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 IRB and HRPP Responsibilities

Linda Coleman
Director of the Yale Human Research Protection Program

Madelon Baranoski
IRB Chair, Yale University

Thursday, August 17, 12-1 pm 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 Q&A 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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The Multi-Regional Clinical Trials Center (MRCT Center)

**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
RETURN OF INDIVIDUAL RESEARCH RESULTS

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.

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

• 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

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.

• Stakeholder Roadmaps
• Determining what to return
• How to return (who/when/how/etc.)
• Result-specific guidance
RETURN OF INDIVIDUAL RESEARCH RESULTS

- Tools and Templates
- Resources for participants
- Version 1 Guidance (2017)
- Case Studies
Supporting Participant Decision-Making

This case study shares an example of how to use an IRR tool to support decision making for potential participants, illustrated by a fictional scenario.

Jamie’s Story

While in her mid-30s, Jamie was diagnosed with multiple sclerosis (MS). With time, her symptoms changed. Unable to explain to her condition, her neuropsychologist questioned the diagnosis. As her symptoms continued to worsen, she was advised to discuss her options. Jamie sought out a new neurologist who confirmed her diagnosis.

Jamie was interested in participating because of her long-term symptoms, and even though Allaine’s disease (AD) was also mentioned, it was her family history of MS that she focused on. As an innovator, Jamie soon received reconstructive genetic counseling before, during, and after the study. Jamie received her results electronically while asleep, without having any counseling to support or advise her.

Jaimie’s results showed that she had two copies of the Apolipoprotein E (APOE) gene, the most prevalent genetic risk factor of AD. At that time, it was estimated that she had a >90% lifetime risk of dementia.

Return to Case Study

Returning Routine Lab Results to Participants

This case study outlines how an industry sponsor can incorporate clinical trial data into their decision-making processes, illustrated by a fictional scenario.

Sponsor Roadmap to Return Lab Results

The roadmap above shows how to handle lab results for a clinical trial. The case study focuses on the pre-study part of the process.

Return to Case Study

Implementing a Robust, Scalable Platform

This case study describes how an industry sponsor can implement a robust and scalable platform for clinical research data, illustrated by a fictional scenario.

Sponsor Roadmap to Return Lab Results

The roadmap above shows steps for sponsors to consider when implementing a robust platform. The case study focuses on the pre-study part of the process.

Return to Case Study

Returning Non-Validated Results

This case study describes how an industry sponsor can handle non-validated results, illustrated by a fictional scenario.

Sponsor Roadmap to Return Lab Results

The roadmap above shows steps for sponsors to consider when handling non-validated results. The case study focuses on the pre-study part of the process.

Return to Case Study

Responsibly Returning Secondary Findings

This case study details the experience of a research team returning secondary findings to participants, illustrated by a fictional scenario.

Sponsor Roadmap to Return Lab Results

The roadmap above shows steps for sponsors to consider when returning secondary findings. The case study focuses on the pre-study part of the process.

Return to Case Study

MRCT Center IRR Digging Deeper

August 17, 2023

https://mrctcenter.org/return-of-individual-results/resources/case-studies/
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REGISTER NOW!
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
- David Leventhal
- Megan McBride
- Lisa Murray
- Nancy Levitan Poorvu
- Sandra Prucka
- Kate Robins
- Jessica Scott
- Carol Weil
- Sarah White
Digging Deeper: Returning Non-Validated Test Results – IRB/HRPP Perspectives

Linda Coleman
Director of the Yale Human Research Protection Program

Madelon Baranoski
IRB Chair, Yale University

Return of Individual Results Case Study

Returning Non-Validated Test Results

This case study describes how an IRB navigated returning results of a new COVID-19 assay from a non-CLIA-certified lab during a public health emergency.

IBD Roadmap to Returning Individual Results

Organizational Review
Protocol Review
Informed Consent
Stated Risk/Study Risks
Maintaining Oversight

Background

A university was creating a repository for current and future research involving the epidemiology and pathogenesis of emerging viral infections including the coronavirus SARS-CoV-2. A secondary aim was to validate a university-developed assay to test for COVID-19.

Samples were collected from hospital inpatients and outpatients either suspected of exposure to COVID-19 or exhibiting symptoms of infection. Samples were first tested in a non-CLIA-certified laboratory using a university-developed assay. All COVID-19 samples were then retested in a CLIA-certified lab to validate the results.

The IRB and researchers considered whether to return unvalidated positive COVID-19 results from the new assay immediately to treating physicians or participants without waiting for CLIA lab confirmation, or to wait for validation.

Approach

The IRB weighed the risks of waiting to get the samples re-tested in a CLIA-certified lab against the violation of the CLIA regulations if they were to return non-CLIA-certified results to participants.

Due to the unique circumstances posed by the COVID-19 pandemic and the contagiousness and significant health risks associated with the virus, the IRB determined that it was an ethical obligation to alert providers to the following:

• A “potential unconfirmed finding” of a positive COVID-19 test
• Samples were being re-tested in a CLIA-certified lab for confirmation
• The CLIA-certified results would be returned to the providers directly for any required action including mandatory reporting to health authorities and hospital infection control