

## Data Transparency and Respect for Persons: Sharing Aggregate and Individual Results with Research Participants

The issue of returning research results, both aggregate summaries of research results, as well as individual results, is an important and complicated ethical issue. The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) has done extensive work in this area and the Secretary's Advisory Committee on Human Research Protections (SACHRP) has made recommendations on the topic,

Both the MRCT Center and SACHRP have supported the return of aggregate and individual research results to participants, based on the principles of Respect for Persons and Beneficence. SACHRP further suggested "that the individual results do not have to be of clinical value to the subjects in order for return to be considered." Whether and what to return, and the issues that should be considered for both investigators and the IRB will be explored.

This webinar will review current efforts and regulations in returning aggregate and individual results to study participants as well as offer suggestions for lowering the barriers for returning results. In addition, useful tools and guidance for the research community will be presented, including advice on how to provide clinical trial participants with plain language summaries of the trial results and information about the outcome of the study as a whole. Our presenter, Dr. Barbara Bierer, Faculty Co-director of the MRCT Center, will also discuss important issues for institutional review boards to consider when reviewing any plan to disclose individual research results and incidental findings to research participants.