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24. Secondary Data Analysis

Completion of this section is required based on the response provided to either question 1-1.2.1, 4-1.1 or 7.2.

24.1* List each pre-existing data set that will be used in the study.

Add

Name	Identifying Info	Is Publicly Available
Departmental registry (e.g. RadQuery, PathNet, OTIS)	PREFERABLY, upload in 24.6 for each line item a data dictionary/data collection sheet/list of data variables to be accessed (presumably primarily from medical record) or received by study team and recorded for analysis.	
external dataset obtained with DUA	If data dictionary upload is not practical (e.g. the full dataset is thousands of line items, but this analysis will be using only a small fraction of them), describe the kinds of information accessed/received e.g. name, gender, age, diagnoses, co-morbidities, county of residence, etc.	
MiChart (study team direct login)	full PHI included; see uploaded data dictionary for fields to be recorded	

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Edit HUM_Data Or Biological Specimen Set

Secondary Data Set Detail

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24.2* Name and source/location of data set. ALSO, describe how you gain access to the data set:

Departmental registry (e.g. RadQuery, PathNet, OTIS)

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

If a data dictionary is uploaded in 24.6 or included in a separate protocol, simply refer to it here.

PREFERABLY, upload in 24.6 for each line item a data dictionary/data collection sheet/list of data variables to be accessed (presumably primarily from medical record) or received by study team and recorded for analysis.

Examples of "types of information":
demographic information; diagnosis codes;
visit history at a clinic; prescription history;
survey responses; employment history; test
scores; test questions.

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset:

Select all that apply:

- Direct Identifiers** - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)
- Coded or Indirect Identifiers** - data record includes a link to direct identifiers, or unique subject characteristics, or a combination of data fields that can be correlated to another dataset
- No Identifiers** (De-identified, Anonymous, or Anonymized) - stored data record is stripped of all identifiers

See U-MIC presentation "[Anonymous, Coded and De-identified Data in Human Subjects Research](#)".

- Direct identifiers: for example, name, street address, MRN, SSN, or date of birth.
- Coded: A "code" or "key" links dataset received to direct identifiers stored separately, permitting "re-identification."
- A dataset might also include "indirect identifiers" without being explicitly coded, by virtue of unique subject characteristics, or if the dataset contains a combination of data fields that can be correlated to another dataset.
- No Identifiers: dataset received CANNOT be linked to direct identifiers: data were collected anonymously, or have been "anonymized" (all direct or indirect identifiers, or codes, have been destroyed before dataset received by study team) Do NOT check "No identifiers" if dataset includes any [HIPAA identifiers](#).

24.5 Upload

- **Any applicable Data Use Agreement(DUA/DSA) - unsigned template OK.** Upload is *not* necessary if this application refers to an [Unfunded Agreement \(UFA\)](#) in [eResearch Proposal Management](#).
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Important information about [naming, editing, uploading, and downloading documents](#).

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Edit HUM_Data Or Biological Specimen Set

Secondary Data Set Detail

Hide Help

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external dataset obtained with DUA

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

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If data dictionary upload is not practical (e.g. the full dataset is thousands of line items, but this analysis will be using only a small fraction of them), describe the KINDS of information accessed/received e.g. name, gender, age, diagnoses, co-morbidities, county of residence, etc.

Examples of "types of information": demographic information; diagnosis codes; visit history at a clinic; prescription history; survey responses; employment history; test scores; test questions.

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset:

Select all that apply:

- Direct Identifiers** - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)
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Data Use Agreements (DUAs) are processed through eResearch Proposal Management, like other Unfunded Agreements (UFAs). For further reference, see http://www.umich.edu/~eresinfo/erpm/docs/PM_UFA_QR.pdf and <http://orsp.umich.edu/unfunded-agreement-types>

As it says in the second paragraph of ORSP's page on the subject, "Faculty, chairs, and departmental administrators do not have the authority to sign these agreements on behalf of the University. Please work with ORSP."

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Secondary Data Set Detail

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MiChart (study team direct login)

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