



Procedure to Submit Research-Related Data Sharing Risk Assessment with Request for Data Use Agreement

Background:

Prior to MetroHealth sharing health-related data in connection with research, the Principal Investigator (PI), or Study Coordinator, with PI's oversight, completes a research-related data sharing risk assessment (RDSRA)¹ which includes a request for data use agreement, if applicable.

Such data sharing includes de-identified data, a limited data set (LDS)², or protected health information containing identifiers beyond that of an LDS. The risk assessment requires the PI to certify that the data to be shared and method for sharing has been reviewed by the Institutional Review Board (IRB).

Process:

1. Requestors may contact Research Administration Business Office (RABO) with a request for a data use agreement. In these cases, RABO provides the below link to the RDSRA to the PI.

Alternatively, the IRB may require an RDSRA as a condition of IRB approval. In this case, the IRB will provide a "Modifications Required to Secure Approval" letter to the PI along with the below link. The RDSRA cannot be submitted before the IRB provides a "Modifications Required to Secure Approval" letter.

For reliant review, the IRB provides the link upon receipt of the IRB approval letter from the external IRB.

Link: [Research-related Data Sharing Risk Assessment \(smartsheet.com\)](https://smartsheet.com)

2. Requestor (the PI, or Study Coordinator with PI's oversight) completes the RDSRA questionnaire.



3. Smartsheet automatically generates notice of a new RDSRA submission to RABO (researchcontracts@metrohealth.org). RABO reviews the submission and adds additional information or documentation as applicable.
 - a. RABO completes this task within 5 business days
 - b. RABO completes the "RABO Review Status" columnNote: The Smartsheet notification emails comes from sender automation@app.smartsheet.com). This may go to Junk due to MetroHealth email security settings. Reviewers alternatively can log in at [Smartsheet for RDSRA](#).
4. RABO's completed review triggers Smartsheet to send automatic notification of a new RDSRA submission to Privacy (HIPAAprivacy@metrohealth.org), Information Security (ISsecurity@metrohealth.org) and Clinical Engineering (clinicalengineering@metrohealth.org), if applicable.
5. Privacy, Information Security and Clinical Engineering (if applicable) complete their review within 7 business days of notification.
6. When reviews are complete, Smartsheet generates an automated notification to Requestor, RABO and the IRB Specialist (if applicable). Requestor adds the documentation to the study application in the eIRB system so that the study can receive final approval from the IRB. RABO coordinates with Legal to finalize any required data use agreement.

The notification to Requestor informs the requestor to submit a Giva ticket at this time if needed.