**Return of (Aggregate/Summary) Results (RoR) to Participants**

**GUIDANCE DOCUMENT**

# **Purpose:**

This document (and accompanying Toolkit and Template) offers general guidelines, tools, resources, and templates for Duke Investigators and Research Teams who are committed to sharing lay-friendly aggregate summary results for return to participants at the end of an investigator-initiated study. This is also known as Return of Results (RoR). There is an accompanying toolkit that includes additional templates and tools in Microsoft Word.

**Note:** This GUIDANCE does NOT apply to multi-site studies or studies where Duke is a participating site in “someone else’s research” (e.g., not the sponsor). In the case of industry- or grant-funded multi-site studies in which Duke is a participating site, the Duke Research Team should strongly encourage the Sponsor, Coordinating Center, or overall Principal Investigator to develop plans to return the aggregate study results to all participants

This document also does not include specific guidance for interim updates to participants in observational, long-term follow-up, registry or extension studies (although many of the same principles found within the guidance apply). For studies such as these (without a finite end), study teams should still consider whether, when, and how often to communicate with participants regarding study progress, learnings, and interim results. Any study publication (abstract, poster, manuscript, etc.) should stimulate the study team to consider whether or not it is an appropriate time to communicate with participants and inform them of the findings or progress to-date.

# **Background:**

Currently the focus of most investigators is to publish results of their research in academic journals; however, these results are often not communicated to the public or to the participants who contributed to the success of the research study. Developing and disseminating lay-friendly research results to participants demonstrates respect and appreciation for their contribution to advancing science at a relatively low cost. At a minimum, Duke Research Teams are expected to share summary/aggregate results with study participants around the time of publication of the primary outcome manuscript.

Summaries should be written with the study participant in mind while also adhering to regulations and policies. Observing principles of readability, including tone, style, language, reading level and ease, layout, cognitive load, and health literacy all facilitate clear communication, which benefits all, regardless of education, literacy level, or familiarity with the clinical research process.

“Adopting ***health literacy universal precautions*** acknowledges that the complexity of the health care system challenges virtually everyone… And it recognizes that ***all patients benefit from clear, actionable information and simple patient education materials***.”[[1]](#footnote-1)

The Duke CTSI Recruitment Innovation Core’s **Research Communication Team** is available to facilitate the planning, development and distribution of summary/aggregate results to participants with processes, templates, editing, graphic design, and dissemination strategies.

# **Principles for the Design, Development, and Distribution of**

# **Return of Results Plain Language Summaries (RoRPLS)**

* **The primary audience for RoR plain language summaries (RoRPLS) are clinical trial participants or their designees**. As such, RoRPLS should be written in simple language with attention to principles of readability, health literacy and numeracy, as well as cultural preferences and needs.
  + RoRPLS may also be provided to the general public, including the media, patient advocacy groups, community-based organizations, etc.
* **Sharing aggregate study results demonstrates respect for the time, effort and commitment of study participants and their partnership** **with the research enterprise**. Results should be shared with all participants (or their legally authorized representatives) who signed consent for the study (and opted to receive the RoRPLS), regardless of whether they completed the study.
* **RoR Plain language summaries should be developed and distributed in a ways that are balanced, factual, and non-promotional.** The RoRPLS should reflect the study findings objectively, without bias.
  + Content for the RoRPLS can come from a variety of sources, including the consent form, protocol, clinical study reports, publications, posters, abstracts, or ClinicalTrials.gov.
  + Content should be clear, focus on the results of the study in question, and provide information about where to turn for questions or additional information.
* **RoRPLS should be reviewed by the study team, a medical communications group (if available) and reviewers with varied experience and perspectives prior to release.** Please see Supplemental Material ([SS1](#SS1)) for a list of potential reviewers.

Every study should plan to share the summary/aggregate results with individual participants in a manner that is easy to access and interpret, preferably delivered according to the participant’s stated preference (e.g., email, website, text message, video, print, etc.). **At minimum, results should be provided to all participants** (or legally authorized representatives/guardians as designated in the ICF) **who were consented** **and have contact information for follow-up**, regardless of whether the participant was later randomized or completed the study **and who have opted to receive results**. RoR Plain language summaries should also be made publicly available to our community.

**PLANNING, EXPECTATIONS & REQUIREMENTS for Return of Results (RoR):**

* Ideally, development of the RoR strategy (see [Appendix A](#AppendixA) for an example/template) should begin during grant planning and/or protocol development.
  + Content and dissemination methods should be designed to be consistent with the characteristics, language and cultural needs, and expectations of the study population. This may necessitate planning for more than one dissemination method.
* RoR summary development and dissemination plans should be adequately resourced, including the costs of developing and delivering videos, print materials, translations, etc. (see [Appendix B](#AppendixB) for a sample budget planning template)
* Optionally, RoR consent and preference statements ([Appendix C](#AppendixC)) could be included in the informed consent document (or as an addendum), allowing participants to determine
  + Whether they want to receive a RoRPLS
  + Whether they would like to designate a third party to also receive the RoRPLS, especially if death[[2]](#footnote-2) of the participant is anticipated (e.g., a study endpoint), likely (e.g., phase 1 oncology studies of salvage chemotherapy), or a known consequence of anticipated (e.g., sepsis related to stem-cell transplant) or unanticipated (e.g., anaphylaxis) adverse events
  + Preferred formats and distribution channel(s)
* RoR summaries involving children able to assent should also take into consideration the child’s choice whether or not to receive the study results. However, ultimately it is the parents’ decision and they should be approached first in most cases. If there is disagreement between the parents and the child (e.g., a teenager or adolescent), the child should be informed that they have a right to the information upon reaching the age of majority (18).
* RoR summaries should be written in concise, plain language following principles of plain language, health literacy, numeracy, good readability, cognitive load and be attentive to cultural and language preferences and needs (Appendix C of the Toolkit and Template)
* RoR summaries must include contact information for participants who may have follow-up questions or concerns
* RoR summaries should be easily accessible and shared with participants’ providers (when appropriate)
* RoR plans and summaries should be reviewed and approved by the IRB (see [Appendix D](#AppendixD) for clarification and recommendations for IRB review and approval after study closure)
* RoR summaries should include the caveat(s) that results may not be applicable to the individual participant as follows:
  + “These results may not affect each person.”
  + “You should talk about these results with your personal provider to decide if these results should affect your clinical care.”
  + Findings from individual research studies are a “piece of the puzzle” and contribute to a larger overall body of work.
* RoR summary dissemination should be planned for one of the following time points:
  + Within one year of study IRB closure
  + Final data analysis
  + Concurrent with the release of the primary outcome publication (clinical trials or release of each major study publication (longitudinal/observational/other studies) or clinicaltrials.gov update
* Studies of illegal or socially unacceptable behaviors such as drug use, domestic violence, and prostitution require special considerations before sharing results with participants that may create the potential for a breach of confidentiality and/or subsequent harm. Studies with certificates of confidentiality should be carefully considered to ensure that returning a RoRPLS will not risk the participant’s privacy or terms of the certificate and should be covered in the ICF.
* Studies of rare diseases that may have a very small number of participants may risk participant confidentiality by increasing the chance that participants may identify themselves or others. If RoR is planned for these studies, this should be covered in the ICF and extra steps taken to protect participant privacy.

**Appendix A: Planning and Delivery Options for Plain Language Summaries** [back to top](#EXPECTATIONS)

**RETURN OF RESULTS PLAN (template)**

|  |  |  |
| --- | --- | --- |
| **We plan to return aggregate lay-friendly study results in the following ways:**  Select all that apply | **Type** | **Distribution Mechanisms** |
| Print (paper) | Regular mail |
| Print (electronic PDF) | Email |
| Website | SMS/Text message |
| Video(s) | Virtual meeting (e.g., Zoom) |
| Presentation | Automated phone message |
| Click or tap here to enter text. | Face-to-face meeting |
| **Our results may include the following:**  Select all that apply | Cover Letter | |
| Frequently Asked Questions document | |
| Infographics | |
| Lay summary (e.g., 1-2 pages) | |
| Executive Summary (e.g., no more than 2-3 pages) | |
| Video(s) | |
| Presentation slides | |
| Link to Primary Outcome Paper | |
| Click or tap here to enter text. | |

**DELIVERY OPTIONS**

**Low burden**

**Moderate burden**

**High burden**

|  |  |  |
| --- | --- | --- |
| **ONE-WAY COMMUNICATION** | **INTERNET-BASED** | **INTERACTIVE** |
| Video summary | Website | Face-to-face meeting |
| Print material (mailed) | Web-portal | Web-based virtual meeting  (e.g., Zoom, Webex) |
| Automated phone-message | Webinar-type presentation | Personal phone calls |
| Recorded Webinar |  | Dynamic email exchanges |

**High Consistency**

**High Consistency**

**High Comprehension**

While one-way and internet-based methods can be done with relatively low burden and higher consistency in format and delivery, interactive options enable follow-up questions and facilitate a dialogue that may lead to greater trust in the research enterprise. A combination of options may be appropriate, depending on the needs of the audience.

Study teams should also consider what follow-up questions may arise and develop a “frequently asked questions” document to post/distribute with the summary results. Retain all questions and responses for review over time to aid in updates to the FAQ that may be necessary.

**Research on Research:** To demonstrate the value of returning results, develop best practices and additional guidance, consider including a method to obtain feedback from recipients regarding comprehension, format and perceived value of the summary.

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**BUDGET PLANNING FOR RETURNING RESULTS TO PARTICIPANTS**

Remember to include the effort needed to create your PLS and distribution process, not just the costs of materials you may need like envelopes or paper. Also, since disseminating your PLS may be 3-5 years away, account for whether costs will increase over today’s costs.

|  |  |
| --- | --- |
| **Distribution Strategy** | **Costs** |
| Print (color print, paper) |  |
| Print (electronic PDF) |  |
| Website |  |
| Video(s) (videographer, studio fees) |  |
| Regular mail (postage, labels, envelopes) |  |
| Email |  |
| SMS/Text message |  |
| Medical Writer |  |
| Graphic Designer |  |
| <other> |  |
| <other> |  |
| <other> |  |
| Total Costs to anticipate |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Tactic | Level of Targeting | Level of Tailoring | Effectiveness | Relative Costs |
| Multimedia, including videos, podcasts, and slide presentations |  |  |  | **$$** |
| Email or regular post |  |  |  | **$** |
| Social media, including blogs and tweets, online discussion forums, Facebook interest groups, open and closed platforms |  |  |  | **$** |
| Small media (brochures, newsletters, posters, flyers) (emailed or mailed) |  |  |  | **$** |
| Websites |  |  |  | **$$** |
| Face to face meeting |  |  |  | **$$$** |
| Interactive web-based meeting (e.g., zoom) |  |  |  | **$** |

Figure 1 Adapted from the [PCORI Dissemination and Implementation Framework and Toolkit](https://www.pcori.org/sites/default/files/PCORI-DI-Toolkit-February-2015.pdf)

**, , ,** indicate high, medium or low opportunity for targeting or tailoring the RoRPLS content and high, medium or low evidence of effectiveness; $$$, $$, $ indicate high, medium and low costs for developing and disseminating.

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**OPTIONAL CONSENT FORM STATEMENTS**

|  |
| --- |
| **Will you tell me the results of the study when it’s complete?** |

***Include the correct options below and delete the rest. Insert anything needed and not covered below***

* Yes. We will tell you and every person in the study about what we learn from the study. Please note that it may take a few years before we have the final study results. We hope to have them by <***enter anticipated date estimate***>.
* We would like to share a summary of the study results in a way that is meaningful and useful to you. Please let us know how you’d like learn of the study results:
  + I would like to get a summary of the study results in email <*email address*>
  + I would like to get a summary of the study results mailed to my home address <*home address*>
  + I would like to get a link to a summary of the study results in a text message at this phone number <*phone number*>
  + I would like to designate someone else to receive the study results on my behalf <*name, contact info*>

***OR***

* **No.** We will not be notifying people in the study about what we find. We will, however, publish the results in an academic journal. (What we publish will not include anything that can identify you though.)

***OR***

**Yes.** We will tell you the overall results of the study. In the future, you will be given a chance to tell us whether or not you want to receive the general results of the study and how you would like to receive them. You do not have to decide about this right now

***OR***

* **Yes.** We plan to share the results of what we learn with everyone in the study. Your participation may end but the study itself will continue until all participants have finished the study. Then the results will be analyzed and the researchers will need time to understand them, which generally takes about a year or so depending on how complicated the analysis is.

Therefore, we will likely send you <*a letter with the overall study results, a letter with a link to the overall study results website*> about a year after the study ends, which we expect to be around [month/year].

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# **Guidance for IRB Submission and Review of Plain Language Summaries**

*Adapted from the* [*MRCT Guidance document, V3.1*](https://mrctcenter.org/wp-content/uploads/2017/12/2017-11-22-Return-of-Aggregate-Results-Guidance-Doc-V-3.1.pdf)*.*

If results will be returned mid-study (for example, along with the scientific publication of primary endpoints) but the study will stay open for secondary endpoint collection or longitudinal observation, the IRB should, in general, review communications with participants.

However, if interim study results are communicated by public dissemination (e.g. posting results on a website), the IRB does not have jurisdiction. Other than recruitment advertisements or retention materials, the IRB does not review web postings such as registration with ClinicalTrials.gov, as long as they meet the expectations and criteria outlined by the Department of Health and Human Services Office of Human Subjects Research Protections^ and the FDA:+

IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: ***the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.***

When a study is closed, however, the situation changes. In the U.S. IRBs are not required to review the plan for, or materials used in, the return of RoRPLS to participants -- unless these plans are described in the study protocol -- ***so long as the RoRPLS will be returned after the study has been closed by the IRB***.

IRB should not need to review and approve a RoRPLS ***if the study has been closed*** for the following three reasons:

1. If the study is closed, the activity is no longer research and there are no human subjects involved in the activity.\*
2. A RoRPLS is not likely to affect the criteria for IRB continued approval at continuing review because:
   1. A RoRPLS does not affect participant recruitment since enrollment is closed and the communications cannot, in that case, be considered coercive or unduly influential on a participant’s decision to join or stay in the study.
   2. A RoRPLS cannot alter or affect the equitable selection of participants since there is no active enrollment occurring.
   3. A RoRPLS cannot alter or affect the risk/benefit ratio as all study-related participant activities are complete, all participants have already been exposed to the physical risks and have been monitored for safety.
   4. A RoRPLS should not adversely affect vulnerable participants.
3. Research data are posted on publicly available registries like ClinicalTrials.Gov or in medical journals without IRB review.
   1. A RoRPLS is a subset of a more complex or technical result summary, written in a non-promotional way and understandable to a broad audience.

^ <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/clinical-trial-websites/index.html>

+ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects>

\*In the US, the Health and Human Services (HHS) definition of “human subject” is “an individual about whom an investigator intervenes or interacts to collect data, or about whom an investigator obtains private identifiable information.” A research result communication after a study has ended involves none of these conditions.

Similarly, the definition of a “human subject” under the USFDA regulations is “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.” In this case, the study has ended and is closed with the IRB, so there is no longer open research and the individuals are no longer participants in the research.

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# **Participant Cover letter template**

Insert appropriate Duke Health Logo

Cover Letter Content:

Dear <Participant>,

**Thank you for participating in the <study title> study!**

As a research volunteer, you are a member of a large group of people all over the world. Volunteers like you help answer important health questions, find new medical treatments, improve public health and the quality of health care.

At Duke Health, we think it is important for you to know the results of the studies you participate in. We hope this will help you understand and feel proud of the important part you play in clinical research. We could not do important research like this without partners like you who work with us to advance science and health and improve outcomes.

If you have any questions about these study results, please contact <name, contact info>.

Sincerely,

Principal Investigator

**Appendix F:**

# **ADDITIONAL RESOURCES**

**HEALTH LITERACY**

**Personal health literacy** is our ability to find, understand and use information and services to inform health-related decisions and actions for ourselves and others.

**Organizational health literacy** is the degree to which organizations equitably enable individuals to find, understand and use information services to inform health-related decisions and actions for themselves and others.

* Multi-Regional Clinical Trials Center [Health Literacy In Clinical Research](https://mrctcenter.org/health-literacy/)
* National Academies of Medicine Discussion Paper: [Ten Attributes of Health Literate Health Care Organizations](https://nam.edu/wp-content/uploads/2015/06/BPH_Ten_HLit_Attributes.pdf)
* Agency for Healthcare Research and Quality [Health Literacy Universal Precautions](https://www.ahrq.gov/health-literacy/improve/precautions/index.html)
  + [Toolkit, 2nd Edition](https://www.ahrq.gov/health-literacy/improve/precautions/toolkit.html)
    - Downloadable [Toolkit](https://www.ahrq.gov/sites/default/files/publications/files/healthlittoolkit2_4.pdf)
  + [Companion Implementation Guide](https://www.ahrq.gov/health-literacy/improve/precautions/guide/index.html)
    - Downloadable [Companion Implementation Guide](https://www.ahrq.gov/sites/default/files/publications/files/healthlit-guide_3.pdf)
* Centers for Disease Control [Health Literacy](https://www.cdc.gov/healthliteracy/index.html) website
  + [Plain Language Materials and Resources](https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html)
  + [Plain Language Thesaurus for Health Communications](https://stacks.cdc.gov/view/cdc/11500/)
  + [Everyday Words for Public Health Communication](https://www.cdc.gov/healthcommunication/everydaywords/) searchable thesaurus
  + [Simply Put](https://www.cdc.gov/healthliteracy/pdf/simply_put.pdf) A guide for creating easy-to-understand materials

**PLAIN LANGUAGE**

Plain language is communication your audience can understand the first time they read or hear it. Per the [Plain Writing Act of 2010](https://www.govinfo.gov/app/details/PLAW-111publ274), plain language is defined as:

Writing that is clear, concise, well-organized and follows other best practices appropriate to the subject or field and intended audience.

Material that is written using plain language enables your audience to find what they need, understand what they find the first time they read or hear it, and use what they find to meet their needs.

* Program for Readability in Science & Medicine (PRISM) [Guide](https://www.kpwashingtonresearch.org/application/files/6415/5500/0956/PRISM_readability_toolkit.pdf) and [Training](https://prism.kpwashingtonresearch.org/course_introduction/splash_page_before_registration.html)
* United Health Group: [Just Plain Clear Glossary](https://www.justplainclear.com/en)
* University of Michigan [Plain Language Medical Dictionary](https://apps.lib.umich.edu/medical-dictionary/)
* National Cancer Institute [Dictionary of Cancer Terms](https://www.cancer.gov/publications/dictionaries/cancer-terms/search?q=heman&redirect=true)
  + National Comprehensive Cancer Network [Informed Consent Language Database](https://www.nccn.org/education-research/nccn-oncology-research-program/informed-consent-language-database)
* Federal [Plainlanguage.gov](https://www.plainlanguage.gov/)
  + [Guidelines](https://www.plainlanguage.gov/guidelines/) (downloadable [Guide](https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf))
  + [Checklist](https://www.plainlanguage.gov/resources/checklists/checklist/)
  + [Humor](https://www.plainlanguage.gov/resources/humor/funny-headlines/) (because we can all use a laugh every once in a while)
* Multi-Regional Clinical Trials [Resources for Patients and Participants](https://mrctcenter.org/blog/projects/resources-for-patients-and-participants/)

**NUMERACY RESOURCES**

Numeracy is the ability to comprehend, use and attach meaning to numbers.

* National Academy of Medicine Discussion Paper: [Strategies to Enhance Numeracy Skills](https://nam.edu/strategies-to-enhance-numeracy-skills/)
* Food and Drug Administration: [Communicating Risks and Benefits: An Evidence-Based User’s Guide](https://www.fda.gov/media/81597/download)
* Health Literacy Missouri Best Practices for Numeracy in Multi-Regional Clinical Trials Center [Return of Aggregate Results](https://mrctcenter.org/blog/projects/return-of-aggregate-results-to-participants/) (pages 82-88).

**RETURNING RESULTS**

* PCORI [Dissemination and Implementation Framework and Toolkit](https://www.pcori.org/sites/default/files/PCORI-DI-Toolkit-February-2015.pdf)
* Multi-Regional Clinical Trials Center [Return of Aggregate Results](https://mrctcenter.org/blog/projects/return-of-aggregate-results-to-participants/)
* Vanderbilt Institute for Clinical and Translational Science [Disseminating Results Back to your Study Participants](https://victr.vumc.org/disseminating-results-to-study-participants/)
* National Academies of Science [Returning Individual Results to Participants: Guidance for a New Research Paradigm](ttps://www.nap.edu/catalog/25094/returning-individual-research-results-to-participants-guidance-for-a-new)
* Multi-Regional Clinical Trials Center [Return of Individual Results](https://mrctcenter.org/blog/projects/return-of-individual-results/)
* Wong CA, Hernandez AF, Califf RM. Return of Research Results to Study Participants: Uncharted and Untested. *JAMA*. 2018;320(5):435–436. doi:10.1001/jama.2018.7898
* Weitzman ER, Magane KM, Wisk LE How Returning Aggregate Research Results Impacts Interest in Research Engagement and Planned Actions Relevant to Health Care Decision Making: Cohort Study. *J Med Internet Res* 2018;20(12):e10647. doi: [10.2196/10647](https://doi.org/10.2196/10647)

**SUPPLEMENTAL MATERIALS:**

**SS 1:** Potential PLS Reviewers

As the PLS is drafted, consider asking one or more of the following to review the content.

|  |  |
| --- | --- |
| **Experience and/or Perspective** | **Possible PLS Reviewer** |
| Content expert in study area | PI or other specialty provider |
| Limited expertise in study area | Community advisory board member |
| No affiliation with the organization | Community member, externally sourced medical writer |
| Limited experience with the therapeutic area, disease or condition | Someone who does not have the condition studied (and is not related to someone who does) |
| Patient-focused communication | Advocacy group member, someone familiar with principles of health literacy, content design, or adult education who can review the PLS for clarity, tone, language, imagery and graphic selection and placement |
| Adequate and low health-literacy skills | Focus group members |
| Clinical research ethics | IRB member with no relationship to the study |
| Some experience in healthcare but not necessarily the therapeutic area, disease or condition studied | Trained patient research advocate |
|  |  |
|  |  |

Consider pilot testing the PLS with a select group of people (including study participants) who can provide candid feedback regarding the layout, format and intended meaning of the summary.

1. Koh, H.K., Brach, C., Harris, L.M., & Parchman, M.L. (2013). A proposed ‘health literate care model would constitute a systems approach to improving patients’ engagement in care. *Health Affairs*, 32(2), 357-67. [↑](#footnote-ref-1)
2. Sensitivity and respect are necessary when having these conversations with participants and should happen early in their participation, preferably as part of the consent conversation. [↑](#footnote-ref-2)