RETURN OF RESULTS TO PARTICIPANTS

Research participants consistently desire and expect to receive research data from the research studies in which they have participated. Expectations about data transparency are evolving in society; returning results anticipates and responds to those expectations.

In general, the Principal Investigator is responsible for disseminating results to the participants as well as to ensure results are contextualized with appropriate medical information and to connect participants with the appropriate health care provider as/if needed. For Sponsor-funded trials, discussion with the Sponsor might be required.

Two categories of results could be recognised: Individual Research Results and Study Results.

- **Individual Research Results**- Any data or test result from a research study that is specific to an individual, such as study arm assignment, test results, or genetic sequencing data.

The determination of whether, when, and how to return individual results, including material incidental findings, to the participants, (including these who finished their participation for whatever reason) should be based, in general, on the nature of the results and their significance. With the exception of returning urgent results, it is important to offer participants a choice as to whether or not to receive their individual research results. Of note, not returning results is strongly discouraged unless there are compelling scientific and ethical reasons.

- *Urgent results and urgent incidental findings* – results outside of normal ranges that may have potential consequence for diagnosis, treatment, or care of the individual should **always be returned** to the medical caregiver and/or the participant as soon as they are confirmed to be valid.

  Things to consider:

  - ✓ *Identify data that could produce an urgent result*
  - ✓ *Make sure those results will have analytical validity and these is a plan for repeating, if/as needed*
  - ✓ *Ensure the consent reflects that the participants will receive urgent results*
  - ✓ *Have a plan for returning results, including expertise available, method of returning, documenting*

- *Routine results and non-urgent incidental findings* - the balance of potential benefits to the individual participant should be weighed against resource requirements and feasibility of implementing return of routine results.

  Things to consider:

  - ✓ *Establish which results should be returned during the study vs after the study completed*

- *End of study individual results*- at a minimum and if feasible, research participants should be offered information regarding their study arm assignment in which they participated after the study concludes. In addition, communication of primary endpoints

should be offered at the end of the study, unless returning these data would compromise the integrity of the study or ongoing studies.

- *Exploratory results* - should be handled on a case-by-case basis.
  Things to consider:
  - ✓ *Results may be confusing to participants and/or their healthcare provider and may cause confusion, stress, and dissatisfaction to participants from not knowing how or when to act upon their results*
  - ✓ *These results can be returned if logistically feasible and if the participant chooses to receive them, unless there is a specific reason to withhold the information.*
  - ✓ *The limitations and/or the absence of current and future interpretation of the data should be made clear.*

- **Study Results**- aggregate results, plain language summaries, or lay summaries that provide study participants with overall findings of a research study.
  Things to consider:
  - ✓ *Have a mechanism for participants to choose whether or not to receive plain language summaries*
  - ✓ *Consider how up to date contact information will be maintained*
  - ✓ *Ensure documents are approved by the REB prior to distribution*

References:
Material used from Multi-Regional Clinical Trails, the MRCT Center of Brigham and Women's Hospital and Harvard, Return of Individual Research Results

Tri-Council Policy Statement 2 (TCPS2) 2018: Dissemination of Research Results: Article 4.8