Informing Study Participants of Research Results: *An Ethical Imperative*

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Consider the following clinical scenario: A 33-year-old accountant, the mother of two children, presented to her family doctor with a breast mass, which she had noticed to be slowly growing for six months. She put off seeing her physician because "breast cancer really just occurs in older women." Staging showed her cancer to be widely metastatic to lungs and bone, and she is offered experimental therapy. Her medical history reveals that she had Hodgkin's disease at age 14 and received radiation therapy as part of a Children's Cancer Group research protocol. She was followed up initially in the pediatric clinic, but had no further contact after she reached the age of 19. Long-term follow up of women treated on this protocol shows an approximately 30-fold increase in risk of breast carcinoma in those who received radiation therapy. Regular mammography is now recommended for all such women beginning 8–10 years after treatment is completed. The patient becomes distraught and angry that she had never been informed of these findings and feels "betrayed and used by the researchers."

In this paper we will argue that fulfilling respect for participants obligates the researcher to offer to provide a summary of research results on completion of the study, including studies of long-term follow up. Moreover, dissemination of research results has traditionally been limited to three channels: scientific meetings and peer-reviewed publications and texts,[1] lay media, and organizations with a special interest in a particular health field.[2] Disclosing results directly to research participants, we suggest, adds a fourth channel and can enhance accurate dissemination of research findings.

Partridge and Winer recently argued that participants in clinical trials should be informed of study results,[3] but we feel that the net should be cast wider to include all participants in human research, not just those enrolled in clinical trials. Here, we will summarize the elements required to offer research results to research participants to address the lack of comprehensive guidelines in this area.

An Obligation to Inform Participants?

The principles of respect for persons, beneficence, and justice are widely recognized to shape the conduct of research with human subjects.

Respect for persons requires that choices made by individuals who are capable of making decisions for themselves be accorded high regard, and this is embodied in the concept and practice of free and informed consent. For the most part, the principle of respect has been interpreted in a limited way. For example, the U.S. Common Rule lists detailed elements required for informed consent at study enrollment, but gives little guidance for operationalizing the principle of respect over the course of research or after its completion. Although the Common Rule does require that "significant new findings developed during the course of research which may relate to the subject's willingness to continue participation ... be provided to the subject" (45 CFR 46.116(b)(5)), showing respect for study participants, we believe, commands more than this.

Respect for persons should extend to informing subjects of research results at the conclusion of the study. This act of offering a summary of research results avoids treating persons solely as a means to an end. In clinical research with health care repercussions, it also places the welfare of the individual in focus, as these research results may have direct and significant implications for the participant.

We contend that results should be offered to all participants, both those who may directly benefit from the disclosure (as in the woman with breast cancer described above) and those who may not benefit directly. This latter group equally deserve to be treated as more than a means to an end, and while the benefits to them may be less concrete they are no less important, and include feelings of self-worth through altruism and pleasure in knowing that one has contributed to an overall enrichment of scientific knowledge. Participants or family survivors of participants who have undergone phase I chemotherapy trials, for example, may be among those who experience real but less tangible benefits—these individuals have no realistic hope that participating will sig-

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nificantly affect the course of their disease, but would benefit by knowing how their participation will help improve outcomes for others.

This understanding of the principle of respect for persons parallels developments in the protection of communities in research. Respect for communities is interpreted broadly to encompass meaningful involvement from the study's genesis through to publication of results.[4] This is reflected by international guidelines for the protection of aboriginal communities, many of which specifically stipulate that the final report be shared with the community.[5] The purpose of these guidelines is to establish protection for communities in recognizing values and interests both in promoting research in unique communities and in avoiding harms that may come from research. It also serves as a model for the peer-reviewed nature reflected in a "final" report that should be required of researchers in providing research results to individual participants.

Respect for the person obligates the researcher to *offer* research results in a clear and understandable manner, but this is quite different from *mandating* disclosure of findings. As we will describe, the process of conveying research results and/or the results themselves may adversely affect the research participant or his or her guardian. Thus respect demands that we recognize the right of every research participant, having been fully informed, to decline to be given the results of studies in which she or he was enrolled.

Balancing the Benefits & Harms of Disclosing Research Results to Participants

The value of sharing research results with participants may be manifested in a number of ways. The benefits may range from being able to directly counsel individuals for whom the results have significant health implications—for example, advising female survivors of Hodgkin's disease who received mantle radiation that they should undergo careful screening in light of increased frequency and earlier onset of breast cancer, as in our clinical scenario—to presenting the general public with a more balanced reflection of scientific results than is often found in the lay press.[6-9]

Figure 1.
Potential Benefits of Offering to Share Research Results with Participants

1. Demonstrating the on-going central nature of the participant's role in research
2. Diminishing the chance that the participant may feel exploited by the researcher
3. Providing information that may enhance quality of life or lead to interventions that may decrease the risk of future harm
4. Disseminating information gleaned from research beyond the traditional medical sphere[41, 42]
5. Raising public awareness of the impact of research on knowledge
6. Emphasizing participants' contribution to the understanding of disease and therapy
7. Enhancing trust in the researchers and the research process

At least one study in cancer epidemiology, for example, found disclosure to be valued by participants (and only infrequently associated with negative effects).[10] And in a climate of increasing distrust of research, open communication may help to foster trust in researchers and in research as an institution.[11] Sharing research results will also signal the openness and accessibility of researchers. It is clear that raising a positive profile of research in general and highlighting the impact of research on health outcomes specifically will also benefit society as a whole. (See Figure 1.)

One should be careful not to overstate the benefits of disclosing research to individual participants, of course. For example, clinical health care studies may provide a clearer picture of how best to manage disease than does anecdotal, individual experience, but the evidence elucidated from even many clinical trials is almost always imperfect and these limitations need to be acknowledged during the disclosure.

Nonetheless, some researchers worry that the disclosure of research results will have a stressful and negative impact on participants,[12] and investigators who offer to share results should be cognizant of this possibility. Figure 2 identifes a number of potential harms that may occur to different parties on disclosure of research findings. These harms may be immediate, such as the psychological stress of revisiting a difficult time or poor outcome, or longer term, such as recommendations based on imprecise results or adverse impact on insurability. Geneticists have struggled with such concerns.[13] In general, the harms that flow from disclosing results to participants will be confined more directly to the individual participant than they will affect research as a whole. A theoretical example of potential harm to research "as a whole" as a consequence of better disclosure of results may be the poorer accrual of new participants given a better understanding that there is risk that research findings

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Figure 2.
Potential Harms of Offering to Share Research Results with Participants

1. Incorrect or harmful medical decisions based on uncertain or unreliable results (especially if the study has not reached adequate maturity)
2. Causing distress for those participants who did not benefit from or may have been harmed by the researcher
3. Rekindling old memories and emotions, especially in the setting of serious illness
4. Emotional distress among family members or others, if the research participant has died
5. Possible discrimination in obtaining employment or insurance for individuals identified to have developed, or to be at high risk of developing complications
6. Possible "survivor guilt" for those assigned to a superior treatment arm of a randomized clinical trial
7. Financial costs to participants and to researchers

may have negative connotations (such as findings that impact upon insurability of groups of individuals). In general, we believe this is unlikely to represent a significant deterrent. If anything, this situation requires researchers to be even more rigorous in providing information to assist participants in deciding whether to receive a summary of research results.

Respect for the choice of not receiving research results clearly needs to be built into programs to offer to share results. For example, parents whose child participated in a phase II drug trial but is now deceased may decide that the process of receiving the research results, with its prospect of reliving the events of the child's death, may prefer not to learn of the study's findings.

We believe that investigators should avoid disclosing results in a psychological or medical vacuum. Studies in occupational epidemiology, for example, demonstrate the importance of providing the opportunity for medical follow-up if medical risks are identified.[14]

Psychological support is also necessary, as participants may have unexpectedly higher levels of anger or anxiety than they themselves would have predicted, as research involving predictive genetic testing has shown.[15]

Impact on Investigators

Disclosure of research results carries with it a burden for researchers. Considerable time and preparation are required if results are to be comprehensively disclosed to a lay audience. As well, when sharing study results involves sharing adverse personal results with individual participants (for example, outcomes of predictive genetic testing), the process may be emotionally difficult and draining for both the participant and the investigator. There are also financial costs associated with programs for sharing results that should be considered in building research budgets. These costs may extend to follow-up medical and psychological care.

Balancing Harms & Benefits

While potential harms for some participants are tangible, they should not prevent researchers from offering to share study results. Appropriate programs must be designed that encompass a comprehensive discussion of the risks and benefits of receiving results, sensitive communication, and provision of meticulous and anticipatory follow-up. Investigators should estimate benefits of disclosure conservatively. Risk prediction should be studied to determine if it is accurate. Patient advocacy groups may be very helpful in contributing to this process, especially when the risks and benefits of disclosure are unclear.

If there is a duty to disclose research results that flows from the principle of respect for persons, then why does it matter if there are risks? In fact, acknowledging possibility of risk allows clinical investigators to develop strategies to minimize risk, and thus to fulfill their obligation of non-maleficence. We contend that there are no conditions under which an offer of disclosure of research results should not be made. It is critical, however, that this disclosure be offered in the context of carefully thought out programs that recognize and address the potential consequences of the results for individual participants.

The clinical testing of individuals for genetic disease shares a number of similarities with disclosure of research to participants in clinical trials. Both require predisclosure counseling that outlines the risk and benefits of receiving results, both require sensitive team approaches, and both may have long-lasting as well as immediate implications for the mental and physical health of the individual. Thus, experience in genetic disease testing may offer insight for developing programs for research disclosure.

The psychological ramifications of predictive testing for Huntington's disease have been widely discussed.[16] Learning that one has a decreased risk for Huntington's disease is associated with a greater sense of well-being, less depression, and less distress.[17] Contrary to what might be

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Figure 3.
Guidelines sharing summary research results

1. A summary of research results should be offered to all human research participants.
2. Research results should be offered as part of the original consent process and re-offered at the conclusion of the study.
3. Researchers should provide a summary to participants of the possible harms and benefits to receiving research results.
4. Researchers should establish a mechanism to maintain contact with research participants with the express intent of facilitating disclosure of research results.
5. Research budgets should reflect the cost of sharing research results.
6. Participants have the right to decline receiving all or part of research results.
7. Research results should, in general, not be shared with participants until the data interpretation has undergone peer review.
8. Research results should be offered in a timely manner by the researcher or a qualified representative.
9. Researchers should offer to provide results in a lay format both orally and in a written summary. These should document the context and the goals of the study, the major findings, limitations of the study findings, any anticipated long-term effects and surveillance required, and how the data will be disseminated.
10. A technical bibliography of the findings of the study should be offered.
11. Medical or psychological needs of research participants should be considered when research results are provided.
12. Follow-up plans for disclosing further research findings from the study should be provided, if appropriate.

expected, studies have shown that individuals who learned they were at increased risk result for Huntington's disease also had an improvement in scores of depression and distress.[18] This was attributed to a reduction of uncertainty, and the opportunity for appropriate planning. A similar positive outcome may be anticipated for research participants for whom uncertainty about outcome and late effects may detract from quality of life, although it is important to acknowledge that results of personal testing may not be the same as receiving general study results. Not all individuals confirmed to have Huntington's disease experienced disclosure of the results of testing as a benefit.[19] In addition, many individuals at risk for Huntington's disease may choose not to be tested.

While experience in genetic testing should be used to help guide the development of guidelines for conveying of research results to research participants, it must not be forgotten that clinical settings are different from research ones. Pilot programs for sharing research results with participants should be studied to determine whether the model suggested by predictive genetic testing holds in the context of clinical trials: Do research participants achieve a positive outcome by revisiting the research (personal sense of well-being based in altruism) or is there a more negative experience? How many individuals decline to receive research results? Is it possible to predict from the type of study (e.g., phase I versus phase III, or large, multi-site versus small and local) whether participants will want to know the results?

Implementing Disclosure of Study Results to Research Participants

Guidelines for sharing research results with research participants are suggested in Figure 3. They are not meant to be rigid, but rather to be a roadmap for researchers in developing a summary of results in a respectful way that supports human dignity, always bearing in mind that it is the right of the participant or the individual who gave consent on behalf of the participant to decline to receive research results.

What information should be disclosed? Various results of studies may be disseminated at several points: interim results may be disclosed while the study is ongoing, for example, after completion of accrual, or after completion of data collection; at the time an abstract is submitted to a scientific meeting; when the manuscript reporting the study undergoes peer review for publication; and after publication of the manuscript. We believe that research results should be disclosed to participants only after the research report has undergone peer review.

Human research studies should always be subject to peer-review to maintain the integrity of the interpretation of the data leading to publication. The same standards of integrity should hold for disclosure of research results to participants—it would undermine the notion of respect to have two standards of public disclosure, one in rigorous peer-review for scientific publication and one of investigator driven interpretation for research participants. This is true whether or not the par-

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ticipant is likely to directly benefit from the findings. Therefore, we believe that disclosure of research results should, in general, be delayed until the results are published or until they have undergone peer review and been accepted for publication.

Premature disclosure of results, that is, before peer-review, may cause harm in many ways, including dissemination of inaccurate results, unnecessary anxiety among participants, and inability to complete a trial without bias.[20] Difficulties with the latter were clearly seen in attempts to determine the efficacy of autologous bone marrow transplant for breast cancer.[21]

Disclosing information that is to be presented as an abstract at a scientific meeting may be problematic. It is well documented that only 40–50% of abstracts presented at meetings are subsequently published as manuscripts.[22-26] As the information contained in abstracts is often neither rigorously peer-reviewed, nor mature,[27] sharing of this information with research participants is generally inappropriate. However, abstract information is often circulated by lay and non-peer-reviewed scientific press. In addition, the median time from abstract presentation at a scientific meeting to manuscript publication is at least 20 months.[24,25] Researchers must be cognizant that data published in abstract form, especially information that is newsworthy, may need to be shared, with caveats, prior to peer review.

Therefore a balance needs to be struck between waiting for peer review and sharing with research participants information published in abstracts. In some cases, it may be appropriate to have a participant representative who can assist the researchers in determining when to disclose abstract information. Consultation will be more difficult in hypothesis-driven research, in which there is no clinical significance to the individuals in the study and therefore no representative group, but consultation is also probably less relevant in this circumstance.

The level of detail of information to be disclosed will vary with the research question, the data available, and the needs of the participant. Figure 4 suggests what should be considered in the disclosure discussion. An individualized approach for clinical disclosure of diagnosis recognizes personal differences in needs and wants. Some research participants will wish to be active collaborators from the start of a trial and some will be content to play the role as "subject."

Although investigators inevitably bring their own biases to the task of interpreting study results, results disclosed to participants must be as free as possible from biased interpretation of data. Similarly, researchers should not practice selective or incomplete disclosure,[28] or allow the disclosure to be driven by special interest groups.[29,30]

It is extremely important to contextualize results for research participants at whatever stage information

Figure 4.

Items to be discussed at the time participants are informed of research results

1. Identify participation of patient in study
2. Identify who gave consent for participation (individual or parent/guardian)
3. Describe consent process and remind participant or parent/guardian of how he or she fits into that process
4. Describe possible harms and benefits of receiving research results
5. Obtain consent to give research results; stop here if consent to provide a summary of research results is not obtained
6. Define in lay language the type of study that the participant took part in (i.e., phase I, II, III, epidemiology)
7. State name and objectives of the study (primary and secondary)
8. State the nature of the participant's involvement (i.e., randomized to study arm, biological samples taken, observations made)
9. State overall results of the study including when the results were first available in relation to the participant completing the study
10. State the explicit overall results of the study
    * Benefits * Harms
11. State anticipated long-term effects and surveillance recommended, if any, for the participant
12. State what has been done with the information obtained from the study
13. State suggested follow-up plans, if any, and arrange for further counseling by appropriate health professional, if needed
14. Provide/offer written copy in lay language of the discussion, if requested. Provide a technical bibliography, if requested.
15. Document: Date of meeting; Who attended meeting; What was said; Follow up plans

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is disclosed since the findings exist in a dynamic of scientific exchange and debate. This discussion should address study design and interpretation of data, acknowledge the limitations of the research, and place the current study in a framework of previous scientific work. Researchers should include discussion of the fact that we know negative studies frequently are not published,[29] and should make clear that the conclusions drawn from the study may change with time and further information.[31] Provisions should be made to allow participants to be notified of significant changes.

▒ *Who should disclose and who should receive research results?* Whenever possible, research results should be disclosed by the investigator or a trained delegate who is familiar with the study and is able to interpret its significance. Ideally, the researcher or his/her delegate presented the original informed consent form and has an ongoing relationship with the participant, although we must acknowledge that results may not be available until many years after the consent was originally obtained and the original informant may no longer be available to participate in disclosure. When appropriate, disclosure should be organized in conjunction with a health care professional—whether the physician or a research coordinator, nurse, or associate—who can assist if participants need further follow up.

Multi-institutional trials may pose challenges for disclosing results to participants, since different institutions may work with populations whose cultural norms call for different forms of communication. It is important to identify at the beginning of the study how the results will be disseminated. It follows that whoever has primary responsibility for over-seeing and coordinating the publication of results, should also be responsible for coordinating disclosure of those results to participants.

Several factors bear on the question of who should receive the research results, for example the competence of the consent giver and the research participant at the time results are to be disclosed. A child participant may now be a competent adult, to whom results should be disclosed directly. The investigator will be responsible for determining the capacity of the research participant to consent to receive study results, and may need the assistance of another individual, such as a family doctor or family member, in making that determination. Special considerations will also apply if the guardian or research participant is deceased. Researchers should look to local legal requirements in terms of notification of next of kin or establishment of guardianship for those unable to consent for thmeselves.

▒ *When should results be shared?* Many health-related studies will include ongoing, routine follow-up of participants during which peer-reviewed data may be disclosed. Nonetheless, some participants are seen very infrequently, if at all, and increasingly new results may become available only years later. To partially ameliorate these difficulties, the original consent form should indicate how and when research results might be disclosed, and make clear who is responsible for maintaining contact and how this should be undertaken. In our highly mobile society, it is not unreasonable to place the onus of providing contact information on the participant. The potential consequences of not maintaining contact (e.g. not learning of health-related findings that are remediable) should be made clear at the time the participant consents to join the study and should be reinforced as the individual's participation ends. Letter or other media, such as an Internet site, could extend this. Every effort should be made to maintain a liaison in studies in which late outcomes may be expected.

The National Institute for Occupational Safety and Health notification programs for subjects of epidemiological studies are instructive.[32,33] Most workers found written information valuable, although accommodation for illiteracy is sometimes necessary. The notification should be timely to avoid a perception of "being the last to know"[31] but not so hasty that the data has not been suitably peer –reviewed.[34,35] The anticipated time to maturity of the data and its planned dissemination should be included in the consent process at the beginning of the study.

▒ *How should results be provided?* We believe that it is not sufficient to refer research participants to the published literature. If there are significant consequences anticipated, disclosure should always occur orally, and preferably face-to-face. Following that initial discussion of substantive clinical results, an Internet site can provide ongoing updates of results in a lay form. Some results, such as summary findings from studies of the biology of disease, can be provided without personal interaction,[36] but even in this situation research participants should have the opportunity to pose questions.

Investigators should disclose results in lay terms and provide a written copy of the research summary and its discussion, along with an appendix directing participants to peer-reviewed publications from the study. The research summary is best prepared by the principal investigator or his/her delegate.

Challenges

In some cases it may not be advisable to wait for peer-reviewed publication before disclosing results to research subjects:

▒ Research results that clearly indicate an immediate need to contact individual participants. These

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results may occur during data gathering but also may be discovered in follow up after the study has closed. These include evidence of preventable harm to either the participant or others around them, such as identification of HIV infection[37,38] or a substantial risk for premature death as a consequence of the study agent. Immediate contact may be directed to the participant, to others at risk, or to other parties as appropriate. Participants should be notified in the consent process that specific information learned in the course of the individual's participation may require researchers to break confidentiality and notify appropriate authorities of the circumstances. There is, of course, an obligation to immediately notify participants of this situation.

Research results that never come to publication. A mechanism should be developed to address the appropriate timing for disclosure of results from studies that are never peer-reviewed or published. Researchers might offer, for example, to provide a summary of results to participants at the completion of the study. This obviates the need to wait for peer review but must be handled carefully, to assure that participants are aware of the limitations of data. A commitment should be made to provide updated information and interpretation in the event that peer review reaches different conclusions.

Results from studies closed prematurely by a data safety monitoring board. While the data safety monitoring board offers a form of peer-review, it is focused specifically on the safety of subjects and is not charged with the same overarching responsibility for assessing a study and its data that publication reviewers have. When studies are closed prior to completion, the data are generally not yet subjected to peer review, nor mature. The researcher is required to urgently inform participants of the rationale for discontinuing the study, and of the specific results when a direct intervention for the participant is required to prevent or reduce harm. In such situations, researchers should stress the importance of ongoing follow up to confirm the interpretation of the findings.[39] Guidelines for early closure of studies should be widely adopted, such as those recommended by the Coalition of National Cancer Cooperative Groups Board of Directors.[40] These guidelines suggest that disclosure should be the norm, prompt, oral with written follow up, voluntary (the participant has the right to decline any or all of the results), and understandable and in sufficient detail for the individual. These guidelines reflect all the elements needed to share research results responsibly after a full study has closed.

Respect Doesn't End with Consent

We have argued that all investigators have an ethical obligation to share research results with participants, and detailed the considerations that must be taken into account in designing a disclosure program. Investigators owe a debt to the many participants who place their trust in science, without whose collaboration the search for new knowledge and treatments would be severely impeded. Fulfilling that trust and recognizing the altruism of research participants requires that investigators provide timely, accurate, and understandable disclosure of research results. We must carefully evaluate the efficacy of the guidelines proposed in this paper and further refine the ongoing disclosure of results.

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