{Database Name} Data Management Plan

UAB {Department Name}

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Document Control

This Data Management Plan is a living document and should be revisited to reflect any changes or on a quarterly basis⁽¹⁾.

Version History

After the final draft has been revised, ownership of this document will be turned over to {name}.

Version	Issue Date	Author(s)	Comment
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Data Management Plan

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INTRODUCTION

Background

The {department} is a prospective cohort of HIV positive patients who receive care from the University of Alabama at Birmingham (UAB) {censored}. The cohort began with a Microsoft Access database in 1995, which has seen many upgrades over the past 25 years. The database is now managed with Microsoft's SQL Server Management Studio (SSMS). Because of the growth of the {database}, there has been an increasing demand on its database and users. The creation of this Data Management Plan (DMP) will help provide standardization, contain problem areas, and allow for more growth of the database.

Purpose

This document intends to:

- Establish the information needs of the {department}
- Standardize some user interactions with the Database
- Bring attention to observations, areas of concern, and known issues with the database
- Delineate the process of expanding improvement and standardization efforts for the database
- Provide a comprehensive source of database information for new and existing {department}
 employees to reference
- Facilitate database documentation (ERDs, data dictionary, metadata, schema change history)
- Provide informational resources for employees to supply to investigators

Scope

This document is meant to serve as a tool and starting point to address observed database issues, rather than a complete solution. Though a portion of the database has been documented to provide an example, the Expansion Guide section details how to continue to expand improvements and create documentation for the entire database.

{department} Mission Statement

"To enhance well-being and promote health equity for individuals and communities through the identification, development, implementation and dissemination of approaches that build upon the strengths of an interdisciplinary team with integrated informatics and research expertise." (2)

UAB POLICIES

This document contains additional guidelines for the {department} department, meant to be supplemental to existing policies provided by UAB. These policies can be found by the links in the table below:

Title	Link
Data Access Policy	{removed}
Data Protection and Security	{removed}
HIPAA: HIPAA Administration	{removed}
HIPAA: Use & Disclosure of Identifiable Health Information for Research	{removed}
HIPAA: Patient Health Information Rights	{removed}
Minimum Security for Computing Devices Rule	{removed}
Data Classification Rule	{removed}
Data Custodian Responsibilities	{removed}
Acceptable Use of Computer and Network Resources	{removed}
Data Protection Rule	{removed}

Table 1 UAB Policy Links

KNOWN ISSUES

Problem	Description	Proposed Solution(s)
Lack of Written Standards	Outside of organization-wide <u>UAB Policies</u> , there are currently no documented standards or processes to guide {department} employees when interacting with the database.	Roles and Responsibilities Standards
Cluttered Database	Tables are often created in the database for reporting or analysis and not removed after. This has resulted in an unnecessarily large and complicated database.	Master Tables Creating New Tables Removing Tables
Ambiguous, Unstandardized Table Names	There are several tables with similar names and unofficial naming conventions, making it difficult to determine which tables are primary.	Naming Convention
Lack of Database Documentation	This database lacks documentation of source information, change history, workflow standards, and basic database information.	Roles and Responsibilities Standards Schema Changes History Report
	2. There are no standardized tools or visuals to inform investigators of what information is available to be used in their research.	Entity Relationship Diagram Data Dictionary Metadata
	3. There are also no tools to help new employees visualize and learn the database.	
Expansion Limitations	The {database} is large. The process of expanding recommendations for creating the necessary documentation to the entire database will take significant time.	The remainder of the database documentation can be done gradually, when the department has the time to spare. Guidelines for this process are outlined in Expansion Guide.

Table 2 Known Issues

ROLES AND RESPONSIBILITIES

Database Manager

The Database Manager (DBM) is an individual with the authority to make, approve, or deny any changes to the database. Additionally, the DBM is responsible for oversight of database use, new user training, as well as directing the team's activities. It is the sole responsibility of the DBM to approve requests for changes to the master tables, as referenced in the Change Request section. The DBM will assign an individual or individuals to take ownership of this document and its maintenance and Expansion Guide through the role of Documentation Manager.

Current Database Manager: {name}

Clinical Data Specialist

The Clinical Data Specialist (CDS) is the individual responsible for providing clinical expertise, receiving data request forms (*Appendix B*), overseeing the data mapping process, and ensuring data distribution for research initiatives complies with IRB requirements and UAB Policies.

Documentation Manager

The Documentation Manager (DM) is an individual responsible for the governance of all elements mentioned in this document. The DM ensures consistency of data models by overseeing the use, accuracy, and expansion of the

Data Dictionary, Naming Conventions, Entity Relationship Diagram, and Metadata^(3, 4). The DM revisits this document quarterly or when changes occur.

Current Documentation Manager: {name}

Data Analyst

The Data Analyst (DA) is an individual who performs duties related to the collection and interpretation of data⁽⁴⁾. Once a research project has been cleared by the CDS and DBM, data analysts may work with the PI to retrieve and analyze data. A DA can alter the database's schema, following guidelines in the Standards section. A DA has a responsibility to ensure proper use and privacy of data accessed, in accordance with UAB Policies.

Principal Investigator

The Principal Investigator (PI) refers to the lead investigator for a research initiative. It is the responsibility of the PI to comply with UAB Policies and IRB requirements for their research regarding use, retention, and disposal of data provided to them by the {department} department.

Team Members

Name	Position Title	Contact
{removed}	Director of Information Technology Operations	{removed}

{removed}	Co-Director Database & IS UAB CFAR	{removed}
{removed}	Data Analyst	{removed}
{removed}	Clinical Data Specialist	{removed}

DATABASE ARCHITECTURE

Most data for the database originate at the {censored}, where employees enter data into UAB's EHR system, powered by Cerner. These data are stored in the UAB Health System Data Warehouse. {department} employees transfer this data into the {database} through PowerInsight, UAB's business objects tool.



Figure 1 Flow of Data

Major Data Sources

Data may also be transferred into the database from other sources:

Source	Contains
PowerInsight	Provides access to UABHS data warehouse. Organization-wide, detailed patient information and EHR data. (2013-current)
Legacy {censored} CPR	Historical patient data from the {censored}'s past Computerized Patient Record system (2004-2012)
Access Database	{censored} Patient Data Prior to the {censored} CPR (1998-2004)
IDX	Appointment data, insurance, some demographics
Patient Reported Outcomes	Signs & symptoms, mental health, medication adherence, substance
(PRO)	abuse, risk factors, etc. See <u>Appendix A</u> for further detail.
Monogram	Resistance Data
LDMS	Specimen Data
REDCap	Survey data for multiple research studies

Social Work Dashboard	{censored} Social Services data
Greenform	Patient register

Table 3 Major Data Sources

Active Collaborations

Reports from the database are generated both on a recurring schedule through standing local, state, national, and international collaborations, and as needed for individual research initiatives. The {database} routinely exchanges data with the programs in the table below:

Name	Description
{removed}	{removed}

Table 4 Active Collaborations

STANDARDS

Naming Conventions

Naming conventions are important for standardizing and simplifying database use in group settings⁽⁵⁾. The following conventions were developed for the {database}, based on the needs of the department.

Table Prefixes

When creating new tables or renaming old tables, the name should follow this pattern⁽⁵⁾:

1. TYPE refers to table classification of the table's use:

Possible Value	Description	
MAIN	This table is a master table . Schema changes must be approved through	
	a <u>Change Request.</u>	
TMP	This table is temporary and will be deleted once it has served its	
	purpose.	
OLD	This table is no longer actively updated but needs to be kept in the	
	database for reference.	

2. **SOURCE** refers to the source system the data were imported from:

Possible Value	Description
PWI	PowerInsight
IDX	IDX
PRO	PRO database
GRE	Greenform
RED	REDCap
CPR	{censored} Legacy CPR
ACC	Access Database
MLT	Multiple Sources

3. DA_PI refers to the initials of owner and/or Principal Investigator for the table. In this example, DA represents the initials of the Data Analyst who owns the table and PI represents the Principal Investigator's Initials. This prefix primarily applies to TMP tables and should not be used for master tables. See examples below:

Possible Value	Description	
ST_JA	Garah Thomas as owner with John Adams as PI	
MJ_AJ	Megan Jones as owner, Andrew James as PI	
CR	Carl Ryan as owner, no Pl	
SK	Samuel Kirk as owner, no Pl	
	Any other name follows this same convention	

4. BKP (optional) indicates that the table is a backup:

Possible Value	Description	
BKP	This table is a backup	
	Other classifications to be determined	

Examples:

A table with visit data from IDX is created to serve as a master table. The table is named **DBO.MAIN_IDX_VISIT**

A backup of this table is created and named **DBO.MAIN_IDX_BKP_VISIT**

Carl Ryan creates a temporary table for analysis which contains patient demographics from PowerInsight and visit information from IDX. There is no PI. The table is named

DBO.TMP_<mark>MLT_CR</mark>_PATIENT_VISIT

Sarah Thomas creates a table for a research project by Principal Investigator, John Adams. This table is populated from PowerInsight and includes patient location data. The table is named DBO.TMP PWI ST JA PATIENT LOCATION

General Naming Guidelines

- Consistency is the most important tool for naming conventions. (5-7)
- Do not use spaces or any special characters, other than underscores.
- Avoid using reserved keywords in object names.
- Avoid using abbreviations, aside from the coded prefixes listed in the tables above. Long names
 are better than ambiguous names.⁽⁵⁾ The maximum length for object names is 128 characters.⁽⁷⁾
- Never use object-type or "Hungarian-style" prefixes such as tbl_ or sp_.^(6, 8)

Guidelines for Table Names

- Table names should be in all CAPS. (9)
- Separate words with underscores. (7, 9)
- Try to keep table names short, if possible.
- Use table guidelines for other database objects such as Triggers, Views, Functions, and Procedures

Guidelines for Column Names

- Use singular word forms (e.g. use "Medication" rather than "Medications").
- Use Pascal Case to separate words (Capitalize the first letter of each word: e.g. ZipCode). (8)
- Fields representing the same data in different tables should have the same names. For example, do not use "Zip" in one table and "ZipCode" in another. (6)

Creating New Tables

- The user who creates a table is designated as the owner. In collaborative efforts, users who are dependent on tables created by another user are designated as co-owners.
- When possible, use other SSMS tools to avoid creating new tables (e.g. temporary tables, views)
- When creating new tables in the database, follow <u>Naming Conventions</u>.

Removing Tables

- Do not remove tables without permission from the owner and co-owners.
- If permission cannot be obtained, consult the Database Manager.
- Master tables should not be removed for any reason without gaining approval via <u>Change Request</u>.
- When creating a table for a temporary purpose, the owner should remove the table within 3 months of completion of its intended use, unless otherwise advised by the Database Manager.
- Data retention for research is the responsibility of the Principal Investigator.

CHANGE MANAGEMENT

Change Request

- Change Requests should be submitted any time a change is made to a master table structure.
- Examples that require a Change Request include (but are not limited to):
 - Adding or removing columns
 - Altering any table properties or column properties
 - Altering relationships with other tables
 - Altering modalities or cardinalities
 - Altering keys
- Change Requests are **not** required for changes that occur to the data within the table.
- To submit a Change Request, the **requestor** should fill out the template in <u>Appendix C</u> and send it in a new email to the Database Manager with the subject: "Change Request"
- The Database Manager may reach out for further discussion or clarification on the proposed change.

Schema Changes History Report

A Schema Changes History report can be generated within SSMS to address the need for a schema change log for the database's master tables. These reports can be run by any database user and can be generated as needed. (10-12) See a report example in Figure 2, below.

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dataedo_sample_dwh tables		User Defined Table	ALTER	04.02.2019 21:49:34	sa

Figure 2 Schema Changes History Report Example⁽¹³⁾

Schema changes include:

- Creating or dropping objects
- Altering object names or attributes

A Schema Changes History report includes:

- Database name
- Object name
- Object type (Table, Trigger, Column, etc.)
- Type of change (CREATE, ALTER or DROP)
- Time of operation
- User who performed the change⁽¹³⁾

In order to generate a Schema Changes History report in SSMS, follow the instructions below:

- 1. Open object explorer
- 2. Right click on a database
- 3. Select Reports>Standard Reports>Schema Changes History (Figure 3 Generate Schema Changes History)

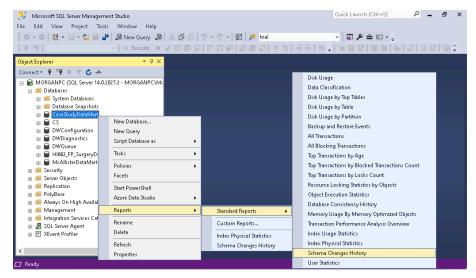


Figure 3 Generate Schema Changes History

DOCUMENTATION

Entity Relationship Diagram

An Entity Relationship Diagram (ERD) provides a visual representation of the database's tables, columns, relationships, keys, cardinalities, and modalities. These visuals serve as a quick reference for new employees or investigators. Figure 4 below is a small portion of the database, documented as an ERD. Expansion Guide contains information on creating ERDs for the rest of the database.

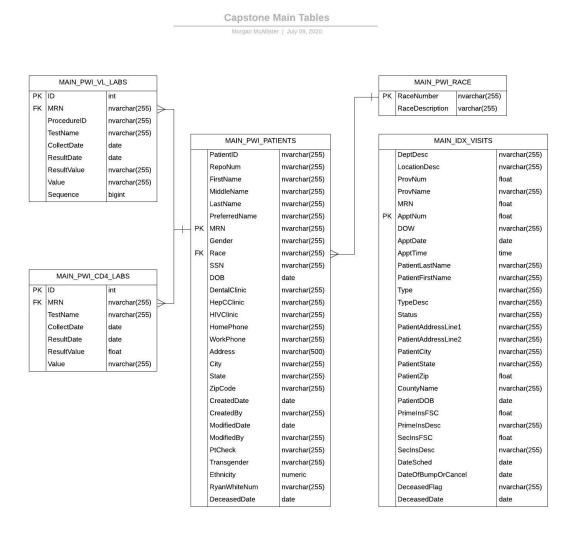


Figure 4 ERD

Data Dictionary

The data dictionary is an Excel spreadsheet file, housed in the shared department folder. It describes each column of each master table so that investigators and employees can gain a thorough understanding, beyond metadata, of data captured⁽¹³⁻¹⁵⁾.

Data elements in the dictionary are described below:

Column Name	Description
Column Name	The name of the column, as it appears in SSMS
Description	Field description
Constraint	Is this field a Primary Key (PK) or Foreign Key (FK) in this table?
Data Type	Designated data type in SQL
Data Format	Usual format of the data, if applicable
Allow Nulls	(Y/N) Can this element be NULL?
Example Value	An example that reflects the requirements of the data element
Acceptable Values	Specifies what range or type of data is acceptable
Notes	Miscellaneous notes pertaining to the field
Data Classification	Is this data Public, Restricted, or Sensitive? Refer to <u>UAB Data Classification</u> and <u>Appendix D</u>
Date Added/Modified	Date this field was added or changed in its original source. Refer to the <u>Schema</u> <u>Changes History Report</u> for details

Table 5 Data Dictionary Elements



Figure 5 Screenshot-Data Dictionary File

Metadata

Viewing Object Descriptions

Descriptions of database objects should also be stored directly in SSMS for **all tables** and for **columns in master tables**⁽¹⁶⁾. This description should match the description in the Data Dictionary. After descriptions are added by following guidelines in <u>Expansion Guide</u>, they can be viewed by following the instructions below:

Table and **View descriptions** can be accessed by right clicking on a table or view in Object Explorer and selecting *Properties > Extended Properties*.

Column descriptions can be viewed right clicking on a table in Object Explorer and selecting Design. Click on a column name. Description can be found in the bottom pane under Column Properties > Table Designer (17).

Viewing Metadata in Object Explorer Details

The Object Explorer Details view option in SSMS can be used to easily view other important metadata for objects in the database, without querying. (18, 19)

1. In SSMS, go to View > Object Explorer Details (Figure 6)



Figure 6 Screenshot- Object Explorer Details

- 2. Select an object in the Object Explorer
- 3. In the Object Explorer Details pane, right click on the column pane to customize the metadata you want to see. Some of the options can be seen in Figure 7 below.

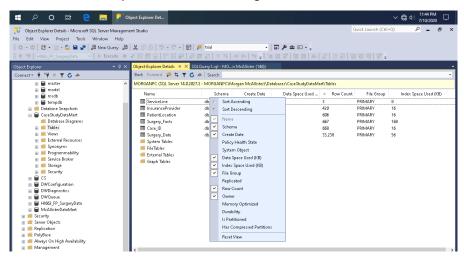


Figure 7 Screenshot-Customize Metadata Selection

18

EXPANSION GUIDE

Master Tables

- Master tables are those designated by the MAIN categorization in the Table Prefixes section.
- Focus on a few tables at a time. Complete all documentation for that table before moving on to the next
- The department should determine what fields are most commonly used and logically compile them into as few master tables as possible.
- Consult the team to make sure all current tables have a purpose.
- Continue gradually consolidating and reducing existing database clutter until all tables are fitted with a naming prefix and documentation

Entity Relationship Diagram

- Follow these instructions to create an ERD in SSMS
- For a printable version, follow this quick <u>tutorial</u> to import most recent SQL schema to Lucidchart.com
- Confirm cardinalities and modalities are correct
- Go to File>Export>JPEG/PDF>Download

Data Dictionary

- As soon as a new master table has been created, a user should fill out the Data Dictionary for the new table and fields.
- Create a new sheet for each table, naming the sheet after the table.
- See Table 5 for dictionary element descriptions.

Metadata

- Use descriptions from the Data Dictionary to fill in descriptions in SSMS for database objects.
- If a Data Dictionary description changes, make changes in the SSMS description as well.
- To add column name descriptions: right click on a table in Object Explorer and select *Design*. Click on a column name. *Description* can be found in the bottom pane under *Column Properties > Table Designer*⁽¹⁷⁾. Click in the field to edit the description.
- To add Table or View descriptions: right click on a table or view in Object Explorer and select Properties > Extended Properties. You may have to add a new field named Description. Enter the table or view description in that field. (18)

Known Issues

- Add problems to the <u>Known Issues</u> table as they come up. Include small improvement ideas as well as major ones.
- Bring these issues up in meetings, assign an owner to the improvement process, and work with the rest of the department to brainstorm solutions that work for everyone.
- Amend this document to reflect those solutions

APPENDIX

Appendix A

PRO Detailed Table⁽²⁾

Si	Patient Reported Outcomes urvey Web App	Connect 1917 Clinic	Palliative 1917 Clinic	5 & 5 1917 Clinic	Hep C 1917 Clinic	iEngage	Supportive Care Kirklin Clinic	Breast Health Kirklin Clinic	Rheumatology Kirklin Clinic	Neurosurgery Children
	PHQ-9 Depression	9	9		9		9			
	PHQ-9 Anxiety	5				5				
	GAD-7 Generalized Anxiety Disorder		7		7					
	Alcohol Consumption (AUDIT-C)	3		r (3	3				9 3
	Substance Abuse (ASSIST)	22			22	32				
	Safety	8								
	MOS-4 Social Support	4				4				
	EuroQoL Quality of Life	5	1		5	5	1			
	HIV Stigma	10								
	FACT-G						46			į.
s	BPI Pain Inventory		15				15			
Z	Symptom Assessment		10		-		10		-	
ME	HIV Symptom Index			20						-
R.C	Distress Thermometer							6		i .
ST	Fatigue Severity Scale (FSS)	[]			9	7 5 - 2 5				
z	PHQ-8D (Depression)					8				
	Sexual risk assessment (HRAP)					23	7 7			
	Coping (9 subscales from Brief COPE)					18				
	HIV Stigma Scale (Berger + Earnshaw)		11,,,			41			: -	
	HIV related self-efficacy (Mallory Johnson)					12				
	IMB for HIV visit adherence (sIMB-RIC)					35			V	
	IMB for ART adherence (IMB-AAQ)		- 1			33		11	in .	93 - 154 3
	ART adherence (ACCTG, VAS, SRS)					4		1	1	
	Rapid-3								12	
	Family Impact Module									36
	Sample Transition Readiness Assessment									27
Nun	nber of questions per Clinic	66	42	20	55	232	81	6	12	63

Appendix B

{department} Data Request Form						
Requesting person/entity:						
(Request originator – include email)						
Sponsor:						
(Account number to be billed for request)						
PI (for project, select most appropriate option below):						
- UAB CFAR member, Other CFAR member, Non CFAR						
member and Other						
Funding (for project, select most appropriate option below): - NIH funded, Not funded and Other						
Research location (Select one from below):						
- UAB CFAR, Other CFAR, Non CFAR institution and Other						
Purpose of request (Intended use of data):						
Has this request been run before? (If "yes" when?):						
If applicable, has a digitized copy of the IRB approval been						
<pre>provided? (Applicable to all UAB {database}Studies)</pre>						
Question(s): [Define question(s) project is designed to address.	This will help us come up with alternatives that may allow us to					
optimize your data request]						
Clearly define nanulation for this data request (Fig. 411 nations with first visit to (consound) primers = 1/1/00 1/1/00).						
Clearly define population for this data request (Ex: All patients with first visit to {censored} primary care 1/1/08-1/1/09):						
Specify, define and period for all requested variables: (Ex: baseline CD4 = CD4 value +/- 6 months from 1^{st} clinic visit date;						
1/1/08-1/1/09						
Comments/Clarifications: [Use this space to clarify preferred n						
etc.), discuss any specific requests involving file type – data deliv	ery, or other comments].					

Please note the following:

- 1. We will do our best to accommodate specifications regarding data delivery, but we cannot accommodate all requests.
- 2. Data requests involving cohort research will not be processed until the project has been formally presented at a {database} Meeting.
- 3. Expect to be contacted within 48 hours of sending a formal request form first for clarification. Once clarified, requests will be placed in the New Request queue and you will be informed of the planned time of completion via email.
- 4. Once you receive data, please review carefully and ensure that it meets your needs. You will have 48 hours to contact us for clarifications/changes to request. Requests for changes received after this time period will result in your query returning to the bottom of the New Request queue.

Appendix C

{database} Change Request Form			
Requestor(s):			
Description of the change:			
Reason for the change:			
Impact of the change:			
Proposed effective date:			
Additional comments:			

Appendix D

UAB Data Classification Table⁽²⁰⁾

Classification Level	Definition	Examples of Data				
Public data	Data that may be disclosed to the general public without harm.	Public phone directory, course catalogs, public research findings, enrollment figures, public web sites, general benefits data, press releases, newsletters, etc.				
Sensitive data	Data that should be kept confidential. Access to these data shall require authorization and legitimate need-to- know. Privacy may be required by law or contract.	FERPA, budgetary plans, proprietary business plans, patent pending information, export controls information and data protected by law.				
Restricted/PHI data	Data that is highly confidential in nature, carries significant risk from unauthorized access, or uninterrupted accessibility is critical to UAB operation. Privacy and Security controls are typically required by law or contract.	HIPAA PHI, Social Security numbers, credit card numbers (PCI DSS), GLBA data, Export Controlled data, FISMA regulated data, log-in credentials, and information protected by non-disclosure agreements.				

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