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Return of Individual Research Results (IRR) Website Launch Webinar

24 March 2022
1-2 pm EDT
https://mrctcenter.org/
Session Agenda

• MRCT Center Introduction
• Importance of Returning Individual Research Results (IRR)
• Evolution of this work
• Remarks from Jamie Tyrone, Patient Advocate
• Review of project update
• Website Demo
• Q&A
The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.
Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

We engage diverse stakeholders in the research enterprise to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Decision to return aggregate and individual results begin with commitment at study design, requires planning, and embodies respect.
**Defining Individual Research Results (IRR)**

**IRR is:**
Any data or test result from a research study that is specific to an individual, such as study arm assignment, lab results, or genetic sequencing data.

**IRR is not:**
Aggregate results, plain language summaries, or lay summaries that provide study participants with overall findings of a research study.
Research participants consistently desire and expect to receive both individual and aggregate research data from the research studies in which they have participated.

Expectations about data transparency and ownership are evolving in society; returning IRR anticipates and responds to those expectations.

Foundational ethical principles in research can and should be applied to the return of IRR to participants.
Version 1, Released in 2017

• Strong case was made for the ethical imperative of returning IRR

• Introduced classification of result types based on timing, actionability, etc.

• Robust set of considerations for returning genetic information

• Presented as a starting point for external stakeholders to build upon
Spectrum of results to return to participants:

- Aggregate research results (plain language summaries)
- Assignment to and results of study arm
- Routine clinical results performed in the course of research
  - Urgent
  - Actionable
  - Personally valuable
  - No known implications
- Incidental findings discovered in the course of a clinical trial
  - Of potential clinical significance or actionable
  - Of uncertain significance
- Research results
  - Of likely or uncertain significance
  - Of potential proprietary importance
  - Genetic/genomic results
- Other results
What should results be shared? Considerations:

- Has the participant opted in to receive results?
- Are the results analytically valid?
- Does the result have clinical validity?
- Are the results urgent, actionable?
- Are the results of personal utility?
- Does sharing the result impact the integrity of the study?
- Does returning the result comply with institutional policies, legal and national laws, and regulations?
Remarks from Jamie Tyrone, Patient Advocate
Need for an update:

- Identified the need for practical, implementation-based resources
- Update/expansion of certain recommendations

IRR Taskforce:

- Convened 10-person taskforce to update the original materials and overall project
  - Included representation from industry, academia, IRB/HRPP, government, and patient advocates
- Objectives:
  - Find common problems and barriers throughout the process of returning IRR
  - Provide guidance/resources to help organizations address and overcome barriers
  - Promote the value of organizations to prepare for and prioritize returning IRR
Challenges Identified

• Perception of a high barrier to entry
• Concerns around liability/fear of the unknown
• Unclear differentiation of responsibilities between and among stakeholders
• Absence of regulatory requirements or guidance on what to return, when, and how
• Difficulty in achieving buy-in throughout the organization

Solutions Created for Version 2 Release

• Guidance on getting started and planning for a gradual progression
• Roadmaps to clarify stakeholder roles and responsibilities
• Re-classification of result types to frame the return of IRR
• Guidance on how to create a return of IRR plan
• Specific tools for implementing the return of IRR
• Topics to review common concerns/complexities with returning IRR
Intended Audience

Research Sponsors
Those developing treatments and financing clinical trials.

IRBs & HRPPs
Those providing ethical reviews of research or managing human research protections programs.

Study Staff & Investigators
Principal Investigators, study team members, and staff at research sites.

Patients & Participants
Those participating in or considering clinical trials, and their family members/caregivers.

The MRCT Center invites review, comment, and suggestions for revision from all stakeholders to MRCT@bwh.harvard.edu
RETURN OF INDIVIDUAL RESEARCH RESULTS

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

• 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.
How to Get Started

Proposed progression of return

Designing a pilot

Who to involve

Methods for returning IRR

Establishing a policy

PROPOSED PROGRESSION

SECONDARY OUTCOMES

ROUTINE RESULTS

PRIMARY OUTCOMES

STUDY ARM ASSIGNMENT

PLAIN LANGUAGE SUMMARIES

URGENT FINDINGS
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
New Result Type Classifications

URGENT

ACTIONABLE

PERSONALLY VALUABLE

NO KNOWN IMPLICATIONS
Determining what to return

Step 1: During the study, when are you collecting data?
Consider the entire clinical trial lifecycle for a participant:
- Recruitment
- Screening
- Informed consent: Participant on study
- On study: Additional testing Randomization
- Participant last visit: End of study treatment
- On-Study visits
- End of trial LPLV
- Data lock
- Data analysis Complete and Reporting

Step 2: What kinds of data will be generated during each period?
Think about the kinds of tests you will perform during each of the above periods:
- Study arm assignment
- Laboratory tests
- Diagnostic imaging
- Genetic sequencing
- Physical or visual examinations
- Socio-behavioral
- Surveys and questionnaires
- Digital or mobile health results
- Patient-reported outcomes (PROs)
- Exploratory results

Step 3: Consider the following questions/domains for each data type during each study period to determine whether to return and what plans must be made to return:

A. URGENCY
- Is there a possibility for a result to require urgent medical attention?
  - Example: A "routine" blood pressure found to be 220/120 mmHg
  - Example: A participant reports suicidal ideation

Steps in a clinical trial
Types of data that may be generated in the trial
Classification of result
Stakeholder Roadmaps

- Roadmap for each stakeholder group
- Provides a basic overview of each role’s responsibility/task during a given time period
- Links to additional guidance or tools relating to each responsibility/task

### How to Use This Page

The overall study roadmap has been divided into three sections:

1. Preparation
2. On Study
3. End of Study

Within each section, click through the considerations at the left to view relevant guidance and links to additional information or resources.

### Preparation

#### Organizational Buy-In

IRBs and HRRPPs are important stakeholders and advisors throughout IRR, particularly during initiation of an IRR pilot or program, at any organization or institution.

- Make sure to stay involved in both guide practices towards those that are beneficial to participants, and to establish appropriate expectations for what should be included to enable appropriate IRR review.

#### Establishing a Policy

- Protocol Review
- Regulations

### On Study

#### Informed Consent

- Plans for IRR should be made during protocol development to enable all relevant details around IRR to be given to the participant during the informed consent process. The IRB should determine which details need to be included in the Informed Consent Form, and which can be communicated in other ways.

- Click here for more on informed consent
How to Return IRR

Who should return result
When it should be returned
How it should be returned
Choice for participant as to whether to receive

Guidance separated by result type

Recommendations for who should return results of different data types:

- **Urgent**
- **Actionable but not urgent**
- **Personally Valuable**
- **No known Implications**

PIs should generally give urgent results to the participant contextualized with appropriate medical information, connect with the healthcare provider, and document the handoff.

Documentation should include the result, referral, and verification of the transfer of responsibility.

It may be necessary to inform the healthcare provider first, and then inform the participant with recommended next steps. These situations include concerns around requisite psychological support systems (e.g., information indicating suicidality), or in settings wherein the nature of the problem might inhibit the ability of the participant to respond.

If the participant is unreachable in an urgent situation and no alternative person has been designated by the participant, the PI and study staff should revert to procedures deployed in clinical settings and submit a report to the IRB as soon as reasonably possible. The medically responsible person affiliated with the trial should be contacted and tasked with this responsibility whether or not that person is the principal or site investigator of the trial.

The PI should determine how to proceed in other special circumstances.

Click here for more about returning this data type.
For each result/data type:

- Definition & examples
- Links to basic considerations (who, when, how, choice)
- Informed consent (IC) guidance
- IC sample language
- Regulatory requirements
- Gathering the participant’s healthcare provider contact info
- Accessing appropriate expertise to interpret results or advise in other capacities
RETURN OF INDIVIDUAL RESEARCH RESULTS

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

• Tools and Templates
• Resources for participants
• 2017 Guidance Documents
• Health Literacy
• Aggregate Results
• Coming soon: Case Studies

Return of individual research results

Return of individual research results

The Return of Individual Research Results (IRR) is the process by which researchers provide participants with the results of their research. This process is important for ensuring that participants have access to information about the outcomes of their participation.

Tools and templates are available to help researchers navigate the IRR process. These tools include checklists, guidelines, and best practices. Resources for participants include information about how to understand and interpret the results of their research.

The 2017 Guidance Documents provide detailed guidance on the IRR process. These documents outline the steps researchers should take to return individual research results to participants.

Health literacy is an important consideration in the IRR process. Research results can be difficult for participants to understand, especially if they have limited medical knowledge. Health literacy resources can help researchers communicate the results of their research in a way that is accessible to all participants.

Aggregate results are results that summarize data from multiple participants. These results can provide valuable insights into the overall impact of the research.

Case studies will be coming soon. These studies will provide real-world examples of how the IRR process can be implemented.

And tools on this website can further enable researchers to return individual research results (IRR) to participants.
Tools & Templates – these and others!

Simple, downloadable tools supporting the adoption of returning IRR in a compliant and respectful way

**RETURN OF RESULTS INFORMATION SHEET**

- **Template Instructions (please fill in template):**
  - This sheet is intended to support the decision and discussion among a participants’ choice to receive results. It should be adopted and/or adopted for the individual study and the choices that the participant may have.
  - The “red type in brackets” below should be changed to reflect the plan of the study and the types of results that a participant has the option to receive below.
  - Add and explain as many different types of results as necessary.
  - Record participants’ choices in your study documents and/or the informed consent form. In addition, check the boxes on this form for participants to take home as a reminder of their decisions.

- **WHAT IS THIS SHEET?**
  - This sheet describes the types of research results that you may choose to (will or may) receive by participating in “insert plan language study title here.”
  - You can choose whether or not to receive these results.
  - Note, however, that we must return urgent results that require medical attention with you and/or your doctor. You do not have a choice with respect to urgent results. We will explain the reasons why below.

- **Can I change my mind about getting my results?**
  - Yes, if you decide to receive results and you change your mind later, you can contact us at any time by: 

- **WHAT WILL I RECEIVE?**
  - No matter what you decide, we will give you another chance to choose whether to receive results on:

- **Result 1: Urgent results that require medical attention**
  - Any result like this must be returned.

- **RESULT 2: Any result like this must be returned**
  - Any result like this must be returned.

**HEALTHCARE PROVIDER CONTACT FORM**

- **What is this form?**
  - In the “insert plan language study title here” study there may be results about you that would be important for healthcare providers or doctors to know. This form seeks permission to contact your healthcare provider or doctor if necessary. We also ask for your contact information.

- **When should we be required to contact your healthcare provider?**
  - When we would be required to contact your healthcare provider (where you don’t have a choice):

- **Reasons you can choose to let us contact your healthcare provider:**
  - “Insert date or reason from study”

- **Do you want us to share these results only with your healthcare provider?**
  - Yes No

- **What if my healthcare provider changes?**
  - If you change healthcare providers, you can contact us at any time with their new information at:

**IRB Approval Checklist:**

**Return of Individual Research Results**

- **The Study Protocol and/or Informed Consent Form (OCF) describes the plan for returning individual research results (IRR). If there is no intention to return IRR, plans and procedures in the event of urgent or incidental findings are still outlined.**

- **The following is included in the Study Protocol:**

- **What results will be returned?**

- **How results will be returned?**

- **Where results will be returned?**

- **Who will return and receive results?**

- **Healthcare provider contact information will be collected if necessary?**

- **Procedure in place for results returned to parent/guardian or legally authenticated representative.**

- **Delegate (close friends or family member) to contact if the participant is not reachable or available?**

- **Delegated to contact in case the participant is deceased?**

- **Appropriate provisions are included for urgent results or urgent incidental findings that may occur during the study and must be returned.**

- **In the case of non-urgent findings, the participant or their legally authorized representative is able to be informed in a timely manner whether to receive their individual results or not.**

- **Participants are given the choice whether or not to receive the information.**

- **There is a plan/system for tracking participant decisions.**

- **Participants will be consented or re-consented as needed when the results are available.**

- **Procedures for communicating results are respectful of the wishes of the participants.**

- **Please provide your healthcare provider’s name, address, and contact information.**

- **If you do not have a healthcare provider, please provide that last place you went for medical care.**

- **Name of provider: Name & address of clinic, hospital, or office.**

- **Provider phone number:**

- **How would you like to receive your results?**

- **We will also review this information at a later visit:**

- **insert pre-specified review time if applicable.**
Tools & Templates

• IRB Approval Checklist for Returning IRR
  o A checklist to assist IRB members and Ethics Committees in reviewing return of IRR plans, based around the U.S. regulatory criteria for IRB approval.

• Healthcare Provider Contact Form Template
  o A template for obtaining permission to contact a participant’s healthcare provider or doctor about individual research results, along with their contact information.

• IRR Information Sheet for Participants Template
  o A template for supporting the decision and discussion around a participants’ choice to receive results, which should be adapted to reflect the plan of the study and the types of results that a participant has the option to receive, along with their decisions to receive them.

• Informed Consent Sample Language
  o Sample language to use in informed consent forms when explaining the different types of individual results that will be generated/returned to participants in a study.

• Resources for Participants
Remember, joining a research study is an important personal decision, and participating in a study is your choice. Be informed. Ask questions. Get answers.

- What kinds of results will you share with me? If you are not sharing any results with me, can you tell me why?
- What happens if you find out something serious or other information about my health?
- Do I have a choice about which findings you share with me? What if I don’t want to know?
- Can I change my mind later about receiving these results?
- How can these results help me?
- Will you tell me about results that might affect my health or a member of my family’s health?
- Could results/findings affect my family planning decisions?
- Could you learn something new about my family history?
- Will you be able to make sure any findings are correct?
- Who can I talk to about these findings?
- Are my research data placed in my regular medical records?
- How will you protect my privacy?
- Who will pay for my follow-up care and treatment if a new medical issue is uncovered as part of the study?
- Will there be future research on any of my samples? Will I learn any of those results?
Additional topics

RETURN OF INDIVIDUAL RESEARCH RESULTS

- Informed Consent
- Regulations
- Liability
- Study Integrity
- Funders
- Genetics

The guidance, recommendations, and tools on this website can further enable researchers to return individual research results (IRR) to participants.
Coming Soon: Identified Areas for Continued Work

- Further review of returning genetic information
- Guidance for biobanks
- Returning IRR to parents, guardians, representatives
- Additional case studies
- And more!

Please reach out to us if you would like to collaborate or have suggestions
Website Demo
mrctcenter.org/return-of-individual-results/
Thank you!

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