

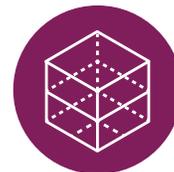


Return of Individual Results to Participants: Principles

The aims of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) Return of Individual Results workgroup were to (1) develop a methodology and principles best suited for return of individual research results; (2) define methods to facilitate disclosure and communication of results to individuals; (3) identify best practices to manage disclosure to and follow-up with individuals; and (4) develop a framework to manage return of results in the global context of clinical research trials. The foundation of the recommendations document and toolkit are 9 principles directly relevant to the return of individual research results.

The principles, developed by the MRCT Center Return of Individual Results Workgroup, address the return of individual results collected during a clinical trial to research participants or their designees. These principles complement previous recommendations for the return of aggregate research results (see <http://mrcctcenter.org/projects/return-of-results-to-participants/>). Individual results are generated in different contexts and at different times during a trial. Whenever a validated result is urgently medically actionable, there is an ethical responsibility to return the relevant result either directly to the physician(s) with primary responsibility for care to the individual or to the participant, documenting the communication and transfer of responsibility.

- 1. Providing individual research results responds to the expressed interests and expectations of many clinical trial participants that their results be communicated to them.**
- 2. Considerations pertaining to the return of individual research results to clinical trial participants should be integrated into the clinical trial and proactively planned.**
- 3. The informed consent process should include information about the sponsor's intention regarding the return of research results and allow for discussion of participants' preferences to receive these results.**
- 4. The plan for the return of individual research results should be reviewed by an independent ethics body overseeing the research to ensure the rights and welfare of research participants are protected.**
- 5. If results are offered, participants should be able to choose whether or not to receive their individual research results.**
- 6. Sponsors and investigators have an obligation to act responsibly when returning individual results, taking into account medical significance, analytical validity and personal utility.**
- 7. Individual research results should be returned in ways and at times that maintain the integrity of the research, insofar as the safety and welfare of the research participants are not at risk.**
- 8. The purpose of research is not clinical care, and return of individual research results cannot substitute for appropriate clinical care and advice.**
- 9. Return of individual research results should be planned and executed in compliance with institutional policies and local, regional, and national laws and regulations.**



Principle 1: Providing individual research results responds to the expressed interests and expectations of many clinical trial participants that their results be communicated to them.

The clinical research enterprise increasingly recognizes that participants can and should be engaged as partners who are actively involved in research and the generation of new scientific knowledge. Providing clinical trial participants with information about them generated through their participation in the trial is important as a matter of respect for individuals' autonomy.

Principle 2: Considerations pertaining to the return of individual research results to clinical trial participants should be integrated into the clinical trial and proactively planned.

In the planning stage, consideration should be given as to whether and how much data to return, which results to return, and when, by whom, and how results will be provided. Resources for the return of individual results process should be allocated accordingly. The operational challenges, feasibility and burdens placed upon investigators, sites and sponsors should be considered at this time.

Principle 3: The informed consent process should include information about the sponsor's intention regarding the return of research results and allow for discussion of participants' preferences to receive these results.

The informed consent process should be explicit as to whether individual research results will be returned to participants and what and when information will be returned. Participants should be informed that they also have the right to change their decision at the time information is made available. If results will not be returned, this should be stated clearly, preferably with an explanation of the rationale for the decision not to return.

Principle 4: The plan for the return of individual research results should be reviewed by an independent ethics body overseeing the research to ensure the rights and welfare of research participants are protected.

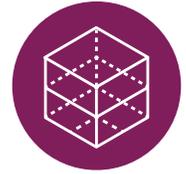
The overall plan for return of individual research results (whether, how, when and by whom results will be disseminated) should be reviewed and approved by an independent body, generally a research ethics committee (REC) or institutional review board (IRB) that is charged with the responsibility of protecting the participants' rights and welfare. The REC/IRB should also review disclosures that were not planned but are deemed necessary for compelling clinical or ethical reasons (e.g., unexpected genetic findings with potential impact on a participant or their family).



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For more information about the MRCT Center's work on the return of individual results, visit: <http://mrctcenter.org/projects/return-of-individual-results/>



Principle 5: If results are offered, participants should be able to choose whether or not to receive their individual research results.

For most categories of results, individuals should have the opportunity to decide whether or not they wish to receive them. Results of critical and immediate clinical importance may represent exceptions to this presumption; that these results will be communicated—and why—should be explained to the participants during the informed consent process.

Principle 6: Sponsors and investigators have an obligation to act responsibly when returning individual results, taking into account medical significance, analytical validity and personal utility.

Participants should be provided access to as much of their data as possible; however, consideration should be given to the validity of the test as well as to the medical, social, and/or personal usefulness of the results to participants. Additionally, communication should use plain language and follow health literacy principles.

Principle 7: Individual research results should be returned in ways and at times that maintain the integrity of the research, insofar as the safety and welfare of the research participants are not at risk.

The plan for returning research results should safeguard the integrity of the study and the ability to attain the study's research aims, insofar as the safety and welfare of research participants are not compromised. Timely return of results will help to ensure that any direct or indirect benefits of the results to the participants will be realized. Study design, the specific type of data and the medical importance of the finding may influence the timing of return.

Principle 8: The purpose of research is not clinical care, and return of individual research results cannot substitute for appropriate clinical care and advice.

The purpose of research is to produce generalizable knowledge for the benefit of society. This differs from medical care that is intended to benefit individual patients. Therefore, it is important to define in the informed consent form the limits of the clinical trial and the role and mission of the researchers in that trial.

Principle 9: Return of individual research results should be planned and executed in compliance with institutional policies and local, regional, and national laws and regulations.

Any plans for return of individual research results should comply with institutional policies of the sponsor and investigator and the sovereign laws and regulations of the jurisdiction in which the participant resides and in which the sponsor, investigator and/or institution operates.



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