

CTSI Informatics Service

Data Request Guidelines

Introduction

The CTSI informatics service team, in partnership with ISD, provides a data export service for researchers requiring retrospective clinical data from eRecord. A researcher must complete the service request form in REDCap to initiate the review process with one of our informaticists. This process verifies compliance with human subject research regulations and prepares the request for data analysts to extract the specified data from eRecord. The service is exclusively for projects that are IRB approved or preparatory to research. We do not process data requests for projects that are not for research (e.g., Quality Improvement).

- For IRB approved studies, data exports must strictly adhere to the study population criteria and data requirements specified in the approved study protocol.
- For preparatory to research requests, which might be used to design a research study, assess the feasibility of conducting a study, or to aid in study recruitment, CTSI follows [URMC HIPAA guidance](#), applying the minimum necessary standard of the Privacy Rule.

Process

Request Summary

Upon receiving a service request, our informaticist will review the submitted information to ensure alignment with your study's approved protocol. A summary of the request will be prepared to ensure that we understand the population criteria and specific variables being requested for export. The summary will include the original request details, and our questions and comments. The objective is to distill the request into identifiable, discrete eRecord data elements that can be exported. This process can require several iterations before assigning it to an analyst. The request summary serves as the central reference document for the data request; it will be provided to an analyst who will use it as the basis for developing the query.

Communication

Every request receives a unique 4-digit request number. To ensure efficient service, please include this request number in all communications with our team and use the "Reply All" option. Communication between URMC domain email accounts that include PHI (such as screenshots or file attachments relevant to the discussion), are permitted. Please note, if there is no response to the request summary within a reasonable timeframe, the ticket will be closed due to inactivity.

Data Export & Delivery

A raw data export will be produced based on the final version of the request summary. Standard file delivery formats are Excel, CSV or text, depending on the volume of data. The CTSI Informatics service team doesn't provide services such as data management, data wrangling/cleansing, and analysis. The requesting party will receive a notification email when the data set is complete, with instructions for accessing the data on UR Box using a provided secure link. The data will be released only to the requesting party, who must be listed as a study team member in the study record on the RSRB site, "Click IRB".

The study team will have twenty business days to evaluate the data and communicate issues or concerns with CTSI. If no response is received within twenty business days, the request will be considered fulfilled and closed, and revisions to the data set will require a new request.

Production Times

Production times for data requests can vary from four to six weeks, depending on the complexity of the requests and the current workload. The start date for the production clock begins when the service request form is completed and submitted. Please note that effective and responsive communication is crucial to ensure timely fulfillment of data requests.