

# NIH Pragmatic Trials Collaboratory Data Sharing Policy

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## Introduction

The Collaboratory Steering Committee recognizes that data sharing promotes many goals of the NIH research endeavor. It is particularly important for [unique data](#) that cannot be readily replicated. Data sharing allows scientists to expedite the translation of research results into knowledge, products, and procedures to improve human health.

There are many reasons to share data from these NIH-supported studies. Sharing data reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new datasets when data from multiple sources are combined.

The Collaboratory Steering Committee agrees that data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and therefore adopts the following policy regarding data sharing:

## Policy

1. Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
2. The Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.
3. Consistent with NIH policy and guidance, Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.
4. Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infrastructure are in place to support timely data sharing for the Collaboratory.