RESEARCH PROFESSIONALS NETWORK

Re-engaging the Engaged: Providing Results Back to Research Participants

RPN Workshop

April 29, 2025

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Learning Objectives

By the end of the workshop, participants will be able to:

1. Explain why it is important to share study results with participants
2. Identify key components of results sharing, appropriate for different types of study design (e.g., individual vs aggregate)
3. Develop a plan to share study results with participants

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"All medical research subjects should be given the option of being informed about the general outcome and results of the study."

World Medical Association. World Medical Association declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013; 310: 2191–2194. https://pubmed.ncbi.nlm.nih.gov/24141714/

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Question for the Group…

Have you worked on a study that shared individual level or aggregate results back to participants?

- Yes
- No
- Not sure

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Why share results with research participants?

- Ethical obligation
- Show appreciation to participants
- Opportunity to better explain results
- Gain participant perspectives
- Explore next steps
- Research staff satisfaction
- Educate participants about their health

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What other reasons for sharing results with participants haven't we mentioned?

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Types of Results to Share

Aggregate Findings

- Overall study findings/outcomes returned at the end of the study or after interim analyses
- e.g., arm unblinding, primary study results

Individual Findings

- The outcomes of research assessments and/or interventions administered to individual participants.
- e.g., results of a MRI or X-ray screen, standard lab results of blood draws (e.g., liver function, white blood cell count), genetic test results from a population-wide genomic screening initiative (e.g., *All of Us, Geisinger MyCode, In Our DNA SC*)*

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Considerations for Aggregate vs Individual Results

Aggregate	Individual
- Show the relevance of findings to each participant - Ensure data is presented without violating privacy - Adapt for differences in literacy, language, and cultural contexts - Poor communication may have a broader impact on trust in the research process	- Need to be particularly careful and prepared when delivering health results (e.g., disease risk, genetic predispositions) - Having the right resources to share to help participants take next steps - Mishandling personal finding can deeply damage participant trust - Results may be inconclusive or uncertain (especially in a research setting!), risking misinterpretation or false reassurance/alarm

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So…How do we share study results with research participants?

Some examples and things to consider…

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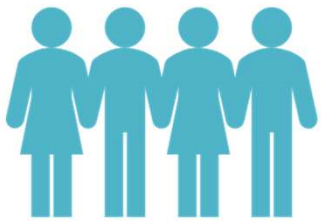

Aggregate Findings

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Returning Aggregate Findings

- Relationships with participants must exist beyond enrollment
- Post-study, participants should be seen as "Research Ambassadors" who can promote involvement and share results
- More studies are embracing participants as members of the research team, including adding study questions or outcomes important to participants

- Returning results is a vital part in empowering participants and demonstrating they are partners in research

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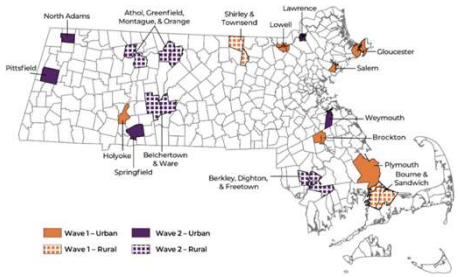
HEALing Communities Study (2019 – 2025)

NIH funded MA, NY, OH, KY to work with 67 highly affected rural and urban communities to reduce opioid overdose deaths by implementing a *process* to deliver evidence-based practices in healthcare, behavioral health, criminal legal settings

Goal: To reduce opioid overdose deaths through implementation of evidence-based practices

- Increase overdose education & naloxone distribution
- Increase access to medications for opioid use disorder
- Increase safer opioid prescribing & dispensing

Communities were the unit of analysis



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Post-study Community Presentations

- Share study results
- Discuss how strategies have been sustained
- Introduce resources
- Show our appreciation for their participation

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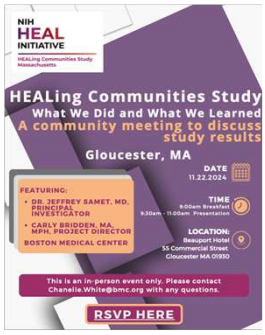
Logistics

- Coordinated with local community member
- Emailed invitation with PDF of publication
- Google form for registration
- In-person preferred, hybrid or zoom if requested
- Held in community partner space or hotel
- Some tailoring of presentation for each community
- 90-120 minutes
- Refreshments



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Successes and Challenges – Presentations

Successes	Challenges
- People appreciate the team returning and sharing results - Communities are proud of their participation and continued success beyond the study - Opportunity for community members to get together again - Research team gains insight on what worked and didn't - Discussion of "what's next"	- Losing contact with participants - Small audiences - Prioritizing what to present in an hour or in a one-page flyer - Retaining study staff for coordination - Advertising with enough advance notice

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Things to Consider – Presentations

- Cost – Plan ahead and budget for expenses
- Staffing resources – scheduling, creating materials (e.g., slides)
- Don't wait too long – people move, leave jobs
- Staff/investigators for presentations
- Invitations – retain up to date contact information
- Participant burden – explore multiple options

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The ADAPTABLE Study

- Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE) was a PCORI funded trial and the first to utilize the PCORnet Research Network
- This national study assessed the optimal dose of aspirin (325mg vs 81 mg) to prevent heart attacks and strokes in people with heart disease while minimizing potential side effects
- Total of 15,076 participants were followed for two years with findings showing no significant difference between 81mg vs 325mg

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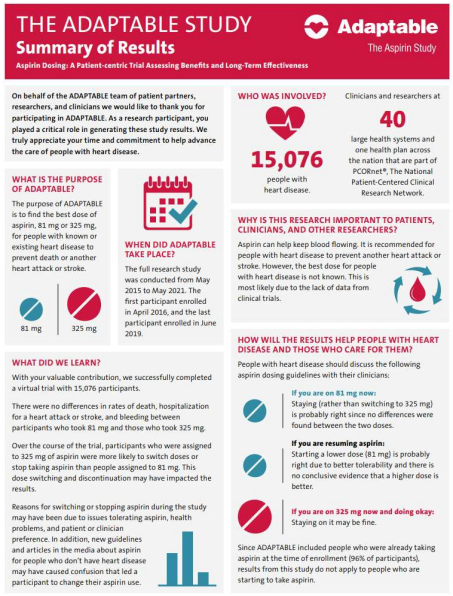
ADAPTABLE Return of Results



THE ADAPTABLE STUDY
Summary of Results
Adaptable
The Aspirin Study

Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness

On behalf of the ADAPTABLE team of patient partners, researchers, and clinicians we would like to thank you for participating in ADAPTABLE. As a research participant, you played a critical role in generating these study results. We truly appreciate your time and commitment to help advance the care of people with heart disease.

WHAT IS THE PURPOSE OF ADAPTABLE?
The purpose of ADAPTABLE is to find the best dose of aspirin, 81 mg or 325 mg, for people with known or existing heart disease to prevent death or another heart attack or stroke.

81 mg | 325 mg

WHEN DID ADAPTABLE TAKE PLACE?
The full research study was conducted from May 2015 to May 2021. The first participant enrolled in April 2016, and the last participant enrolled in June 2019.

WHO WAS INVOLVED?
15,076 people with heart disease.
Clinicians and researchers at 40 large health systems and one health plan across the nation that are part of PCORnet®, The National Patient-Centered Clinical Research Network.

WHY IS THIS RESEARCH IMPORTANT TO PATIENTS, CLINICIANS, AND OTHER RESEARCHERS?
Aspirin can help keep blood flowing. It is recommended for people with heart disease to prevent another heart attack or stroke. However, the best dose for people with heart disease is not known. This is most likely due to the lack of data from clinical trials.

WHAT DID WE LEARN?
With your valuable contribution, we successfully completed a virtual trial with 15,076 participants.

There were no differences in rates of death, hospitalization for a heart attack or stroke, and bleeding between participants who took 81 mg and those who took 325 mg.

Over the course of the trial, participants who were assigned to 325 mg of aspirin were more likely to switch doses or stop taking aspirin than people assigned to 81 mg. This dose switching and discontinuation may have impacted the results.

Reasons for switching or stopping aspirin during the study may have been due to issues tolerating aspirin, health problems, and patient or clinician preference. In addition, new guidelines and articles in the media about aspirin for people who don't have heart disease may have caused confusion that led a participant to change their aspirin use.

HOW WILL THE RESULTS HELP PEOPLE WITH HEART DISEASE AND THOSE WHO CARE FOR THEM?
People with heart disease should discuss the following aspirin dosing guidelines with their clinicians:

If you are on 81 mg now:
Staying (rather than switching to 325 mg) is probably right since no differences were found between the two doses.

If you are resuming aspirin:
Starting a lower dose (81 mg) is probably right due to better tolerability and there is no conclusive evidence that a higher dose is better.

If you are on 325 mg now and doing okay:
Staying on it may be fine.

Since ADAPTABLE included people who were already taking aspirin at the time of enrollment (96% of participants), results from this study do not apply to people who are starting to take aspirin.

- ADAPTABLE study used "Adaptors" to design study and help disseminate results
- What are the highlights of overall RoR?
  - Thank the participant!
  - Number of people involved
  - Short summary of study question in easy-to-understand terms (no medical jargon)
  - What did we learn
  - How will this help others like them
  - Next steps for research and how to stay involved


A group of "Adaptors," patient partners who helped design the study and disseminate its results.

https://ctsi.duke.edu/sites/default/files/2021-12/ADAPTABLE_Study_final.pdf

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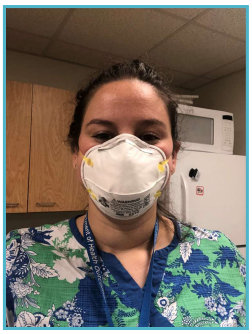

A tired coordinator eager for return of results

The HERO Study

- Healthcare Worker Exposure Response & Outcomes of Hydroxychloroquine Trial (HERO-HCQ) began in April 2020 to see if HCQ was a safe and effective way to prevent COVID-19 among people who worked in healthcare settings
- Participants were randomized to HCQ (study drug) or placebo and asked to take tablets for 30 days. Nasal swabs, blood samples and surveys were collected on participants
- While oral HCQ appeared to be safe among participants, the study was not able to determine whether HCQ could prevent COVID-19 infection
- Medical workers found themselves as both researcher and participant...and understanding the importance of efficient return of results
- Let's keep this study in mind...

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Dos and Don'ts – Informational Materials

Do	Don't
- Ask participants to share if they are comfortable - Be available to answer questions from participants - Highlight important next steps for the participant and research topic - Make results available in the language of the participant - Disseminate on sponsor social media if allowed	- Use technical/medical jargon - Make the flyer/email/post too wordy - Provide little to no follow-up from participants after RoR is released - Use personal social media accounts to post results - Downplay the importance of participant involvement or results if findings are not significant

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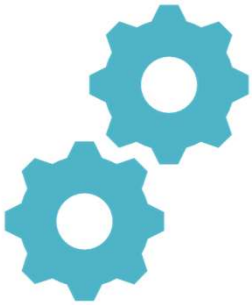

Now Let's Practice!

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How this works

Padlet:

- Let's discuss ideas on how to do return of results together
- Please use the address or qr code below to open the padlet
- All responses are anonymous, no login required
- To add a comment, click the + sign below each category:

- We will do one section for 1-2 mins then move to the next section
- You can like or add a comment to a post
- Let's try out on the test section: https://padlet.com/broth423/ror

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Let's Brainstorm Return of Results

Scenario: It's Summer of 2021 and after a year of hard work, you are ready to return results for the HERO-HCQ project.

- Remember...
  - Your audience are members of the medical community and primarily front-line workers
  - We want to disseminate this information as efficiently and effectively as possible
  - Return of Results Brainstorm Activity:

https://padlet.com/broth423/ror

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https://heroesresearch.org/wp-content/uploads/2021/10/HERO-HCQ_summary-of-results_31aug2021.pdf

Let's use HERO-HCQ as an example for developing an RoR Flyer

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HERO

Healthcare Worker Exposure Response & Outcomes of Hydroxychloroquine Trial (HERO-HCQ)

2021 08 31 HERO HCQ Lay Summary V1.0

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Individual Findings

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Returning Individual Findings

What do we know? Study participants desire (and often expect) their research results to be returned to them!

Returning research findings is also an important element of participant-centricity and respect.

Why do participants want results? A sense of individual ownership of their data, potential personal benefits, learning and sharing important information with their family members, and an expectation of respect and mutual trust.

Participants may also want to receive their results as a benefit to the community they represent.

How could participants use their results?

Health decisions: inform medical care or preventive actions

Lifestyle changes: adjust habits based on findings (e.g., diet, exercise)

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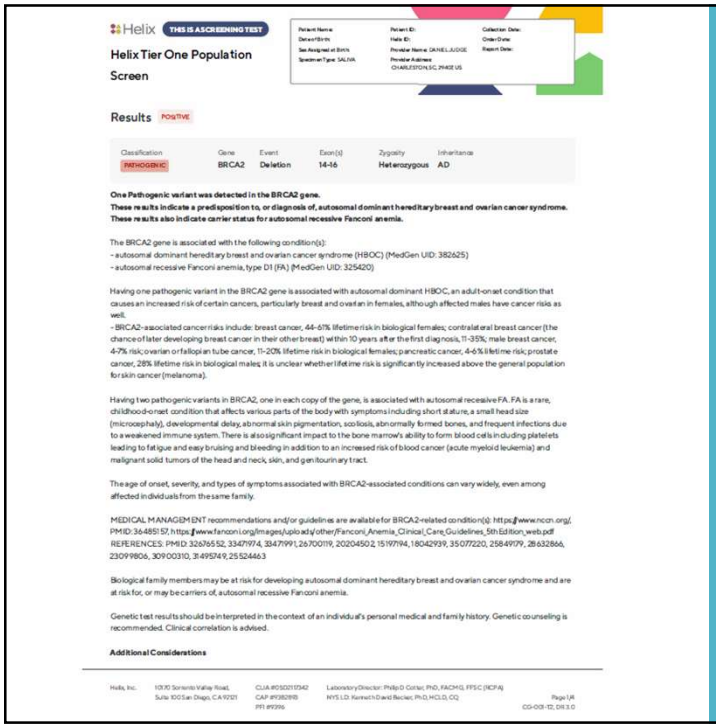

Helix THIS IS A SCREENING TEST

Helix Tier One Population Screen

Results POSITIVE

Classification	Gene	Event	Exon(s)	Zygosity	Inheritance
PATHOGENIC	BRCA2	Deletion	14-16	Heterozygous	AD

One Pathogenic variant was detected in the BRCA2 gene.
These results indicate a predisposition to, or diagnosis of, autosomal dominant hereditary breast and ovarian cancer syndrome.
These results also indicate carrier status for autosomal recessive Fanconi anemia.

The BRCA2 gene is associated with the following condition(s):
- autosomal dominant hereditary breast and ovarian cancer syndrome (HBOC) (MedGen UID: 382625)
- autosomal recessive Fanconi anemia, type D1 (FA) (MedGen UID: 325420)

Having one pathogenic variant in the BRCA2 gene is associated with autosomal dominant HBOC, an adult-onset condition that causes an increased risk of certain cancers, particularly breast and ovarian in females, although affected males have cancer risks as well.
- BRCA2-associated cancer risks include: breast cancer, 44-61% lifetime risk in biological females; contralateral breast cancer (the chance of later developing breast cancer in their other breast) within 10 years after the first diagnosis, 11-35%; male breast cancer, 4-7% risk; ovarian or fallopian tube cancer, 11-20% lifetime risk in biological females; pancreatic cancer, 4-6% lifetime risk; prostate cancer, 28% lifetime risk in biological males; it is unclear whether lifetime risk is significantly increased above the general population for skin cancer (melanoma).

Having two pathogenic variants in BRCA2, one in each copy of the gene, is associated with autosomal recessive FA. FA is a rare, childhood-onset condition that affects various parts of the body with symptoms including short stature, a small head size (microcephaly), developmental delay, abnormal skin pigmentation, scoliosis, abnormally formed bones, and frequent infections due to a weakened immune system. There is also significant impact to the bone marrow's ability to form blood cells including platelets leading to fatigue and easy bruising and bleeding in addition to an increased risk of blood cancer (acute myeloid leukemia) and malignant solid tumors of the head and neck, skin, and genitourinary tract.

The age of onset, severity, and types of symptoms associated with BRCA2-associated conditions can vary widely, even among affected individuals from the same family.

MEDICAL MANAGEMENT recommendations and/or guidelines are available for BRCA2-related condition(s): https://www.nccn.org/. PMID: 36485157, https://www.fanconi.org/images/uploads/other/Fanconi_Anemia_Clinical_Care_Guidelines_5thEdition_web.pdf
REFERENCES: PMID: 32676552, 33471974, 33471991, 26700119, 20204502, 15197194, 18042939, 35077220, 25849179, 28632866, 23099806, 30900310, 31495749, 25524463

Biological family members may be at risk for developing autosomal dominant hereditary breast and ovarian cancer syndrome and are at risk for, or may be carriers of, autosomal recessive Fanconi anemia.

Genetic test results should be interpreted in the context of an individual's personal medical and family history. Genetic counseling is recommended. Clinical correlation is advised.

Additional Considerations

Helix, Inc. 1010 Sorrento Valley Road, Suite 100 San Diego, CA 92121 CLIA #05D2117342 CAP #9382818 PFI #9396 Laboratory Director: Philip D. Cotter, PhD, FACMG, FFSC (RCPA) NYS I.D. Kenneth David Becker, Ph.D, MCLD, CQ Page 1/4 CG-003-12, DX 3.0

In Our DNA SC

- Population-wide genomic screening initiative launched in **November 2021**
- No-cost genomic screening for the **CDC Teir 1 conditions:**
  - **Hereditary Breast and Ovarian Cancer**
  - **Lynch Syndrome**
  - **Familial Hypercholesterolemia**
- Goal: **100,000 enrollments**
- Participants identified with a CDC Teir 1 condition are offered no-cost **genetic counseling**
- **Return of results**
  - Normal/negative: returned to the participant's electronic medical record (Epic), MyChart
  - Abnormal/positive: results disclosed to participants by study staff via IRB approved RoR scripts

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Impact on Participants

- Satisfaction with participation accompanied by minimal decision regret
- Responses were consistent over time
- Most participants completed some type of screening and/or discussed their results with a healthcare provider
- Post-test genetic counseling was nearly universally completed
- Subsequent healthcare behaviors were influenced

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Successes and Challenges

Successes	Challenges
- Results disclosed to 791 research participants - Playing a role in patient-care - Uptake in clinical services - Building relationships with service lines - Receiving participant feedback in real-time	- Unable to contact 56 participants - 221 participants declined next-steps (genetic counseling) - Psychological impact on participants - Training/comfort of study staff performing return or results - Navigating research vs. clinical care

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Things to Consider

Ethical

Beneficence: duty to protect participants' rights and well-being by maximizing the possible benefits to participants and minimizing risk of harm

A duty to provide and act upon urgent, actionable findings for study participants. For example, reporting to a participant an abnormal liver function test result

*Transparency: e*xpectations about data transparency and ownership are evolving in society; returning individual research results anticipates and responds to those expectations

IRB Review

Consider materials that will need to be reviewed and approved by the IRB (e.g., RoR scripts)

Staffing and Training

Staffing and training your research team appropriately to be able to navigate these conversations with participants

Balance

Research vs. clinical care

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Dos and Don'ts

Do	Don't
- Plan for return of results early - Explain the risks and benefits of receiving results - Have support and resources lined up - Respect participant privacy - Clearly communicate any limitations of the data - Tailor communication and adapt to participant language, literacy, and cultural background - Document the process	- Avoid implying results are always diagnostic or actionable - Don't use only written reports - Don't ignore potential emotional impact, - Avoid sharing unreliable or unvalidated findings - Don't assume that one size fits all - Don't violate laws, regulations, or guidelines

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Now Let's Practice!

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Role Play

- **Learn** about key talking points for delivering individual research findings
- **Observe** an example research return of results
- **Engage** in group discussion

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Key Points & Checklist

KEY POINTS:

- **Primary goals of the call**
  - Disclose results
  - Encourage the participant to engage in next steps (if applicable)
    - Referral to specialist, additional testing
  - Share resources
    - Patient advocacy groups, informational sites, provider locators
- **Call should take about 10 – 15 minutes**
  - If the conversation goes longer, the study team member should redirect the participant to the study PI or appropriate clinical care team member

CHECKLIST:

Use this checklist as a guide to ensure that all talking points have been discussed during your call with the participant.

☐ Introduce yourself, state purpose of call
☐ Assess participant's memory of participating in research study
☐ Disclose that you will be providing results; ask if they would like to include anyone in the conversation
☐ Provide brief summary of the study/testing
☐ Disclose findings
☐ Discuss implications of findings
☐ Pause for questions/comments/concerns
☐ Discuss next-steps
☐ Assess if participant is interested in moving forward with next-steps
☐ Share resources
☐ Explain to participant how they will receive their results (e.g., patient portal, mailed copy)
☐ Provide contact information for follow-up

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Prompt

Mrs. Kraft is a research participant in the GeneWell genomic screening study at East Coast Hospital. Participants enrolled in the GeneWell study receive free genomic screening for the CDC Teir 1 conditions. Mrs. Kraft's results have come back positive for a genetic variant in the BRCA1 gene, which increases her risk of developing breast and ovarian cancer over her lifetime. As part of the study, she will need to be contacted re

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Summary

- Research participants are interested in receiving study results!
- Two major categories: Aggregate vs. Individual
- Various ways to go about returning results- consider what will work best for your participants and community
- Success and challenges, things to consider, dos and don'ts
- Resources

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Food for Thought

How do you see your team engaging in returning research findings?

What can you identify as potential barriers to delivering results to research participants?

If you have been a participant in a research study that returned results, what went well? What could have been better?

What ethical challenges could arise in returning results to research participants?

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Resources

US Department of Health and Human Services:

Sharing Study Data and Results: Return of Individual Results

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard:

Return of Aggregate Research Results Website

Return of Individual Research Results Website

Health Research Authority:

Communicating Study Findings to Participants: Guidance

Google Search:

Sharing Results with Research Participants

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