*DON'T GHOST YOUR STUDY: PROPER CLOSEOUT FOR IRB AND IT**

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*Title by Terrier GPT

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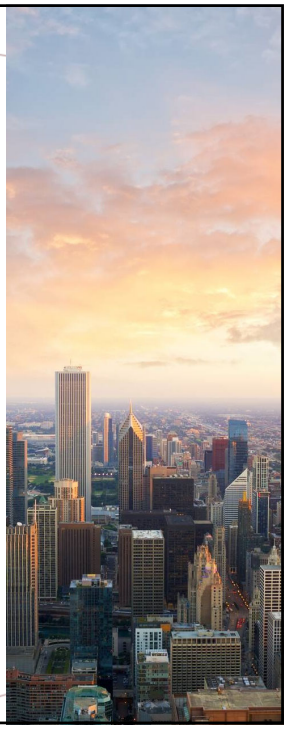
Learning objectives:

- What we owe our participants: Revisiting our ethical framework
- Appropriate inputs and responses for IRB Continuing Review and Closure Forms
- IRB Expectations for Communication of Results to Participants
- IT Expectations: Data storage, safekeeping, and destruction
- Case studies
- Continued in Part 2 Panel: March 2026



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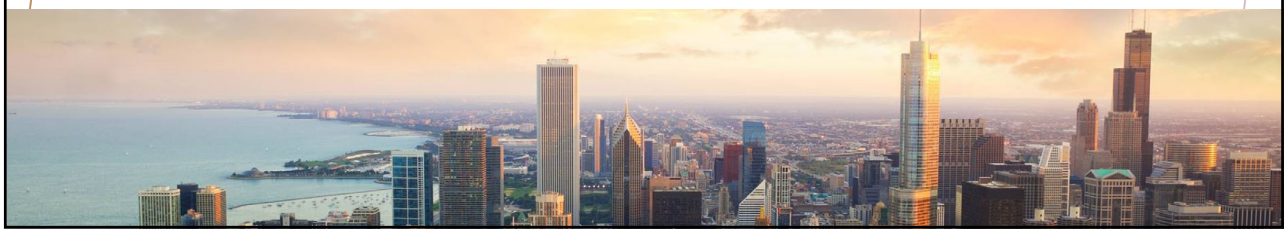
THE BELMONT REPORT: OUR ETHICAL FRAMEWORK



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What Do We Owe Participants?

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

BELMONT REPORT

- Respect for Persons
- Beneficence
- Justice

45 C.F.R. PART 46 and 21 C.F.R. PARTS 50, 56

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What We Owe Participants (Per The Belmont Report)

- Informed Consent part of Respect for Persons
- Respect = participants as equal partners
  - Autonomous agents
  - Self-determination
- Respect also means:
  - Relationship
  - Results – not just individual-specific. What did you learn from doing the study?
  - Publication does not = communication of results to participants.

**Read the Belmont Report | HHS.gov

THE BELMONT REPORT

Office of the Secretary

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

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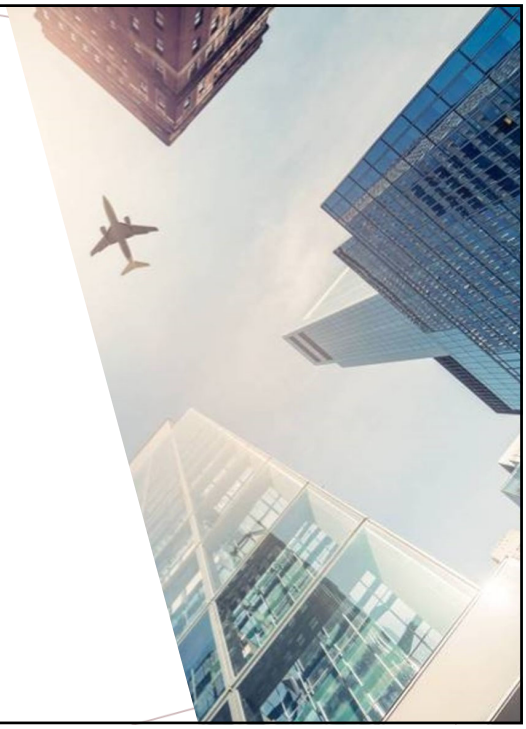
IRB CONTINUING REVIEW AND CLOSURE FORMS

MORE THAN FORMS



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Continuing Review / Closure Rationale

*To approve a study, the IRB concludes study risks are minimized, study has a positive r/b ratio, and data handled appropriately, among other criteria.

1. The purpose of Continuing Review:
    1. To ensure regular and consistent enrollment, particularly if powered, to maintain evidence of benefit
    2. To understand if data patterns require sharing new risks or with participants to ensure participants can continue to make informed decisions
    3. To understand if minor deviations require an amendment or intervention to minimize risk
    4. To follow study retention patterns / complaints and provide extra support to maximize benefit

2. The purpose of Study Closure:
    1. To demonstrate consistent follow-through with required close-out procedures and confirm final enrollment
    2. To demonstrate close-out with participants that maintains respect for persons
    3. To demonstrate appropriate data handling procedures that maintains respect for persons and r/b ratio.
    4. To inform the IRB that study oversight is no longer needed

3. CR/ Closure milestones:
    1. Exempt- CR due every 3 years. Close from INSPIR home page.
    2. Expedited – Status Check-in, CR due every 3 years. Closure Report when milestone reached. IRB Closure letter confirmation.
    3. Expedited- CR due every year. Closure Report when milestone reached. IRB Closure letter confirmation.
    4. Full Board - CR due at least every year until study reaches data analysis only. Closure Report when milestone reached. IRB Closure letter confirmation.

*Allowing a study to lapse does not = closure. This is non-compliance. You will not be approved for new research with lapsed studies.

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What We Mean: "Study Status"

Continuing Review asks:

What is the status of this study? (please select one):

- ○ Intending to enroll but no one has yet been enrolled, no records collected
- ◉ Actively enrolling
- ○ Closed to enrollment. Research interventions are still proceeding*
- ○ Closed to enrollment. Research interventions are complete. Collection of ongoing data that is part of routine clinical care is still proceeding
- ○ Closed to enrollment. Research interventions and collection of routine clinical data are complete. Analysis of identifiable data is still in progress

Closure asks:

1.2 What is the status of this study? For more information, click here

- ◉ All research activities (including all interventions, long-term follow-up and analysis using personally-identifiable information) have been completed. The study is closed.
- ○ If the study was never started (i.e., no subjects were enrolled), please check here.

- "Enrolling" means "consenting" or "Adding private identifiable information" to a dataset (secondary analysis).
- IRB expects to see progression from top of list to bottom
- Closure form confirms the logical step after CR options no longer true.
- Problems:
    - Secondary analysis studies claim not to enroll
    - CR reporting sometimes bounces back up status without amendment
    - People may try to close while still analyzing identifiable data.

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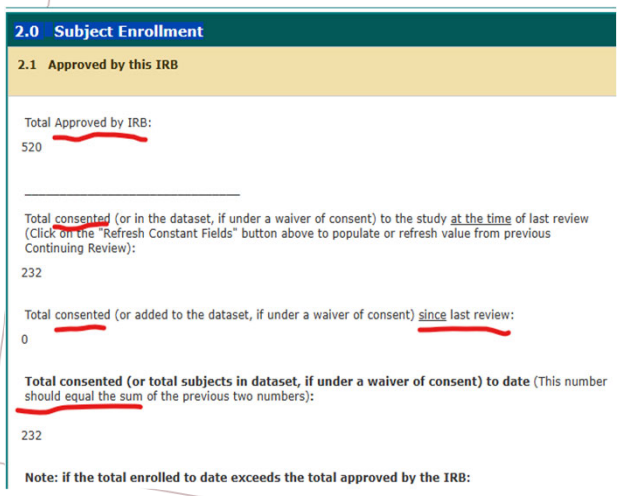
What We Mean: Consent = "Enrollment"



2.0 Subject Enrollment

2.1 Approved by this IRB

Total Approved by IRB:

520

Total consented (or in the dataset, if under a waiver of consent) to the study at the time of last review (Click on the "Refresh Constant Fields" button above to populate or refresh value from previous Continuing Review):

232

Total consented (or added to the dataset, if under a waiver of consent) since last review:

0

Total consented (or total subjects in dataset, if under a waiver of consent) to date (This number should equal the sum of the previous two numbers):

232

Note: if the total enrolled to date exceeds the total approved by the IRB:

- Teams are "in charge of human subjects" when they "enroll"
- Enrollment numbers = # of consented to the study.
- Ideally, study enrolls consistently until it meets its stated goal or cap.
- **Problems:**
  - Numbers reported are sometimes FEWER than previous Continuing Reviews,
  - Numbers not populated at all.
  - Numbers reported are those randomized or for whom data was analyzed, not those consented.

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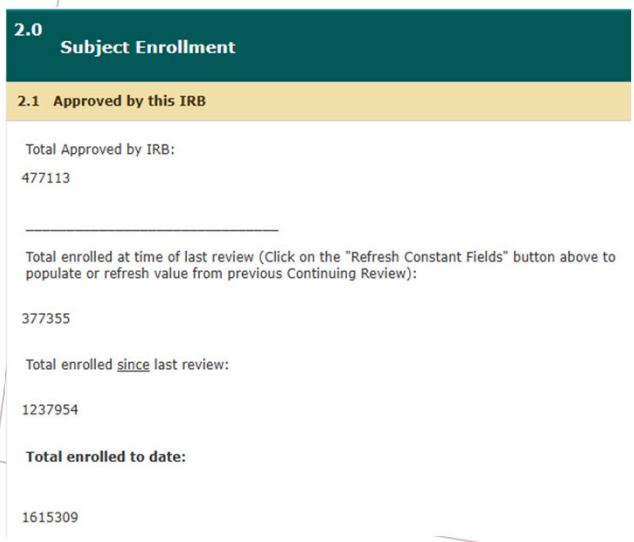
What We Mean: Consent = "Enrollment"



2.0 Subject Enrollment

2.1 Approved by this IRB

Total Approved by IRB:

477113

Total enrolled at time of last review (Click on the "Refresh Constant Fields" button above to populate or refresh value from previous Continuing Review):

377355

Total enrolled since last review:

1237954

Total enrolled to date:

1615309

- Closure forms should not have numbers to add, unless the study was completed within its initial review cycle.
- Problems:
  - Numbers reported are sometimes FEWER than previous Continuing Reviews.
  - CR reported numbers steady for years, then different numbers reported at closure.
  - No demographics reported when study clearly collected demographic info

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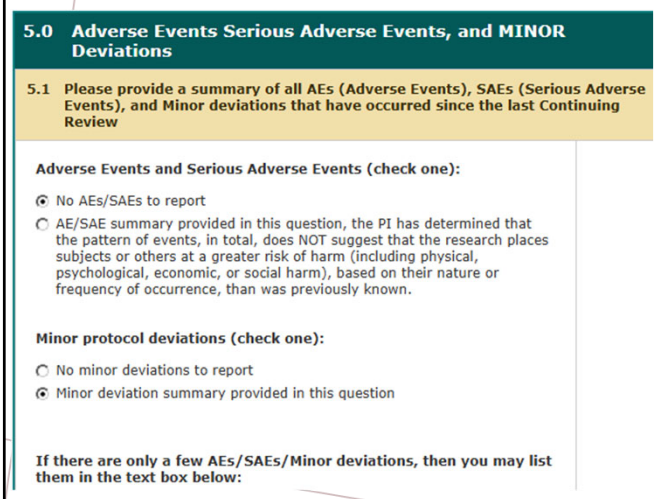
What We Mean: Adverse Events And Deviations



5.0 Adverse Events Serious Adverse Events, and MINOR Deviations

5.1 Please provide a summary of all AEs (Adverse Events), SAEs (Serious Adverse Events), and Minor deviations that have occurred since the last Continuing Review

Adverse Events and Serious Adverse Events (check one):

- (•) No AEs/SAEs to report
- ( ) AE/SAE summary provided in this question, the PI has determined that the pattern of events, in total, does NOT suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm), based on their nature or frequency of occurrence, than was previously known.

Minor protocol deviations (check one):

- ( ) No minor deviations to report
- (•) Minor deviation summary provided in this question

If there are only a few AEs/SAEs/Minor deviations, then you may list them in the text box below:

- IRB looks for patterns year-over-year, against what is reasonably expected for the population.
- Problem: Almost always reported as "none", even where there is an obvious deviation like allowing a study to expire.
  - Know your definitions per our policies
  - HRPP Policies | Office of Human Research Affairs – adverse event
  - HRPP Policies | Office of Human Research Affairs – minor deviation

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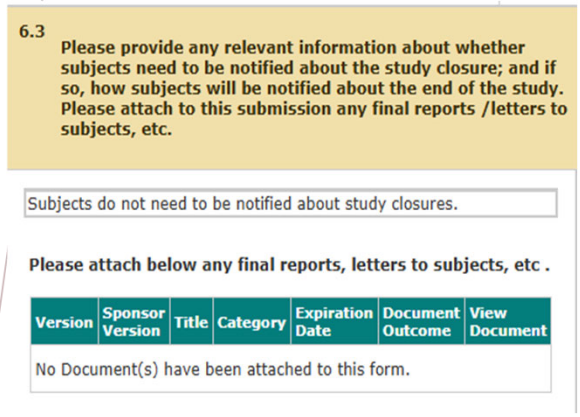
What We Mean: "Participant Notification"



6.3 Please provide any relevant information about whether subjects need to be notified about the study closure; and if so, how subjects will be notified about the end of the study. Please attach to this submission any final reports /letters to subjects, etc.

Subjects do not need to be notified about study closures.

Please attach below any final reports, letters to subjects, etc .

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.						

- Secondary analysis studies under waivers likely appropriate to not notify
- If the study directly interacted with participants, participant notification about study results is an ethical expectation.
- Problems:
  - "subjects do not need to be notified".
  - "Study closed as expected, subjects haven't been involved since active participation ended years ago."
  - "n/a."

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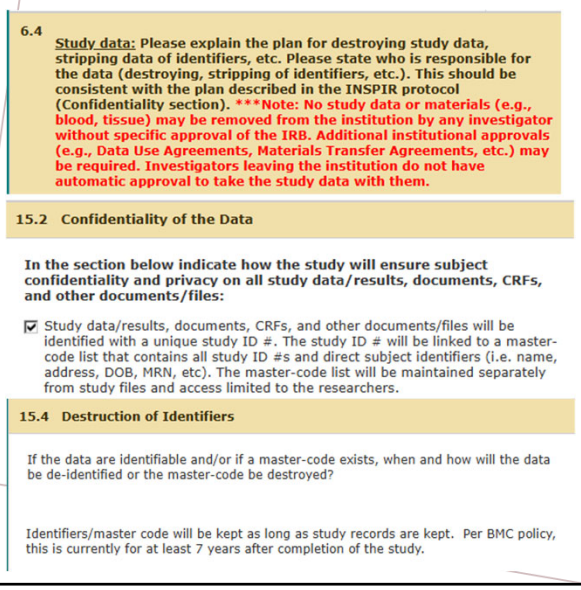
What We Mean: "Data Handling"



6.4 **Study data:** Please explain the plan for destroying study data, stripping data of identifiers, etc. Please state who is responsible for the data (destroying, stripping of identifiers, etc.). This should be consistent with the plan described in the INSPIR protocol (Confidentiality section). ***Note: No study data or materials (e.g., blood, tissue) may be removed from the institution by any investigator without specific approval of the IRB. Additional institutional approvals (e.g., Data Use Agreements, Materials Transfer Agreements, etc.) may be required. Investigators leaving the institution do not have automatic approval to take the study data with them.

15.2 Confidentiality of the Data

In the section below indicate how the study will ensure subject confidentiality and privacy on all study data/results, documents, CRFs, and other documents/files:

☑ Study data/results, documents, CRFs, and other documents/files will be identified with a unique study ID #. The study ID # will be linked to a master-code list that contains all study ID #s and direct subject identifiers (i.e. name, address, DOB, MRN, etc). The master-code list will be maintained separately from study files and access limited to the researchers.

15.4 Destruction of Identifiers

If the data are identifiable and/or if a master-code exists, when and how will the data be de-identified or the master-code be destroyed?

Identifiers/master code will be kept as long as study records are kept. Per BMC policy, this is currently for at least 7 years after completion of the study.

- Responses to this question in the Closure Form should reflect what was most recently approved in your application.
- Problems with Closure Reports:
  - States all data was destroyed when someone left institution
  - Does not distinguish between master code and dataset
  - No one in charge of moving to dormant space and destroying
  - Not in line with or opposite what was approved in application

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CR Times Guidance of IRB Expectations

- See: Clinical Research Newsletter from Boston University Medical Center
  - **Planning a Move to a New Institution?** March 2023 Issue
    - Close study or
    - Transfer study to a new PI here at BMC/BU Medical Campus, or
    - Transfer study to the new institution.
  - **Closing Time: The Dos and Don'ts of Study Closure** June/July 2022 Issue

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How do you Demonstrate Respect for Persons?

- If investigator has limited time at institution:
  - Not start study
  - Ensure another PI can take over
  - Tell participants about the limited time to complete / likelihood of getting results or information
- If things change, what do you owe participants?
  - Clear communication about who is taking over the study.
  - An honest account of what PI able to accomplish
  - What will be done with the data so it can still have value to others or summary of information or results.
  - A show of gratitude /appreciation for participation.
- What do investigators owe the IRB?
  - Update of PI to INSPIR BEFORE the previous PI leaves.
  - An honest account by new PI of expectation to continue the study as stated, or will end enrollment but continue with data analysis, etc
  - Examples of communication with participants of study closure and results.
  - Real information at study closure: Thoughtful, thorough, consistent with approved application, and acknowledges the value of the participant.

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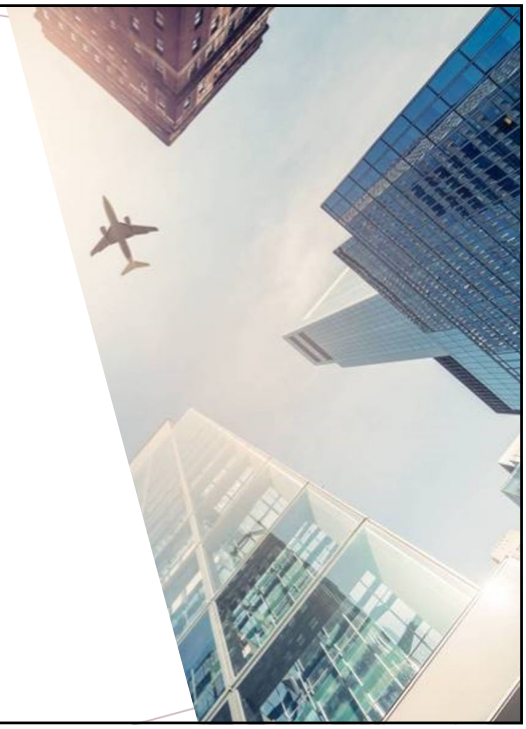
CASE STUDY



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- Expedited 6, 7 study: Needs assessment of patients with severe mental health issues with purpose of integrating mental health into a separate department. Sought to enroll 60; but enrolled only 10.
- Closure report stated: *"Insufficient sample for analysis. Study is being closed due to problems with recruitment, as well as main PI moving to a new state and unable to continue the study….No subjects need to be notified. Data has been deleted from files. Paper materials (consent forms) have been shredded."*

- Audience Question: What are some problems with this response?
- Audience Question: How could this have been done differently?

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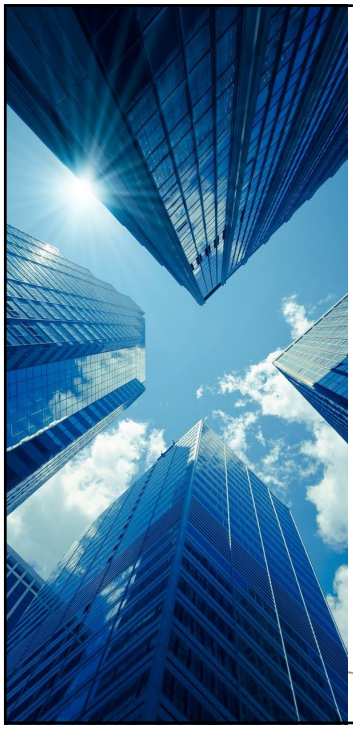

DATA STORAGE, SAFEKEEPING, AND DESTRUCTION

- Transfer data from apps to BU or BMC network drive
  - Including BU apps, like REDCap
  - Is OneDrive Ok?
  - Is a thumb drive in my office ok?
  - Is there a place for Ph.D/grad students to store research data?

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CASE STUDY FROM DAVID

- PI passed, and study was transferred to another PI
  - data left on app that was never brought down
- Document procedures
  - Have an inventory of all locations of data
  - Verify transfer/destruction at end of study

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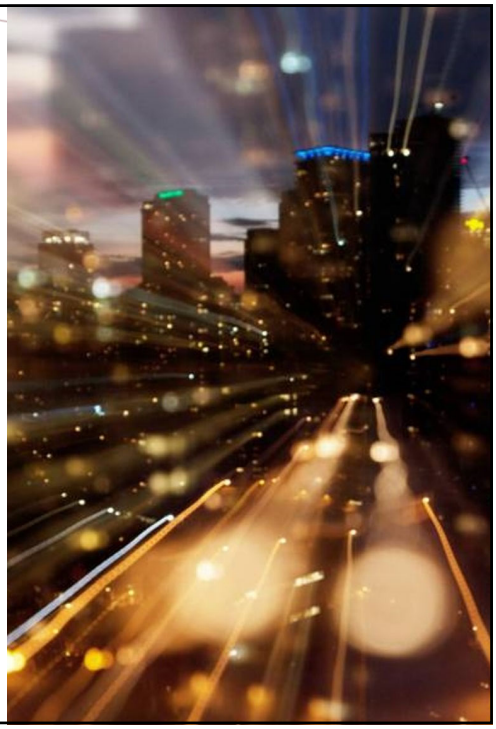
When It's Done Well

The amazing impact of investing the time to communicate results with participants.

Positively affects:

1. Future willingness to participate in research
2. Strengthens relationship to institution
3. Ensures trust in the research enterprise
4. Funding if PI confident that recruitment can be met



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Plain Language Summaries

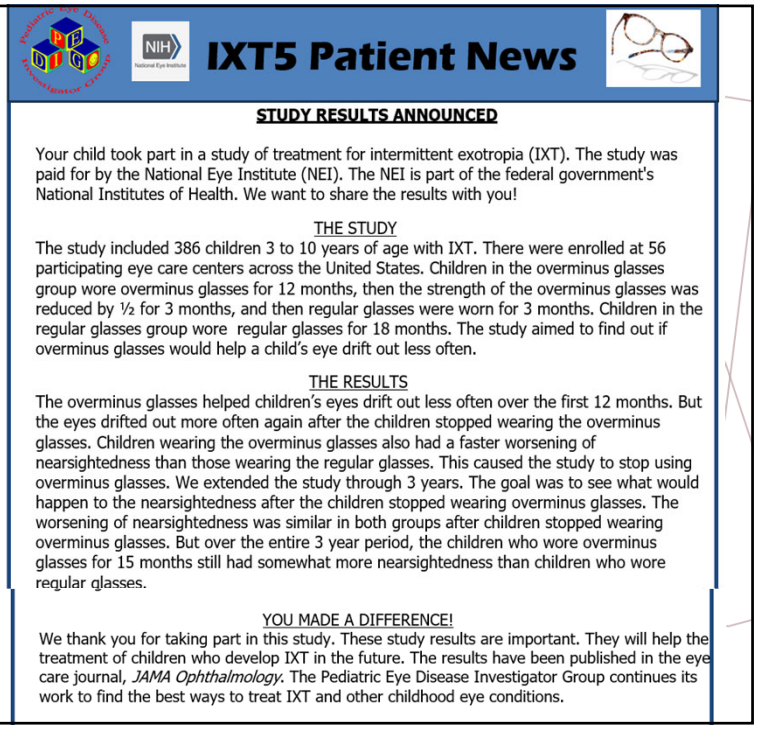
Research shows participants want communication of study achievements from studies they participate in

Supported by the Multi-Regional Clinical Trials Center guidance:

Operational Planning for Plain Language Summaries and Return of Results - The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Example: 35356 Dr. Stephen Christiansen

"A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia"



IXT5 Patient News

STUDY RESULTS ANNOUNCED

Your child took part in a study of treatment for intermittent exotropia (IXT). The study was paid for by the National Eye Institute (NEI). The NEI is part of the federal government's National Institutes of Health. We want to share the results with you!

THE STUDY

The study included 386 children 3 to 10 years of age with IXT. There were enrolled at 56 participating eye care centers across the United States. Children in the overminus glasses group wore overminus glasses for 12 months, then the strength of the overminus glasses was reduced by ½ for 3 months, and then regular glasses were worn for 3 months. Children in the regular glasses group wore regular glasses for 18 months. The study aimed to find out if overminus glasses would help a child's eye drift out less often.

THE RESULTS

The overminus glasses helped children's eyes drift out less often over the first 12 months. But the eyes drifted out more often again after the children stopped wearing the overminus glasses. Children wearing the overminus glasses also had a faster worsening of nearsightedness than those wearing the regular glasses. This caused the study to stop using overminus glasses. We extended the study through 3 years. The goal was to see what would happen to the nearsightedness after the children stopped wearing overminus glasses. The worsening of nearsightedness was similar in both groups after children stopped wearing overminus glasses. But over the entire 3 year period, the children who wore overminus glasses for 15 months still had somewhat more nearsightedness than children who wore regular glasses.

YOU MADE A DIFFERENCE!

We thank you for taking part in this study. These study results are important. They will help the treatment of children who develop IXT in the future. The results have been published in the eye care journal, *JAMA Ophthalmology*. The Pediatric Eye Disease Investigator Group continues its work to find the best ways to treat IXT and other childhood eye conditions.

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Participant Newsletter - FHS

Microbiome Study

What we learned from the Microbiome study during Exam 3

We discovered certain bacteria in the gut that actually eat … and breaks down … cholesterol. These bacteria are associated with a significantly lower level of "bad" (LDL) cholesterol in the bloodstream. This discovery is almost as important as genetics for understanding how cholesterol moves through the body! It might help prevent cardiovascular disease!

This is a research study to learn more about your microbiome and how the microbes in it affect your overall health. We intend to explore how the bacteria in your gut and digestive tract affect heart health and risk of diabetes. Participants will be asked to collect a stool sample at home and send it to our lab for analysis.

*From their Fall 2022 newsletter: https://www.framinghamheartstudy.org/participants/fhs-newsletters/

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QUESTIONS?

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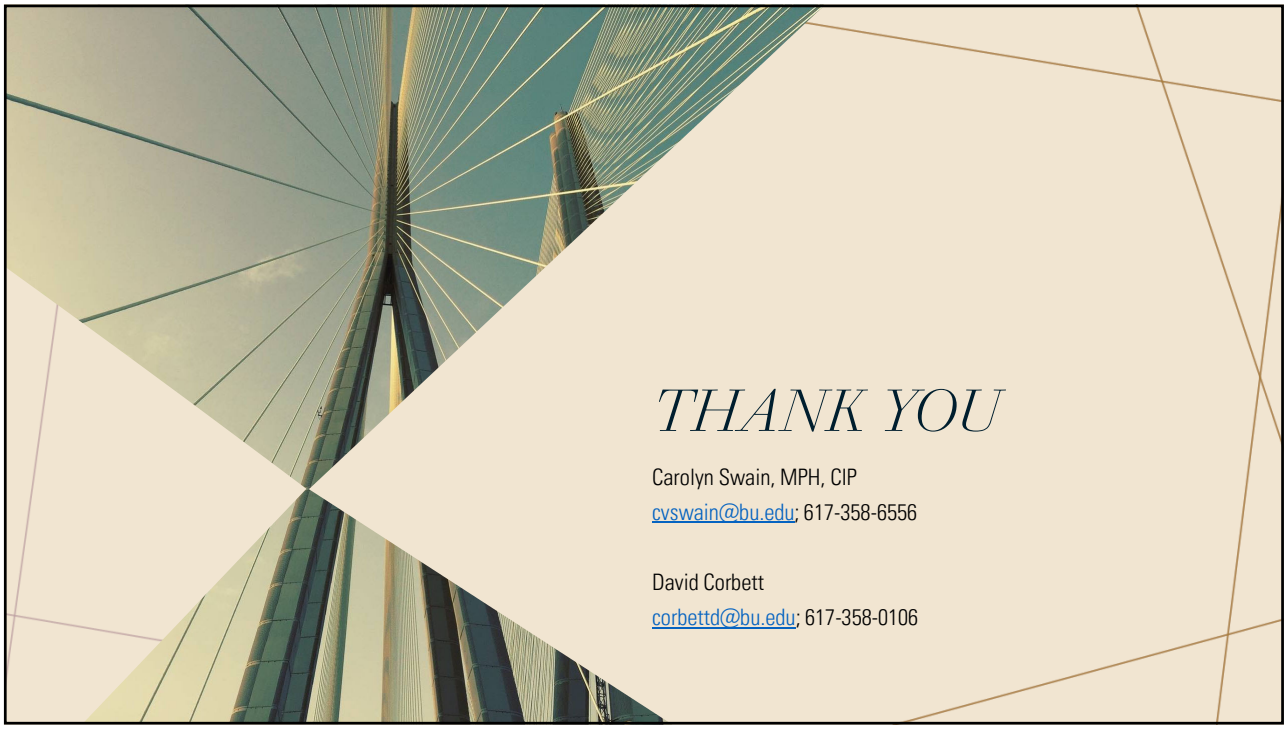
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