

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Disclosure of Test Results to Subjects	Date Effective April 19, 2005	Supercedes P&P dated November 18, 2004

BACKGROUND

Human subjects research often includes testing to detect or measure physical attributes, physiological states, or the presence of exogenous or endogenous factors. For some tests the need to report results to subjects is clear; interpretation of the results is straightforward and there are agreed guidelines on appropriate actions, such as specific treatment, behavioral change or preventive measures. For others, however, there may be disagreement or uncertainty concerning interpretation of the results; what actions, including treatment, are appropriate; or whether the recommended treatment is available. In such situations, it may not be clear whether it is necessary or appropriate to report test results to subjects.

This document provides guidance on when test results and counseling should be given to research subjects and describes how CHR makes determinations on this issue.

JHSPH POLICY AND PROCEDURES

General Principles

When subjects agree to be tested as part of a research study, there is an implicit assumption that they will be informed of results that have implications for their present or future health status. Thus, investigators should ensure that test results are provided to subjects in a timely manner when:

- diagnostic tests are accurately performed, and
- the results are clinically-relevant, i.e. they indicate the need for, and guide the selection of, effective treatment or measures for prevention, and
- effective treatment or other intervention is available.

Test results that provide a diagnosis for which treatment is not available locally, but possibly available elsewhere, may also be reported to study subjects at their request, when investigators consider this to be appropriate, or when required by CHR. When testing is done for rare or unusual conditions and the probability of a positive result is remote, reporting only positive or abnormal results is reasonable, unless the subject specifically requests that negative results be reported.

Circumstances in Which Reporting of Test Results May Not Be Required

There are, however, situations in which reporting of test results may not be required. Some examples are:

- the disorder identified by the test is mild and self-limited;
- there is lack of agreement in the medical/scientific community as to the meaning of the test result or what action it indicates, e.g., medical treatment, behavioral change or other intervention;
- the results will not be available in time to provide effective treatment or preventive action;
- the study participant is fully informed about the disease or condition and chooses not to receive the information,
- the test is performed on unlinked or anonymous specimens, or
- the test identifies a condition that is not treatable, and which, when revealed, may cause the subject psychological stress. This may, however, be balanced by the potential to relieve psychological stress by providing a presumptive diagnosis for an illness, even when it is not treatable.

These considerations notwithstanding, subjects should be given the opportunity to request the result of any test when the meaning of the test is well established.

Decision Process

When deciding whether to report test results to subjects, investigators should consider:

- the seriousness of the subject's condition, including the risk that a serious illness or condition may develop;
- the accuracy with which the findings of the test identify or predict the illness or condition, or serve to guide effective treatment or preventive measures; and
- whether agreed effective measures are available to avoid or ameliorate the illness or condition.

Using these three criteria, and the General Principles stated above, investigators should classify each test in the Research Plan, including standard clinical tests, tests used only for research purposes, and tests that may be the subject of investigation, as yielding results that:

- are of such potential importance or benefit to the subjects that they must be promptly disclosed ; or
- are of possible importance or benefit to subjects, but the investigator can exercise judgment, on a test by test basis, to disclose them or not; or
- are of no importance or meaning to the subjects and, thus, do not require disclosure, although the subjects may request disclosure.

The Research Plan and Consent Form

The Research Plan should include a section on "Disclosure of Test Results" that lists the tests to be done and indicates which results would, or would not, be reported to study subjects. Where reporting would not be done, the decision should be explained and justified, with references as appropriate. The consent form should also state which test results would and would not be reported, including which ones would only be reported if requested by the subject.

Provision of Counseling and Referral or Treatment

When test results are reported to subjects they should be counseled as to their meaning. When the result indicates the need for a specific treatment or preventive measure that is locally available, researchers should also advise subjects on how to access the treatment.

If treatment is not locally available, but could feasibly be provided by the researchers within the resources of the study, the results should be reported, subjects should be counseled and the treatment should be provided.

RESOURCES & REFERENCES

National Bioethics Advisory Commission. 1999. Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Volume 1: pp. 71-72