

SHARING AGGREGATE RESEARCH RESULTS WITH PARTICIPANTS

Some commentators have advocated routinely offering research results to study participants.[1, 2] However, there is ongoing debate over the scope and limits of investigators' responsibilities in this regard. At a time when veterans are increasingly interested in understanding biomedical information and its impact on their health, researchers in VHA lack clear guidance on the ethics of either sharing or withholding study results from research participants.

Background

A 2006 review identified 30 national and international policies and guidelines concerning researchers' obligation to return research results,[3] of which 21 were published in the previous decade. Nevertheless, there are no overarching regulatory policies, either in VA or emanating from federal agencies responsible for oversight of human subjects research, that govern the release of results to participants, and a recent study found that a majority of American Institutional Review Boards (IRBs) had no available policy on point.[4] Researchers offer results infrequently, perhaps no more than 40% of the time.[5, 6] Even when results are offered, there is no consensus regarding the method for communicating them.

Aggregate study results represent synthesized data and conclusions drawn from groups of research participants. Such results are often reported to the public at large, at least in summary form. The sharing of aggregate results with individual study subjects is widely supported by clinicians and especially participants, who typically express a desire to be contacted with the results even if they are not helped by the research[7] or the results have negative implications.[8]

Ethical considerations

Arguments in favor of sharing aggregate results with research participants are

grounded in the nature of the relationship between researchers and participants. For one thing, such communication reinforces the collaborative nature of the research relationship, strengthening the relationship through mutual promise-keeping. Thus, the participants' promise to take part according to the project's design is reciprocated by the researchers' promise to share the project's results. Respect for participants is promoted because they are treated as individuals and not just as means to the researchers' ends. In fact, some study subjects may feel that their participation gives them a "right" to the results because they are helping to produce the results. This is especially likely to occur among long-term participants. Sharing may also advance the common good by raising public awareness of clinical research generally.

Results sharing is also appropriate as an extension of a broader VA commitment to the community involved in the study. This commitment is an important part of sustaining VA's strong relationships with our veteran patient community. Moreover, when service-connected conditions are the subject of the research, sharing is an appropriate recognition of a special obligation owed to Veterans who incurred the condition as a result of their military service.

Arguments against sharing results include concerns that, for a given person, the research summary may be misleading or even worthless. Privacy is also a concern because in order to communicate the results, the researchers will have to retain identifying information (e.g., addresses or phone numbers) about the participants. Another impediment to sharing results is cost; researchers will have to dedicate time and resources to preparing a lay summary and contacting study subjects.

A less convincing suggestion is that results should not be disclosed because the infor-



mation may cause anger, anxiety, or other negative psychological consequences.[5, 9] Participants could be similarly affected

FACTORS WEIGHING IN FAVOR OF SHARING –

- the investigation is on a disease that the subjects have
- the disease or condition being studied is closely associated with service-connected conditions
- the project makes onerous or intimate demands on participants
- participants are involved through multiple contacts or for an extended time

FACTORS WEIGHING AGAINST SHARING –

- participants do not have the disease being investigated
- sharing would require the keeping of personally identifiable information that would otherwise not be required by the study design
- the cost of directly contacting each study participant is prohibitive
- the demands on participants' time and bodies are minimal

by other information they receive outside of the study which might have an impact on their health, and there is no evidence to suggest that participants would be at greater risk for these consequences than would

non-participants who learned about the study results.

Sharing results of particular studies

Research should proceed within an ethical framework that supports the collaborative relationship between investigators and veterans, and that enhances veterans' trust in the research and their ongoing relationships with VHA. For each study, researchers and research administrators within VHA should specifically address whether and how results should be communicated to participants and the broader veteran community.

For particular studies the decision whether or not to share, and in what form, should be made as part of the IRB approval process and should be stated in the informed consent documents. The IRB may evaluate whether to share results based on the degree and nature of the participants' involvement and the degree of risk to which participation exposes them. Thus, sharing is especially appropriate where participants have the disease being investigated (especially if the disease or condition is service-connected), the project has made onerous or intimate demands on them, or they have been involved with the study for an extended period, as, for example, in an investigational study of a drug or medical device. These considerations do not apply where the participants do not have the disease being investigated or the demands on their time and bodies have been minimal and brief. Once the decision has been made to communicate results, researchers must keep this promise at the end of the study.

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