Returning Individual Research Results and Data: Digging Deeper

A 3-part webinar series about the specific ethical, operational, and technical challenges to returning individual research results and data to participants.

Pfizer’s Participant Data Return Solution – Thursday, July 27, 12-1pm EDT
IRB and HRPP Responsibility – Thursday, August 17, 12-1pm EDT
Genetic Testing – Thursday, September 21, 12-1pm EDT
Returning Individual Research Results and Data: Digging Deeper into Genetic Testing

Megan Frone
Board-certified Genetic Counselor at the National Cancer Institute

Thursday, September 21, 12-1pm EDT
Welcome!

You are part of a community of people that cares about returning individual results and data to participants!

To limit disruptions, please keep yourself muted.

Questions can be submitted via the chat function.

Closed Captioning is available.

The recording will be available within a few days of this session.
Disclaimer

• The opinions expressed today are those of the speakers and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any other organization, government, or entity.

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• We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables.

• There are no personal financial conflicts of interest to disclose.
Our Vision
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Return of Individual Research Results (IRR) Project - Timeline

November 2017
• Original IRR toolkit and guidance documents released

January 2021
• Taskforce to create updated operational and implementation-oriented tools and resources

March 2022
• Release of updated IRR resources, guidance, and project-specific website

April-May 2023
• Launch of IRR case studies and webinar detailing experience from the field

July-Sep 2023
• IRR Digging Deeper meeting series to continue the conversation
MRCT Center Return of Individual Research Results

RETURN OF INDIVIDUAL RESEARCH RESULTS

ABOUT | GETTING STARTED | HOW TO RETURN IRR | RESOURCES | TOPICS

Return of Individual Research Results

The MRCT Center is proud to release these updated resources. The guidance, recommendations, and tools on this website can further enable researchers to return individual research results (IRR) to participants.

Learn More

https://mrctcenter.org/return-of-individual-results/
RETURN OF INDIVIDUAL RESEARCH RESULTS

ABOUT | GETTING STARTED | HOW TO RETURN IRR | RESOURCES | TOPICS

- How to use this website
- How to get started
- Why to get started

Return of Individual Research Results

The MRCT Center is proud to release these updated resources. The guidance, recommendations, and tools on this website can further enable researchers to return individual research results (IRR) to participants.
RETURN OF INDIVIDUAL RESEARCH RESULTS

- Stakeholder Roadmaps
- Determining what to return
- How to return (who/when/how/etc.)
- Result-specific guidance

Return of Individual Research Results

The MRCT Center is proud to release these updated resources. The guidance, recommendations, and tools on this website can further enable researchers to return individual research results (IRR) to participants.
RETURN OF INDIVIDUAL RESEARCH RESULTS

- Tools and Templates
- Resources for participants
- Version 1 Guidance (2017)
- Case Studies
IRR Case Studies: Experiences from the Field

**Return of Individual Results Case Study**

**Supporting Participant Decision-Making**

This case study shares an example of how new tools to support decision making for potential participants can help in the informed consent process.

**Return of Individual Results Case Study**

**Returning Routine Lab Results to Part**

This case study outlines how an industry sponsor managed the return of routine laboratory results to participants.

**Return of Individual Results Case Study**

**Implementing a Robust, Scalable Process**

This case study describes how a mid-size sponsor implemented a robust and scalable process for returning individual results to participants.

**Return of Individual Results Case Study**

**Returning Non-Validated Test Results**

This case study discusses the return of non-validated test results to participants.

**Return of Individual Results Case Study**

**Responsibly Returning Secondary Findings**

This case study examines the return of secondary findings to participants.

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**Jamie’s Story**

While in her mid-30s, Jamie was diagnosed with breast cancer. She describes her symptoms as quite unusual and her condition as uncommon. She %s till something was wrong and that her symptoms were not normal.

Jamie was instructed to participate because of her no prior symptoms, and even though she wasn’t invasive, her family history of breast cancer was on her radar screen. As an advanced breast cancer patient, Jamie was instructed not to undergo genetic counseling before, during, and after the study. As she had no other symptoms, Jamie received her results electronically while she was in the hospital, having received any counseling or advice on the subject.

As calculations showed, she had two copies of the ApoE4 genotype, the most prevalent genetic risk factor for AD. At that time, it was estimated that she lived a lifetime risk of developing the disease.

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**IRR Case Studies: Experiences from the Field**

[https://mrctcenter.org/return-of-individual-results/resources/case-studies/](https://mrctcenter.org/return-of-individual-results/resources/case-studies/)
Special thanks!

Thank you to the taskforce members who contributed to the IRR update in 2021 and our other Case Study authors:

- Barbara Bierer
- Anna Kang Liu
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- Carol Weil
- Sarah White

Jamie Tyrone
Patient Advocate

Doris Zallen
Virginia Tech

Paula Boyles
Pfizer

Linda Coleman
Yale University

September 21, 2023
Digging Deeper: Responsibly Returning Secondary Findings

**Megan Frone**  
National Cancer Institute

**Return of Individual Results**

*Case Study*

*Responsibly Returning Secondary Findings*

This case details the experience of a research team returning secondary findings to participants in a genetic testing study.

**Researcher Roadmap to Returning Individual Results**

The roadmap above shows steps for researchers to consider when planning to return individual results to participants. This case study focuses on the pre- and post-study parts of the timeline illustrated by the green circle and red triangle.

**Background**

This case details the experience of a research team studying a group of various disorders, termed Inherited Bone Marrow Failure Syndrome (IBMFS), characterized by the failure of bone marrow to produce blood. IBMFS has a significant risk of progressing to cancer (such as leukemia and lymphoma) and typically has an underlying inherited genetic cause. A study was designed to identify underlying inherited genetic causes of IBMFS in families with multiple affected members.

During the design of the study, the research team planned to return individual genetic testing results of IBMFS-related genes to participants. As a consequence of genetic sequencing, the team anticipated that they might discover unrelated but important genetic findings that may need to be shared with the participants. During the research study, genetic sequencing revealed that an adult female patient had a previously unidentified pathogenic variant in BMT1, a gene that can cause myelodysplastic syndrome. Pathogenic variants in BMT1 can lead to myelodysplastic syndrome and ovarian cancer syndrome, an adult onset disorder with increased risk of breast and ovarian cancers in females, male breast cancer, and several other cancer risks.

**Approach**

Anticipating unrelated but potentially important genetic findings, the research team was able to implement the following structured approach to return secondary findings to patients. The plan outlined a clear path for the research team to implement when secondary findings arose, reducing the need for ethical and legal consultations while the study was ongoing. Not only did this plan save time and resources, but most importantly, it protected the rights, health, and wellbeing of the research participants. Based on experience, the research team noted that any plan for the return of secondary genetic findings should include detailed guidance on:
Disclaimer: Today’s content represents the work and opinions of the presenter and does not constitute official positions of the National Institutes of Health (NIH), National Cancer Institute (NCI) or the U.S. Department of Health & Human Services (HHS).