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Return of Results FAQ

Why should results be returned to participants?

Research participants have long voiced the desire and expectation for the return of research results when participating in studies. A survey conducted by Harvard/Brigham and Women's Hospital Multi-Regional Clinical Trials Center (MRCT) revealed the following:

- 90% of participants want to know the results of their clinical trial.
- 68% of participants would not participate in future trials if not informed of results.
- 73% of participants say getting results after the end of the trial as an important consideration.
- 95% of research ethics board chairs strongly support return of results.

Regulations abroad and in the US have likewise called for the return of results:

- EU Parliament Regulation No 536/2014
  - Sponsor of a clinical trial must submit a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within defined timelines.
- Declaration of Helsinki Paragraph 26
  - All medical research subjects should be given the option of being informed about the general outcome and results of the study.
- US Federal Law
  - Submission of basic results (participant flow, baseline characteristics, outcome measures, statistical analyses, adverse events) for most clinical trials onto the Clinicaltrials.gov database is generally required no later than 1 year after completion date.

What are examples of results that can be returned to participants?

Research results can include individual and aggregate results. Individual results refer to the outcomes of the research assessments and/or interventions for an individual participant. Examples of individual results may include an individual's lab results on bloodwork, their BMI, score on a research instrument, or imaging such as echocardiogram.

In contrast, aggregate results refer to the outcomes of the study and do not contain reference to individually identifiable data. Examples of aggregate results may include whether the study met its endpoints or confirmed the research hypotheses. Generally, aggregate results are those published in journal publications or presented at research conferences.

Source: https://www.advarra.com/blog/return-of-research-results-to-study-participants/

What are potential risks associated with return of results?

For the Participant

- Possible adverse psychosocial effects (e.g., feelings of uncertainty, stress, anxiety, depression).
- Inappropriate actions from inaccurate, misleading, or over-interpreted results.
- Social consequences from results (e.g., stigmatization, economic impact, adverse impacts on interpersonal relationships).

For the Research Enterprise

- Risk of misinterpretation of results by the participant, particularly when there are no established guidelines relevant to the results.
- Financial costs and effort associated with returning results to participants.
- Routine disclosure of individual results may conflate the purposes of research with clinical care.
- Potential legal liability for negligence (if results are found inaccurate).

What are potential benefits associated with return of results?

For the Participant

- Obtain actionable results that may guide clinical decisions, affect health, or quality of life.
- Some participants are interested in learning more about themselves.
- Implications for reproductive planning, family members, partners.
- Reciprocation makes participants feel appreciated for their contributions.

For the Research Enterprise

- Increased trust and public engagement.
- Stimulate greater transparency and interest in contributing to research.
- Improved efficiency, generalizability, and patient-centeredness in research.
- Return of results could incentivize participation in research.
- Patient and participant-communities may better connect, compare results, and work with investigators to answer research questions relevant to affected individuals.

Source: https://nap.nationalacademies.org/catalog/25094/returning-individual-research-results-to-participants-guidance-for-a-new

How do I implement return of results in my study?

If you are a researcher that would like to conduct Barth syndrome research at Barth Syndrome Foundation's (BSF) International Scientific, Medical & Family Conference or are seeking recruitment support, BSF can work with your research team and IRB to incorporate the return of results to participants for your study.

BSF can provide draft language for IRB submissions and work with your team to devise a plan for return of results. Please contact Melissa Huang (melissa.huang@barthsyndrome.org) for assistance.

What other research groups have adopted the use of returning results to participants?

- National Institutes of Health: All of Us Research Program
- Simons Foundation SPARK Autism research programs
- Genetic Alliance
- GenomeConnect
- Mayo Clinic: Cardiolipin Profiling for Barth Syndrome Screening and Characterization study

Recommended language for the Informed Consent for returning results to participants

Consent language – Example 1 Aggregate and Individual Results

(courtesy of Simons Foundation SPARK)

We will return to you overall study results. If you agree, we may return to you limited information about the research results of questionnaires you complete about yourself and/or your minor children/dependents. We will not return adults' results from surveys filled out by others (such as parents or spouses). You may find this information useful for sharing with schools or medical professionals.

Consent language – Example 2 Aggregate and Individual Results

(courtesy of NIH All of Us Research Program)

Results about you

Over the many years of the "All of Us" Research Program, we will study lots of things about your data and samples. We will give you results from what we study. You will be able to choose if you want to see them.

Results that might tell you about your health

These are results that could help a healthcare provider to take better care of you. For example, if any of your physical measurements are outside of what we would expect, we will tell you so you can follow-up with your healthcare provider. You will have to pay for the cost of follow-up care with your own healthcare provider.

Results that would not tell you about your health

These results might be interesting to you, but they probably would not help a healthcare provider take better care of you. For example, these results might come from tests that are still experimental.

Results about the group

These are reports of what researchers learn about health from studying data and samples from all the different people in the "All of Us" Research Program. You can get these reports, as well as general news and updates about All of Us at www.joinallofus.org. While researchers might learn results about you from studying your All of Us data and samples, you may not be able to see all of these results.

Not medical care

"All of Us" is not medical care, medical advice, or treatment. If you need care, contact your healthcare provider.

Consent language – Example 4 Individual Results

(courtesy of GenomeConnect)

If GenomeConnect learns about any potential updates about your genetic testing results, would you like us to contact you via email about these updates?

As we learn more about genetic changes, their relationship to health might change. Some updates might impact your medical care while others will not. Such updates are rare, so most participants will not receive updates. It is not possible for GenomeConnect to identify all updates related to participants' genetic test results.

Answering "Yes" means that you may be contacted by the GenomeConnect team if we learn about potential updates to your genetic test results. We would email you and direct you back to your doctor or a healthcare provider in your area to discuss this more.

__ Yes __ No
Print Name of Research Participant _____
Research Participant's Signature _____

Consent language – Example 4 Individual Results

(courtesy of MayoClinic)

The blood sample you provide for this study will be used to find your monolysocardiolipins (MLCL) to cardiolipins (CL) in your blood. MLCL and CL are lipids present in your blood, and their relative buildup or absence, also known as the ML/CL ratio, may be a helpful biomarker for diagnosing individuals with Barth syndrome in the future. This is not a genetic test, and we do not have proof of the clinical significance of these results at this time.

Read the following statement and mark your choice:

I would like to obtain the results of my MLCL/CL ratios testing:

__ Yes __ No
Please initial here _____
Date _____