



Overview of Document

As part of the PCORI Open Science Pilot Project, the MRCT Center developed a clear, plain language Data Sharing Section of an Informed Consent Form (ICF), which can be introduced into study protocol ICFs in order to enable the secondary use of collected data for open science. By explaining data sharing in a simple and transparent manner, this template intends to communicate the key information that potential research participants would want to know in order to provide meaningful, broad consent to the unspecified future uses of their data for secondary research.

We recommend that this template language be inserted into the Privacy and Confidentiality section of an Informed Consent Form, or that it be added to an Informed Consent Form as a new section entitled “Data Sharing.”

Template Data Sharing Section of an Informed Consent Form

Data Sharing

We will gather information about you as part of your participation in this research study. The information that we gather may include personal information, such as your name, address, and birth date; information from your medical record; and new information about you, such as the results or findings from study-related tests and study-specific procedures.

To advance science, medicine, and public health, we will share information about you from this research study with other researchers, but only after personal information that may identify you has been removed. We remove your name, address, and medical record number, as well as other data that could identify you. If you would like more details about the kind of information that we remove from our files, we are happy to provide them upon request. The remaining information can be combined with other people's data to help researchers' understanding of how to stay healthy, why diseases develop, how to best diagnose and treat diseases, and how to develop new medicines or medical devices.

We will do everything we can to protect your privacy before sharing your de-identified data with other researchers but, despite best efforts, there is still a very small chance that you could be re-identified. To minimize this risk, we will follow all relevant data protection laws. If, at any point during or after this study, you think that you may have been re-identified, please contact us and let us know. Because we remove your contact information from the files that we share, we will not have a way to contact you individually.