Increased interest in groups that are “socially identifiable” is not surprising given the nature of genetics. Beginning with the Human Genome Diversity Project (HGDP) in the early 1990s, researchers have had an interest in finding out why members of a population with a common ancestor are particularly vulnerable or resistant to certain diseases. In the Havasupai case, this was true for both the original intent of the study and the later intent of the ASU researchers, as they were originally seeking to find out why diabetes was so prevalent, but wound up reporting that a Havasupai ancestor had been schizophrenic. The failure of HGDP

was, in fact, a precursor to the failure of ASU researchers in the Havasupai case. Native Americans concerned about the possible consequences of HGDP's findings on their tribe's dignity were part of the reason the "plug was pulled" on HGDP (McGregor 2007, 359). Similarly, the Havasupai tribal council banished ASU researchers from their grounds after the latter published information about tribal migration and ancestry that contradicted the tribe's origin and migration story, thus possibly causing them to lose their rights to their sacred Grand Canyon land. Thus, the increased interest in doing research on groups has brought with it intense scrutiny about the results that should or should not be published by researchers.

Misconduct by researchers, while severe, is not the first time Native American trust has been betrayed by Western civilization. Deborah Morton et al. list tribal grievances against non-Native peoples as "theft of land, culture, language, children, sovereignty, natural resources, artifacts, and ancestral bones and native symbols, as well as lack of respect for values, culture, tribes, elders, individuals, religion, and sovereignty" (Morton et al. 2013, 2160). Given this long list of conflicts where Native Americans were downright disrespected by outsiders, it is not surprising that research misconduct has caused many tribes to refuse or even banish researchers from nearby universities.

In order to heal the divide between Native American tribes and researchers and ensure ethical research conduct, some ethicists have proposed new laws and regulations for researchers to adhere to. For example, Michelle Mello and Leslie Wolf propose a new informed consent process known as "tiered consent," in which participants in a study are given a sort of consent "menu" where they can specify what is and is not appropriate use of their sample (Mello and Wolf 2010, 204). However, in addition to it being logistically impossible to keep track of all the potential uses of each *anonymized* sample against the wishes of the *named* person who donated

it, calls such as this one for regulatory reform actually further marginalize Native American tribes. As Nanibaa' Garrison discovered when she interviewed IRB chairs and researchers in the aftermath of the Havasupai case, increased scrutiny of consent forms is only causing them to become more broad, causing Native American tribes to be less inclined to agree to an "all in" option for research studies, leaving them with no other option but not to participate at all (Garrison 2012, 216). She also points out that "increased regulation and broad consent language may... shift attention away from thinking about equal access ... for research" (Garrison 2012, 216), evidencing that both Native American tribes and researchers are less inclined to work with each other in research if new regulatory reforms are introduced. It is therefore clear that regulatory reforms intended to protect Native Americans have had the opposite effect when it comes to working with tribes, further marginalizing them and preventing them from participating in research.

While some have sought to increase regulation on researchers, other proposed solutions advocate making it easier for Native American tribes to seek redress against rogue researchers. For example, Kristof Van Assche et al. argue for three important reforms to the tort system so that tribes like the Havasupai can be compensated for their losses as a result of research misconduct. Namely, Van Assche et al. call for a fiduciary relationship between researchers and their subjects (so that participants can seek reparation for breach of fiduciary duty) and an expanded scope of harm to include dignitary harms, which they define as harms resulting from "participants not being treated with the dignity they deserve" (Van Assche et al. 2013, 54). They also claim that easing the burden of proof on the tribe to prove such harms would help them win lawsuits, thus making it more imperative for researchers to work with them ethically (Van Assche et al. 2013, 79-81). While these solutions do indeed make it easier for tribes to seek

financial compensation, they do absolutely nothing to heal the divide between researchers and tribes, which is in fact the real threat to continuing research, as long, drawn-out court fights would only add bitterness to an already toxic situation. Consequently, it is clear that amending existing tort law to allow for more lawsuits between tribes and researchers will only perpetuate the existing climate of distrust between the two sides, preventing future beneficial research.

Instead of cumbersome regulatory and legal reforms, research ethics should focus on cooperation between researchers and tribes and a balance of tribal beliefs and scientific goals. Because tribe and group members are the best advocates for their values and researchers are the best advocates for scientific progress, a sensible solution is to have the two parties work together in Community Based Participatory Research (CBPR). Anna Harding et al. present their version of CBPR when working with the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). They lay a framework for negotiation between tribal elders and researchers that includes agreement on the “purpose of the project, types of material and data collected,” constraints on “material and data use,” agreements about “data access and security,” risk-benefit analysis, and mutual review of any potential publications (Harding et al. 2012, 9). The negotiation and agreement on each major part of the research project thus allows tribal leaders, who are used to speaking for the entire tribe, to know and understand what they are agreeing to and be advocates for the researchers in recruiting participants. The interests of both parties are then properly balanced: researchers are able to make discoveries and produce publications while the tribe is able to gain knowledge about diseases or other genetic traits that characterize it.

In addition to addressing the balance between scientific values and cultural beliefs, implementation of CBPR prevents any Havasupai-like case from occurring in the future because it successfully bridges the present gap in trust between researchers and Native American tribes.

To begin, CBPR forces researchers to reveal the real project scope to tribal elders, and thus in the Havasupai case the tribal council would have only given license for diabetes research. The tribal council can then monitor this research by making sure constraints on sample use are properly implemented, and could demand the return of samples were these agreements violated. This component of CBPR rectifies a key cultural difference between researchers and Native Americans: the value of blood samples. Katherine Drabiak-Syed discusses the long-held Havasupai (although not uniquely Havasupai) belief that members need to have all of their blood buried with their bodies in order to pass over to the “spirit life.” Accordingly, she states, the three members of the tribe who passed away while the study was ongoing were never able to pass over to the “spirit life,” causing emotional harm to their families (Drabiak-Syed 2010, 214). CBPR addresses this grievance, as agreements over material access allow tribal families to access the blood samples and bury their loved ones in peace. Once again, the ability of CBPR to address the failures in the Havasupai case shows its applicability in working with Native American tribes when researchers are not privy to key parts of tribal culture.

An interesting extension of CBPR that best represents its goal is the introduction of a tribal IRB that has both input and final say in all parts of a study involving tribal members. Morton discusses her group’s experience with the California Indian Health Council (IHC) IRB, in which she states that the IHC IRB was able to analyze cultural risks and benefits effectively because they themselves were tribal members and therefore experts in tribal beliefs. Meanwhile, since they were all employed by the tribal clinic, IRB members were also professionals in science and could therefore effectively negotiate a research proposal and make sure that consent forms were understood by tribal members while accurately reflecting the goals of the study (in this particular case, consent forms were read aloud to the participants, which allowed researchers

to easily confirm subjects' understanding of what would occur in the trial). Finally, the tribal IRB promoted participation among patients of the tribal clinic and reviewed any potential publications with medical expertise (Morton et al. 2013, 2162). Most importantly, every tribal member who received services from the clinic was assured that the researchers could be trusted, allowing them to "release their... negative concepts of ... university scientists" (Morton et al. 2013, 2162). While the tribal IRB does add an extra level of tribal authority to CBPR in giving the tribe final say over all decisions surrounding a study, it can be viewed as an extension of CBPR because it effectively accomplishes all that CBPR sets out to do: ensure ethical research while bridging the trust gap between researchers and tribal participants. While it is not essential for CBPR, the tribal IRB is certainly a useful tool for tribes that are adequately suited for it.

It will inevitably be argued by those who favor the regulation approach that CBPR is simply too cumbersome and therefore discourages researchers from working with Native American tribes. However, CBPR is, by definition, a way of *increasing* participation from tribal members in research. In fact, CBPR represents the most effective path to work with Native American tribes because, by its implementation, tribal members are more inclined to trust researchers and therefore participate in the study enthusiastically. The alternative, where members feel forced to participate and are not actively encouraged by their tribal council, all while feeling a looming sense of fear and distrust for researchers, is far more dangerous. So CBPR is not just a way to ethically do research on tribes; it is a way to encourage tribes to participate in research and ensure trust between the members of the tribe and the researchers who work with them.

While CBPR is undoubtedly the most effective way to work with tribes and ensure ethical research in small, structured groups, many of its opponents argue that it cannot be

effectively generalized to groups other than small Native American communities. But there are many groups that have their own motives for research and have a structure similar to Native American tribes that also feel a sense of distrust for the researchers. For example, foundations centered on looking for cures for rare diseases, often started by parents whose children are inflicted with the disease, present a good opportunity to conduct CBPR. In these cases, the fight of parents against time is pitted against the slow process of proprietary publication and intellectual property rights in a cultural battle. In *Greenberg vs. Miami Children's Hospital*, parents that were part of a Canavan disease foundation sued a Miami Hospital after it halted research and testing on the disease by claiming a royalty on use of the gene for Canavan disease that one of its researchers had discovered (Lewis 2012, 200-201). Here it is clear that the importance of the ownership of the gene trumped the parents' fight against time. But a CBPR-type agreement prior to the research being conducted would have prevented these values from ever coming into conflict, as the parents would have been able to stipulate prior to the research being conducted that their goal was for the test to be offered free of charge. For example, Hannah's Hope Fund, a group run by parents of children with giant axonal neuropathy (GAN), supplies grants to and monitors researchers in a CBPR-type collaboration, allowing both sides to retain ownership of any discoveries so that future progress will not be impeded (Lewis 2012, 168). It is therefore clear that the use of CBPR is not limited to Native Americans; it can also prevent other cultural-scientific conflicts, such as this one that pitted scientific ownership against parents' concern for their children's health.

CPBR can also be applied when researchers are looking to work with larger, unstructured groups that share a socially identifiable trait. As with small, structured groups, members of larger groups such as the African American or Hispanic communities can suffer from dignitary harms

as a result of research. For example, conclusions about a particular disease, such as schizophrenia, having a higher incidence among either population would lead to stigmatization just as it did with the Havasupai. In this case, it is still possible for the group to have leaders chosen from its ranks that can effectively represent the interests of its members. When implemented in this manner, CBPR can be effective when working with larger, unstructured populations.

An excellent way for CBPR to be applied among larger populations is for the group to select an internal structure for itself. Lainie Freidman Ross et al. explore the complexities of working with unstructured groups, arguing for the implementation of CBPR among these populations. They offer three possible avenues by which groups can become structured: researchers can choose representatives of the group, a third party organization can empower the group to structure itself, or the researchers can empower the group to structure itself (Ross et al. 2010, 11). The first case, as Ross points out, is toxic since instructions from leaders that the group might not perceive as legitimate will likely be ignored. However, if the group is able to structure itself, those leaders will be perceived as legitimate and can therefore effectively negotiate for the group, implementing CBPR effectively and ensuring ethical research in the same way as for Native American tribes.

The means by which leaders and representatives are selected for CBPR will vary from group to group. Consider two representative examples, the African American community and the community of homeless people in Ohio. The African American community is a large group which spans all regions of the education spectrum. As a result, there is no shortage of potential experts that could form an “African American IRB” and/or become leadership that negotiates with researchers. The difficulty here is in selecting representatives, but in reality this is not as

complex a task as it seems. In fact, African Americans and other large, diverse communities already have leadership in place through organizations such as the NAACP and Congressional Black Caucus. These leaders already represent and speak for the African American community on a variety of social justice issues, and it is not unreasonable to add research ethics to this list. The idea for developing “internal leadership” of larger, unstructured groups would therefore be to effectively combine the leadership from already established sub-groups, leaning on informal leaders of the entire group to form a “council” of experts in medicine and other leaders that could effectively work with researchers to implement CBPR.

On the other end of the spectrum, groups that have little gap in education level and yet no established leadership, such as the homeless, might be unable to find effective leadership simply because of their nature. For these groups, a third party source that already interacts with the group should be chosen to both represent and empower the group to select some representation. Ross points to the fact that there are already organizations in place that care for homeless people by providing them food, shelter, and clothing (Ross 2010, 11). It is obvious that these groups have the best interests of the homeless at heart, and so allowing them to negotiate with researchers in a CBPR-type collaboration would ensure that the homeless would both benefit from a research study and be protected from any possible dignitary harms that might result from it. Furthermore, third party groups already familiar with the homeless would be able to bridge the cultural divide between one group of people whose goal is to survive each day and another whose jobs are in jeopardy if all they do is “survive” without a publication. Therefore, CBPR can be effectively implemented and ensure ethical research with larger, unstructured socially identifiable groups whose cultures are also different from that of researchers so long as proper leaders are selected for the group, whether through third party or internal means.

It is often at this point that opponents of CBPR reject it, finding it absurd that any large, more diverse group can be represented against a larger research institution to the group members' satisfaction. They contend that the collective culture of Native American tribes is what allows group representation by the tribal council to supersede individual autonomy, and that as a result it is not possible to apply CBPR in non-tribal settings (Harding et al 2012, 6). However, these opponents miss the point that allowing individuals to participate in research despite objections from group leaders opens up the entire group to third party harms, no matter whether the group places value on the individual or collective identity. They also fail to offer any effective alternatives other than increased laws and regulations, which once again remove justice from research by marginalizing groups. As Ross states, researchers having to negotiate with leadership *in addition* to individuals can only protect individuals further (Ross 2010, 11). The fact that these leaders are either part of the group or advocates for a vulnerable group, and therefore well-versed in their culture, only strengthens the case that they protect it, as they undoubtedly keep the group and its members' best interests at heart. Thus selecting leadership for a group to implement CBPR provides the additional protection it needs against dignitary and cultural harms, some of which could be caused by individuals who unknowingly subject their peers to third party harms via their participation.

The final question to be answered after considering smaller and larger groups is how to ethically work with large groups that do not share a socially identifiable trait. In this case, no changes to current regulations are necessary because there is no risk of cultural, dignitary, or third party harms. For example, consider a sample of the people of Arizona that just so happens to include a member of the Havasupai. Some would argue that the Havasupai sample should be clearly marked so that it is not used for any tests that are not condoned by the tribe, but this

argument misses the point entirely. The purpose of CBPR, and any possible reform for that matter, is to bridge the gap between conflicting cultural values and in doing so protect against dignitary and cultural harms that could result from research. In the case of research on large, non-socially identifiable groups, there are no novel cultural values to be concerned with aside from basic human decency. In this case, marking the sample as Havasupai, as opposed to keeping it anonymized, would only open up the possibility of cultural harms, as tests done on the sample would be known to give results about Havasupai blood. According to Mello and Wolf, “case law is fairly clear” that researchers are permitted to use anonymized samples in any way they wish without seeking donor consent (Mello and Wolf 2010, 205). This should not be changed for large, non-socially identifiable groups because it will be impossible to line up any results from an anonymized sample with a particular socially identifiable group, therefore making it impossible to do any harm to this group. Some contend that the sample should be marked Havasupai in order to prevent it from being used in an objectionable way, but this path creates the need for burdensome record-keeping which could once again marginalize tribal members in addition to opening up the possibility of stigmatization. Therefore, current law provides adequate protections for large groups where any one particular sample cannot be identified as from a person with a socially identifiable trait.

It is clear that necessary changes to research practice when working with groups are most drastic for small, structured groups and are not necessary for large groups that do not share a common trait. This scale of changes can also be lined up with the strength of the cultural values of a particular group. The stronger and closer-knit a particular community is, the more precautions must be taken when working with it in human subjects research. For small, tribal communities, researchers should implement CBPR and work with tribal leaders and, if possible,

a tribal IRB to ensure ethical and responsible study scope, data gathering and access, and publication of results that do not inadvertently inflict harm on a group. This framework can also be adapted to larger, unstructured communities with more informal leadership, where leaders can be selected through third party or internal framework. These larger groups still have cultural values that are different than those of the researchers, although they might be less obvious and more nuanced than those of Native American tribes. Leaders who are also experts in the group's culture can therefore only *help* protect the group against harm, as they hold the groups' best interest at heart and can ensure ethical research is done. Finally, for groups that do not share any identifiable traits and thus no distinct cultural values, no changes are necessary as existing regulation ensures anonymizing of samples and renders it impossible for any harm to be done. Implementing CBPR-type reforms when working with groups will eliminate the stigmatization that surrounds researchers who are simply attempting to make scientific progress while healing the trust gap between researchers and participants, making human subjects research great again.

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