

community or the broader public. This system sponsors a kind of paternalism that is at odds with liberal democratic precepts of individual autonomy and inclusive democratic deliberation.

The concept of the "autonomy of science from the social institutions that legitimated it" may have become (or may have always been) an illusion, as science historian Dhruv Raina has pointed out (10). However, even falling short of complete autonomy, there are many ways in which ethics advice can be kept independent of political and vested interests without depriving the state of its ultimate prerogative to decide on normative issues regulating its social life. This is what the contributions assembled in this special issue make very clear. Thus, the dialogue between researchers, ethics committees and populations should be increased, scientific experts should be awarded special training in ethics before joining ethics committees, inter- and supra-national organisations should be involved in procedures of international moderation and consensus-building, and, finally, decisions over life and death should always be conducted in close dialogue with the community of concerned patients and the broader public. Since social rules, unlike natural laws, involve individual and collective interpretation, adaptation to local contexts, and cultural sensitivity, their enactment and enforcement necessitate a maximum of democratic participation at all levels.

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Towards local participation in the creation of ethical research guidelines

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Abstract

Research ethics committees are entrusted with implementing guidelines to protect both scientists and human subjects of research from harm. These guidelines are often based on western contexts and may not resonate with the local moral traditions of the communities that they seek to protect. In this essay, we discuss how using principles of deliberative democracy with a "local derivation" approach may help in the drafting and implementation of ethical guidelines for research that better serve society.

The Havasupai Indians of the United States (US) struggle with phenomenally high rates of diabetes. The disease has ravaged

their community and left its members desperate for aid. In the early 1990s, help seemed to arrive when research scientists from the University of Arizona came to the Havasupais' home deep in the Grand Canyon. The researchers offered to provide genetic clues to the tribe's diabetes epidemic in exchange for individual blood samples. Formal ethical procedures related to the project appeared fulfilled: researchers received approval from a research ethics committee (REC), and the participating Havasupai gave their consent. At the time, the partnership between the researchers and the Havasupai seemed unproblematic.

Researchers then used information gained through an analysis of the Havasupais' blood to locate their ancestors far from

where the Havasupai believe their origins to be and to study links between illness and inbreeding. This challenged the tribe's cultural wisdom and embarrassed the Havasupai. Tribal members argued that this use of their blood violated their rights and filed a lawsuit against the participating researchers (1). The researchers argued in their defence that research on migration and inbreeding is an essential component of investigating the genetics of a disease among an isolated population. They held that any perceived wrongdoing was solely the result of miscommunication and misunderstanding (1,2).

The Havasupai case calls attention to longstanding ethical questions around scientific research involving scientists and subjects of research, particularly those from different backgrounds (3-5). Today, cross-cultural and cross-national collaborations are proliferating at a pace faster than most communities, particularly those in the global South, can react to them (6). Consequently, researchers and government agencies often have insufficient time, experience, and resources to generate local ethical guidelines to regulate these new research relationships and reduce any harm that may result from them. Instead, ethical guidelines from the US, Canada, and western Europe are often adopted wholesale or, at best, reshaped to fit local circumstances (7). Frequently, these guidelines are then applied by hastily assembled RECs with little sustained effort to ensure that implementation is equitable and ethical. As a result, it is often the case that neither the design nor the implementation of ethical guidelines for research resonates with the local moral traditions of the communities that they seek to protect (8).

In addition to reminding us of important ethical problems in research, the Havasupai case makes it clear that differences in moral reasoning can vary even within a single western nation. We must acknowledge that ethical guidelines based on western values may not fit even multicultural western societies. Accordingly, single countries may need to have multiple RECs to address alternative local needs while also complying with national standards.

Furthermore, the Havasupai case makes clear that sustained, respectful, and inclusive dialogue between researchers, the subjects of research, and other pertinent actors can reduce the potential harm arising from research that is cross-national and/or cross-cultural. Accordingly, a suggestion has been made to foster an inductive approach to creating more culturally sensitive and effective ethical guidelines for research (7). This approach - a strategy of "local derivation" - uses local moral concepts as the basis of guidelines. Knowledge of ethics developed in the West is used to illustrate how moral ideas are translated into regulatory guidelines. This approach begins a conversation among a diverse set of actors - ranging from policymakers and government actors to local community members and lay people - about how best to move from the moral ideas of a society to creating a system for ethics oversight. This conversation allows all involved parties to learn from each other. Key to this process is mutual respect and

continued communication with the goal of producing ethical guidelines that represent the beliefs, values, and needs of the populations that such guidelines serve.

The local derivation approach has not yet been put into practice. Nonetheless, deliberative democracy processes have promoted public participation in other areas where the creation of regulations must respond to the realities of research and local needs. Like the strategy of local derivation, deliberative democracy aims to foster mutual respect and open dialogue between actors with varied backgrounds. Deliberative democracy is lauded as a means for creating better informed, legitimate, and more broadly "owned" policies (9). The literature on deliberative democracy can inform the local derivation approach and advance the potential for RECs to be more attuned to a diversity of beliefs, values, and experiences (see, for example, 10-17).

Much of the literature on deliberative democracy describes how best to foster public participation in what may be characterised by four cyclical stages in the policy design and implementation process (18). We can apply insights from this literature to advance locally situated ethical guidelines for research.

The first stage consists of analytical or diagnostic work, when the information relevant to the design and implementation of guidelines is gathered. Public participation can and should be the broadest at this stage, so that the concerns and needs of actors from an array of cultural, socioeconomic, racial, religious, and ethnic backgrounds are included in any future decision-making. It has been suggested (7) that information gathering should take place through induction: the public must be solicited for their contribution no matter what values they hold. Public participation should accommodate all people, addressing physical, financial, and other challenges that could possibly prevent someone from contributing. And while a certain amount of public education is necessary to obtain constructive feedback, this education should use dominant western theories and practices sparingly and only as a model of how one uses moral tradition to inform policy. Surveys, deliberative polling, national discussions and public comment periods are some strategies that may facilitate public participation during this first stage (12).

The formation of a strategy for creating and implementing ethical guidelines occurs during Stage Two. While continued direct involvement of the public is ideal, at this stage it is likely that such involvement will lessen because of the resources needed to draft policies. Accordingly, the information gathered in the first stage must inform whatever draft guidelines emerge in this second one. Reliance on prior data collection demonstrates how vital it is that Stage One produces the most comprehensive and representative information possible. However, even with this prior input, direct representation that gives voice to a variety of viewpoints should still be present in the second stage. Consensus conferences, citizen juries and scenario workshops are examples of different methods to ensure that local populations continue to inform guidelines

(11-13). Empirical evidence about the risks and benefits of each of these deliberative methods will help determine how best to adopt these strategies in the creation of representative and effective ethical guidelines (see, for example 14-17).

Stage Three releases the guidelines for review, debate, and approval, rejection, or revision. Ideally, the guidelines will be equally endorsed by both scientists and groups at risk. Redrafting is necessary if there is strong opposition to the guidelines. This stage is essential for ensuring that any resulting guidelines meet the needs not only of specific local actors but also of the broader research and regulatory communities. Finding common ground among diverse opinions undoubtedly will be difficult, and repeating the prior two stages may be required.

Once ethical guidelines receive comprehensive approval, they are implemented in a fourth and final stage. Implementation includes continued dialogue with the public, especially marginalised communities and those most at risk during any scientific research. As society and science change, the nature and potential impact of research will be transformed. An REC must therefore be flexible to the evolving needs of the society that it serves, repeating any and all of the previous stages as necessary to ensure that ethical guidelines continue to best serve the intended populations.

If public participation in the four stages of ethical guideline design and implementation is to be effective, those leading these efforts must avoid what has been called the “expertise barrier”- the formal and informal rules of technical policymaking domains (including those relevant to ethical guidelines for scientific research) that make it difficult for actors without the dominant expertise to engage as equals (19). This barrier results from (often western) assumptions about the notion of public ignorance in matters of science and the regulation of research, the belief that scientific and empirical knowledge is value free, and the idea that if the public better understands quantitative facts it will agree with the ethical decisions of elites (20). For example, the lead scientist in the Havasupai study maintained that she “was doing good science,” and the University of Arizona defended this position for years (1). But the definition of “good science” is not value free. To the researchers involved, good science meant discovering scientific facts about illness, behaviour, and ancestry. But to the Havasupai, such science undermined the tribe’s cultural narratives while shaming its members in deeply personal ways. Had the type of inclusive dialogue that we call for taken place initially and throughout the study, all the parties involved could have better understood the social, cultural and scientific implications of the research

and addressed it accordingly. In confronting the expertise barrier head-on, local derivation is an inclusive approach that advances the design and implementation of ethical guidelines to the benefit of society, its members, and the work of science.

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